

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Selection Criteria:

Product Name:				
Product Active Ingredient:				
Active Ingredient:	CARBO	XYMETHYLCELL	ULOSE	SODIUM
Active Moiety:				
FDA Received Date:	From:	01-Jan-2022	To:	24-Feb-2023
MedDRA® Version*:	25.1			
Total Cases**:	301			
Number of Pages:	536			

Disclaimer: Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, manufacturer or product caused or contributed to the event. The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of these events.

^{*. &}quot;MedDRA® Version" refers to the name and version of the dictionary in use at the time the cases were retrieved from the FDA Adverse Event Reporting System (FAERS). MedDRA Medical Dictionary for Regulatory Activities (MedDRA®) is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to code adverse events, medication errors and other information associated with the use of medical products. A MedDRA® Preferred Term (PT) is used to standardize a "medical concept" in a report. For example, a report of "heart attack" or "myocardial infarct" are standardized to the same Preferred Term, "Myocardial Infarction". MedDRA is updated twice a year.

^{**. &}quot;Total Cases" reflects the number of individual patient case reports associated with the product of interest that were submitted to FDA within the specified time period. A case consists of an initial report and any follow-up reports submitted to FDA. Because FDA may receive reports on the same patient from more than one source, some of these cases may be duplicate patient reports.



The information in this report is generated from the FDA Adverse Event Reporting System (FAERS) by using a report query where suspect product(s) or active ingredients are selected from a standardized dictionary and a date range is specified as search criteria. The table below provides the definitions for field headings that are listed on the report.

FAERS data have limitations, including the following. There is no certainty that the reported event was actually due to the product. Reports are often incomplete - a blank field means that no data were provided. FDA does not receive reports on all adverse events that occur with a product. Many factors can influence whether or not an event will be reported, therefore, FAERS data cannot be used to compare products or calculate how frequently an event occurs in the U.S. population.

Field Heading	Definition
FDA Received Date	The date that FDA received the most recent information regarding a case, either as an initial report or follow-up report. The FDA Received Date may not be the same as the date that the event occurred. The event may have occurred days or even months (or years) before the report was sent to (and received by) FDA. Note the displayed date on the report may be later than the query date range if FDA received follow-up information for a case. FDA provides the most current case information available.
Case #	A unique number assigned by FDA that identifies a FAERS case. A case includes the information received in the initial report plus any additional information received in follow-up reports.
Case Type	There are three case types in FAERS: Expedited (15-Day): submitted to FDA by manufacturers; these are reports containing serious, unexpected adverse events Nonexpedited: submitted periodically to FDA by manufacturers; these are reports containing adverse events other than those qualifying for expedited (15-day) reporting. Direct: submitted "directly" to FDA by healthcare professionals, patients and other consumers.
Health Prof	Indicates whether the initial source who provided information about the event is a health professional. Possible values are; Y - Yes, N – No or the field is blank if it was not reported
Outcomes	Based on FDA regulations, the reported outcome(s) determines whether a case is serious. The outcome categories include congenital anomaly/birth defect (CA), death (DE), disability (DS), hospitalization (HO), life-threatening (LT), other serious important medical event (OT), and required intervention to prevent permanent impairment/damage (RI). A case can have more than one outcome.
Mfr Control #	The Manufacturer Control Number is the manufacturer's unique identifier associated with the case. Also referred to as the Company Report Number.
503B Facility	Indicates whether the organization that sent the report to FDA is an outsourcing facility. An outsourcing facility is a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B of the Food, Drug, and Cosmetic Act. Possible value is Y – Yes.
Age	The patient's age, with age unit, based on information provided in the report.
Sex	Patient sex (Male, Female, Unknown).



Country	The country where the event occurred. If not reported, then the country of the reporter. The International Organization for Standardization (ISO) 3166-1 alpha-3 country code is used as an abbreviation for the country.
Preferred Term	A Medical Dictionary for Regulatory Activities (MedDRA®) Preferred Term (PT) is used to standardize a "medical concept" in a report. For example, a report of "heart attack" or "myocardial infarct" are standardized to the same Preferred Term, "Myocardial Infarction". MedDRA is a medical terminology developed under the support of the International Conference on Harmonization (ICH) and is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). MedDRA is used by FDA, other regulatory agencies, and pharmaceutical manufacturers to "code" adverse events, medication errors and other information associated with the use of medical products.
Product	Name of a drug or biologic in the case report. A product name can appear as either a brand name (trade name) or an active ingredient name, depending on what was reported.
Comp.	Indicates whether the suspect product is a compounded drug, as identified in the report. Compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Possible value is Y – Yes.
отс	Indicates whether the suspect product is an over-the-counter (OTC) drug, as identified in the report. OTC drug products are those drugs that are available to consumers without a prescription. Possible value is Y – Yes.
Role	There are two roles for products listed on the cases. Suspect (S) identifies the product(s) that the initial reporter deemed most likely to be associated with the event. Concomitant (C) identifies products taken at the same time as the suspect product, but not deemed by the initial reporter as being associated with the event.
Route	Reported route of product administration (e.g., oral, topical, injection, sublingual, inhalation).
Dosage Text	Refers to the amount of the product that was taken or given to a patient, and the frequency of administration. For example, 20 mg twice daily.
Duration	The length of time the product was used. For example, if someone reported taking Drug A from January 1 to January 30, the duration would be 30 days.
Mfr	The manufacturer of the product, as indicated in the report.



FDA Received Date	Case #	Case Type	Health	Prof Ou	ıtcomes	Mfr Control	# 503B Facility	<u>Age</u>	Sex Co	untry
30-Dec-2021	20185068	EXPEDITED (15-DAY)	Y	01	Γ	CA-SANOFI U 2021SA41134			Female	
Preferred Term	Pro	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>Mfr</u>	
Drug Ineffective; Macu Degeneration	Metr Para Ator Alpra Amo	ncodyl ronidazole acetamol vastatin Calcium azolam oxicillin Trihydrate hromycin		N N N N N N	SSSSSSS		Unk		Sanofi Sanofi Not Repo Not Repo Not Repo Not Repo	orted orted orted
	Beta Bude Bude	amethasone Dipropionate amethasone Valerate esonide esonide esonide		N N N N	S S S S		Unk		Not Repo Not Repo Not Repo Not Repo Not Repo	orted orted orted
	Calc	cium Carbonate		N	S		Unk		Not Repo	orted
	Carr	mellose Sodium		N	S		Unk		Not Repo	orted
	Ceti	rizine Hydrochloride		N	S		Unk		Not Repo	orted
	Clar	ithromycin		N	S		Unk		Not Repo	orted
	Clar	ithromycin		N	S		Unk		Not Repo	orted
	Clot	rimazole		N	S		Unk		Not Repo	orted
	Desc	onide		N	S		Unk		Not Repo	orted
	Diph	nenhydramine Hydrochloride		N	S		Unk		Sanofi	
	Ergo	ocalciferol		N	S		Unk		Sanofi	
	Fluti	casone Furoate		N	S		Unk		Not Repo	orted
	Fluti	casone Furoate		N	S		Unk		Not Repo	orted
	Glyd	cerine		N	S	Oral	Unk		Not Repo	orted
	Hydi	rochlorothiazide		N	S		Unk		Not Repo	orted
	Hydi	rochlorothiazide		N	S		Unk		Not Repo	orted
	Mag	nesium Sulfate		N	S		Unk		Not Repo	orted
	Mag	nesium Oxide		N	S		Unk		Not Repo	orted



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Mesalazine	N	S		Unk	Sanofi
Mesalazine	N	S		Unk	Sanofi
Morphine Sulfate	N	S		Unk	Not Reported
Mupirocin	Ν	S	Topical	Unk	Not Reported
Nadolol	Ν	S	•	Unk	Not Reported
Nicoderm	N	S	Transdermal	Unk	Sanofi
Nicotine	N	S	Transdermal	Unk	Sanofi
Nicotine Polacrilex	N	S		Unk	Not Reported
Pantoprazole	N	S		Unk	Not Reported
Prednisone	N	S		Unk	Not Reported
Pregabalin	N	S		Unk	Not Reported
Sodium Chloride	N	S	Other	Unk	Not Reported
Sulfamethoxazole/Trimethoprim	N	S		Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Sanofi
Zinc Oxide	N	S		Unk	Sanofi
Ertapenem Sodium	N	S		Unk	Not Reported
Fluticasone Propionate	N	S		Unk	Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S		Unk	Not Reported
Sinus Rinse	N	S	Nasal	Unk	Not Reported
Humira	N	S	Subcutaneous	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S		Unk	Not Reported
Calcium Carbonate/Vitamin D3	N	S		Unk	Not Reported
Vitamin D3	N	S		Unk	Not Reported
Cupric Oxide	N	S		Unk	Not Reported
Dilaudid	N	S		Unk	Not Reported
Flovent	N	S		Unk	Not Reported
Imodium	N	S		Unk	Not Reported
Macrogol 3350;Magnesium Sulfate;Potassium Chloride;	N	S		Unk	Not Reported



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			um Sulfate;S in Calcium		N	S		Unk				Not Reported
		•	Palmitate		N	S		Unk				Not Reported
		Zeaxant			N	S		Unk				Not Reported
		Acetam	inophen		N	S		Unk				Not Reported
		Calcium Valsarta	Carbonate/Vitamin D3 In		N N	C C						Not Reported Not Reported
FDA Received Date	Case #		Case Type	Health	Prof	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jan-2022	197116	12	EXPEDITED (15-DAY)	Y		ОТ	CA-Astra 2021A67	aZeneca- 74515			Female	CAN
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	Text	<u>Duration</u>		<u>Mfr</u>
Drug Ineffective; Macu Degeneration	ular	Azithror	nycin		N	S	Unknown	Unk				Not Reported
FDA Received Date	Case #		Case Type	Health	Prof	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jan-2022	202147	70	EXPEDITED (15-DAY)	Υ		ОТ		DUS ACEUTICALS VDP-2021-			Unknow	'n
Preferred Term		Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosage	Text	Duration		<u>Mfr</u>
Drug Ineffective; Macu	ular	Ergocal	ciferol		N	S	Unknown	Unkno	wn			Validus
Degeneration		Bisacod	yl		N	S	Unknown					Not Reported
		Metroni	dazole		Ν	S	Unknown					Not Reported
		Paracet	amol		Ν	S	Unknown					Not Reported
		Atorvas	tatin Calcium		Ν	S	Unknown					Not Reported
		Alprazo	lam		Ν	S	Unknown					Not Reported
		Amoxici	llin Trihydrate		Ν	S	Unknown					Not Reported
		Azithror	nycin		Ν	S	Unknown					Not Reported
		Betame	thasone Dipropionate		Ν	S	Unknown	Unk				Not Reported
		Betame	thasone Valerate		N	S	Unknown					Not Reported

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Budesonide	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Unknown		Not Reported
Carmellose Sodium	N	S	Unknown		Not Reported
Cetirizine Hydrochloride	N	S	Unknown		Not Reported
Clarithromycin	N	S	Unknown		Not Reported
Clarithromycin	N	S	Unknown		Not Reported
Clotrimazole	N	S	Unknown		Not Reported
Desonide	N	S	Unknown		Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown		Not Reported
Fluticasone Furoate	N	S	Unknown		Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Oral		Not Reported
Hydrochlorothiazide	N	S	Unknown		Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown		Not Reported
Magnesium Oxide	N	S	Unknown		Not Reported
Mesalazine	N	S	Unknown		Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown		Not Reported
Mupirocin	N	S	Topical		Not Reported
Nadolol	N	S	Unknown		Not Reported
Nicoderm	N	S	Transdermal		Not Reported
Nicotine	N	S	Transdermal		Not Reported
Nicotine Polacrilex	N	S	Unknown		Not Reported
Pantoprazole	N	S	Unknown		Not Reported
Prednisone	N	S	Unknown		Not Reported
Pregabalin	N	S	Unknown		Not Reported
Sodium Chloride	N	S	Unknown	Other	Not Reported



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		methoxazole And		N	S	Unknown				No	t Reported
		ncinolone Acetonide		N	S	Intra-articula	r			No	t Reported
	Zinc	Oxide		N	S	Unknown				No	t Reported
	Ertap	enem Sodium		N	S	Unknown				No	t Reported
	Flutic	asone Propionate		N	S	Unknown				No	t Reported
		nicidin;Neomycin Sulfate; myxin B Sulfate		N	S	Unknown				No	t Reported
	Sinus	Rinse		N	S	Nasal				No	t Reported
	Humi	ra		N	S	Subcutaneou	us			No	t Reported
	Hydro	ine Sulfate;Diphenoxylate ochloride		N	S	Unknown				No	t Reported
	Calci	um Carbonate/Vitamin D3		N	S	Unknown				No	t Reported
	Vitam	nin D3		Ν	S	Unknown				No	t Reported
	Cupri	ic Oxide		N	S	Unknown				No	t Reported
	Dilau	did		N	S	Unknown				No	t Reported
	Flove	ent		N	S	Unknown				No	t Reported
	Imodi	ium		N	S	Unknown				No	t Reported
	Sulfa	ogol 3350;Magnesium te;Potassium Chloride; ssium Sulfate;S		N	S	Unknown				No	t Reported
		rocin Calcium		Ν	S	Unknown				No	t Reported
	Xanto	ofyl Palmitate		N	S	Unknown				No	t Reported
	Zeax	anthin		N	S	Unknown				No	t Reported
	Aceta	aminophen		N	S	Unknown	Unk			No	t Reported
	Calci	um Carbonate/Vitamin D3		N	С	Unknown	Unkno	own		No	t Reported
	Valsa	artan		N	С	Unknown	Unk			No	t Reported
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Co	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jan-2022	20340268	EXPEDITED (15-DAY)	N		ОТ	PHARM	ENMARK MACEUTICALS- MK069753			Unknown	CAN
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	



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Drug Ineffective; Macu Degeneration	ular Azithro	omycin		N	S	Unknown	Unk			Not	Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jan-2022	20340686	EXPEDITED (15-DAY)	N	(ОТ	US-ALLE 22016851				Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mfr	
Eye Discharge; Eye Irritation; Macular Degeneration	Reger	er-Eyes Lite		N	С	Ophthalmic	Unk			Not	Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jan-2022	20344634	EXPEDITED (15-DAY)	Υ	(ОТ	CA-GLEN PHARMA 2022GM	CEUTICALS-			Unknown	CAN
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	Duration	Mfr	
Drug Ineffective; Macu Degeneration	ılar Azithro	omycin		N	S	Unknown	Unk			Not	Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jan-2022	20344747	EXPEDITED (15-DAY)	N	(ОТ	CA-GLEN PHARMA 2022GM	CEUTICALS-			Unknown	CAN
Preferred Term	Produ	<u>ict</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	Mfr	
Drug Ineffective; Macu Degeneration	ular Azithro	omycin		N	S	Unknown	Unk			Not	Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jan-2022	20349431	EXPEDITED (15-DAY)	N	(ОТ	CA-GLEN PHARMA 2022GM	CEUTICALS-			Unknown	CAN
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	Duration	Mfr	
Drug Ineffective; Macu Degeneration	ılar Azithro	omycin		N	S	Unknown	Unk			Not	Reported



FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jan-2022	20350084	EXPEDITED (15-DAY)	N	(OT		NMARK ACEUTICALS- K069752			Unknown	CAN
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	Duration	<u>Mfr</u>	
Drug Ineffective; Macu Degeneration	ılar Azithı	romycin		N	S	Unknown	Unk			No	t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jan-2022	20354622	EXPEDITED (15-DAY)	N	(TC		NMARK ACEUTICALS- IK069750			Unknown	CAN
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	Duration	<u>Mfr</u>	
Drug Ineffective; Macu Degeneration	ılar Azithı	romycin		N	S	Unknown	Unk			No	t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jan-2022	20386254	EXPEDITED (15-DAY)	N	(TC	US-ALLE 2202500				Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosage	<u> Text</u>	Duration	<u>Mfr</u>	
Cerebrovascular Accio Covid-19; Off Label Us		reens Brand Eye Emollient		N	С		Unk, E	Bid		No	t Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Feb-2022	15660222	NON-EXPEDITED	N	ŀ	HO, OT		MEDICAL, INC BUS00055			Unknown	USA
Preferred Term	<u>Prod</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	Duration	<u>Mfr</u>	
Adverse Event; Atrial Fibrillation; Diarrhoea; Hypersensitivity; Inson Mastication Disorder; Product Dose Omissic Issue; Sepsis; Skin Exfoliation; Speech Disorder; Stomatitis;	nnia;	r B Complex /01995301/		N	С	Unknown	Unk			No	t Reported



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Thyroid Mass; Vomiting	g										
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Feb-2022	19611752	EXPEDITED (15-DAY)	N		ОТ		OUS CEUTICALS /DP-2021-			Unknown	USA
Preferred Term	Produ	ct	Comp.	OTC	Role	Route	<u>Dosage</u>	e Text	Duration	<u>Mfr</u>	
Drug Ineffective; Macu Degeneration		omycin omycin		N N	s s	Unknown Unknown	Unk Unk				t Reported t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Feb-2022	20496957	EXPEDITED (15-DAY)	Υ		ОТ		TOL-MYERS COMPANY- 2-020350			Female	CAN
Preferred Term	Produ	ct	Comp.	OTC	Role	Route	<u>Dosage</u>	e Text	Duration	<u>Mfr</u>	
Drug Ineffective; Macu Degeneration	lar Azithro	omycin		N	S	Unknown				No	t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Feb-2022	20512841	DIRECT			DS				62 YR	Female	USA
Preferred Term	Produ	ct	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Alopecia; Back Pain; Chills; Dysphonia; Eye Swelling; Fatigue; Ocu Hyperaemia; Palpitatio Peripheral Swelling; Peripheral Swelling; Peripheral Swelling; Respiratory Tract Congestion; Seborrhos Skin Exfoliation; Throa Tightness; Umbilical Erythema; Vision Blurr	Probio lar ons; ea; t	'S Multivitamin tic			CC						t Reported t Reported



FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Mar-2022	2054696	1 EXPEDITED (15-DAY)	Υ		ОТ	CA-00950 2203CAN				Female	CAN
Preferred Term	<u> </u>	Product	Comp.	OTC	Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>	<u>Mfı</u>	<u>:</u>
Drug Ineffective; Macu Degeneration	ular <i>A</i>	Azithromycin		N	S	Unknown		age Form: Not cified		No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Mar-2022	2054841	7 NON-EXPEDITED	N			US-ALLER 2108671U			90 YR	Female	USA
Preferred Term	<u> </u>	Product	Comp.	OTC	Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>	<u>Mfı</u>	<u>.</u>
Blindness Transient;	١	Nifepine		N	С	Oral	Unk			No	ot Reported
Device Delivery Syste Issue; Eye Inflammation; Eye Pair Eye Irritation; Eye Pair Eyelid Ptosis; Liquid Product Physical Issue Ocular Hyperaemia; Product Packaging Quantity Issue	on; " n;	Multivitamin /00097801/		N	С		Unk			No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Mar-2022	2058437	9 EXPEDITED (15-DAY)			HO, OT	CA-B.Brau -2126691	ın Medical Ir	nc.	71 YR	Female	CAN
Preferred Term	<u> </u>	Product	Comp.	OTC	Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>	<u>Mf</u> ı	[
Chronic Sinusitis; Drug Ineffective; Dyspepsia Infusion Related Reac Macular Degeneration Malaise; Nausea; Off	i; E ction;	Aacrogol/Potassium/Sodium Bicarbonate		N	S					No	ot Reported



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Decreased											
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Apr-2022	19420055	EXPEDITED (15-DAY)	Υ	(ОТ	CA-AstraZeneo 2021A509529	ca-			Female	CAN
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>otc</u>	Role	Route	Dosage	<u>Text</u>	Duration	Mfr	
Drug Ineffective; Macu Degeneration		omycin omycin		N N	S S	Unknown Unknown					Reported Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-May-2022	19888005	EXPEDITED (15-DAY)	Y	(ОТ	CA-GLENMAR PHARMACEU 2021GMK0680	TICALS-			Unknown	CAN
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage	e Text	Duration	Mfr	
Drug Ineffective; Macu Degeneration	ılar Azithro	omycin		N	S	Unknown	Unk			Not	Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-May-2022	20891706	EXPEDITED (15-DAY)	Υ	(ОТ	CA-JNJFOC- 20220550680				Female	CAN
Preferred Term	Produ	<u>ict</u>	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mfr	
Drug Ineffective; Macu Degeneration	ılar Azithro	omycin		N	S	Unknown				Not	Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-May-2022	20892479	EXPEDITED (15-DAY)	Υ	(ОТ	CA-JNJFOC- 20220553090				Female	CAN
Preferred Term	Produ	<u>ıct</u>	Comp.	<u>otc</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	Mfr	
Drug Ineffective; Macu Degeneration	ılar Azithro	omycin		N	S	Unknown				Not	Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jun-2022	20171525	EXPEDITED (15-DAY)	Υ	(ОТ	CA-SANOFI U 2021SA411798				Female	CAN



Preferred Term	Produ	<u>ict</u>	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	Mfr	
Drug Ineffective; Macu Degeneration	ılar Azithro	omycin		N	S	Unknown				Not	t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jun-2022	20257544	EXPEDITED (15-DAY)	Υ		HO, OT		IITHKLINE- 1AMR091370			Unknown	CAN
Preferred Term	Produ	<u>ict</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	Duration	Mfr	
Chronic Sinusitis; Drug Ineffective; Dyspepsia Infusion Related Reac Macular Degeneration Malaise; Nausea; Off Label Use; Pain; Paraesthesia Oral; Procedural Pain; Pyre. Therapeutic Product E Incomplete; Weight Decreased	tion; ; ; xia;	omycin		N	S		Unk			Not	t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jun-2022	20190428	EXPEDITED (15-DAY)	Υ	1	ОТ	CA-VALID PHARMAC	US CEUTICALS			Unknown	USA
						LLC-CA-VI 014737	DP-2021-				
Preferred Term	<u>Produ</u>	<u>ict</u>	Comp.	OTC	Role	LLC-CA-V	DP-2021- <u>Dosage</u>	<u>· Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macu			Comp.	<u>OTC</u> N	Role S	LLC-CA-V 014737		· Text	<u>Duration</u>		t Reported
Drug Ineffective; Macu	ılar Azithro		Comp. Health	N		LLC-CA-V 014737 Route	Dosage Unk	Text 503B Facility	<u>Duration</u>		
Drug Ineffective; Macu Degeneration	ılar Azithro	omycin	Health	N Prof	S	LLC-CA-VI 014737 Route Unknown	Dosage Unk rol # FI US-			Not	t Reported
Drug Ineffective; Macu Degeneration FDA Received Date 07-Jun-2022	Azithro	Case Type EXPEDITED (15-DAY)	Health	N Prof	S Outcomes	LLC-CA-VI 014737 Route Unknown Mfr Cont CA-SANO	Dosage Unk rol # FI US-	503B Facility		Not Sex	Country CAN
	Case # 20156875	Case Type EXPEDITED (15-DAY)	Health N	N Prof	S Outcomes	LLC-CA-VI 014737 Route Unknown Mfr Cont CA-SANOI 2021SA40	Unk rol # FI US- 6867	503B Facility	Age	Sex Female	Country CAN



FDA Received Date	Case #	Case Type	Health	Prof (<u>Dutcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jun-2022	20156876	EXPEDITED (15-DAY)	N	(TC	CA-SAN 2021SA				Female	CAN
Preferred Term	<u>Produ</u>	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	Duration	Mfr	
Drug Ineffective; Macu Degeneration		omycin omycin		N N	S S		Unk				ot Reported ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Jun-2022	20157047	EXPEDITED (15-DAY)	N	(TC	CA-SAN 2021SA				Female	CAN
Preferred Term	Produ	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	e Text	Duration	Mfr	
Drug Ineffective; Macu	ılar Azithr	omycin		N	S		Unk			No	t Reported
Degeneration	Azithr	omycin		N	S	Unknown				No	t Reported
	Ertape Ertape			N N	S S	Unknown					t Reported t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Jun-2022	20989193	EXPEDITED (15-DAY)	N	(OT	CA-0095 2206CA	507513- N005691			Female	CAN
Preferred Term	<u>Produ</u>	uct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>	Mfr	
Drug Ineffective; Macu Degeneration	ılar Azithr	omycin		N	S	Unknown	Not S _l	pecified		No	t Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Dutcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Jun-2022	20833155	EXPEDITED (15-DAY)	Υ	ŀ	HO, OT		SMITHKLINE- 019AMR000333			Unknown	CAN
Preferred Term	Produ	uct	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	<u>Duration</u>	Mfr	
Chronic Sinusitis; Drug		ım Carbonate,		N	S	Unknown	Unk			Gla	axosmithkline
Ineffective; Dyspepsia Infusion Related Reac Macular Degeneration Malaise; Nausea; Off	tion; Calciu	calciferol ım Carbonate, calciferol		N	S		Unk			Gl	axosmithkline



Label Use; Pain; Paraesthesia Oral; Procedural Pain; Pyrexia; Therapeutic Product Effect Incomplete; Weight Decreased

Habitrol	N	S		Unk	Glaxosmithkline
Nicotine	N	S		Unk (Transdermal Patch)	Glaxosmithkline
Nicoderm	N	S	Topical	Unk	Glaxosmithkline
Nicoderm	N	S	Unknown	Unk	Glaxosmithkline
Nicoderm	N	S	Unknown	Unk	Glaxosmithkline
Nicoderm	N	S	Unknown	Unk	Glaxosmithkline
Nicotine Polacrilex	N	S		Unk	Glaxosmithkline
Nicotine Polacrilex	N	S		Unk	Glaxosmithkline
Pantoprazole	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Diphenhydramine	N	S		Unk	Not Reported
Diphenhydramine	N	S		Unk	Not Reported
Multivitamins	N	S		Unk	Glaxosmithkline
Zinc Oxide	Υ	S		Unk	Glaxosmithkline
Zinc Oxide	Υ	S		Unk	Glaxosmithkline
Acetaminophen +	N	S		Unk	Not Reported
Pseudoephedrine Salinex	N	S	Nasal	Unk	Not Reported
Magnesium Sulfate	N	S	เงสรสเ	Unk	Not Reported
D-Alpha Tocopherol	N	S			Glaxosmithkline
Niquitin 4 Mg Mint Lozenge	N	S		Unk Unk	Glaxosmithkline
Magnesium Oxide	N	S		Unk	Not Reported
Magnesium Sulfate Inj	N	S		Unk	Not Reported
Vitamin E	N	S			Glaxosmithkline
Nicotinamide	N	S		Unk	Not Reported
Magnesium Hydroxide	N	S		Unk	Not Reported
Avamys	N	S		Unk	Not Reported
Avamys	N	S		Unk, Spray Meter Dose	Not Reported
Ergocalciferol	N	S		Unk	Not Reported
Ligodalolielol	IN	3		3000 lu	Not Nepotted

Ergocalciferol

Unknown

Unk

S

Ν

Not Reported



				<u> </u>	
Flovent	N	S		Unk (Spray Metered Dose)	Not Reported
Flovent	N	S		Unk	Not Reported
Bactroban (Mupirocin)	N	S	Topical	Unk	Not Reported
Bactroban (Mupirocin)	N	S	Topical	Unk	Not Reported
Bactroban (Mupirocin)	N	S		Unk	Not Reported
Azithromycin Dihydrate	N	S	Oral	Unk	Not Reported
Azithromycin Dihydrate	N	S		Unk	Not Reported
Betamethasone Dipropionate	N	S		Unk	Not Reported
Betamethasone Dipropionate	N	S		Unk	Not Reported
Clotrimazole	N	S		Unk	Not Reported
Clotrimazole	N	S		Unk	Not Reported
Metronidazole	N	S		Unk	Not Reported
Metronidazole	N	S		Unk	Not Reported
Metronidazole	N	S		Unk	Not Reported
Metronidazole	N	S		Unk	Not Reported
Triamcinolone Acetonide	N	S		Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Alprazolam	N	S		Unk	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Alprazolam	N	S	Unknown	0.25 Mg	Not Reported
Atorvastatin	N	S		Unk	Not Reported
Biaxin XI	N	S		Unk	Not Reported
Biaxin XI	N	S		Unk (Tablet Extended Release)	Not Reported
Clarithromycin	N	S		Unk	Not Reported
Clarithromycin	N	S		Unk	Not Reported
Desonide	N	S		Unk	Not Reported
Desonide	N	S		Unk	Not Reported
Ertapenem Sodium	N	S	Intramuscular	Unk	Not Reported



				<u> </u>		
Ertapenem Sodium	N	S	Nasal	Unk		Not Reported
Glycerine	N	S	Oral	Unk		Not Reported
Glycerine	N	S		Unk		Not Reported
Humira	N	S	Subcutaneous	Unk	2190 DAY	Not Reported
Humira	N	S	Subcutaneous	Unk		Not Reported
Nadolol	N	S		40 Mg		Not Reported
Nadolol	N	S		Unk		Not Reported
Nadolol	N	S		Unk		Not Reported
Prednisone	N	S		Unk		Not Reported
Prednisone	N	S		Unk		Not Reported
Pregabalin	N	S		Unk		Not Reported
Pregabalin	N	S	Unknown	150 Mg		Not Reported
Pregabalin	N	S		Unk		Not Reported
Refresh Tears	N	S	Ophthalmic	Unk		Not Reported
Refresh Tears	N	S		Unk		Not Reported
Sinus Rinse	N	S	Nasal	Unk		Not Reported
Hydromorphone Hydrochloride	N	S		Unk		Not Reported
Budesonide	N	S	Oral	Unk (Sustained-Release Capsule)		Not Reported
Budesonide	N	S	Respiratory (inhalation)	Unk		Not Reported
Budesonide	N	S		Unk		Not Reported
Mesalazine	N	S		Unk		Not Reported
Mesalazine	N	S		Unk (Delayed And Extended Release)		Not Reported
Morphine Sulfate	N	S		Unk		Not Reported
Morphine Sulfate	N	S	Topical	Unk		Not Reported
Morphine Sulfate	N	S		Unk		Not Reported
Morphine Sulfate	N	S		Unk		Not Reported
Statex (Simvastatin)	Ν	S	Unknown	Unk		Not Reported



				<u> </u>	
Sulfamethoxazole + Tmp	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole + Tmp	N	S	Unknown	200 Mg	Not Reported
Kenalog (Triamcinolone Acetonide)	N	S	Intra-articular	Unk	Not Reported
Kenalog (Triamcinolone Acetonide)	N	S		Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk 1 In 6 Hours	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk, Q 4 Week	Not Reported
Loperamide Hydrochloride	N	S		Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	4 Df, Qd	Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Df, Qd	Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Df, Qid	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk	Not Reported
Dextropropoxyphene/ Paracetamol	N	S		Unk	Not Reported
Zeaxanthin	N	S	Oral	Unk	Not Reported
Xantofyl Palmitate	N	S	Oral	Unk	Not Reported
Atorvastatin Calcium	N	S		Unk	Not Reported
Betamethasone Valerate	N	S		Unk	Not Reported
Cetirizine Hydrochloride	N	S		Unk	Not Reported
Cetirizine Hydrochloride	N	S		Unk	Not Reported
Cetirizine Hydrochloride	N	S		Unk	Not Reported
Anhydrous Pantoprazole Sodium	N	S		Unk	Not Reported
Cupric Oxide + Folic Acid + Nicotinamide + Zinc	N	S		Unk	Not Reported
Isoniazid + Pyridoxine Hydrochloride + Sulfamethoxazole + Trimethoprim	N	S		Unk	Not Reported
Amoxicillin Trihydrate	N	S		Unk	Not Reported
Amoxicillin Trihydrate	N	S		Unk	Not Reported
Imodium	N	S		Unk	Not Reported
Jackson'S Mineral Salts Sodium	N	S		Unk	Not Reported



FDA Adverse Event Reporting System Freedom of Information Act (FOIA) **Detailed Report**

Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage	e Text	Duration	<u> </u>	<u>Mfr</u>
23-Jun-2022	20995740	EXPEDITED (15-DAY)	N		ОТ	CA-ORGANO O2206CANO				Female	USA
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Contro	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
	Magr	nesium Carbonate		N	S		Unk				Not Reported
	Vitam	nin D3		N	S		Unk				Not Reported
		dium Chlor									
		ogol 3350 + Potassium ride + Sodium Bicarbonate		N	S		Unk				Not Reported
		um Chlorid									
	Macr	ogol 3350 + Potassium ride + Sodium Ascorbate +		N	S						Not Reported
		nicidin/Neomycin te/Polymyxin B Sulfate		N	S		Unk				Not Reported
	Gluco	onate + Vitamin D									·
		um Carbonate + Calcium		N	S	Oral	Unk Unk				Not Reported
		Oxide		N	S	Oral	Unk				Not Reported
		olax (Bisacodyl)		N	S	Transplacental	Unk				Not Reported
		olax (Bisacodyl)		N N	S	Tananta	Unk				Not Reported
		um Chloride um Chloride		N N	S S	Nasal	Unk				Not Reported Not Reported
	-	ochlorothiazide um Chloride		N	S		Unk				Not Reported
	-	ochlorothiazide		N	S	Endocervical	Unk				Not Reported
	-	ochlorothiazide		N	S	Endocervical	Unk				Not Reported
	-	ochlorothiazide		N	S	Subcutaneous	Unk				Not Reported
	Hydro	ochlorothiazide		N	S	Endocervical	100 M	lg			Not Reported
	+ Citr Bicar Calci	ric Acid + Sodium rbonate) um Carbonate + calciferol + Zinc Oxide		N	S		Unk Unk				Not Reported
	_	eryl Trinitrate Seltzer (Acetylsalicylic Acid		N N	S S	Oral	Unk				Not Reported Not Reported



FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Macu Degeneration	ılar <i>A</i>	Azithromycin		N	S	Unknown	Not Specified		No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Jun-2022	2100065	4 EXPEDITED (15-DAY)	N		ОТ	CA-0095075 2206CAN00			Female	CAN
Preferred Term	<u>!</u>	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	<u>Mf</u> ı	<u>r</u>
Drug Ineffective; Macu Degeneration	ılar <i>A</i>	Azithromycin		N	S	Unknown	Unk; Dosage Form: No Specified	t	No	ot Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Jun-2022	2101785	3 EXPEDITED (15-DAY)	N		ОТ	CA-ORGAN O2206CAN			Female	CAN
Preferred Term	<u>!</u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Drug Ineffective; Macu Degeneration	ılar <i>A</i>	Azithromycin		N	S	Unknown	Unk; Dosage Form: No Specified	ot	No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jun-2022	2016917	9 EXPEDITED (15-DAY)	Υ		ОТ	CA-SANOF 2021SA411			Female	CAN
Preferred Term	!	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u> ı	<u>r</u>
Drug Ineffective; Macu Degeneration	ılar <i>F</i>	Azithromycin		N	S	Unknown	Unk		No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Jul-2022	2103371	6 EXPEDITED (15-DAY)	Υ		ОТ	CA-PURDU 2022-02948			Female	CAN
Preferred Term	<u> </u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Drug Ineffective; Macu	ılar <i>A</i>	Azithromycin		N	S	Unknown	Unk		No	ot Reported
Degeneration		Calcium;Calcium Carbonate; Colecalciferol		N	С	Unknown	Unk		No	ot Reported



FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

							Dotalloa	Roport				
Product Comp. OTC Role Route Dosage Text Duration Mfr	FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Not	08-Jul-2022	20126840	EXPEDITED (15-DAY)	Υ		ОТ					Female	CAN
Page	Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	e Text	Duration	<u>Mfr</u>	
	Drug Ineffective; Macu Degeneration	ular Azithro	mycin		N	S	Unknown	Unkno	own		No	t Reported
Product Comp. OTC Role Route Dosage Text Duration Mfr	FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Not Reported Not Reported Regeneration Not Regorted Reg	08-Jul-2022	20198439	EXPEDITED (15-DAY)	N		ОТ	PHARMA LLC-CA-	CEUTICALS			Unknown	USA
Product Comp. OTC Role Route Dosage Text Duration Mfr	Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	e Text	Duration	<u>Mfr</u>	
	Drug Ineffective; Macu Degeneration	ular Azithro	mycin		N	S	Unknown				No	t Reported
Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr Product Comp. OTC Role Route Dosage Text Duration Mfr Product Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr Product Comp. OTC Role Route Dosage Text Duration Mfr Product Comp. OTC Role Route Dosage Text Duration Mfr Product Comp. OTC Role Route Dosage Text Duration Mfr Product Comp. OTC Role Route Dosage Text Duration Mfr Product Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country Product Comp. OTC Role Route Dosage Text Duration Mfr Product Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country Product Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country Product Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country Product Case Type Health Prof Case Mfr Control # 503B Facility Age Sex Country Product Case Type Health Prof Case Mfr Control # 503B Facility Age Sex Country Product Case Type Health Prof Case Mfr Control # 503B Facility Age Sex Country Product Case Type Health Prof Case Mfr Control # 503B Facility Age Sex Country Product Case Type Type Type Type Type Type Type Typ	FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Product Regeneration	11-Jul-2022	21064881	EXPEDITED (15-DAY)	Y		ОТ					Female	CAN
Tegeneration Te	Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>Mfr</u>	
11-Jul-2022 21064882 EXPEDITED (15-DAY) Y OT CA-PURDUE-USA-2022-0294949 Female CAN	Drug Ineffective; Macu Degeneration	ular Azithro	mycin		N	S	Unknown	Unk			No	t Reported
Preferred Term Product Comp. OTC Role Route Dosage Text Duration Mfr Orug Ineffective; Macular Azithromycin N S Unknown Unk FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country 12-Jul-2022 20482953 EXPEDITED (15-DAY) Y OT CA-GLAXOSMITHKLINE-	FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Orug Ineffective; Macular Azithromycin N S Unknown Unk FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country 12-Jul-2022 20482953 EXPEDITED (15-DAY) Y OT CA-GLAXOSMITHKLINE-	11-Jul-2022	21064882	EXPEDITED (15-DAY)	Y		ОТ					Female	CAN
Degeneration FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country 12-Jul-2022 20482953 EXPEDITED (15-DAY) Y OT CA-GLAXOSMITHKLINE-	Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	e Text	Duration	<u>Mfr</u>	
12-Jul-2022 20482953 EXPEDITED (15-DAY) Y OT CA- GLAXOSMITHKLINE-	Drug Ineffective; Macu Degeneration	ular Azithro	mycin		N	S	Unknown	Unk			No	t Reported
GLAXOSMITHKLINE-	FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
	12-Jul-2022	20482953	EXPEDITED (15-DAY)	Y		ОТ	GLAXOS				Unknown	CAN



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Preferred Term	Prod	luct	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>Mf</u> ı	•
Drug Ineffective; Macu Degeneration	lar Azith	romycin		N	S		Unk			No	t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Jul-2022	20495962	EXPEDITED (15-DAY)	N	(TC		SMITHKLINE- AMR028721			Unknown	CAN
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	Duration	<u>Mfı</u>	:
Drug Ineffective; Macu Degeneration	lar Azith	romycin		N	S	Unknown	Unk			No	t Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jul-2022	21043081	EXPEDITED (15-DAY)	Y	(TC	CA-BAYI 2022A09				Female	CAN
Preferred Term	Prod	luct	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	Duration	<u>Mfı</u>	•
Drug Ineffective; Macu Degeneration	lar Azith	romycin		N	S	Unknown				No	t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Jul-2022	16679201	EXPEDITED (15-DAY)	Υ	ŀ	HO, OT		SMITHKLINE- AMR133655			Unknown	CAN
Preferred Term	Prod	<u>luct</u>	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	Duration	<u>Mfı</u>	•
Chronic Sinusitis; Drug		um Carbonate,		N	S	Unknown	Unk			GI	axosmithkline
neffective; Dyspepsia; nfusion Related React	tion; Calci	ecalciferol um Carbonate,		N	S		Unk			GI	axosmithkline
Macular Degeneration; Malaise; Nausea; Off	; Choic Habit	ecalciferol trol		N	S		Unk			GI	axosmithkline
Label Use; Pain; Paraesthesia Oral;	Nicot	tine		N	S		Unk			GI	axosmithkline
Procedural Pain; Pyrex	kia; Nicod	derm		Ν	S	Topical	Unk			GI	axosmithkline
Therapeutic Product E	ffect Nicot	tine Polacrilex		N	S	•	Unk			GI	axosmithkline
Incomplete; Weight Decreased	Panto	oprazole		N	S	Unknown	Unk			No	t Reported
	Dinh	enhydramine		Υ	S		Unk			GI	axosmithkline



Multivitamins	N	S		Unk	Glaxosmithkline
Zinc Oxide	Υ	S		Unk	Glaxosmithkline
Acetaminophen + Pseudoephedrine	Υ	S		Unk	Glaxosmithkline
Salinex	Υ	S	Nasal	Unk	Glaxosmithkline
Magnesium Sulfate	N	S		Unk	Not Reported
D-Alpha Tocopherol	N	S		Unk	Glaxosmithkline
Niquitin 4 Mg Mint Lozenge	N	S		Unk	Glaxosmithkline
Magnesium Oxide	N	S		Unk	Not Reported
Magnesium Sulfate Inj	N	S		Unk	Not Reported
Vitamin E	N	S		Unk	Glaxosmithkline
Nicotinamide	N	S		Unk	Not Reported
Ergocalciferol	N	S		Unk	Not Reported
Vitamin D3	N	S		Unk	Not Reported
Azithromycin Dihydrate	N	S	Oral	Unk	Not Reported
Betamethasone Dipropionate	N	S		Unk	Not Reported
Clotrimazole	N	S		Unk	Not Reported
Metronidazole	N	S		Unk	Not Reported
Metronidazole	N	S		Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Triamcinolone Acetonide	N	S		Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Alprazolam	N	S		Unk	Not Reported
Atorvastatin	N	S		Unk	Not Reported
Biaxin XI	N	S		Unk	Not Reported
Clarithromycin	N	S		Unk	Not Reported
Desonide	N	S		Unk	Not Reported
Ertapenem Sodium	N	S		Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Glycerine	N	S		Unk	Not Reported



			= = = = = = = = = = = = = = = = = = = =			
Humira	N	S	Subcutaneous	Unk	2190 DAY	Not Reported
Nadolol	N	S		40 Mg		Not Reported
Nadolol	N	S		Unk		Not Reported
Prednisone	N	S		Unk		Not Reported
Pregabalin	N	S		Unk		Not Reported
Refresh Tears	N	S	Ophthalmic	Unk		Not Reported
Refresh Tears	N	S		Unk		Not Reported
Sinus Rinse	N	S	Nasal	Unk		Not Reported
Hydromorphone Hydrochloride	N	S		Unk		Not Reported
Budesonide	N	S	Oral	Unk		Not Reported
Mesalazine	N	S		Unk		Not Reported
Morphine Sulfate	N	S		Unk		Not Reported
Statex (Simvastatin)	N	S	Unknown	Unk		Not Reported
Sulfamethoxazole + Tmp	N	S	Unknown	Unk		Not Reported
Gramicidin/Neomycin Sulfate/Polymyxin B Sulfate	Ν	S	Unknown	Unk		Not Reported
Kenalog (Triamcinolone Acetonide)	N	S	Intra-articular	Unk		Not Reported
Kenalog (Triamcinolone Acetonide)	N	S		Unk		Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk 1 In 6 Hours		Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk, Q 4 Week		Not Reported
Loperamide Hydrochloride	N	S		Unk		Not Reported
Loperamide Hydrochloride	N	S	Oral	4 Df, Qd		Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Df		Not Reported
Dextropropoxyphene/ Paracetamol	Ν	S		Unk		Not Reported
Triamcinolone	N	S	Intra-articular	Unk		Not Reported
Zeaxanthin	N	S	Oral	Unk		Not Reported
Xantofyl Palmitate	N	S	Oral	Unk		Not Reported
Atorvastatin Calcium	N	S		Unk		Not Reported
Atropine Sulphate +	N	S	Oral	4 Df, Qd		Not Reported



Diphenoxylate Hydrochloride Atropine Sulphate + Diphenoxylate Hydrochloride	N	S	Oral	1 Df	Not Reported
Atropine Sulphate + Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Betamethasone Valerate	N	S		Unk	Not Reported
Cetirizine Hydrochloride	N	S		Unk	Not Reported
Cetirizine Hydrochloride	N	S		Unk	Not Reported
Anhydrous Pantoprazole Sodium	N	S		Unk	Not Reported
Macrogol 3350 + Potassium Chloride + Sodium Bicarbonate + Sodium Sulfa	N	S		Unk	Not Reported
Cupric Oxide + Folic Acid + Nicotinamide + Zinc	N	S		Unk	Not Reported
Fructose/Glycerol/Sodium Chloride	N	S	Oral	Unk	Not Reported
Isoniazid + Pyridoxine Hydrochloride + Sulfamethoxazole + Trimethoprim	N	S		Unk	Not Reported
Calcium + Magnesium Oxide + Vitamin D3	N	S		Unk	Not Reported
Amoxicillin Trihydrate	N	S		Unk	Not Reported
Amoxicillin Trihydrate	N	S		Unk	Not Reported
Imodium	N	S		Unk	Not Reported
Jackson'S Mineral Salts Sodium Chloride	N	S		Unk	Not Reported
Nicomorphine	N	S		Unk	Not Reported
Glyceryl Trinitrate	N	S	Oral	Unk	Not Reported
Calcitriol + Calcium Carbonate + Zinc	N	S		Unk	Not Reported
Alka-Seltzer (Acetylsalicylic Acid + Citric Acid + Sodium Bicarbonate)	N	S		Unk	Not Reported
Calcium Carbonate + Colecalciferol + Zinc Oxide	N	S		Unk	Not Reported
Bromhexine Hydrochloride + Sulfamethoxazole +	N	S		Unk	Not Reported



Trimethoprim	NI				Not Deposts d
Difenoxin Hydrochloride	N	S		Unk	Not Reported
Azithromycin	N	S		Unk	Not Reported
Hydrochlorothiazide	N	S		100 Mg	Not Reported
Hydrochlorothiazide	N	S	Subcutaneous	Unk	Not Reported
Hydrochlorothiazide	N	S		Unk	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
Gramicidin/Neomycin/Nystatin/Tr iamcinolone	N	S		Unk	Not Reported
Atropine Sulfate	N	S		Unk	Not Reported
Sodium Chloride	N	S		Unk	Not Reported
Dulcolax (Bisacodyl)	N	S	Transplacental	Unk	Not Reported
Dulcolax (Bisacodyl)	N	S		Unk	Not Reported
Macrogol + Sodium Bicarbonate + Sodium Chloride + Potassium Chloride	N	S		Unk	Not Reported
Zinc Oxide	N	S	Oral	Unk	Not Reported
Diphenoxylate Hydrochloride	N	S		Unk	Not Reported
Moviprep	N	S		Unk	Not Reported
Betamethasone Sodium Phosphate	N	S		Unk	Not Reported
Methotrexate	N	S		Unk	Not Reported
Betamethasone + Mupirocin	N	S	Topical	Unk	Not Reported
Mentha Arvensis	N	S		Unk	Not Reported
Zinc Chloride Benzydamine	N N	S S		Unk	Not Reported Not Reported
Amoxicillin	N	С		Unk	Not Reported
Valsartan	N	С		Unk	Not Reported
Avamys	N	S		Unk	Glaxosmithkline
Amoxicillin Trihydrate	N	S		Unk	Not Reported
Bactroban (Mupirocin)	N	S	Topical	Unk	Glaxosmithkline
Bisacodyl	N	S	·	Unk	Not Reported



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Bisacodyl	N	S	Transplacental	Unk	Not Reported
Cetirizine	N	S	·	Unk	Glaxosmithkline
Diphenhydramine Hydrochloride	N	S	Oral	50 Mg	Not Reported
Diphenhydramine Hydrochloride	N	S		Unk	Not Reported
Flovent	N	S		Unk	Glaxosmithkline
Sulfamethoxazole + Trimethoprim	N	S		Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Calcium Carbonate + Vitamin D3	N	S		Unk	Not Reported
Colecalciferol	N	S		Unk	Not Reported
Nicotine	N	S		Unk	Not Reported
Dextropropoxyphene + Acetaminophen	N	S		Unk	Not Reported
D-Alpha Tocopherol	N	S		Unk	Not Reported
Zinc Oxide	N	S		Unk	Not Reported
Gramicidin + Polymyxin B	N	S		Unk	Not Reported
Statex (Simvastatin)	Ν	S		Unk	Not Reported
Niquitin 4 Mg Mint Lozenge	N	S		Unk	Not Reported
Trimethoprim	Ν	S		Unk	Not Reported
Nicotinamide	N	S		Unk	Not Reported
Triamcinolone	N	S		Unk	Not Reported
Acetaminophen + Pseudoephedrine	N	S		Unk	Not Reported
Isoniazid + Pyridoxine Hydrochloride + Sulfamethoxazole + Trimethoprim	N	S		Unk	Not Reported
Macrogol 3350 + Potassium Chloride + Sodium Bicarbonate + Sodium Sulfa	N	S		Unk	Not Reported
Macrogol + Sodium Bicarbonate + Sodium Chloride + Potassium Chloride	N	S		Unk	Not Reported
Glyceryl Trinitrate	N	S	Oral	Unk	Not Reported



		Salinex (I	Macrogol + Propylene		N	S		'	Unk				Not F	Reported
		Glycol + S Alka-Selt	Sodium Chloride) zer (Acetylsalicylic Acid cid + Sodium		N	S			Unk					Reported
		Bicarbona Vitamin E	ate)		N	S			Unk				Not F	Reported
			Carbonate +		N	S			Unk				Not F	Reported
		Cholecalo Mupirocir			N	S	Topica	I	Unk				Glax	osmithkline
		Mupirocir	า		N	S	Topica	ıl	Unk				Glax	osmithkline
		Mupirocir	n Calcium		Ν	S	•		Unk				Not F	Reported
			in/Neomycin		N	S			Unk				Not F	Reported
			olymyxin B Sulfate n Chloride		N	S			Unk				Glax	osmithkline
		Magnesiu	um Sulfate Injection		N	S			Unk				Not F	Reported
		Macrogol	(Ascorbic Acid + Kcl + 3350 + Nacl + Sodium		N	S							Not F	Reported
		Ascorbat Magnesiu	um Clofibrate		N	S			Unk				Not F	Reported
		Ubidecar			N	S			Unk					Reported
		Prometha	azine Hydrochloride			S			OTIK					Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof	Outcomes	<u>!</u>	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>		Country
28-Jul-2022	211438	84	EXPEDITED (15-DAY)	N		ОТ		CA-PURDUE-U 2022-0295563	SA-			Female	:	CAN
Preferred Term		Product		Comp.	OTO	Role	Route	<u>9</u>	Dosage	<u> Text</u>	<u>Duration</u>		<u>Mfr</u>	
Drug Ineffective; Macu Degeneration	ılar	Azithromy	ycin		N	S	Unknov	wn	Unk				Not F	Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	<u>!</u>	Mfr Control #		503B Facility	<u>Age</u>	<u>Sex</u>		Country
28-Jul-2022	211438	85	EXPEDITED (15-DAY)	Υ		ОТ		CA-PURDUE-U 2022-0295557	SA-			Female	•	CAN
Preferred Term		Product		Comp.	OTO	Role	Route	2	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>	
Drug Ineffective; Macu Degeneration	ılar	Azithromy	ycin		N	S			Unk				Not I	Reported

Date - Time: 11-Apr-2023 10:56:54 AM EST



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cor	ntrol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Aug-2022	21160831	EXPEDITED (15-DAY)	Y	0	Γ	CA-PURI 2022-029	DUE-USA- 95672			Female	CAN
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Drug Ineffective; Macu Degeneration	ılar Azith	romycin		N	S	Unknown	Unk			No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Aug-2022	19431517	EXPEDITED (15-DAY)	Y	0	Γ	CA-TAKE 2021TUS				Female	CAN
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	<u>Mf</u>	<u>.</u>
Drug Ineffective; Macu Degeneration	ılar Azith	romycin		N	S	Unknown				No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cor	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Aug-2022	21239521	EXPEDITED (15-DAY)	N	0.	Γ	US-ALLE 2222542	-			Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	Mf	<u>r</u>
Accidental Exposure T Product; Product Use Complaint; Skin Cance		astatinum Natricum		N	С					No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cor	ntrol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Aug-2022	16599628	EXPEDITED (15-DAY)	Y	0	Γ	CA-AURO APL-2019	OBINDO-AUR- 9-040214			Female	CAN
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	<u>Dosag</u>	e Text	Duration	Mf	<u>.</u>
Drug Ineffective; Drug		kicillin		N	S	Unknown	Unk			Αι	ırobindo
Interaction; Drug Leve Increased; Electrocardiogram Qt	I Amlo	dipine Tablets		N	S	Unknown	1 Dos Day	sage Form, Once A		Αι	ırobindo
Prolonged; Macular		orazole		N	S	Unknown	Unk				ırobindo
Degeneration; Schizoaffective Disord	er	astatin		N	S	Unknown	Unk				ot Reported
	Atorv	astatin Tablets		N	S	Unknown	Unk			No	ot Reported



Azithromycin	N	S	Unknown	Unk	Eugia Pharma
Clozapine	N	S	Unknown	1 Dosage Form, Once A Day	Aurobindo
Clozapine	N	S	Unknown	3 Dosage Form, Once A Day	Aurobindo
Metronidazole	N	S	Unknown	Unk	Aurobindo
Olanzapine Oraldispersible Tablet	N	S	Unknown	2 Dosage Form, Once A Day	Aurobindo
Olanzapine Oraldispersible Tablet	N	S	Unknown	1 Dosage Form, Once A Day	Aurobindo
Pantoprazole	N	S	Unknown	Unk	Aurobindo
Pregabalin Capsules	N	S	Topical	150.0 Milligram	Not Reported
Simvastatin Tablet	N	S	Unknown	Unk	Aurobindo
Sulfamethoxazole+Trimethoprim	N	S	Unknown	200.0 Milligram	Aurobindo
Valsartan	N	S	Vaginal	Unk	Aurobindo
Valsartan	N	S	Intracerebral	Unk	Aurobindo
Acetaminophen;Caffeine	N	S	Unknown	2 Dosage Form	Not Reported
Acetaminophen;Caffeine	N	S	Unknown	Unk	Not Reported
Aluminum Hydroxide	N	S	Oral	30 Milliliter	Not Reported
Acetaminophen	N	S	Unknown	Unk	Not Reported
Acetaminophen	N	S	Unknown	2 Dosage Form	Not Reported
Acetaminophen	N	S	Unknown	3 Dosage Form	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Unk	Not Reported
Acetaminophen; Dextropropoxyphene	N	S	Unknown	Unk	Not Reported
Adalimumab	N	S	Subcutaneous	Unk	Not Reported
Adalimumab	N	S	Unknown	Unk	Not Reported
Apo Hydro	N	S	Endocervical	Unk	Not Reported
Apo Hydro	N	S	Endocervical	100.0 Milligram	Not Reported
Ascorbic Acid;Copper; Tocopherol;Xantofyl;Zeaxanthin;	N	S	Unknown	Unk	Not Reported



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Zinc Avamys	N	S	I la la acces	Unic	Not Reported
•			Unknown	Unk	•
Aluminium Hydroxide/Magnesium	N	S	Unknown	30.0 Milliliter	Not Reported
Hydroxide/Simethicone					
Ambroxol Hydrochloride;	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride Atropine Sulfate\Diphenoxylate	N	S			Not Reported
Hydrochloride	IN	3	Oral	Unk	Not Reported
Atropine Sulfate	N	S	Oral	Unk	Not Reported
Apo-Ranitidine	N	S	Unknown	1 Dosage Form, Two	Not Reported
•			Onknown	Times A Day	•
Bactrim	N	S	Unknown	200 Milligram	Not Reported
Bactroban	N	S	Unknown	Unk	Not Reported
Betaderm	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Benzydamine Hydrochloride	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Transplacental	Unk	Not Reported
Bromhexine Hydrochloride;	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole;Trimethoprim Budesonide	N	S	0 1		Not Reported
			Oral	Unk	•
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Calcium Carbonate;Vitamin D Nos	N	S	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D3	N	S	Unknown	Unk	Not Reported
Cholecalciferol	N	S	Unknown	Unk	Not Reported
Calcium;Magnesium;Vitamin D	N	S	Unknown	Unk	Not Reported
Cetirizine	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	1 Dosage Form, Two Times A Day	Not Reported



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Cupric Oxide	N	S	Unknown	Unk	Not Reported
Calcium Carbonate;	N	S	Unknown	Unk	Not Reported
Ergocalciferol Calcitriol;Calcium Carbonate; Zinc	N	S	Intra-articular	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Divigel	N	S	Unknown	Unk	Not Reported
Dilaudid	N	S	Unknown	Unk	Not Reported
Diphenhydramine	N	S	Unknown	Unk	Not Reported
DI-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
Divalproex Sodium	N	S	Unknown	Unk, Two Times A Day	Not Reported
Dulcolax	N	S	Unknown	Unk	Not Reported
Estradiol	N	S	Vaginal	1 Dosage Form	Not Reported
Entocort	N	S	Oral	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Fluviral	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Ophthalmic	Unk	Not Reported
Flumist Quadrivalent	N	S	Nasal	Unk	Not Reported
Flovent	N	S	Unknown	Unk	Not Reported
Fructose;Glycerol;Sodium Chloride	N	S	Oral	Unk	Not Reported
Imodium	N	S	Oral	Unk Unk, Four Times/Day	Not Reported
Gramicidin\Neomycin\Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Ichthammol;Zinc	N	S	Unknown	Unk	Not Reported
Gramicidin;Polymyxin B	N	S	Unknown	Unk	Not Reported
Gramicidin;Neomycin;Nystatin; Triamcinolone	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Glycerol;Sodium Stearate	N	S	Oral	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported

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				•	
Glycerol;Ichthammol	N	S	Unknown	Unk	Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B	N	S	Unknown	Unk	Not Reported
Gramicidin;Neomycin Sulfate	N	S	Unknown	Unk	Not Reported
Glycerol	N	S	Oral	Unk	Not Reported
Habitrol	N	S	Unknown	Unk	Not Reported
Humira	N	S	Subcutaneous	Unk	Not Reported
Hydrochlorothiazide	N	S	Subcutaneous	100 Milligram	Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Unk	Not Reported
Isoniazid;Pyridoxine Hydrochloride; Sulfamethoxazole;Trimethoprim	N	S	Unknown	Unk	Not Reported
Influenza Vaccine	N	S	Unknown	Unk	Not Reported
Kenalog	N	S	Intra-articular	Unk	Not Reported
Levothyroxine	N	S	Unknown	1 Dosage Form	Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Dosage Form (1 Every 4 Weeks)	Not Reported
Lomotil	N	S	Oral	Unk Unk, Four Times/Day	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Multivitamins	N	S	Unknown	Unk	Not Reported
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate; Sodium Chloride	N	S	Unknown	Unk	Not Reported
Macrogol;Potassium Chloride; Sodium Bicarbonate;Sodium Chloride	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Topical	Unk	Not Reported
Ms Ir	N	S	Unknown	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Mupirocin Calcium	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Maalox	N	S	Unknown	30 Milligram Per Millilitre	Not Reported



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Mentha Arvensis	N	S	Unknown	Unk	Not Reported
Mezavant	N	S	Unknown	Unk	Not Reported
Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Macrogol 4000;Potassium Chloride;Sodium Bicarbonate; Sodium Chloride;So	N	S	Unknown	Unk	Not Reported
Macrogol 3350	N	S	Unknown	Unk	Not Reported
Mupirocin/Betamethasone Dipropionate	N	S	Topical	Unk	Not Reported
Nadolol	N	S	Intra-articular	40 Milligram	Not Reported
Nicoderm	N	S	Transdermal	Unk	Not Reported
Nicotine	N	S	Transdermal	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Neomycin Sulfate	N	S	Unknown	Unk	Not Reported
Niquitin Mint	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Paracetamol	N	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Subcutaneous	Unk	Not Reported
Polyethylene Glycol;Potassium Chloride;Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Premarin	N	S	Unknown	5 Gram	Not Reported
Premarin	N	S	Unknown	0.5 Gram	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Endocervical	Unk	Not Reported
Potassium Chloride	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Pms Azithromycin	N	S	Unknown	Unk	Not Reported
Potassium Chloride;Sodium Bicarbonate;Sodium Sulfate	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S		Unk	Not Reported
Rexulti	N	S	Unknown	Unk	Not Reported



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Ranitidine Hydrochloride	N	S	Unknown	150 Milligram, Two Times A Day	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Refresh Tears	N	S	Intraocular	Unk	Not Reported
Salinex	N	S	Nasal	Unk	Not Reported
Sinus Rinse	N	S	Nasal	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Intraocular	Unk	Not Reported
Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Nasal	Unk	Not Reported
Sodium Bicarbonate;Sodium Chloride	N	S	Unknown	Unk	Not Reported
Statex	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported
Triamcinolone	N	S	Intra-articular	Unk	Not Reported
Vitamin D3	N	S	Unknown	1 Dosage Form	Not Reported
Vitamin D3	N	S	Unknown	1 Dosage Form	Not Reported
Vitamins Nos	N	S	Unknown	Unk	Not Reported
Valproate Semisodium	N	S	Unknown	2 Dosage Form, Once A Day	Not Reported
Vitamin E	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zopiclone	N	S	Unknown	1 Dosage Form, Once A Day	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Calcium Carbonate;Vitamin D Nos	N	С	Unknown	Unk	Not Reported
Valsartan	N	С	Unknown	Unk	Not Reported
Brexpiprazole	N	S	Unknown		Not Reported
Neomycin Sulfate Sulfamethoxazole\Trimethoprim		S S			Not Reported Not Reported

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FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

							- -			
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Con	trol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Aug-2022	21242211	NON-EXPEDITED	Y			ALC2021	US005793		Female	USA
Preferred Term	<u>Pr</u>	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Product Administration Error	o Or	nega-3-Acid Ethyl Ester		N	S	Oral	Take 2 Capsule (2 G Total) By Mouth Every Morning And Evening		N	lot Reported
	Ox	kybutynin		N	S	Oral	Take 0.5-1 Tablet(2.5- Mg Total) By Mouth 3 Times A Day	5	N	lot Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Con	trol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Aug-2022	21244536	EXPEDITED (15-DAY)	N	(ЭТ	CA-BAXT 2022BAX			Female	CAN
Preferred Term	<u>Pr</u>	oduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Drug Ineffective; Macu Degeneration	lar Az	ithromycin		N	S	Unknown	Dosage Form Was Not Specified		N	lot Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Con	trol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Aug-2022	21246694	EXPEDITED (15-DAY)	Υ	(OT	CA-BAX1 2022BAX			Female	CAN
Preferred Term	<u>Pr</u>	oduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Drug Ineffective; Macu Degeneration	lar Az	ithromycin		N	S	Unknown	Dosage Form: Not Specified		N	lot Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Con	trol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Aug-2022	21260656	EXPEDITED (15-DAY)	Y	(OT	CA-BAXT 2022BAX			Female	CAN
Preferred Term	Pr	oduct	Comp.	<u>otc</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Drug Ineffective; Macu		etronidazole		N	S	Unknown	Unk		В	axter
Degeneration	So	dium Chloride		N	S	Endosinusial	Unk		В	axter

Note: If the field is blank, there is no data.



Acetaminophen	N	S	Unknown	Unk	Not Reported
Adalimumab	N	S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Ambroxol Hydrochloride	N	S	Unknown	Unk	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Atropine	N	S	Oral	Unk	Not Reported
Atropine	N	S	Unknown	Unk	Not Reported
Avamys	N	S	Unknown	Dosage Form: Spray Metered Dose	Not Reported
Azithromycin	N	S	Oral	Dosage Form Not Specified	Not Reported
Azithromycin Dihydrate	N	S	Unknown	Unk	Not Reported
Azithromycin Dihydrate	N	S	Oral	Unk	Not Reported
Bactrim	N	S	Unknown	Dosage Form Not Specified	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Dosage Form Not Specified	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Dose Form: Tablet (Extended Release)	Not Reported
Bisacodyl	N	S	Unknown	Dosage Form Not Specified	Not Reported
Budesonide	N	S	Unknown	Dosage Form Not Specified	Not Reported
Calcium Carbonate	N	S	Unknown	Dosage Form Not Specified	Not Reported



Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Calcium Gluconate	N	S	Unknown	Dosage Form Not Specified	Not Reported
Cetirizine	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Dosage Form Not Specified	Not Reported
Clotrimazole	N	S	Unknown	Dosage Form Not Specified	Not Reported
Cupric Oxide	N	S	Unknown	Dosage Form Not Specified	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Dosage Form Not Specified	Not Reported
Dilaudid	N	S	Unknown	Dosage Form Not Specified	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
DI-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
Entocort	N	S	Unknown	Dose Form: Capsule Sustained Release	Not Reported
Ergocalciferol	N	S	Unknown	Dosage Form Not Specified	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Flovent	N	S	Unknown	Dosage Form Not Specified	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Oral	Dosage Form: Liquid Oral	Not Reported
Glycerol	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Gramicidin;Neomycin Sulfate; Polymycin B	N	S	Unknown	Unk	Not Reported
Humira	N	S	Subcutaneous	Dose Form: Solution Subcutaneous	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported



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Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Kenalog	N	S	Unknown	Dosage Form: Suspension Intra-Articular	Not Reported
Lomotil	N	S	Oral	1 Every 6 Hours	Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Every 1 Day	Not Reported
Macrogol;Macrogol 3350; Potassium Chloride;Sodium Bicarbonate;Sodium Ch	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Dosage Form Not Specified	Not Reported
Mesalazine	N	S	Unknown	Dosage Form Not Specified	Not Reported
Morphine Sulfate	N	S	Unknown	Dosage Form Not Specified	Not Reported
Ms Ir	N	S	Unknown	Dosage Form Not Specified	Not Reported
Mupirocin	N	S	Topical	Dosage Form: Ointment Topical	Not Reported
Mupirocin	N	S	Unknown	Dosage Form: Ointment	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Unknown	Dosage Form Not Specified	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Dosage Form Not Specified	Not Reported
Pentasa	N	S	Unknown	Dosage Form Not Specified	Not Reported
Prednisone	N	S	Unknown	Dosage Form Not Specified	Not Reported
Pregabalin	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S	Unknown	Dosage Form Not	Not Reported

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Note: If the field is blank, there is no data.



FDA Adverse Event Reporting System Freedom of Information Act (FOIA) **Detailed Report**

						Specified			
	Refres	h Tears	N	S	Ophthalmic	Dosage Form: Drops Ophthalmic		No	t Reported
	Saline	X	N	S	Endosinusial	Dosage Form: Solution Nasal		No	t Reported
	Sinus I	Rinse	N	S	Endosinusial	Dosage Form: Solution Nasal		No	t Reported
	Sodiun	n Carboxymethylcellulose	N	S	Unknown	Unk		No	t Reported
	Sodiun	n Carboxymethylcellulose	N	S	Ophthalmic	Unk		No	t Reported
	Sodiun	n Stearate	N	S	Oral	Unk		No	t Reported
	Statex		N	S	Unknown	Dosage Form Not Specified		No	t Reported
	Sulfam	nethoxazole;Trimethoprim	N	S	Unknown	Dosage Form Not Specified		No	t Reported
	Triamo	cinolone	N	S	Intra-articular	Unk		No	t Reported
	Triamo	sinolone Acetonide	N	S	Intra-articular	Dosage Form: Suspension Intra-Articular		No	t Reported
	Trimetl	hoprim	N	S	Unknown	Unk		No	t Reported
	Valsart	tan	N	S	Unknown	Dosage Form Not Specified		No	t Reported
	Valsart	tan	N	S	Intracardiac	Unk		No	t Reported
	Vitamir	n D3	N	S	Unknown	Unk		No	t Reported
	Xantof	yl Palmitate	N	S	Unknown	Unk		No	t Reported
	Zeaxar	nthin	N	S	Unknown	Unk		No	t Reported
	Zinc Cl	hloride	N	S	Unknown	Unk		No	t Reported
	Zinc O	xide	N	S	Unknown	Dosage Form Not Specified		No	t Reported
	Calciur	m	N	С	Unknown	Unk		No	t Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age Sex	<u> </u>	Country
29-Aug-2022	21264552	EXPEDITED (15-DAY)	N	ОТ	US-ALLERGAN- 2227275US		Fer	nale	USA



Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Macular Degeneration Visual Impairment	;	Refresh Classic Refresh Optive		N N	S S	Ophthalmic				Allergan Allergan
		Restasis		N	S	Ophthalmic				Allergan
		Cellufresh		N	S	Ophthalmic				Not Reported
		Cellullesii		IN	<u> </u>	Ophthalmic				Not Reported
FDA Received Date	Case #	<u>Case Type</u>	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Aug-2022	21274	EXPEDITED (15-DAY)	Υ	(ТС	CA-AstraZen 2022A29787			Female	e CAN
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Drug Ineffective; Macu	ılar	Pulmicort		N	S	Unknown				Astrazeneca
Degeneration		Budesonide		Ν	S	Unknown				Not Reported
		Entocort		Ν	S	Unknown				Not Reported
		Acetaminophene		Ν	S	Unknown				Not Reported
		Adalimumab		Ν	S	Subcutaneous				Not Reported
		Alprazolam		Ν	S	Unknown				Not Reported
		Ambroxol Hydrochloride		Ν	S	Unknown				Not Reported
		Amoxicillin Trihydrate		Ν	S	Unknown				Not Reported
		Hydrochlorothiazide		Ν	S	Unknown				Not Reported
		Atorvastatin Calcium		Ν	S	Unknown				Not Reported
		Atorvastatin Calcium		Ν	S	Unknown				Not Reported
		Atropine		Ν	S	Oral				Not Reported
		Atropine		Ν	S	Unknown				Not Reported
		Avamys		Ν	S	Unknown				Not Reported
		Azithromycin		Ν	S	Oral				Not Reported
		Azithromycin Dihydrate		Ν	S	Unknown				Not Reported
		Azithromycin Dihydrate		Ν	S	Oral				Not Reported
		Bactrim		Ν	S	Unknown				Not Reported
		Betamethasone		Ν	S	Unknown				Not Reported



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Betamethasone Valerate	N	S	Unknown	Not Reported
Betamethasone Valerate	N	S	Unknown	Not Reported
Biaxin XI	N	S	Unknown	Not Reported
Bisacodyl	N	S	Unknown	Not Reported
Calcium Carbonate	N	S	Unknown	Not Reported
Calcium Gluconate	N	S	Unknown	Not Reported
Calcium Gluconate	N	S	Unknown	Not Reported
Cetirizine	N	S	Unknown	Not Reported
Clarithromycin	N	S	Unknown	Not Reported
Clotrimazole	N	S	Unknown	Not Reported
Cupric Oxide	N	S	Unknown	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Not Reported
Calcium Ascorbate	N	S	Unknown	Not Reported
Desonide	N	S	Unknown	Not Reported
Dilaudid	N	S	Unknown	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown	Not Reported
DI-Alpha Tocopheryl Acetate	N	S	Unknown	Not Reported
Ergocalciferol	N	S	Unknown	Not Reported
Ertapenem Sodium	N	S	Unknown	Not Reported
Flovent	N	S	Unknown	Not Reported
Fluticasone Furoate	N	S	Unknown	Not Reported
Glycerine	N	S	Oral	Not Reported
Glycerol	N	S	Unknown	Not Reported
Gramicidin	N	S	Unknown	Not Reported
Neomycin/Gramicidin/Polymyxin B	N	S	Unknown	Not Reported
Humira	N	S	Subcutaneous	Not Reported
Hydrochlorothiazide	N	S	Unknown	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Not Reported



Kenalog	N	S	Intra-articular	Not Reported
Lomotil	N	S	Oral	Not Reported
Loperamide	N	S	Oral	Not Reported
Hydrochloride/Simeticone Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride	N	S	Unknown	Not Reported
Magnesium Sulfate	N	S	Unknown	Not Reported
Mesalazine	N	S	Unknown	Not Reported
Metronidazole	N	s	Unknown	Not Reported
Morphine Sulfate	N	s	Unknown	Not Reported
Ms Ir	N	S	Unknown	Not Reported
Mupirocin	N	S	Topical	Not Reported
Mupirocin	N	S	Unknown	Not Reported
Mupirocin Calcium Dihydrate	N	S	Unknown	Not Reported
Nadolol	N	S	Unknown	Not Reported
Nicoderm	N	S	Unknown	Not Reported
Nicotinamide	N	S	Unknown	Not Reported
Nicotine	N	S	Unknown	Not Reported
Nicotine Polacrilex	N	S	Unknown	Not Reported
Pantoprazole	N	S	Unknown	Not Reported
Pentasa	N	S	Unknown	Not Reported
Prednisone	N	S	Unknown	Not Reported
Pregabalin	N	S	Unknown	Not Reported
Refresh Tears	N	S	Ophthalmic	Not Reported
Salinex	N	S	Endosinusial	Not Reported
Sinus Rinse	N	S	Endosinusial	Not Reported
Sodium Carboxymethyl Cellulose	N	S	Ophthalmic	Not Reported
Sodium Carboxymethyl Cellulose	N	S	Unknown	Not Reported

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Sodium Chloride

Sodium Stearate

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Endosinusial

Oral

					-	Olai				
	Sta	tex		Ν	S	Unknown				Not Reported
	Sul	famethoxazole/Trimethoprim		Ν	S	Unknown				Not Reported
	Tria	amcinolone		Ν	S	Intra-articular				Not Reported
	Tria	amcinolone Acetonide		Ν	S	Intra-articular				Not Reported
	Trir	methoprim		Ν	S	Unknown				Not Reported
	Val	sartan		N	S	Intracardiac				Not Reported
	Val	sartan		Ν	S	Unknown				Not Reported
	Vita	amin D3		Ν	S	Unknown				Not Reported
	Xaı	ntofyl Palmitate		Ν	S	Unknown				Not Reported
	Zea	axanthin		N	S	Unknown				Not Reported
	Zin	c Chloride		Ν	S	Unknown				Not Reported
	Zin	c Oxide		N	S	Unknown				Not Reported
	Cal	lcium		N	С	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol # 503B Facility	<u>Age</u>	Sex	Country
31-Aug-2022	21280026	DIRECT			RI			75 YR	Male	USA
Preferred Term	<u>Pro</u>	<u>oduct</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Eye Infection Bacteria		eratears Extra Dry Eye erapy		Υ	S	Ophthalmic	Frequency : As Needed;			Akorn
	Cp: Mic Mit Mo Flo			N N N N N	0000000					Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

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Not Reported

Not Reported



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	K		N	С				No	ot Reported
	Ashw	vaganda	N	С				No	ot Reported
	Bosw	vellia	N	С				No	ot Reported
	Zinc		N	С				No	ot Reported
	Copp	er	N	С				No	ot Reported
	Rutin	l	N	С				No	ot Reported
	Mela	tonin	N	С				No	ot Reported
	Alpha	a Lipoid Acid	N	С				No	ot Reported
	Asta	kanthin	N	С				No	ot Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04 Con 2022	20200022	EVDEDITED (15 DAV)	V	HO OT	CA		71 VD	Fomolo	CAN

01-Sep-2022 20290023 EXPEDITED (15-DAY) Y HO, OT CA-GLAXOSMITHKLINE-CA2021AMR262195

Preferred Term	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>Mfr</u>
Abdominal Pain; Chronic	Amoxicillin Trihydrate		N	S	Unknown	Unk		Not Reported
Sinusitis; Drug Ineffective; Dyspepsia; Infusion	Betamethasone		N	S	Unknown	Unk		Not Reported
Related Reaction; Macular	Betamethasone Valerate		N	S	Unknown	Unk		Not Reported
Degeneration; Malaise; Nausea; Off Label Use;	Metronidazole		N	S	Unknown	Unk		Not Reported
Pain; Paraesthesia Oral;	Fluticasone Furoate		N	S	Unknown	Unk, Spray Metered Do	se	Glaxosmithkline
Procedural Pain; Pyrexia; Therapeutic Product Effect	Sulfamethoxazole +		N	S	Unknown	200 Mg		Not Reported
Incomplete; Weight Decreased	Trimethoprim Sulfamethoxazole + Trimethoprim		N	S	Unknown	Unk		Not Reported
	Avamys		N	S	Unknown	Unk		Glaxosmithkline
	Clotrimazole		Υ	S	Unknown	Unk		Glaxosmithkline
	Fluticasone Propionate		N	S	Unknown	Unk		Glaxosmithkline
	Betamethasone Dipropionate		N	S	Unknown	Unk		Not Reported
	Mupirocin		N	S	Topical	Unk		Glaxosmithkline
	Mupirocin		N	S		Unk		Glaxosmithkline
	Tocopherol		N	S	Unknown	Unk		Not Reported
	Triamcinolone Acetonide		N	S	Intra-articular	Unk		Not Reported
	Triamcinolone Acetonide		N	S	Unknown	Unk		Not Reported
	Bisacodyl		Ν	S	Transplacental	Unk		Not Reported



				-	
Bisacodyl	N	S	Unknown	Unk	Not Reported
Cetrizin	N	S	Unknown	Unk	Not Reported
Colecalciferol	N	S	Unknown	Unk	Not Reported
Potassium Chloride	N	S	Unknown	Unk	Not Reported
Paracetamol	N	S	Unknown	Unk	Not Reported
Calcium + Colecalciferol	N	S	Unknown	Unk	Not Reported
Amoxicillin	N	S	Unknown	Unk	Not Reported
Glycerol (Glycerin)	N	S	Oral	Unk	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Unk	Not Reported
Macrogol	N	S	Unknown	Unk	Not Reported
Alprazolam	N	S	Unknown	0.25 Mg	Not Reported
Alprazolam	N	S	Respiratory (inhalation)	Unk	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Azithromycin	N	S	Unknown	Unk	Not Reported
Adalimumab	N	S	Subcutaneous	Unk	Not Reported
Budesonide	N	S	Respiratory (inhalation)	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Potassium Chloride	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	40 Mg	Not Reported
Nadolol	N	S		Unk	Not Reported
Gramicidin/Neomycin	N	S	Unknown	Unk	Not Reported



Sulfate/Polymyxin B Sulfate Gramicidin/Neomycin	N	S	Unknown	Unk	Not Reported
Sulfate/Polymyxin B Sulfate Atropine + Diphenoxylate	N	S	Oral	Unk	Not Reported
Atropine + Diphenoxylate	N	S	Unknown	1 Df	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
Desonide	Ν	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	Ν	S		Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Unk	Not Reported
Ertapenem Sodium	N	S	Respiratory (inhalation)	Unk	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Unknown	150 Mg	Not Reported
Pregabalin	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Carmellose Sodium	N	S	Ophthalmic	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Infliximab	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Calcium Citrate	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Moviprep	N	S	Unknown	Unk Powder For Oral Solution	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported



				- 1	
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Natural Vitamin E	N	S	Unknown	Unk	Not Reported
Isoniazid + Pyridoxine Hydrochloride + Sulfamethoxazole + Trimethoprim	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Valsartan	N	S	Oral	40 Mg, Qd	Not Reported
Valsartan	N	S	Oral	4 Df, Qd	Not Reported
Calcium + Colecalciferol	N	S	Unknown	Unk	Not Reported
Entocort	N	S	Oral	Unk	Not Reported
Pulmicort	N	S	Respiratory (inhalation)	Unk	Not Reported
Benadryl (Diphenhydramine Hydrochloride)	N	S	Oral	50 Mg	Not Reported
Gramicidin/Neomycin Sulfate/Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole + Tmp	N	S		200 Mg	Not Reported
Sulfamethoxazole + Tmp	N	S	Oral	1 Df	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Tocopherol	N	S	Unknown	Unk	Not Reported
Lomotil (Atropine + Diphenoxylate)	N	S	Oral	Unk	Not Reported
Dextropropoxyphene + Acetaminophen	N	S	Unknown	Unk	Not Reported
Ambroxol Hcl + Cetirizine Hcl	N	S	Unknown	Unk	Not Reported
Azithromycin Dihydrate	N	S	Unknown	Unk	Not Reported
Calcitriol + Calcium Carbonate + Zinc	N	S	Unknown	Unk	Not Reported
Diphenhydramine	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported



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		Magnesi	ium Oxide		N	S	Unknown	Unk				Not Reported
		Simvasta	atin		Ν	S	Unknown	Unk				Not Reported
		Sinus Ri	nse		Ν	S	Unknown	Unk				Not Reported
		Triamcin	olone		Ν	S	Unknown	Unk				Not Reported
		Trimetho	pprim		Ν	S	Unknown	Unk				Not Reported
		Loperan	nide Hydrochloride		Ν	S	Oral	Unk				Not Reported
		Acetami Phospha	nophen + Codeine		N	S		Unk				Not Reported
		Nicotina			Ν	S	Unknown	Unk				Not Reported
		Metoclop	oramide Hydrochloride		Ν	С	Oral	Unk				Not Reported
		Loperan	nide		Ν	С	Oral	4 Df, Qd				Not Reported
		Calcium			Ν	С	Unknown	Unk				Not Reported
		Calcium	Carbonate + Vitamin D		Ν	С	Unknown	Unk				Not Reported
		Calcium	& Ergocalciferol		N	С		Unk				Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol# <u>50</u>	3B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Sep-2022	213095	75	EXPEDITED (15-DAY)	N		ОТ	US-ALLERO 2228854US				Male	USA
referred Term		Product	<u>t</u>	Comp.	OTO	Role	Route	Dosage Te	<u>xt</u>	<u>Duration</u>		Mfr
Abnormal Sensation In Eye; Blindness Transi Eye Swelling; Ocular Hyperaemia		Refresh	Optive		Υ	S	Ophthalmic	2 Gtt, Qd				Allergan
FDA Received Date	Case #		Case Type	Health	Prof	Outcomes	Mfr Contro	ol # 50	3B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Sep-2022	213271	07	EXPEDITED (15-DAY)	N		ОТ	US-ALLER(2229615US				Femal	e USA
referred Term		Product	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Te	<u>xt</u>	Duration		Mfr
cataract; Therapeutic		Refresh	Optive		Υ	S		Unk				Allergan



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Sep-2022	2133841	14 EXPEDITED (15-DAY)	N	07	-	US-ALLER 2229532US				Female	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	Duration	<u>N</u>	<u>lfr</u>
Cataract; Eye Irritation	i 1	Refresh Optive Gel Drops Y		Υ	S		Unk			1	Not Reported
FDA Received Date	Case #	Case Type	Health	Prof Ou	ıtcomes	Mfr Conti	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Sep-2022	2016961	17 EXPEDITED (15-DAY)	Υ	07	-	CA-SANOF 2021SA41				Female	CAN
Preferred Term	,	<u>Product</u>	Comp.	OTC	Role	Route	Dosage	e Text	Duration	<u>N</u>	<u>lfr</u>
Drug Ineffective; Macu	ılar	Triamcinolone Acetonide		N	S	Intra-articular	Unk			9	Sanofi
Degeneration	1	Paracetamol		N	S		Unk			1	Not Reported
		Alprazolam		N	S	Unknown	Unk			1	Not Reported
		Sulfamethoxazole/Trimethoprim Amoxicillin Trihydrate		N N	S S	Unknown	Unk				Not Reported Not Reported
		Atorvastatin Calcium		N	S	Unknown	Unk			1	Not Reported
		Azithromycin		N	S	Unknown	Unk			1	Not Reported
	1	Betamethasone Dipropionate		N	S	Unknown	Unk			1	Not Reported
	1	Betamethasone Valerate		N	S	Unknown	Unk			1	Not Reported
	1	Bisacodyl		N	S	Unknown	Unk			9	Sanofi
	I	Budesonide		N	S	Respiratory (inhalation)	Unk			1	Not Reported
	(Calcium Carbonate		N	S	Unknown	Unk			1	Not Reported
	(Cetirizine Hydrochloride		N	S	Unknown	Unk			1	Not Reported
	(Clarithromycin		N	S	Unknown	Unk			1	Not Reported
	(Clotrimazole		N	S	Unknown	Unk			1	Not Reported
	1	Desonide		N	S	Unknown	Unk			1	Not Reported
	1	Hydrochlorothiazide		N	S	Unknown	Unk			1	Not Reported
		Carmellose Sodium Mesalazine		N N	S S	Unknown	Unk				Not Reported Sanofi



	Gly	cerine	N	S	Unknown	Unk			N	lot Reported
	Pre	dnisone	N	S	Unknown	Unk			N	lot Reported
	Pre	gabalin	N	S	Unknown	Unk			N	lot Reported
	Nic	oderm	N	S	Unknown	Unk			S	anofi
	Moi	rphine Sulfate	N	S	Unknown	Unk			N	lot Reported
	Muj	pirocin	N	S	Topical	Unk			N	lot Reported
	Nac	dolol	N	S	Unknown	Unk			N	lot Reported
	Nic	otine Polacrilex	N	S	Unknown	Unk			N	lot Reported
	Dip	henhydramine	N	S	Unknown	Unk			S	anofi
	Erg	ocalciferol	N	S	Unknown	Unk			S	anofi
	Flut	ticasone Furoate	N	S	Unknown	Unk			N	lot Reported
	Azit	thromycin Dihydrate	N	S	Unknown	Unk			N	lot Reported
	Ber	nzydamine	N	S	Unknown	Unk			N	lot Reported
	Ada	alimumab	N	S	Subcutaneous	Unk			N	lot Reported
	Soc	crogol;Potassium Chloride; lium Bicarbonate;Sodium oride	N	S	Unknown	Unk			N	lot Reported
		ticasone Propionate	N	S	Unknown	Unk			N	lot Reported
	Erta	apenem Sodium	N	S	Unknown	Unk			N	lot Reported
	Vita	amins Nos	N	S	Unknown	Unk			N	lot Reported
	Ace	etaminophen	N	S	Unknown	Unk			N	lot Reported
		nzydamine resh Tears	N N	S S	Ophthalmic	Ophth	halmic Drops			lot Reported lot Reported
	Met	tronidazole	N	С	Unknown	Unk	·		N	lot Reported
	Val	sartan	N	С	Unknown	Unk			N	lot Reported
	Sul	famethoxazole\Trimethoprim		S					N	lot Reported
FDA Received Date	Case #	Case Type	Health Prof	<u>Outcomes</u>	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Sep-2022	20208262	EXPEDITED (15-DAY)	Υ	ОТ	US-VALIDUS PHARMACEU LLC-CA-VDP-: 014728				Unknown	USA



Preferred Term	Product	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	Duration	<u>Mfr</u>
Drug Ineffective; Macular	Ergocalciferol		N	S	Unknown	Unk		Validus
Degeneration	Triamcinolone Acetonide		N	S	Intra-articular	Unk		Not Reported
	Paracetamol		N	S	Unknown	Unk		Not Reported
	Alprazolam		N	S	Unknown	Unk		Not Reported
	Amoxicillin Trihydrate		N	S	Unknown	Unk		Not Reported
	Atorvastatin Calcium		N	S	Unknown	Unk		Not Reported
	Azithromycin		N	S	Unknown	Unk		Not Reported
	Betamethasone Dipropionate		N	S	Unknown	Unk		Not Reported
	Betamethasone Valerate		N	S	Unknown	Unk		Not Reported
	Bisacodyl		N	S	Unknown	Unk		Not Reported
	Budesonide		N	S		Unk, Inhalational		Not Reported
	Calcium Carbonate		N	S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride		N	S	Unknown	Unk		Not Reported
	Clarithromycin		N	S	Unknown	Unk		Not Reported
	Clotrimazole		N	S	Unknown	Unk		Not Reported
	Desonide		N	S	Unknown	Unk		Not Reported
	Hydrochlorothiazide		N	S	Unknown	Unk		Not Reported
	Carmellose Sodium		N	S	Unknown	Unk, Eye Drops Solution	n	Not Reported
	Mesalazine		N	S	Unknown	Unk		Not Reported
	Glycerine		N	S	Unknown	Unk		Not Reported
	Prednisone		N	S	Unknown	Unk		Not Reported
	Pregabalin		N	S	Unknown	Unk		Not Reported
	Nicoderm		N	S	Unknown	Unk		Not Reported
	Morphine Sulfate		N	S	Unknown	Unk		Not Reported
	Mupirocin		N	S	Topical	Unk		Not Reported
	Nadolol		N	S	Unknown	Unk		Not Reported
	Nicotine Polacrilex		N	S	Unknown	Unk		Not Reported
	Diphenhydramine		N	S	Unknown	Unk		Not Reported



	Flu	uticasone Furoate		N	S	Other	Unk, Nasal Spray			Not Reported
	Az	tithromycin Dihydrate		N	S	Unknown	Unk			Not Reported
	Ве	enzydamine		N	S	Unknown	Unk			Not Reported
	Ad	lalimumab		N	S	Subcutaneous	Unk			Not Reported
	So	acrogol;Potassium Chloride; odium Bicarbonate;Sodium oloride		N	S	Unknown	Unk			Not Reported
		uticasone Propionate		Ν	S	Unknown	Unk			Not Reported
	Eri	tapenem Sodium		Ν	S	Unknown	Unk			Not Reported
	Vit	tamins Nos		N	S	Unknown	Unk			Not Reported
	Ac	etaminophen		N	S	Unknown	Unk			Not Reported
	Ве	enzydamine		Ν	S	Unknown	Unk			Not Reported
		ılfamethoxazole And imethoprim		N	S	Unknown	Unk			Not Reported
	Re	efresh Tears		N	S	Ophthalmic	Unk, Ophthalmic Drops			Not Reported
	Me	etronidazole		N	С	Unknown	Unk			Not Reported
	Va	lsartan		N	С	Unknown	Unk			Not Reported
	Su	Ilfamethoxazole\Trimethoprim			S					Not Reported
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Sep-2022	21372107	EXPEDITED (15-DAY)	N		ОТ	US-ALLERGAN 2230307US	I-		Female	USA
referred Term	<u>Pr</u>	oduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Cataract	Re	efresh Tears		Υ	S	Ophthalmic				Not Reported
	Re	efresh Optive		N	S	Ophthalmic	Unk			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Sep-2022	21372111	EXPEDITED (15-DAY)	N		ОТ	US-ALLERGAN 2229990US	I-		Female	USA
referred Term	<u>Pr</u>	oduct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Neovascular Age-Rela Macular Degeneration		efresh Tears		Υ	S	Ophthalmic	Unk			Allergan



Date - Time: 11-Apr-2023 10:56:54 AM EST

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date C	Case #	Case Type	Health	Prof Ou	ıtcomes	Mfr Cont	rol # 503B Facility	Age	Sex	Country
23-Sep-2022 2	21372129	EXPEDITED (15-DAY)	N	01	-	US-ALLER 2230426U			Unknown	USA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>.</u>
Cataract; Product Container Issue	Refre	sh Plus		Υ	S				No	t Reported
FDA Received Date 0	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Cont	rol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
26-Sep-2022 2	20488075	EXPEDITED (15-DAY)	Υ	НС	O, OT	CA-APOTE 2022AP00		71 YR	Female	CAN
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	Mf	:
Chronic Sinusitis; Drug	Amox	kicillin Trihydrate		N	S	Unknown	Unk		No	ot Reported
Ineffective; Dyspepsia; Infusion Related Reactio	Atorv	astatin		N	S	Unknown	Unk		Ap	otex
Macular Degeneration;		aminophen		N	S	Unknown	Unk		Αp	otex
Malaise; Nausea; Off Label Use; Pain;	Bisac	codyl		N	S	Unknown	Unk		No	t Reported
Paraesthesia Oral;	Cetiri	zine		N	S	Unknown	Unk		Ap	otex
Procedural Pain; Pyrexia Therapeutic Product Effe		um Carbonate		N	S	Unknown	Unk		No	t Reported
Incomplete; Weight	Clarit	hromycin		N	S	Unknown	Unk		Ap	otex
Decreased	Diphe	enhydramine		N	S	Unknown	Unk		Ap	otex
	Diphe	enhydramine		N	S	Oral	50 Milligram		Ap	otex
	Metro	onidazole		N	S	Unknown	Unk		No	t Reported
	Nicot	ine		N	DS	Unknown	Unk		Ap	otex
	Nado	lol		N	S	Unknown	40 Milligram		No	t Reported
	Predr	nisone		N	S	Unknown	Unk		No	t Reported
	Panto	pprazole		N	S	Unknown	Unk		Ap	otex
	Prega	abalin		N	S	Unknown	150 Milligram		Ap	otex
	Flutic	asone		N	DS	Unknown	Unk		Ap	otex
	Alpra	zolam		N	S	Unknown	0.25 Milligram		Ap	otex
	Azith	romycin		N	S	Unknown	Unk		Ap	otex

Note: If the field is blank, there is no data.



				!		
Loperamide	N	S	Oral	Unk		Apotex
Potassium Chloride	N	S	Unknown	Unk		Apotex
Hydromorphone	N	S	Endocervical	Unk		Not Reported
Hydromorphone	N	S	Unknown	Unk		Not Reported
Sulfamethoxazole, Trimethoprim	N	S	Unknown	200 Milligram		Apotex
Simvastatin	N	S	Unknown	Unk		Apotex
Metoclopramide	N	S	Oral	Unk		Apotex
Hydrochlorothiazide	N	S	Unknown	Unk		Apotex
Trimethoprim	N	S	Unknown	Unk		Not Reported
Avamys	N	S	Unknown	Unk		Not Reported
Bactrim	N	S	Unknown	Unk		Not Reported
Benadryl [Diphenhydramine	N	S	Oral	50 Milligram		Not Reported
Hydrochloride] Biaxin XI	N	S	Unknown	Unk		Not Reported
Cholecalciferol	N	S	Unknown	Unk		Not Reported
Cupric Oxide	N	S	Unknown	Unk		Not Reported
Clotrimazole	N	S	Unknown	Unk		Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk		Not Reported
Desonide	N	S	Unknown	Unk		Not Reported
Dilaudid	N	S	Unknown	Unk		Not Reported
Entocort	N	S	Oral	Unk		Not Reported
Ertapenem Sodium	N	S	Unknown	Unk		Not Reported
Flovent	N	S	Unknown	Unk		Not Reported
Glycerol	N	S	Oral	Unk		Not Reported
Gramicidin;Neomycin Sulfate; Polymycin B	N	S	Unknown	Unk		Not Reported
Humira	N	S	Unknown	Unk		Not Reported
Humira	N	S	Subcutaneous	Unk	6 YR	Not Reported
Infliximab	N	S	Intravenous (not otherwise specified)	Unk		Not Reported
Isoniazid/Pyridoxine	N	S	Unknown	Unk		Not Reported



Hydrochloride/Sulfamethoxazole /Trimethoprim					
Macrogol;Potassium Chloride; Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Mupirocin	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Pms Azithromycin	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S		Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Sodium Chloride	N	S	Nasal	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Adalimumab	N	S	Subcutaneous	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Unknown	1 Dosage Form	Not Reported
Betamethasone Valerate	N	S	Unknown	0.122 Gram	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Macrogol	N	S	Unknown	Unk	Not Reported



Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Acetaminophen;	N	S	Unknown	Unk	Not Reported
Dextropropoxyphene Ambroxol;Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Azithromycin Dihydrate	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Calcitriol;Calcium Carbonate; Zinc	N	S	Unknown	Unk	Not Reported
Cupric Oxide;Folic Acid;Nicotinic Acid;Zinc	N	S	Unknown	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Unknown	Unk	Not Reported
Glycerin	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Gramicidin;Polymyxin B	N	S	Unknown	Unk	Not Reported
Macrogol;Potassium Chloride; Sodium Bicarbonate;Sodium Chloride	N	S	Unknown	Unk	Not Reported
Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Glycerinum	N	S	Unknown	Unk	Not Reported
Tocopherols Mixed	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Infa-3 [Gramicidin;Neomycin Sulfate;Polymyxin B]	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Sinus Rinse	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride; Zinc Oxide	N	S	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D3	N	S	Unknown	Unk	Not Reported
Lomotil [Loperamide	N	S	Oral	Unk	Not Reported



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Hydrochloride]

		Lomotil [Hydroch	Loperamide Ioridel		N	С	Unknown	ι	Jnk		1	Not Reported	
		Loperan			Ν	С	Oral	4	4 Milligram, Qd		1	Not Reported	
		Loperam	iide		Ν	С	Oral	4	4 Dosage Form, Qd		1	Not Reported	
		Benadry Hydroch	l [Diphenhydramine loride]		N	С	Unknown	ι	Jnk		١	Not Reported	
		Metoclop	oramide Hydrochloride		Ν	С	Oral	ι	Jnk		1	Not Reported	
		Valsarta	n		Ν	С	Oral	4	4 Dosage Form, Qd		1	Not Reported	
		Valsarta	n		Ν	С	Oral	4	40 Milligram, Qd		1	Not Reported	
		Calcium	Ergocalciferol		N	С	Unknown	ι	Jnk		1	Not Reported	
		Calcium	Gluconate		Ν	С	Unknown	ι	Jnk		1	Not Reported	
		Dipheno	xylate Hydrochloride		Ν	С	Unknown	ι	Jnk		1	Not Reported	
		Neomyc	in Sulfate		Ν	С	Unknown	ι	Jnk		1	Not Reported	
		Calcium	Carbonate/Vitamin D3		Ν	С	Unknown	ι	Jnk		1	Not Reported	
		Sodium	Stearate		Ν	С	Unknown	ι	Jnk		1	Not Reported	
		Calcium	Colecalciferol		Ν	С	Unknown	ι	Jnk		1	Not Reported	
			Atropine Sulfate;		Ν	С	Unknown	ι	Jnk		1	Not Reported	
		Calcium	xylate Hydrochloride] Lactate;Calcium ite;Ergocalciferol		N	С	Unknown	ι	Jnk		1	Not Reported	
		Benadry	l Allergy nydramine		N	С	Unknown	ι	Jnk		1	Not Reported	
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof	Outcomes	Mfr Con	trol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
27-Sep-2022	213797	'28	EXPEDITED (15-DAY)	Υ		HO, OT	CA-Astra; 2022A32			71 YR	Female	CAN	
Preferred Term		Product		Comp.	OTO	Role	Route	Do	osage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>	
Chronic Sinusitis; Drug		Budesor	iide		N	S	Unknown				1	Not Reported	
Ineffective; Dyspepsia; Infusion Related React		Acetami	nophen		Ν	S	Unknown				1	Not Reported	
Macular Degeneration;		Adalimu	mab		Ν	S	Subcutaneous				1	Not Reported	
Malaise; Nausea; Off Label Use; Pain;		Alprazolam			N	S	Unknown				Not Reported		



Paraesthesia Oral; Procedural Pain; Pyrexia; Therapeutic Product Effect Incomplete; Weight Decreased

			Dotalloa Itt	port	
Amoxicillin	N	S	Unknown		Not Reported
Amoxicillin Trihydrate	N	S	Unknown		Not Reported
Atorvastatin Calcium	N	S	Unknown		Not Reported
Diphenoxylate	N	S	Oral		Not Reported
Hydrochloride/Atropine Sulfate Diphenoxylate Hydrochloride/Atropine Sulfate	N	S	Oral	1.0df Unknown	Not Reported
Azithromycin	N	S	Unknown		Not Reported
Betamethasone	N	S	Unknown		Not Reported
Betamethasone Valerate	N	S	Unknown		Not Reported
Bisacodyl	N	S	Unknown		Not Reported
Calcium Carbonate	N	S	Unknown		Not Reported
Cetirizine Hydrochloride	N	S	Unknown		Not Reported
Clarithromycin	N	S	Unknown		Not Reported
Clotrimazole	N	S	Unknown		Not Reported
Cupric Oxide	N	S	Unknown		Not Reported
D-Alpha Tocopherol	N	S	Unknown		Not Reported
Desonide	N	S	Unknown		Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown		Not Reported
Ertapenem Sodium	N	S	Unknown		Not Reported
Fluticasone Furoate	N	S	Unknown		Not Reported
Fluticasone Propionate	N	S	Unknown		Not Reported
Glycerine	N	S	Unknown		Not Reported
Glycerol	N	S	Oral		Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical		Not Reported
Infa-3 [Gramicidin;Neomycin Sulfate;Polymyxin B]	N	S	Unknown		Not Reported
Infliximab	N	S	Intravenous (not otherwise specified))	Not Reported
Loperamide Hydrochloride	N	S	Unknown		Not Reported
Macrogol	N	S	Unknown		Not Reported



				•	
Magnesium Sulfate	N	S	Unknown		Not Reported
Mesalazine	N	S	Unknown		Not Reported
Metronidazole Morphine Sulfate Mupirocin	N N N	S S S	Tanical		Not Reported Not Reported Not Reported
Nadolol	N	S	Topical Unknown	40.0mg Unknown	Not Reported
Nicoderm	N	S	Unknown	40.0mg Onknown	Not Reported
Nicotine Polacrilex	N	S	Unknown		Not Reported
Pantoprazole	N	S	Unknown		Not Reported
Prednisone	N	S	Unknown		Not Reported
Pregabalin	N	S	Unknown	150.0mg Unknown	Not Reported
Sodium Bicarbonate	N	S	Unknown	156.011g Officiowii	Not Reported
Sodium Carboxymethyl Cellulose	N	S	Unknown		Not Reported
Sodium Chloride	N	S	Respiratory (inhalation)		Not Reported
Sulfamethoxazole/Trimethoprim	N	S	Unknown	200.0mg Unknown	Not Reported
Triamcinolone Acetonide	N	S	Unknown	C	Not Reported
Vitamin D3	N	S	Unknown		Not Reported
Xantofyl Palmitate	N	S	Unknown		Not Reported
Zeaxanthin	N	S	Unknown		Not Reported
Zinc Oxide	N	S	Unknown		Not Reported
Valsartan	N	С	Unknown		Not Reported
Lomotil	N	С	Unknown		Not Reported
Benadryl Allergy	N	С	Unknown		Not Reported
Calcium Gluconate	N	С	Unknown		Not Reported
Calcium Lactate/Ergocalciferol/Calcium Phosphate	N	С	Unknown		Not Reported
Metoclopramide Hydrochloride	N	С	Unknown		Not Reported



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FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Oct-2022	2140460	1 EXPEDITED (15-DAY)	N	C	T	US-ALLERO 2231339US	BAN-			Female	USA
Preferred Term	Ī	Product	Comp.	<u>OTC</u>	Role	Route	<u>Dosag</u>	<u>e Text</u>	Duration		<u>Mfr</u>
Expired Product	F	Refresh Optive Sensitive		Υ	S	Ophthalmic	Unk				Allergan
Administered; Eye Pai Macular Degeneration	Г	lydroxychloroquine Preservision		N N	S C		Unk				Not Reported Not Reported
	N	Multivitamins		N	С						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Oct-2022	2140792	3 EXPEDITED (15-DAY)	Υ	C	T	ALC2022CA	004488			Female	CAN
Preferred Term	<u> </u>	Product	Comp.	OTC	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>		<u>Mfr</u>
Drug Ineffective; Macu	ılar <i>A</i>	Atropine Sulfate		N	S	Unknown					Alcon
Degeneration	P	Adalimumab		N	S	Subcutaneous	Unk				Not Reported
	P	moxicillin Trihydrate		N	S	Unknown	Unk				Not Reported
	A	Atorvastatin Calcium		N	S	Unknown	Unk				Not Reported
	C	Clarithromycin		N	S	Unknown	Unk				Not Reported
		Diphenhydramine Hydrochloride		N	S	Unknown	Unk				Not Reported
	H	Hydromorphone Hydrochloride		N	S	Unknown					Not Reported
	N	Magnesium Sulfate		N	S	Unknown					Not Reported
	N	Norphine Sulfate		N	S	Unknown					Not Reported
	F	Pantoprazole Sodium		N	S	Unknown					Not Reported
	F	Pregabalin		N	S	Unknown					Not Reported
	Т	riamcinolone Acetonide		N	S	Intra-articular	Unk				Not Reported
	A	Acetaminophen		N	S	Unknown					Not Reported
	A	Acetylsalicylic Acid		N	S	Unknown					Not Reported
	A	Alprazolam		N	S		Unk				Not Reported
	P	Alprazolam		N	S	Unknown	Unk				Not Reported

Note: If the field is blank, there is no data.



				•	
Amoxicillin	N	S	Unknown		Not Reported
Azithromycin	N	S	Unknown		Not Reported
Betamethasone	N	S	Unknown		Not Reported
Betamethasone Valerate	N	S	Unknown		Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Unknown		Not Reported
Calcium Citrate	N	S	Unknown		Not Reported
Cetirizine Hydrochloride	N	S	Unknown		Not Reported
Clotrimazole	N	S	Unknown		Not Reported
Cupric Oxide	N	S	Unknown		Not Reported
D-Alpha Tocopheryl Acetate	N	S	Unknown		Not Reported
Desonide	N	S	Unknown		Not Reported
Difenoxin Hydrochloride	N	S	Oral		Not Reported
Ertapenem Sodium	N	S	Unknown		Not Reported
Fluocinolone Acetonide	N	S	Unknown		Not Reported
Fluticasone Furoate	N	S	Unknown		Not Reported
Glycerol	N	S	Oral		Not Reported
Gramicidin	N	S	Unknown		Not Reported
Hydrochlorothiazide	N	S	Endocervical		Not Reported
Ichthammol And Zinc Oxide	N	S	Unknown		Not Reported
Macrogol	N	S	Unknown		Not Reported
Mesalazine	N	S	Unknown		Not Reported
Metronidazole	N	S	Unknown		Not Reported
Mupirocin	N	S	Topical		Not Reported
Nadolol	N	S	Unknown		Not Reported
Neomycin	N	S	Unknown		Not Reported
Nicoderm	N	S	Unknown		Not Reported
Nicotine Polacrilex	N	S	Unknown		Not Reported



		Polymy	kin B Sulfate		N	S	Unknown					Not Reported
		Prednis	one		N	S	Unknown					Not Reported
		Sodium	Carboxymethylcellulose		N	S	Ophthalmic					Not Reported
		Sodium	Chloride		N	S	Unknown					Not Reported
		Sulfame	ethoxazole		N	S	Unknown					Not Reported
		Vitamin	D Nos		N	S	Unknown					Not Reported
		Vitamin	D3		N	S	Unknown					Not Reported
		Xantofy	Palmitate		N	S	Unknown					Not Reported
		Zeaxant	thin		N	S	Unknown					Not Reported
		Hyrimoz	[Adalimumab]		N	С	Unknown					Not Reported
		Valsarta	ın		N	С	Unknown					Not Reported
		Vitamin	A [Retinol]		N	С	Unknown					Not Reported
FDA Received Date	Case #		Case Type	Health	Prof Ou	tcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2022	214160	87	DIRECT								Unknow	n USA
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>le Text</u>	<u>Duration</u>		<u>Mfr</u>
Drug Ineffective		Therate Therate			N N	S C						Not Reported Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Oct-2022	213740	54	EXPEDITED (15-DAY)	Υ	ОТ		NVSC2022C	CA214430			Female	CAN
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>le Text</u>	<u>Duration</u>		<u>Mfr</u>
Drug Ineffective; Macu	ular	Adalimu	mab		N	S	Subcutaneous	Unk				Novartis
Degeneration		Amoxici	llin		N	S	Unknown	Unk				Novartis
		Amoxici	llin Trihydrate		N	S	Unknown	Unk				Novartis
					N	S	Unknown	Unk				Novartis
		Atorvas	tatin Calcium			-	O.11101111	OTTIN				
			tatin Calcium e Sulfate		N	S	Unknown	Unk				Not Reported



				•	
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium	N	S	Unknown	Unk	Novartis
Pregabalin	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Novartis
Acetaminophen	N	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Unk	Not Reported
Alprazolam	N	S		Unk	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Azithromycin	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Calcium Citrate	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Difenoxin Hydrochloride	N	S	Oral	Unk	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Fluocinolone Acetonide	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Glycerol	N	S	Oral	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported



	H	Hydrochlo	orothiazide		N	S	Endocervical	Unk				Not Reported	_
	le	chthamm	nol And Zinc Oxide		Ν	S	Unknown	Unk				Not Reported	
	N	Macrogol			Ν	S	Unknown	Unk				Not Reported	
	N	Mesalaziı	ne		Ν	S	Unknown	Unk				Not Reported	
	N	Metronida	azole		Ν	S	Unknown	Unk				Not Reported	
	N	Mupirocir	ı		Ν	S	Topical	Unk				Not Reported	
	١	Nadolol			Ν	S	Unknown	Unk				Not Reported	
	١	Neomycir	1		Ν	S	Unknown	Unk				Not Reported	
	١	Nicoderm			Ν	S	Unknown	Unk				Not Reported	
	١	Nicotine F	Polacrilex		Ν	S	Unknown	Unk				Not Reported	
	F	Polymyxii	n B Sulfate		Ν	S	Unknown	Unk				Not Reported	
	F	Prednisor	ne		Ν	S	Unknown	Unk				Not Reported	
	5	Sodium C	Carboxymethylcellulose		Ν	S	Ophthalmic	Unk				Not Reported	
	5	Sodium C	Chloride		Ν	S	Unknown	Unk				Not Reported	
	5	Sulfametl	noxazole		Ν	S	Unknown	Unk				Not Reported	
	١	/itamin D)		Ν	S	Unknown	Unk				Not Reported	
	١	/itamin D	93		Ν	S	Unknown	Unk				Not Reported	
	>	Kantofyl F	Palmitate		Ν	S	Unknown	Unk				Not Reported	
	Z	Zeaxanth	in		Ν	S	Unknown	Unk				Not Reported	
	\	/alsartan			Ν	С	Unknown	Unk				Not Reported	
	\	/itamin A			N	С	Unknown	Unk				Not Reported	
FDA Received Date	Case #		Case Type	Health	Prof	Outcomes	Mfr Control	<u>#</u>	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
12-Oct-2022	2141416	66	EXPEDITED (15-DAY)	N		HO, OT	CA-JNJFOC- 20220962772			71 YR	Female	CAN	
Preferred Term	<u> </u>	<u>Product</u>		Comp.	OTO	Role	Route	Dosage	e Text	Duration]	<u>Mfr</u>	
Chronic Sinusitis; Drug		Remicade	e		N	S	Intravenous drip					Not Reported	
Ineffective; Dyspepsia: Infusion Related Reac		Cetirizine	Hydrochloride		Ν	S	Unknown					Not Reported	
Macular Degeneration Malaise; Nausea; Off		Acetamin	ophen		N	S	Unknown					Not Reported	



Label Use; Pain; Paraesthesia Oral; Procedural Pain; Pyrexia; Therapeutic Product Effect Incomplete; Weight Decreased

IKATION			Detailed Report	
Adalimumab	N	S	Subcutaneous	Not Reported
Alprazolam	Ν	S	Unknown	Not Reported
Amoxicillin	Ν	S	Unknown	Not Reported
Atorvastatin Calcium	Ν	S	Unknown	Not Reported
Atropine	Ν	S	Oral	Not Reported
Azithromycin	Ν	S	Unknown	Not Reported
Betamethasone	Ν	S	Unknown	Not Reported
Betamethasone Dipropionate	Ν	S	Unknown	Not Reported
Betamethasone Valerate	Ν	S	Unknown	Not Reported
Bisacodyl	Ν	S	Unknown	Not Reported
Budesonide	Ν	S	Unknown	Not Reported
Calcium & Vitamin D3 Calcium Carbonate	N N	S S	Unknown	Not Reported Not Reported
Clarithromycin	N	S	Unknown	Not Reported
Clotrimazole	N	S	Unknown	Not Reported
Cupric Oxide	Ν	S	Unknown	Not Reported
D-Alpha Tocopherol	Ν	S	Unknown	Not Reported
Desonide	Ν	S	Unknown	Not Reported
Diphenhydramine Hydrochloride	Ν	S	Unknown	Not Reported
Ertapenem Sodium	Ν	S	Unknown	Not Reported
Fluticasone Furoate	Ν	S	Unknown	Not Reported
Fluticasone Propionate	N	S	Unknown	Not Reported
Glycerine	N	S	Oral	Not Reported
Glycerinum	N	S	Unknown	Not Reported
Gramicidin	N	S	Unknown	Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Not Reported
Loperamide	N	S	Unknown	Not Reported
Magnesium Sulfate	N	S	Unknown	Not Reported



Mesalazine	N	S	Unknown	Not Reported
Metronidazole	N	S	Unknown	Not Reported
Morphine Sulfate	N	S	Unknown	Not Reported
Mupirocin	N	S	Topical	Not Reported
Nadolol	N	S	Unknown	Not Reported
Nicoderm	N	S	Unknown	Not Reported
Nicoderm	N	S	Unknown	Not Reported
Nicotine	N	S	Unknown	Not Reported
Nicotine Polacrilex	N	S	Unknown	Not Reported
Pantoprazole Potassium Chloride	N N	S S	Unknown	Not Reported Not Reported
Prednisone	N	S	Unknown	Not Reported
Pregabalin	N	S	Unknown	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Not Reported
Sodium Chloride Sodium Chloride	N N	S S	Unknown	Not Reported Not Reported
Sulfamethoxazole	N	S	Unknown	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Not Reported
Vitamin D3	N	S	Unknown	Not Reported
Xantofyl Palmitate	N	S	Unknown	Not Reported
Zeaxanthin	N	S	Unknown	Not Reported
Zinc Oxide	N	S	Unknown	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	N	С	Unknown	Not Reported
Calcium Lactate	N	С	Unknown	Not Reported
Lomotil [Atropine Sulfate; Diphenoxylate Hydrochloride]	N	С	Unknown	Not Reported
Lomotil [Loperamide Hydrochloride]	N	С	Unknown	Not Reported
Metoclopramide Hydrochloride	N	С	Unknown	Not Reported
Valsartan	N	С	Unknown	Not Reported



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Oct-2022	16835715	EXPEDITED (15-DAY)	Υ	0	Т	CA- GLAXOSMI CA2019168				Unknown	CAN
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	e Text	Duration	<u>Mfr</u>	
Drug Ineffective; Macu	ılar Parad	cetamol		Υ	S	Unknown	Unk			Gla	xosmithkline
Degeneration	Parad	cetamol		Υ	S	Unknown	Unk			Gla	xosmithkline
	Nicod	derm		N	S	Transdermal	Unk, F	Patch		No	Reported
	Nicod	derm		N	S	Unknown	Unk			No	Reported
	Nicod	derm		N	S		Unk			No	Reported
	Cetiri	zine Hydrochloride		N	S	Unknown	Unk			No	Reported
	Cetiri	zine Hydrochloride		N	S	Unknown	Unk			No	Reported
	Flutio	asone Furoate		N	S	Unknown	Unk			No	Reported
	Flutio	asone Furoate		N	S	Ophthalmic	Unk			No	Reported
	Diphe	enhydramine Hydrochloride		N	S	Unknown	Unk			No	Reported
	Mupi	rocin		N	S	Topical	Unk			No	Reported
	Mupi	rocin		N	S	Topical	Unk			No	Reported
		cetamol + Pseudoephedrine ochloride		N	S	Unknown	Unk				Reported
	Imod	ium		N	S	Oral	Unk			No	Reported
	Zinc	Oxide		N	S	Unknown	Unk			No	Reported
	Alpra	zolam		N	S	Unknown	Unk			No	Reported
	Alpra	zolam		N	S	Unknown	Unk			No	Reported
	Alpra	zolam		N	S	Respiratory (inhalation)	Unk			No	Reported
	Alpra	zolam		N	S	Unknown	Unk			No	Reported
	Apo I	Hydro		N	S	Unknown	Unk			No	Reported
	Amox	kicillin Trihydrate		N	S	Unknown	Unk			No	Reported
	Atorv	astatin Calcium		N	S	Unknown	Unk			No	Reported
	Atorv	astatin Calcium		N	S	Unknown	Unk			No	Reported



Atorvastatin Calcium	N	S	Unknown	Unk		Not Reported
Desonide	N	S	Unknown	Unk		Not Reported
Ergocalciferol	N	S	Unknown	Unk		Not Reported
Dilaudid	N	S	Unknown	Unk		Not Reported
Entocort	N	S	Unknown	Unk		Not Reported
Bisacodyl	N	S	Unknown	Unk		Not Reported
Bisacodyl	N	S	Unknown	Unk		Not Reported
Ertapenem Sodium	N	S	Unknown	Unk		Not Reported
Ertapenem Sodium	N	S	Unknown	Unk		Not Reported
Flovent	N	S	Unknown	Unk		Not Reported
Flovent	N	S	Unknown	Unk		Not Reported
Glycerine	N	S	Oral	Unk, Liquid		Not Reported
Glycerine	N	S	Oral	Unk		Not Reported
Glycerine	N	S	Unknown	Unk		Not Reported
Gramicidin\Neomycin\Polymyxin B Sulfate	N	S	Unknown	Unk		Not Reported
Habitrol	N	S	Transdermal	Unk		Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Suspension		Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk		Not Reported
Humira	N	S	Subcutaneous	Unk		Not Reported
Humira	N	S	Subcutaneous	Unk	6 YR	Not Reported
Humira	N	S	Unknown	Unk	6 YR	Not Reported
Humira	N	S	Subcutaneous	Unk		Not Reported
Lomotil (Atropine + Diphenoxylate)	N	S	Oral	Unk		Not Reported
Lomotil (Atropine + Diphenoxylate)	N	S	Oral	Unk		Not Reported
Salinex (Macrogol + Propylene Glycol + Sodium Chloride)	N	S	Nasal	Unk		Not Reported
Sinus Rinse	N	S	Nasal	Unk		Not Reported
Sinus Rinse	N	S	Intra-articular	Unk		Not Reported
Statex (Morphin)	N	S	Unknown	Unk		Not Reported



				<u>- </u>	
Bactrim	N	S	Unknown	Unk	Not Reported
Bactrim	N	S	Unknown	Unk	Not Reported
Avamys	N	S	Unknown	Metered Dose, Spray	Not Reported
Avamys	N	S	Unknown	Metered Dose, Cutaneous Spray	Not Reported
Azithromycin Dihydrate	N	S	Unknown	Unk	Not Reported
Azithromycin Dihydrate	N	S	Oral	Unk	Not Reported
Bactroban	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Tablet (Extended Release)	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Macrogol + Potassium Chloride + Sodium Bicarbonate + Sodium Chloride +	N	S	Unknown	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Ms Ir	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk, Drops	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Refresh Tears	N	S	Unknown	Unk	Not Reported
Trimethoprim And Sulfamethoxazole	N	S	Unknown	Unk	Not Reported



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Trimethoprim And	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Oral	Unk	Not Reported
Mesalamine	N	S	Unknown	Unk	Not Reported
Mesalamine	N	S	Unknown	Unk	Not Reported
Dulcolax (Bisacodyl)	N	S	Unknown	Unk	Not Reported
Gramicidin + Polymyxin B	N	S	Unknown	Unk	Not Reported
Macrogol	N	S	Unknown	Unk	Not Reported
Macrogol + Potassium Chloride + Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Pms Azithromycin	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Endocervical		Not Reported
Hydrochlorothiazide	N	S	Oral	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Unk	Not Reported
Ertapenem	N	S	Unknown	Unk	Not Reported
Fluticasone	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported



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Hydromorphone	N	S	Unknown	Unk	Not Reported
Hydromorphone	N	S	Unknown	Unk	Not Reported
Neomycin B Sulfate	N	S	Unknown	Unk	Not Reported
Potassium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Colecalciferol	N	S	Unknown	Unk	Not Reported
Tocopherol Vitamin E	N	S	Unknown	Unk	Not Reported
Aspirin\Caffeine	N	S	Unknown	Unk	Not Reported
Amoxicillin	N	S	Unknown	Unk	Not Reported
Atorvastatin	N	S	Unknown	Unk	Not Reported
Atropine Sulfate + Diphenoxylate	N	S	Oral	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Valsartan	N	S	Unknown	Unk	Not Reported
Valsartan	N	С	Unknown	Unk	Not Reported
Glycerol	N	S	Unknown	Unk	Not Reported
Glycerol	N	S	Oral	Unk	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Adalimumab	N	S	Subcutaneous	Unk	Not Reported
Adalimumab	N	S	Unknown	Unk	Not Reported
Adalimumab	N	S	Subcutaneous	Unk	Not Reported
Gramicidin/Neomycin Sulfate/Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Neomycin Sulfate	N	S	Unknown	Unk	Not Reported
Neomycin	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Oct-2022	2069556	5 EXPEDITED (15-DAY)	N		ОТ	ALC20220	CA001693			Female	CAN
Preferred Term	<u> </u>	Product	Comp.	<u>OT(</u>	Role	Route	<u>Dosag</u>	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Drug Ineffective; Macu	ılar <i>A</i>	Atropine Sulfate		N	S	Unknown	Unk			А	lcon
Degeneration	A	Atropine Sulfate		N	S	Oral				N	lot Reported
	A	Acetaminophen		N	S	Unknown	Unk			N	lot Reported
	A	Acetaminophen		N	S	Unknown	Unk			N	lot Reported
	A	Atorvastatin Calcium		N	S	Unknown	Unk			N	lot Reported
	A	Atorvastatin Calcium		N	S	Unknown	Unk			N	lot Reported
		Atropine Sulfate; Diphenoxylate		N	S	Oral	Unk			N	lot Reported
	P	Hydrochloride Atropine Sulfate;Diphenoxylate Hydrochloride		N	S	Oral	Unk			Ν	lot Reported
		Azithromycin		N	S	Oral	Unk			N	lot Reported
	A	Azithromycin		N	S	Oral	Unk			N	lot Reported
	A	Azithromycin		N	S	Unknown	Unk			N	lot Reported
	E	Betamethasone Dipropionate		N	S	Unknown	Unk			N	lot Reported
	E	Betamethasone Dipropionate		N	S	Unknown	Unk			N	lot Reported
	E	Betamethasone Valerate		N	S	Unknown	Unk			N	lot Reported
	E	Bisacodyl		N	S	Unknown	Unk			N	lot Reported
	E	Bisacodyl		N	S	Unknown	Unk			N	lot Reported
	E	Budesonide		N	S	Respiratory (inhalation)	Unk			Ν	lot Reported
	E	Budesonide		N	S	Respiratory (inhalation)	Unk			N	lot Reported
	C	Clarithromycin		N	S	Unknown	Unk			N	lot Reported
	C	Clarithromycin		N	S	Unknown	Unk			N	lot Reported
	C	Clarithromycin		N	S	Unknown				N	lot Reported
	C	Clotrimazole		N	S	Unknown	Unk			N	lot Reported



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Clotrimazole	N	S	Unknown	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
DI-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
DI-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Dilaudid	N	S	Unknown	Unk	Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Ertapenem Sodium	N	S	Unknown		Not Reported
Fluticasone	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Humira	N	S	Subcutaneous	Unk	Not Reported
Humira	N	S	Subcutaneous	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Infa-3 [Gramicidin;Neomycin Sulfate;Polymyxin B]	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Every 1 Months	Not Reported
Magnesium	N	S	Unknown	Unk	Not Reported
Magnesium Clofibrate	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported



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Metronidazole	N	S	Unknown	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Mupirocin	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Sinus Rinse	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Endosinusial	Unk	Not Reported
Sodium Chloride	N	S	Endosinusial	Unk	Not Reported
Sulfamethoxazole And Trimethoprim	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole And	N	S	Unknown	Unk	Not Reported



Trimethoprim Triamcinolone Acetonide	N	S	lates setimals	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular		Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Vitamin D [Vitamin D Nos]	N	S	Intra-articular	Unk	Not Reported
			Unknown	Unk	•
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown		Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Valsartan	N	С	Unknown		Not Reported
Valsartan	N	С	Vaginal	Unk	Not Reported
Acetaminophen;	N	S	Unknown	Unk	Not Reported
Dextropropoxyphene Amoxicillin	N	S	Unkanya	Hale	Not Reported
Amoxicillin	N	S	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D3			Unknown	Unk	•
	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Diphenhydramine	N	S	Unknown	Unk	Not Reported
Diphenhydramine	N	S	Unknown	Unk	Not Reported
Loperamide	N	S	Unknown	Unk	Not Reported
Mentha Arvensis	N	S	Unknown	Unk	Not Reported
Alprazolam	N	S	Unknown		Not Reported
Alprazolam	N	S	Unknown		Not Reported
Adalimumab	N	S	Unknown	Subcutaneous	Not Reported



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Ambroxol Hydrochloride	N	S	Unknown	Unk	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Avamys	N	S	Unknown	Unk	Not Reported
Cetirizine	Ν	S	Unknown	Unk	Not Reported
Apo-Hydrochlorothiazide	N	S	Endocervical		Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Flovent	N	S	Unknown		Not Reported
Glycerine	Ν	S	Unknown	Unk	Not Reported
Glycerol	Ν	S	Oral	Unk	Not Reported
Infa-3 [Gramicidin;Neomycin Sulfate;Polymyxin B]	N	S	Unknown	Unk	Not Reported
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate; Sodium Chloride	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Msir	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Sodium Stearate	N	S	Oral	Unk	Not Reported
Triamcinolone	N	S	Intra-articular	Unk	Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported
Zinc Chloride	N	S	Unknown		Not Reported
Acetylsalicylic Acid	N	S	Oral	Unk	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported



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		Neomycin Sulfate		N	S	Unknown	Unk				Not Reported
		Macrogol		Ν	S	Unknown	Unk				Not Reported
		Bactrim		Ν	S	Unknown	Unk				Not Reported
		Entocort		Ν	S	Unknown	Unk				Not Reported
		Gramicidin		Ν	S	Unknown	Unk				Not Reported
		Gramicidin		Ν	S	Unknown	Unk				Not Reported
		Vitamin D3		N	S	Unknown	Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Oct-2022	214804	97 EXPEDITED (15-DAY)	Υ		ОТ	CA-AstraZe 2022A3451				Female	CAN
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	Duration	<u>!</u>	<u>Vlfr</u>
Drug Ineffective; Macul	lar	Pulmicort		N	S	Unknown					Not Reported
Degeneration		Budesonide		Ν	S	Unknown					Not Reported
		Entocort		Ν	S	Unknown					Not Reported
		Acetaminophen		Ν	S	Unknown					Not Reported
		Adalimumab		Ν	S	Subcutaneous					Not Reported
		Alprazolam		Ν	S	Unknown					Not Reported
		Ambroxol Hydrochloride		Ν	S	Unknown					Not Reported
		Apohydrochlorothiazide		Ν	S	Unknown					Not Reported
		Atorvastatin Calcium		Ν	S	Unknown					Not Reported
		Atorvastatin Calcium		Ν	S	Unknown					Not Reported
		Atropine Sulfate		Ν	S	Unknown					Not Reported
		Azithromycin		Ν	S	Oral	Dose U	nkwnon			Not Reported
		Bactrim		Ν	S	Unknown					Not Reported
		Betamethasone Dipropionate		N	S	Unknown					Not Reported
		Betamethasone Valerate		N	S	Unknown					Not Reported
		Bisacodyl		N	S	Unknown					Not Reported
		Bisacodyl		Ν	S	Unknown					Not Reported



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Calcium Carbonate/Vitamin D3	N	S	Unknown	Not Reported
Calcium Gluconate	N	S	Unknown	Not Reported
Clarithromycin	N	S	Unknown	Not Reported
Cupric Oxide	N	S	Unknown	Not Reported
Desonide	N	S	Unknown	Not Reported
Diphenhydramine	N	S	Unknown	Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown	Not Reported
Ergocalciferol	N	S	Unknown	Not Reported
Flovent	N	S	Unknown	Not Reported
Fluticasone Furoate	N	S	Unknown	Not Reported
Glycerine	N	S	Oral	Not Reported
Humira	N	S	Subcutaneous	Not Reported
Hydrochlorothiazide	N	S	Oral	Not Reported
Hydromorphone	N	S	Unknown	Not Reported
Hydromorphone	N	S	Unknown	Not Reported
Macrogol	N	S	Unknown	Not Reported
Magnesium Sulfate	N	S	Unknown	Not Reported
Mesalazine	N	S	Unknown	Not Reported
Ms Ir	N	S	Unknown	Not Reported
Mupirocin	N	S	Unknown	Not Reported
Nicoderm	N	S	Unknown	Not Reported
Nicotinamide	N	S	Unknown	Not Reported
Nicotine Polacrilex	N	S	Unknown	Not Reported
Pantoprazole	N	S	Unknown	Not Reported
Pentasa	N	S	Unknown	Not Reported
Prednisone	N	S	Unknown	Not Reported
Sinus Rinse	N	S	Unknown	Not Reported
Sodium Carboxymethyl	N	S	Unknown	Not Reported
Cellulose Sodium Chloride	N	S	Unknown	Not Reported
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Date - Time: 11-Apr-2023 10:56:54 AM EST

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	Sodiu	ım Stearate		N	S	Oral			- 1	Not Reported
	Sulfa	methoxazole/Trimethoprim		N	S	Unknown			ļ	Not Reported
	Triam	ncinolone		Ν	S	Intra-articular			,	Not Reported
	Trime	ethoprim		Ν	S	Unknown			,	Not Reported
	Valsa	artan		Ν	S	Intracardiac			,	Not Reported
	Vitam	nin D3		Ν	S	Unknown			,	Not Reported
	Xanto	ofyl Palmitate		Ν	S	Unknown			,	Not Reported
	Zeax	anthin		N	S	Unknown			ļ	Not Reported
	Zinc	Chloride		N	S	Unknown			ļ	Not Reported
	Zinc	Oxide		Ν	S	Unknown			!	Not Reported
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Oct-2022	21481021	EXPEDITED (15-DAY)	N		ОТ	US-ALLER 2234087US			Female	USA
Preferred Term	Prod	uct	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u> </u>	<u>Mfr</u>
Cataract; Eye Irritation Hypersensitivity; Medi Device Implantation; Fhinking Abnormal		esh Optive Advanced ervative-Free		Y	S	Ophthalmic	Unk		,	Allergan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Oct-2022	21493223	NON-EXPEDITED	N			US-ALLER 2205203US			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTO	Role	Route	Dosage Text	Duration	<u>n</u>	<u>Mfr</u>
Eye Pruritus	Comb	oigan[R]		N	S		Unk, Bid			Allergan
	Refre	sh Tears		N	S		Unk		i	Allergan
	Latar	noprost		N	S		0.005% Eye Drops, On A Day At Bedtime	ce	ļ	Not Reported
				N	S		Unk		ļ	Not Reported
	Dorzo	olamide Hcl								
	Dorzo Vynd			N	С		61 Mg, Qd		į	Not Reported



ADIVI	11115						Detailed Re	eport			
		Levothy	roxine		N	С		100 Mg, Qd		N	ot Reported
		Simvast	atin		Ν	С		40 Mg, Qd		N	ot Reported
		Baby As	pirin		N	С		81 Mg, Qd		N	ot Reported
FDA Received Date	Case #	<u> </u>	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Oct-2022	20741	566	EXPEDITED (15-DAY)	N		HO, OT	CA-009507513 2204CAN0071		71 YR	Female	CAN
Preferred Term		Produc	<u>t</u>	Comp.	OTO	Role Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>ir</u>
	neffective; Dyspepsia; Infusion Related Reaction; Ilacular Degeneration; Ilalaise; Nausea; Off Ilabel Use; Oct.	Invanz Remicad	de		N N	S S	Intravenous (not otherwise specified)			lerck ot Reported
	1;	Acetami	nophen		N	S	Unknown			N	ot Reported
Label Use; Pain;		Acetylsa	alicylic Acid		N	S	Unknown	Not Specified		N	ot Reported
	araesthesia Oral; rocedural Pain; Pyrexia;	Adalimu	mab		Ν	S	Subcutaneous			N	ot Reported
rocedural Pain; Pyrexia; herapeutic Product Effect		Alprazol	am		Ν	S	Unknown	0.25 Milligram		N	ot Reported
Incomplete; Weight		Amoxici	llin		Ν	S	Unknown			N	ot Reported
Decreased		Atorvast	atin Calcium		Ν	S	Unknown			N	ot Reported
		Atropine	;Diphenoxylate		N	S	Oral			N	ot Reported
		Avamys			N	S	Unknown			N	ot Reported
		Azithron	nycin		N	S	Unknown			N	ot Reported
		Benadry Hydroch	l [Diphenhydramine lloride]		N	S				N	ot Reported
		Betamet			N	S	Unknown				ot Reported
		Betamet	thasone Valerate		N	S	Unknown	0.122 Gram		N	ot Reported
		Biaxin X Bisacod			N N	S S	Unknown				ot Reported ot Reported
		Budesor	nide		N	S	Unknown			N	ot Reported
		Calcium	;Colecalciferol		Ν	S	Unknown			N	ot Reported
		Calcium	Carbonate		Ν	S	Unknown			N	ot Reported
		Calcium	Citrate		Ν	S	Unknown	Not Specified		N	ot Reported
		Cetirizin	e Hydrochloride		N	S	Unknown	•		N	ot Reported



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Clarithromycin	N	S	Unknown		Not Reported
Clotrimazole	N	S	Unknown		Not Reported
Cupric Oxide	N	S	Unknown		Not Reported
D-Alpha Tocopherol	N	S	Unknown		Not Reported
Desonide	N	S	Unknown		Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown		Not Reported
Entocort Fluticasone Furoate	N N	S S	Unknown		Not Reported Not Reported
Fluticasone Propionate Glycerine	N N	S S	Unknown		Not Reported Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B	N	S	Unknown		Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical		Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride Hydrochlorothiazide	N N	S S	Endocervical		Not Reported Not Reported
Isoniazid;Pyridoxine Hydrochloride; Sulfamethoxazole;Trimethoprim	N	S			Not Reported
Lomotil [Atropine Sulfate; Diphenoxylate Hydrochloride]	N	S			Not Reported
Macrogol	N	S	Unknown		Not Reported
Macrogol 3350	N	S	Oral		Not Reported
Magnesium Sulfate	N	S	Unknown		Not Reported
Mesalazine	N	S	Unknown		Not Reported
Metronidazole	N	S	Unknown		Not Reported
Morphine Sulfate	N	S	Unknown		Not Reported
Mupirocin	N	S	Topical		Not Reported
Nadolol	N	S	Oral	40.0 Milligram	Not Reported
Natural Vitamin E [Tocopherol]	N	S	Unknown		Not Reported
Nicoderm	N	S	Topical		Not Reported
Nicotine	N	S	Unknown		Not Reported



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		Nicotine Polacrilex Pantoprazole			N N	S S	Unknown				Not Reported Not Reported	
		Potassium Chloride			N	S	Unknown				Not Reported	
		Prednisone			N	S	Unknown				Not Reported	
		Pregabalin			N	S	Unknown	150 Milligram			Not Reported	
		Pulmicort Sodium Bicarbonate			N N	S S	Unknown	Not Specified			Not Reported Not Reported	
		Carboxy Methyl Cellul Sodium	ose		N	S	Unknown	•			Not Reported	
		Sodium Chloride			N	S	Nasal				Not Reported	
		Sulfamethoxazole And Trimethoprim	t		N	S	Unknown	200 Milligram			Not Reported	
		Triamcinolone Aceton	ide		N	S	Intra-articular	Dosage Form: Suspensio Intraarticular	n		Not Reported	
		Valsartan Vitamin D3			N N	S S	Unknown				Not Reported Not Reported	
		Xantofyl Palmitate			N	S	Unknown				Not Reported	
		Zeaxanthin			N	S	Unknown				Not Reported	
		Zinc Oxide			N	S	Unknown				Not Reported	
		Calcium;Ergocalcifero Loperamide	I		N N	C C	Unknown				Not Reported Not Reported	
		Metoclopramide Hydro	ochloride		N	С					Not Reported	
FDA Received Date	Case #	Case Type		<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
31-Oct-2022	214994	41 EXPEDITED	(15-DAY)	N		ОТ	US-ALLERGAN 2233583US	l-		Female	USA	
Preferred Term		Product		Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	!	<u>//fr</u>	
Cataract; Eye Irritation Eye Pain; Product Del	ivery	Refresh Relieva Pf			Y	S	Ophthalmic	One Drop Per Eye , 3 To Times A Day	6		Not Reported	
Mechanism Issue; Pro Quality Issue; Product Complaint; Strabismus	Use	Refresh Relieva Pf			Y	S	Ophthalmic	One Drop Per Eye , 3 To Times A Day	6		Not Reported	
F,		Prednisone			N	С	Ophthalmic	Unk			Not Reported	
		Vitamin D3 Colace			N N	C C					Not Reported Not Reported	



		um Fibre asis Multidose		N N	C DS						Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Nov-2022	21521873	EXPEDITED (15-DAY)	N	(OT	US-ALLERG 2235484US	SAN-			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	<u>e Text</u>	Duration	<u>!</u>	<u>Vlfr</u>
Cataract; Erythema Of Eyelid; Eye Irritation; E Pain; Ocular Hyperaer	ye	sh Digital Pf		Υ	S	Ophthalmic	Unk				Allergan
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Nov-2022	21530938	EXPEDITED (15-DAY)	N	(OT	US-ALLERG 2235535US	SAN-			Male	USA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	e Text	Duration	<u> </u>	<u>Mfr</u>
Cataract Operation	Refre	sh Tears		Υ	S						Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Nov-2022	19013615	EXPEDITED (15-DAY)	Υ	(OT	CA-AstraZer 2021A11663				Female	CAN
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Drug Ineffective; Macu	ılar Entoc	cort		N	S	Oral					Not Reported
Degeneration	Pulm	icort		N	S	Respiratory (inhalation)					Not Reported
	Aceta	aminophen		N	S	Unknown					Not Reported
	Alpra	zolam		N	S	Unknown					Not Reported
	Amox	kicillin Trihydrate		Ν	S	Unknown					Not Reported
	Atorv	astatin		N	S	Unknown					Not Reported
	Avam	nys		N	S	Unknown					Not Reported
	Azith	romycin Dihydrate		N	S	Unknown					Not Reported
	Bactr	oban		N	S	Unknown					Not Reported
	Betad	derm		N	S	Unknown					Not Reported



			-	
Betamethasone Dipropionate	N	S	Unknown	Not Reported
Biaxin XI	N	S	Unknown	Not Reported
Bisacodyl	N	S	Unknown	Not Reported
Calcium Carbonate	N	S	Unknown	Not Reported
Calcium Carbonate With Vitamin D	N	S	Unknown	Not Reported
Clarithromycin	N	S	Unknown	Not Reported
Cetirizine	N	S	Unknown	Not Reported
Clotrimazole	N	S	Unknown	Not Reported
Desonide	N	S	Unknown	Not Reported
Dilaudid	N	S	Unknown	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Not Reported
Ertapenem Sodium	N	S	Unknown	Not Reported
Flovent	N	S	Unknown	Not Reported
Glycerin	N	S	Oral	Not Reported
Gramicidin/Polymyxin B	N	S	Unknown	Not Reported
Habitrol	N	S	Unknown	Not Reported
Kenalog	N	S	Intra-articular	Not Reported
Lomotil	N	S	Oral	Not Reported
Metronidazole	N	s	Unknown	Not Reported
Ms Ir	N	s	Unknown	Not Reported
Multivitamine	N	S	Unknown	Not Reported
Mupirocin	N	S	Unknown	Not Reported
Nadolol	N	S	Unknown	Not Reported
Nicoderm	N	S	Unknown	Not Reported
Niquitin	N	S	Unknown	Not Reported
Pantoprazole	N	S	Unknown	Not Reported
Pentasa	N	S	Unknown	Not Reported
Sodium Bicarbonate/Macrogol/Potassiu	N	S	Unknown	Not Reported
m Chloride				



	Bactrir	n		N	S	Unknown					Not Reported
		cinolone Acetonide		N	S	Unknown					Not Reported
	Vitami			N	S	Unknown					Not Reported
	Humira			N	S	Subcutaneous					Not Reported
	·	Oxide		N	S	Unknown					Not Reported
	Neomy B Sulfa	ycin/Gramicidin/Polymyxin		N	S	Unknown					Not Reported
	Macro Chloric	gol 3350/Sodium de/Sodium onate/Potassium Chloride		N	S						Not Reported
		ine Hydrochloride		N	S	Unknown					Not Reported
		noxylate Hydrochloride tropine Sulphate		N	S						Not Reported
		yl Palmitate		N	S	Unknown					Not Reported
	Zeaxa Zinc C			N N	S S	Unknown					Not Reported Not Reported
	Magne Valsar	esium Sulfate tan		N N	S C	Unknown					Not Reported Not Reported
	Calciu Apo H	m Carbonate With Vit D ydro		N N	C C	Unknown					Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Nov-2022	21550779	EXPEDITED (15-DAY)	N	(ОТ	US-ALLERGA 2235750US	۸N-			Female	USA
Preferred Term	Produ	<u>ict</u>	Comp.	OTC	Role	Route	Dosage	<u>e Text</u>	Duration]	<u>Mfr</u>
Cataract	Dofros	h Relieva		Υ	S						Allergan



Date - Time: 11-Apr-2023 10:56:54 AM EST

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	<u>#</u>	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Nov-2022	21568	012	EXPEDITED (15-DAY)	N	C	T	US-ALLERG 2236281US	AN-			Female	USA
Preferred Term		Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Glaucoma; Macular Degeneration; Multiple Allergies; Reaction To Preservatives		Refresh	Optive Sensitive		Y	S		Unk			A	llergan
FDA Received Date	Case #	<u>#</u>	Case Type	<u>Health</u>	Prof C	utcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Nov-2022	20178	153	EXPEDITED (15-DAY)	N	Н	O, OT	CA-SANOFI 2021SA4120			71 YR	Female	CAN
Preferred Term		Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Chronic Sinusitis; Drug		Triamci	nolone Acetonide		N	S		Unk			S	anofi
Ineffective; Dyspepsia Infusion Related Reac		Triamci	nolone Acetonide		N	S	Intra-articular	Unk			S	anofi
Macular Degeneration	; Tria	Triamci	nolone Acetonide		Ν	S		Unk			S	anofi
Malaise; Nausea; Off Label Use; Pain;		Triamci	nolone Acetonide		N	S	Intra-articular	Unk			S	anofi
Paraesthesia Oral;		Triamci	nolone Acetonide		N	S	Intra-articular	Unk			S	anofi
Procedural Pain; Pyre		Amoxic	illin (Salt Not Specified)		N	S		Unk			N	ot Reported
Therapeutic Product E Incomplete; Weight	пест	Amoxic	illin Trihydrate		N	S		Unk			N	ot Reported
Decreased			illin Trihydrate		N	S						ot Reported
			illin Trihydrate illin Trihydrate		N N	S S						ot Reported ot Reported
		Budeso			N	S	Oral	Unk				ot Reported
		Budeso	nide		N	S	O.a.	Unk			N	ot Reported
		Budeso	nide		N	S	Oral		pecified		N	ot Reported
		Budeso	nide		N	S	Oral	Unk			N	ot Reported
		Bisacoo	dyl		N	S		Unk			S	anofi
		Bisacoo Bisacoo			N N	S S		Not Sp	pecified			anofi anofi
		Bisacoo Cetirizir	dyl ne Hydrochloride		N N	S S		Unk			_	anofi ot Reported

Note: If the field is blank, there is no data.



Cetirizine Hydrochloride Cetirizine Hydrochloride Cetirizine Hydrochloride Alprazolam	N N N	S S S		Unk	Not Reported Not Reported Not Reported Not Reported
Alprazolam Alprazolam Alprazolam	N N N	S S S		0.25 Mg	Not Reported Not Reported Not Reported
Paracetamol	N	S		Unk	Not Reported
Hydrochlorothiazide	N	S		Unk	Not Reported
Hydrochlorothiazide Hydrochlorothiazide Hydrochlorothiazide Atorvastatin Calcium	N N N	\$ \$ \$ \$		Unk	Not Reported Not Reported Not Reported Not Reported
Atorvastatin Calcium Atorvastatin Calcium	N N	S S		Not Specified	Not Reported Not Reported
Atorvastatin Calcium Mesalazine	N N	S S		Unk	Not Reported Sanofi
Mesalazine	N	S		Unk	Sanofi
Mesalazine	N	S		Not Specified	Sanofi
Mesalazine	N	S	Unknown	Unk	Sanofi
Calcium Carbonate	N	S		Unk	Not Reported
Azithromycin	N	S		Unk	Not Reported
Azithromycin Azithromycin	N N	S S		Not Specified	Not Reported Not Reported
Azithromycin Betamethasone Dipropionate	N N	S S		Unk	Not Reported Not Reported
Betamethasone Dipropionate Betamethasone Dipropionate	N N	S S		Not Specified	Not Reported Not Reported
Betamethasone Dipropionate Betamethasone Valerate	N N	S S		Unk	Not Reported Not Reported
Betamethasone Valerate Betamethasone Valerate Betamethasone Valerate	N N N	S S S		0.122 G	Not Reported Not Reported Not Reported
Clarithromycin	N	S		Unk	Not Reported



Clarithromycin Clarithromycin	N N	S S		Not Specified	Not Reported Not Reported
Clarithromycin Clarithromycin Sodium Chloride	N N N	S S S		·	Not Reported Not Reported Not Reported
Sodium Chloride		S		Unk	
Sodium Chloride	N	5	Respiratory (inhalation)	Unk	Not Reported
Clotrimazole	N	S		Unk	Not Reported
Clotrimazole	N	S		Unk	Not Reported
Clotrimazole	N	S		Not Specified	Not Reported
Clotrimazole	N	S		Unk	Not Reported
Clotrimazole	N	S		Unk	Not Reported
Metronidazole	N	S		Unk	Sanofi
Metronidazole	N	S		Unk	Sanofi
Metronidazole	N	S		Not Specified	Sanofi
Desonide	N	S		Unk	Not Reported
Desonide	N	S		Unk	Not Reported
Desonide	N	S		Not Specified	Not Reported
Desonide	N	S		Unk	Not Reported
Desonide	N	S		Unk	Not Reported
Diphenhydramine Hydrochloride	N	S		Unk	Sanofi
Diphenhydramine Hydrochloride	N	S		Unk	Sanofi
Diphenhydramine Hydrochloride	N	S		Unk	Sanofi
Diphenhydramine Hydrochloride	N	S		Unk	Sanofi
Hydromorphone Hydrochloride	N	S		Unk	Not Reported
Hydromorphone Hydrochloride	N	S		Unk	Not Reported
Hydromorphone Hydrochloride	N	S		Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Unk	Not Reported
Morphine Sulfate	N	S		Unk	Not Reported
Morphine Sulfate	N	S		Unk	Not Reported
				Olik	



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Mor	phine Sulfate	N	S		Not Specified	Not Reported
Mor	phine Sulfate	N	S		Unk	Not Reported
Flut	icasone Furoate	N	S		Unk	Not Reported
Mup	pirocin	N	S	Topical	Unk	Not Reported
Mup	pirocin	N	S		Unk	Not Reported
Mup	pirocin	N	S	Topical	Unk	Not Reported
Mup	pirocin	N	S	Topical	Unk	Not Reported
Mup	pirocin	N	S		Unk	Not Reported
Nac	lolol	N	S		Unk	Not Reported
Nac Nac Nac Nac Nico	dolol dolol	N N N N	S S S S S		Unk	Not Reported Not Reported Not Reported Not Reported Sanofi
Nico	otine	N	S		Unk	Sanofi
Nico	otine	N	S		Not Specified	Sanofi
Nico	otine	N	S		Unk	Sanofi
Nico	otine	N	S		Unk	Sanofi
Pan	itoprazole	N	S		Unk	Not Reported
Pan	itoprazole	N	S		Unk	Not Reported
Pan	itoprazole	N	S		Not Specified	Not Reported
	itoprazole dnisone	N N	S S		Unk	Not Reported Not Reported
Pre	dnisone	N	S		Unk	Not Reported
Pre	dnisone	N	S		Not Specified	Not Reported
Pre	dnisone	N	S		Unk	Not Reported
Pre	dnisone	N	S		Unk	Not Reported
Pre	gabalin	N	S		Unk	Not Reported
Pre	gabalin	N	S		Unk	Not Reported
Pre	gabalin	N	S		Unk	Not Reported
Pre	gabalin	N	S		150 Mg	Not Reported
	-					· ·



Sodium Bicarbonate	N	S		Unk	Not Reported
Simvastatin	N	S		Unk	Not Reported
Simvastatin Simvastatin Simvastatin Simvastatin Potassium Chloride	N N N N	\$ \$ \$ \$ \$		Unk	Not Reported Not Reported Not Reported Not Reported Not Reported
Colecalciferol	N	S		Unk	Not Reported
Colecalciferol Colecalciferol Nicoderm	N N N	S S S		Unk	Not Reported Not Reported Sanofi
Nicoderm	N	S		Unk	Sanofi
Nicoderm	N	S		Unk	Sanofi
Nicoderm	N	S		Unk	Sanofi
Nicoderm	N	S		Unk	Sanofi
Glycerol	N	S		Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Glycerine	N	S		Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Glycerine	N	S		Unk	Not Reported
Tocopherol	N	S		Unk	Not Reported
Loperamide Hydrochloride	N	S		Unk	Not Reported
Macrogol	N	S		Unk	Not Reported
Magnesium Sulfate	N	S		Unk	Not Reported
Zinc Oxide	N	S		Not Specified	Sanofi
Zinc Oxide Zinc Oxide Cupric Oxide	N N N	S S S		Unk	Sanofi Sanofi Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S		Unk	Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S		Not Specified	Not Reported



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Gramicidin;Neomycin Sulfate;	N	S		Unk	Not Reported
Polymyxin B Sulfate Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S		Unk	Not Reported
Adalimumab	N	S	Subcutaneous	Unk	Not Reported
Adalimumab	N	S	Subcutaneous		Not Reported
Adalimumab	N	S	Subcutaneous		Not Reported
Adalimumab	N	S	Subcutaneous		Not Reported
Sodium Carboxymethylcellulose	N	S		Unk	Not Reported
Ertapenem Sodium	Ν	S		Unk	Not Reported
Ertapenem Sodium	Ν	S		Unk	Not Reported
Ertapenem Sodium	N	S		Unk	Not Reported
Ertapenem Sodium	N	S		Unk	Not Reported
Ertapenem Sodium	N	S		Unk	Not Reported
Sulfamethoxazole	N	S		Unk	Not Reported
Sulfamethoxazole	N	S		Unk	Not Reported
Sulfamethoxazole	N	S		Unk	Not Reported
Sulfamethoxazole	N	S		Unk	Not Reported
Sulfamethoxazole	N	S		Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral		Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S		1 Df	Not Reported
Infliximab	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Fluticasone Propionate	N	S		Unk	Not Reported
D-Alpha Tocopherol	N	S		Unk	Not Reported
Calcimax-Op [Calcitriol;Calcium Carbonate;Zinc]	N	S	Intra-articular	Unk	Not Reported
Calcimax-Op [Calcitriol;Calcium Carbonate;Zinc]	N	S	Intra-articular		Not Reported
Calcimax-Op [Calcitriol;Calcium	N	S	Intra-articular		Not Reported



	Carbonate;Zinc] Refresh Tears		N	S	Ophthalmic	Unk			Not Reported
	Refresh Tears		N	S	Ophthalmic	OTIK			Not Reported
	Refresh Tears		N	S	Ophthalmic				Not Reported
	Acetaminophen		Ν	S		Not Specified			Not Reported
	Acetaminophen Avamys		N N	S S		Spray, Metered Dose			Not Reported Not Reported
	Avamys Avamys Vitamin D3		N N N	S S S		Unk			Not Reported Not Reported Not Reported
	Vitamin D3 Xantofyl Palmitate		N N	S S		Unk			Not Reported Not Reported
	Xantofyl Palmitate		Ν	S		Unk			Not Reported
	Xantofyl Palmitate		Ν	S		Unk			Not Reported
	Zeaxanthin Forte		N	S		Not Specified			Not Reported
	Zeaxanthin Forte		N	S		Unk			Not Reported
	Valsartan		N	С		Unk			Not Reported
	Valsartan		N	С		Unk			Not Reported
	Benadryl Allergy [Diphenhydramine Hydrochloride]		N	С		Unk			Not Reported
	Calcium Gluconate		N	С		Unk			Not Reported
	Calcium Lactate;Calcium		N	С		Unk			Not Reported
	Phosphate;Colecalciferol Lomotil [Loperamide Hydrochloride]		N	С		Unk			Not Reported
	Metoclopramide Hydrochloride		Ν	С		Unk			Not Reported
FDA Received Date Case	# Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Nov-2022 21579	ege3 EXPEDITED (15-DAY)	Υ		ОТ	CA-BAUSCHBL 2022-021079	-BL-		Female	e CAN
Preferred Term	<u>Product</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Neomycin And Polymyxin B Sulfates And Gramicidin		N	S	Unknown				Bausch And Lomb



Ophthalmic Soln Sodium Chloride	N	s	Endosinusial		Not Reported
Budesonide	N	S	Unknown		Not Reported
Mesalazine	N	S	Unknown		Not Reported
Metronidazole	N	S	Unknown		Not Reported
Triamcinolone	N	S			Not Reported
Triamcinolone Acetonide	N	S	Intra-articular		Not Reported
Acetaminophene	N	S	Intra-articular		Not Reported
Adalimumab	N	S	Unknown		Not Reported
Alprazolam	N	S	Subcutaneous		Not Reported
·			Unknown		•
Ambroxol Hydrochloride	N	S	Unknown		Not Reported
Amoxicillin Trihydrate	N	S	Unknown		Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown		Not Reported
Atorvastatin Calcium	N	S	Unknown		Not Reported
Atorvastatin Calcium	N	S	Unknown		Not Reported
Atropine	N	S	Oral		Not Reported
Atropine	N	S	Unknown		Not Reported
Avamys	N	S	Unknown	Spray (Metered Dose Inhaler)	Not Reported
Azithromycin Dihydrate	N	S	Oral		Not Reported
Bactrim	N	S	Unknown	Not Specified	Not Reported
Betamethasone Dipropionate	N	S	Unknown		Not Reported
Betamethasone Valerate	N	S	Unknown		Not Reported
Betamethasone Valerate	N	S	Unknown		Not Reported
Biaxin XI	N	S	Unknown	Extended Release	Not Reported
Bisacodyl	N	S	Unknown		Not Reported
Calcium Carbonate	N	S	Unknown		Not Reported
Calcium Carbonate	N	S	Unknown		Not Reported
Calcium Gluconate	N	S	Unknown		Not Reported
Cetirizine	N	S	Unknown		Not Reported



				<u> </u>	
Clarithromycin	N	S	Unknown	Not Specified	Not Reported
Clotrimazole	N	S	Unknown	·	Not Reported
Cupric Oxide	N	S	Unknown		Not Reported
D-Alpha Tocopherol	N	S	Unknown		Not Reported
Desonide	N	S	Unknown		Not Reported
Dilaudid	N	S	Unknown		Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown		Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown		Not Reported
DI-Alpha Tocopheryl Acetate	N	S	Unknown		Not Reported
Entocort	N	S	Unknown	Sustained Release	Not Reported
Ergocalciferol	N	S	Unknown		Not Reported
Ertapenem Sodium	N	S	Unknown		Not Reported
Flovent	N	S	Unknown		Not Reported
Fluticasone Furoate	N	S	Unknown		Not Reported
Glycerine	N	S	Oral		Not Reported
Glycerol	N	S	Unknown		Not Reported
Gramicidin	N	S	Unknown		Not Reported
Humira	N	S	Subcutaneous		Not Reported
Hydrochlorothiazide	N	S	Unknown		Not Reported
Hydromorphone Hydrochloride	N	S	Subcutaneous		Not Reported
Kenalog	N	S	Intra-articular		Not Reported
Lomotil	N	S	Oral		Not Reported
Loperamide Hydrochloride	N	S	Oral		Not Reported
Polyethylene Glycol 3350\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride	N	S	Intra-articular		Not Reported
Magnesium Sulfate	N	S	Unknown		Not Reported
Morphine Sulfate	N	S	Unknown		Not Reported
Ms Ir	N	S	Unknown		Not Reported



				<u> </u>	
Mupirocin	N	S	Topical		Not Reported
Mupirocin	N	S	Unknown		Not Reported
Nadolol	N	S	Unknown		Not Reported
Nicoderm	N	S	Unknown	Patch	Not Reported
Nicotinamide	N	S	Unknown		Not Reported
Nicotine	N	S	Unknown		Not Reported
Nicotine Polacrilex	N	S	Unknown		Not Reported
Pantoprazole	N	S	Unknown		Not Reported
Pentasa	N	S	Unknown		Not Reported
Prednisone	N	S	Unknown		Not Reported
Pregabalin	N	S	Unknown		Not Reported
Pulmicort	N	S	Unknown		Not Reported
Refresh Tears	N	S	Ophthalmic	Drops	Not Reported
Furosemide	N	S	Endosinusial	Solution Nasal	Not Reported
Sinus Rinse	N	S	Endosinusial	Solution Nasal	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown		Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic		Not Reported
Sodium Stearate	N	S	Oral		Not Reported
Statex	N	S	Unknown		Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown		Not Reported
Trimethoprim	N	S	Unknown		Not Reported
Valsartan	N	S	Intracardiac	Intracardiac	Not Reported
Valsartan	N	S	Unknown		Not Reported
Vitamin D3	N	S	Unknown		Not Reported
Xantofyl Palmitate	N	S	Unknown		Not Reported
Zeaxanthin	N	S	Unknown		Not Reported
Zinc Chloride	N	S	Unknown		Not Reported
Zinc Oxide	N	S	Unknown		Not Reported
Calcium [Calcium Citrate]	N	С	Unknown		Not Reported

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Note: If the field is blank, there is no data.



FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	<u>#</u> <u>5</u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Nov-2022	17929893	EXPEDITED (15-DAY)	N		ОТ	CA-Accord-18	6201			Female	CAN
Preferred Term	<u>Pi</u>	roduct	Comp.	OTC	Role	Route	Dosage To	<u>ext</u>	<u>Duration</u>	<u>Mf</u>	<u>.</u>
Drug Ineffective; Macu	ılar At	orvastatin		N	S	Unknown				No	ot Reported
Degeneration	Hy Pa Si Ad Al Ar Ap	regabalin ydrochlorothiazide antoprazole mvastatin cetaminophen prazolam moxicillin oo Hydro		2222 2 22 2	\(\text{\text{\$0}} \text{\$0}	Unknown Unknown Unknown				No No No No No No	ot Reported
		/amys etamethasone		N	S	Unknown Unknown	Spray, Mo Also Reco Betameth Dipropion	nasone			ot Reported
	Bi	axin XI		N	S		Tablet (E Release)	xtended-		No	ot Reported
	Cá Cá Cl Cl Dá Dí	sacodyl alcium Carbonate W/Vitamin D etirizine arithromycin otrimazole esonide phenhydramine ntocort		N	555555555555555555555555555555555555555		,	Sustainedreleas	se	No No No No No No	ot Reported of Reported of Reported of Reported of Reported of Reported of Reported of Reported
	Fl	tapenem Sodium ovent lycerin		N N N	S S S	Oral	Liquid Or			No	ot Reported ot Reported ot Reported
	_	ramicidin /Neomycin/Polymyxin B		N	S		1			No	ot Reported
		umira		N	S	Subcutaneous	Solution S	Subcutaneous	6 YR		ot Reported
	Ke	enalog		N	S	Intra-articular	Suspensi	on Intra- Articul	ar	No	ot Reported



Potassium Chloride W/Sodium Chlorid	N	S	Unknown		Not Reported
Metronidazole	N	S	Unknown		Not Reported
Ms Ir	N	S	Unknown		Not Reported
Mupirocin	N	S		Route: Topical	Not Reported
Nadolol	N	S	Unknown		Not Reported
Nicoderm	N	S	Unknown		Not Reported
Nicotine Polacrilex Pentasa	N N	S S	Unknown		Not Reported Not Reported
Pms-Azithromycin	N	S	Unknown		Not Reported
Prednisone	N	S	Unknown		Not Reported
Pulmicort	N	S	Unknown		Not Reported
Refresh Tears	N	S		Drops Ophthalmic	Not Reported
Sulfamethoxazole W/Trimethoprim	N	S	Unknown		Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Suspension Intra- Articular	Not Reported
Vitamin D3	N	S	Unknown		Not Reported
Sinus Rinse	N	S	Unknown		Not Reported
Valsartan	N	С	Vaginal		Not Reported
Azithromycin	N	S	Unknown		Not Reported
Bactroban	N	S	Unknown		Not Reported
Betaderm	N	S	Unknown		Not Reported
Dilaudid	N	S	Unknown		Not Reported
Habitrol	N	S	Unknown		Not Reported
Lomotil	N	S	Oral	4 Every 1 Days	Not Reported
Sodium Chloride	N	S	Unknown		Not Reported
Loperamide	N	S	Oral	4 Every 1 Days	Not Reported
Adalimumab	N	S	Subcutaneous	Solution Subcutaneous	Not Reported
Budesonide	N	S	Unknown		Not Reported
Calcium Carbonate	N	S	Unknown		Not Reported
Hydromorphone Hydrochloride	N	S	Unknown		Not Reported



				-	,
Mesalazine	N	S	Unknown		Not Reported
Nicotine	N	S	Unknown		Not Reported
Carboxymethylcellulose Sodium	N	S	Unknown	Ophthalmic	Not Reported
Vitamin D3	N	С	Unknown		Not Reported
Atropine W/Diphenoxylate	N	S	Oral		Not Reported
Bactrim Cholecalciferol Cupric Oxide Tocopherol Magnesium Sulfate Morphine Sulfate Sodium Chloride	N N N N N N N N N N N N N N N N N N N	55555		Intra Nasal	Not Reported
Xantofyl Palmitate Nitroglycerin	N N	S S	Oral		Not Reported Not Reported
Pseudoephedrine Acetaminophen W/Dextropropoxyphene	N N	S S			Not Reported Not Reported
Potassium W/Sodium Chloride Minerals Glyceryl Trinitrate	N N N	S S S	Oral		Not Reported Not Reported Not Reported
Gramicidin Imodium Macrogol Nystatine Polymyxin B Sulfate Potassium Phosphate Monobasic	N N N N N N N N N N N N N N N N N N N	55555			Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
Sodium Chloride Statex Vitamin C Vitamins Nos Ergocalciferol Sodium Bicarbonate Zeaxanthin Zinc Oxide Acetylsalicylic Acid	X	000000000			Not Reported
Neomycin Sulfate Polyethylene Glycol	N N	S S			Not Reported Not Reported



							Dotalloa IX	port			
			W/Glycerin/Sodium		N	S	Oral			N	lot Reported
		Chloride Potassiu	ım Chloride		N	S				N	lot Reported
			ol,Cetirizine		Ν	S				N	lot Reported
		Hydroch Valsarta			N	S				N	lot Reported
			\lchthammol		N	Š				N	lot Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Nov-2022	216113	343	EXPEDITED (15-DAY)	N		ОТ	US-ALLERGAI 2237597US	N -		Female	USA
Preferred Term		Product	<u>I</u>	Comp.	OTC	Role	Route	Dosage Text	Duration	<u>M</u>	<u>fr</u>
Cataract; Conjunctivitis	6	Refresh	Digital Pf		Υ	S	Ophthalmic	Unk		А	llergan
FDA Received Date	Case #		Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Nov-2022	183285	537	EXPEDITED (15-DAY)	Υ		HO, OT	CA-AstraZeneo 2020SF24442	ca-		Female	CAN
Preferred Term		Product	<u> </u>	Comp.	OTC	Role	Route	Dosage Text	Duration	<u>M</u>	<u>fr</u>
Chronic Sinusitis; Drug		Budesor	nide		N	S	Other			N	lot Reported
Ineffective; Dyspepsia; Infusion Related React		Entocort			Ν	S	Oral			N	lot Reported
Macular Degeneration; Malaise; Nausea; Off		Pulmicor	rt		N	S	Respiratory (inhalation)			A	strazeneca
Label Use; Pain; Paraesthesia Oral;		Atorvast	atin Calcium		N	S	Unknown			N	lot Reported
Procedural Pain; Pyrex	кіа;	Alprazola	am		Ν	S	Oral	0.25 Mg		N	lot Reported
Therapeutic Product E	ffect	Alprazola	am		N	S	Oral			N	lot Reported
Incomplete; Weight Decreased		Calcium	Carbonate		Ν	S	Unknown			N	lot Reported
		Magnesi	um Sulfate		N	S	Unknown			N	lot Reported
		Metronid	lazole		N	S	Unknown			N	lot Reported
		Metronid	lazole		N	S	Unknown			N	lot Reported
		Morphine	e Sulfate		Ν	S	Unknown			N	lot Reported
		Pregaba	lin		Ν	S	Oral			N	lot Reported
		Pregaba	lin		N	S	Oral	150 Mg		N	lot Reported

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Note: If the field is blank, there is no data.

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Paracetamol	N	S	Unknown			Not Reported
Amoxicillin	N	S	Unknown			Not Reported
Amoxicillin	N	S	Unknown			Not Reported
Amoxicillin	N	S	Unknown			Not Reported
Apo Hydro	N	S	Endocervical			Not Reported
Diphenoxylate	N	S	Oral			Not Reported
Hydrochloride/Atropine Sulfate Avamys	N	S	Halmanna	Material Dana		Not Reported
Avamys	N	S	Unknown	Metered Dose		Not Reported
Azithromycin Dihydrate	N	S	Unknown			Not Reported
Betamethasone	N	S	Unknown			Not Reported
Betamethasone Dipropionate	N	S	Unknown			Not Reported
Biaxin XI	N	S	Unknown	T		Not Reported
Biaxin XI	N	S	Oral	Tablet (Extendedrelease)		Not Reported
Biaxin XI	N	S	Unknown	Tablet (Extendedrelease)		Not Reported
Dulcolax	N	S	Unknown	Tablet (Extendedrelease)		Not Reported
Cetirizine Hydrochloride	N	S	Unknown			Not Reported
Clarithromycin	N	S	Unknown			Not Reported
Clarithromycin	N	S	Oral			Not Reported
•	N N		Oral			•
Clotrimazole		S	Unknown			Not Reported
Cupric Oxide	N	S	Unknown			Not Reported
Desonide	N	S	Unknown			Not Reported
Dilaudid	N	S	Unknown			Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown			Not Reported
DI-Alpha Tocopheryl Acetate	N	S	Unknown			Not Reported
Ertapenem Sodium	N	S	Unknown			Not Reported
Flovent	N	S	Unknown			Not Reported
Glycerine	N	S	Oral			Not Reported
Gramicidin	N	S	Unknown			Not Reported
Humira	N	S	Subcutaneous	5	YR	Not Reported



				<u> </u>	
Humira	N	S	Subcutaneous		Not Reported
Humira	N	S	Unknown		Not Reported
Triamcinolone Acetonide	N	S	Intra-articular		Not Reported
Sodium Sulfate/Macrogol 3350/Sodium Chloride/Sodium Bicarbonate/Potassium Chloride	N	S	Urethral		Not Reported
Sodium Sulfate/Macrogol 3350/Sodium Chloride/Sodium Bicarbonate/Potassium Chloride	N	S	Urethral		Not Reported
Sodium Sulfate/Macrogol 3350/Sodium Chloride/Sodium Bicarbonate/Potassium Chloride	N	S	Urethral		Not Reported
Sodium Sulfate/Macrogol 3350/Sodium Chloride/Sodium Bicarbonate/Potassium Chloride	N	S	Urethral		Not Reported
Msir	N	S	Unknown		Not Reported
Mupirocin	N	S	Topical		Not Reported
Mupirocin	N	S	Topical		Not Reported
Nadolol	N	S	Oral	40 Mg	Not Reported
Nadolol	N	S	Oral		Not Reported
Nicoderm	N	S	Transdermal		Not Reported
Nicotine	N	S	Unknown		Not Reported
Nicotine Polacrilex	N	S	Unknown		Not Reported
Pantoprazole	N	S	Unknown		Not Reported
Mezavant	N	S	Unknown		Not Reported
Prednisone	N	S	Unknown		Not Reported
Refresh Tears	N	S	Ophthalmic		Not Reported
Sulfamethoxazole/Trimethoprim	N	S	Unknown		Not Reported
Vitamin D3	N	S	Unknown		Not Reported
Xantofyl Palmitate	N	S	Oral		Not Reported
Zeaxanthin	N	S	Oral		Not Reported
Zinc Oxide	N	S	Oral		Not Reported
Bactroban	N	S	Topical		Not Reported



Betaderm	N	S	Unknown		Not Reported
Nicotine	N	S	Transdermal		Not Reported
Kenalog	N	S	Intra-articular		Not Reported
Kenalog	N	S	Intra-articular		Not Reported
Kenalog	N	S	Intra-articular		Not Reported
Lomotil	N	S	Oral	0.025/ 2.5 Mg4 Every 1	Not Reported
Sodium Chloride	N	S		Days	Not Reported
Statex	N	S	Nasal		Not Reported
Ergocalciferol	N	S	Unknown	00001	Not Reported
Alka-Seltzer		S	Unknown	3000 lu	Not Reported
	N		Unknown		·
Bactrim	N	S	Unknown		Not Reported
Vitamin-E	N	S	Unknown		Not Reported
Polymyxin B Sulfate	N	S	Unknown		Not Reported
Neomycin Sulfate	N	S	Unknown		Not Reported
Sinus Rinse	N	S	Nasal		Not Reported
Sinus Rinse	N	S	Intra-articular		Not Reported
Habitrol	N	S	Transdermal		Not Reported
Pseudoephedrine Hydrochloride/Paracetamol	N	S	Unknown		Not Reported
Vitamins Nos	N	S	Oral		Not Reported
Acetaminophen	N	S	Unknown		Not Reported
Potassium Chloride	N	S	Unknown		Not Reported
Vitamin D3	N	S	Unknown		Not Reported
Vitamin D3	N	S	Unknown		Not Reported
Vitamin E	N	S	Unknown		Not Reported
Vitamin D Nos/Calcium	N	S	Unknown		Not Reported
Carbonate Pentasa	N	S			Not Reported
Sodium Chloride	N N	S	Unknown		Not Reported
			Nasal		·
Mesalazine	N	S	Unknown		Not Reported



				•	
Pms Azithromycin	N	S	Unknown		Not Reported
Hctz	N	S	Unknown		Not Reported
Acetylsalicylic Acid	N	S	Unknown		Not Reported
Azithromycin	Ν	S	Unknown		Not Reported
Glycerol	Ν	S	Oral		Not Reported
Moviprep	Ν	S	Unknown		Not Reported
Metoclopramide Hydrochloride	Ν	S	Unknown		Not Reported
Paracetamol	N	S	Unknown		Not Reported
Bisacodyl	N	S	Unknown		Not Reported
Lekovit Ca	N	S	Unknown		Not Reported
Sodium Bicarbonate\Sodium Chloride	N	S	Unknown		Not Reported
Xantofyl Palmitate	Ν	S	Unknown		Not Reported
Calcium Citrate	N	S	Unknown		Not Reported
Calcium Phosphate	N	S	Unknown		Not Reported
Hydromorphone Hydrochloride	N	S	Unknown		Not Reported
Sulfamethoxazole/Trimethoprim	N	S	Unknown	200 Mg	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk 1 In 6 Hours	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk, Q 4 Week	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral		Not Reported
Loperamide Hydrochloride	Ν	S	Oral		Not Reported
Paracetamol/Dextropropoxyphen e	N	S	Unknown		Not Reported
Betamethasone Valerate	N	S	Topical		Not Reported
Nicotinamide/Cupric Oxide/Folic Acid/Zinc	N	S	Unknown		Not Reported
Imodium	N	S	Unknown		Not Reported
Glyceryl Trinitrate	N	S	Unknown		Not Reported
Hydrochlorothiazide	N	S	Endocervical	100 Mg	Not Reported
Hydrochlorothiazide	N	S	Unknown	100 Mg	Not Reported



		_		
Ichthammol/Glycerol	N	S	Unknown	Not Reported
Valsartan	N	S	Unknown	Not Reported
Vitamin A	N	S	Unknown	Not Reported
Sodium Stearate	N	S	Unknown	Not Reported
Atorvastatin	N	S	Unknown	Not Reported
Mentha Arvensis	N	S	Unknown	Not Reported
Sodium	N	S	Unknown	Not Reported
Chloride/Glycerol/Fructose Difenoxin Hydrochloride	N	S	Unknown	Not Reported
Nicotinamide/Cupric Oxide/Folic Acid/Zinc	N	S	Unknown	Not Reported
Promethazine Hydrochloride	N	S	Unknown	Not Reported
Paracetamol/Dextropropoxyphen	N	S	Unknown	Not Reported
e Calcitriol/Calcium Carbonate/Zinc	N	S	Unknown	Not Reported
Sulfamethoxazole/Bromhexine Hydrochloride/Trimethoprim	N	S	Unknown	Not Reported
Mupirocin/Betamethasone	N	S	Unknown	Not Reported
Betamethasone Sodium Phosphate	N	S	Unknown	Not Reported
Benzydamine	N	S	Unknown	Not Reported
Neomycin\Polymyxin B Sulfate	N	S	Unknown	Not Reported
Fluticasone Furoate	Ν	S	Unknown	Not Reported
Zinc Chloride	N	S	Unknown	Not Reported
Sodium Stearate	N	S	Unknown	Not Reported
Sodium Carboxymethyl	N	S	Unknown	Not Reported
Cellulose Ms Ir	N	S	Unknown	Not Reported
Cefixime	N	S	Unknown	Not Reported
Calcium Gluconate	N	S	Unknown	Not Reported
Adalimumab	N	S	Unknown	Not Reported
Benzydamine Hydrochloride	N	S	Unknown	Not Reported



							•			
	(Calcium Citrate/Magnesium Oxide/Calcium Carbonate/Colecalciferol/Calciu n Phosphate		N	S	Unknown				Not Reported
	5	Simvastatin		N	S	Unknown			1	Not Reported
	N	/linerals\Vitamins		N	S	Unknown			1	Not Reported
	\	/alsartan		N	С	Unknown			1	Not Reported
		Atropine Sulfate Sulfamethoxazole\Trimethoprim			S S					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof Ou	<u>itcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Nov-2022	2163558	1 EXPEDITED (15-DAY)	N			US-ALLERGA 2235429US	N-		Unknown	USA
Preferred Term	<u> </u>	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>N</u>	<u>lfr</u>
Product Contamination		Refresh Tears		Υ	S		Unk		A	Allergan
Microbial; Product Deli Mechanism Issue	livery									
		Case Type	Health	Prof Ou	ıtcomes	Mfr Control	# 503B Facility	Age	<u>Sex</u>	Country
Mechanism Issue				Prof Ou		Mfr Control CA-JNJFOC- 20190913993	# 503B Facility	<u>Age</u>	<u>Sex</u> Female	<u>Country</u> CAN
Mechanism Issue FDA Received Date 24-Nov-2022	Case # 1681532					CA-JNJFOC-	# 503B Facility Dosage Text	Age Duration	Female	
Mechanism Issue FDA Received Date 24-Nov-2022 Preferred Term	Case # 1681532	5 EXPEDITED (15-DAY)	Y	ТО	-	CA-JNJFOC- 20190913993	-		Female	CAN
Mechanism Issue FDA Received Date 24-Nov-2022 Preferred Term Drug Ineffective; Macu	Case # 1681532 <u>F</u> ular N	5 EXPEDITED (15-DAY) Product	Y	01 <u>0TC</u>	Role	CA-JNJFOC- 20190913993 Route Transdermal	-		Female	CAN
Mechanism Issue FDA Received Date 24-Nov-2022 Preferred Term Drug Ineffective; Macu	Case # 1681532 Lular	5 EXPEDITED (15-DAY) Product Nicoderm	Y	OTC N	Role S	CA-JNJFOC- 20190913993 Route	-		Female	CAN Ifr Not Reported
Mechanism Issue FDA Received Date 24-Nov-2022 Preferred Term Drug Ineffective; Macu	Case # 1681532 Idar N	5 EXPEDITED (15-DAY) Product Nicoderm Nicoderm	Y	OTC N N	Role S S	CA-JNJFOC-20190913993 Route Transdermal Unknown	-		Female M	CAN Ifr Not Reported Not Reported
Mechanism Issue FDA Received Date 24-Nov-2022 Preferred Term Drug Ineffective; Macu	Case # 1681532 ighthar No. 100	5 EXPEDITED (15-DAY) Product Vicoderm Vicoderm Vicoderm	Y	OTC N N N	Role S S S	CA-JNJFOC-20190913993 Route Transdermal Unknown Unknown	-		Female N	CAN Ifr Not Reported Not Reported Not Reported
Mechanism Issue FDA Received Date 24-Nov-2022 Preferred Term Drug Ineffective; Macu	Case # 1681532 I I I I I	5 EXPEDITED (15-DAY) Product Nicoderm Nicoderm Nicoderm Cetirizine Hydrochloride	Y	OTC N N N N	Role S S S S	CA-JNJFOC-20190913993 Route Transdermal Unknown Unknown Unknown	-		Female M	CAN Ifr Not Reported Not Reported Not Reported Not Reported
Mechanism Issue FDA Received Date 24-Nov-2022 Preferred Term Drug Ineffective; Macu	Case # 1681532 ighthar N N C	EXPEDITED (15-DAY) Product Vicoderm Vicoderm Vicoderm Cetirizine Hydrochloride Cetirizine Hydrochloride	Y	OTC N N N N N N N N	Role S S S S S	CA-JNJFOC-20190913993 Route Transdermal Unknown Unknown Unknown Unknown	-		Female N	CAN Ifr Not Reported Not Reported Not Reported Not Reported Not Reported
Mechanism Issue FDA Received Date 24-Nov-2022 Preferred Term Drug Ineffective; Macu	Case # 1681532 Jular N Co	EXPEDITED (15-DAY) Product Nicoderm Nicoderm Cetirizine Hydrochloride Cetirizine Hydrochloride Cetirizine Hydrochloride	Y	OTC N N N N N N N N N N N N N N N N N N	Role S S S S S S	CA-JNJFOC-20190913993 Route Transdermal Unknown Unknown Unknown Unknown Unknown Unknown	-		Female M N N N N N N N N N N N N	CAN Ifr Not Reported
Mechanism Issue FDA Received Date	Case # 1681532 ightar N Comparison of the com	EXPEDITED (15-DAY) Product Nicoderm Nicoderm Cetirizine Hydrochloride Cetirizine Hydrochloride Cetirizine Hydrochloride Cetirizine Hydrochloride	Y	OTC N N N N N N N N N N N N N N N N N N	Role S S S S S S S S	CA-JNJFOC-20190913993 Route Transdermal Unknown Unknown Unknown Unknown Unknown Unknown Unknown Unknown	-		Female N N N N N N N N N N N N N	CAN Ifr Not Reported Not Reported



			_		
Paracetamol	N	S	Unknown		Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown		Not Reported
Paracetamol/Pseudoephedrine Hcl	N	S	Unknown		Not Reported
Imodium	N	S	Oral		Not Reported
Zinc Oxide	N	S	Unknown		Not Reported
Alprazolam	N	S	Oral		Not Reported
Alprazolam	N	S	Unknown		Not Reported
Alprazolam	N	S	Unknown	Route Of Administration: Inhalation	Not Reported
Alprazolam	N	S	Unknown		Not Reported
Amoxicillin Trihydrate	N	S	Unknown		Not Reported
Apo Hydro	N	S	Unknown		Not Reported
Atorvastatin Calcium	N	S	Unknown		Not Reported
Atorvastatin Calcium	N	S	Unknown		Not Reported
Atorvastatin Calcium	N	S	Unknown		Not Reported
Desonide	N	S	Unknown		Not Reported
Dilaudid	N	S	Unknown		Not Reported
Entocort	N	S	Unknown		Not Reported
Ertapenem Sodium	N	S	Unknown		Not Reported
Ertapenem Sodium	N	S	Unknown		Not Reported
Flovent	N	S	Unknown		Not Reported
Flovent	N	S	Unknown		Not Reported
Glycerine	N	S	Oral		Not Reported
Glycerine	N	S	Unknown		Not Reported
Glycerine	N	S	Oral		Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown		Not Reported
Habitrol [Nicotine]	N	s s	Transdermal		Not Reported
Kenalog [Triamcinolone Acetonide]	N	5	Unknown		Not Reported



Kenalog [Triamcinolone	N	S	Intra-articular		Not Reported
Acetonide] Kenalog [Triamcinolone	N	S	Intra-articular		Not Reported
Acetonide] Humira	N	S	Subcutaneous	6 YR	Not Reported
Humira	N	S	Subcutaneous	6 YR	Not Reported
Humira	N	S	Unknown	6 YR	Not Reported
Humira	N	S	Subcutaneous	6 YR	Not Reported
Lomotil [Atropine Sulfate;	N	S	Oral		Not Reported
Diphenoxylate Hydrochloride] Lomotil [Atropine Sulfate; Diphenoxylate Hydrochloride]	N	S	Oral	Unk	Not Reported
Salinex [Macrogol;Propylene Glycol;Sodium Chloride]	N	S	Nasal		Not Reported
Sinus Rinse	N	S	Nasal		Not Reported
Sinus Rinse	N	S	Intra-articular		Not Reported
Statex [Morphine Sulfate]	N	S	Unknown		Not Reported
Bactrim	N	S	Unknown		Not Reported
Bactrim	N	S	Unknown		Not Reported
Triamcinolone Acetonide	N	S	Intra-articular		Not Reported
Triamcinolone Acetonide	N	S	Intra-articular		Not Reported
Vitamin D3	N	S	Unknown		Not Reported
Vitamin D3	N	S	Unknown		Not Reported
Avamys	N	S	Unknown	Metered Dose	Not Reported
Avamys	N	S	Unknown		Not Reported
Azithromycin Dihydrate	N	S	Unknown		Not Reported
Azithromycin Dihydrate	N	S	Oral		Not Reported
Bactroban [Mupirocin]	N	S	Unknown		Not Reported
Betaderm [Betamethasone]	N	S	Unknown		Not Reported
Betamethasone Dipropionate	N	S	Unknown		Not Reported
Biaxin XI	N	S	Unknown	Tablet (Extended Release)	Not Reported
Biaxin XI	N	S	Unknown	,	Not Reported

Date - Time: 11-Apr-2023 10:56:54 AM EST

Note: If the field is blank, there is no data.



Biaxin XI	N	S	Unknown		Not Reported
Bisacodyl	N	S	Unknown		Not Reported
Bisacodyl	N	S	Unknown		Not Reported
Vitamins With Minerals	N	S	Unknown		Not Reported
Clarithromycin	N	S	Oral		Not Reported
Clarithromycin	N	S	Unknown		Not Reported
Clotrimazole	N	S	Unknown		Not Reported
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate; Sodium Chloride;So	N	S	Unknown		Not Reported
Metronidazole	N	S	Unknown		Not Reported
Ms Ir	N	S	Unknown		Not Reported
Mupirocin	N	S	Topical		Not Reported
Mupirocin	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Oral		Not Reported
Nadolol	N	S	Unknown		Not Reported
Pantoprazole	N	S	Unknown		Not Reported
Pentasa	N	S	Unknown		Not Reported
Prednisone	N	S	Unknown		Not Reported
Pregabalin	N	S	Oral		Not Reported
Pregabalin	N	S	Unknown		Not Reported
Pulmicort	N	S	Unknown		Not Reported
Refresh Tears	N	S	Ophthalmic		Not Reported
Refresh Tears	N	S	Unknown		Not Reported
Refresh Tears	N	S	Ophthalmic		Not Reported
Sulfamethoxazole And Trimethoprim	N	S	Unknown		Not Reported
Sulfamethoxazole And Trimethoprim	N	S	Unknown		Not Reported
Sodium Chloride	N	S	Unknown		Not Reported
Xantofyl Palmitate	N	S	Unknown		Not Reported



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Zeaxanthin	N	S	Unknown	Not Reported
Cupric Oxide	N	S	Unknown	Not Reported
D-Alpha Tocopheryl Acetate	N	S	Unknown	Not Reported
Magnesium Sulfate	N	S	Unknown	Not Reported
Calcium Carbonate	N	S	Unknown	Not Reported
Ergocalciferol	N	S	Unknown	Not Reported
Mesalamine	N	S	Unknown	Not Reported
Mesalamine	N	S	Unknown	Not Reported
Vitamins Nos	N	S	Unknown	Not Reported
Dulcolax [Bisacodyl]	N	S	Unknown	Not Reported
Gramicidin;Polymyxin B	N	S	Unknown	Not Reported
Macrogol	N	S	Unknown	Not Reported
Macrogol;Potassium Chloride; Sodium Bicarbonate	N	S	Unknown	Not Reported
Pms Azithromycin	N	S	Unknown	Not Reported
Betamethasone Valerate	N	S	Topical	Not Reported
Betamethasone Valerate	N	S	Unknown	Not Reported
Betamethasone Valerate	N	S	Unknown	Not Reported
Hctz	N	S	Unknown	Not Reported
Morphine Sulfate	N	S	Unknown	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Not Reported
Azithromycin	N	S	Unknown	Not Reported
Betamethasone	N	S	Unknown	Not Reported
Ertapenem	N	S	Unknown	Not Reported
Fluticasone	N	S	Unknown	Not Reported
Glycerol	N	S	Unknown	Not Reported
Glycerol	N	S	Oral	Not Reported
Gramicidin	N	S	Unknown	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Not Reported
Hydrochlorothiazide	N	S	Oral	Not Reported



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Hydrochlorothiazide	N	S	Unknown	Not Reported
Hydromorphone	N	S	Unknown	Not Reported
Hydromorphone	N	S	Endocervical	Not Reported
Mesalazine	N	S	Unknown	Not Reported
Moviprep [Ascorbic Acid; Macrogol 3350;Potassium Chloride;Sodium Ascorb	N	S	Unknown	Not Reported
Neomycin B Sulfate	N	S	Unknown	Not Reported
Potassium Chloride	N	S	Unknown	Not Reported
Sodium Bicarbonate	N	S	Unknown	Not Reported
Vitamin D3 1000	N	S	Unknown	Not Reported
Vitamin E [Tocopherol]	Ν	S	Unknown	Not Reported
Adalimumab	N	S	Subcutaneous	Not Reported
Adalimumab	N	S	Subcutaneous	Not Reported
Adalimumab	N	S	Unknown	Not Reported
Fluticasone Furoate	N	S	Unknown	Not Reported
Fluticasone Furoate	N	S	Ophthalmic	Not Reported
Hydromorphone Hydrochloride	Ν	S	Unknown	Not Reported
Aspirin\Caffeine	Ν	S	Unknown	Not Reported
Amoxicillin	N	S	Unknown	Not Reported
Atorvastatin	N	S	Unknown	Not Reported
Atropine Sulfate;Difenoxin Hydrochloride	N	S	Oral	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Not Reported
Valsartan	N	S	Unknown	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Unknown	Not Reported
Mupirocin Calcium	N	S	Unknown	Not Reported
Mupirocin Calcium	N	S	Topical	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Not Reported



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Infa-3 [Gramicidin;Neomycin Sulfate;Polymyxin B]	N	S	Unknown	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Not Reported
Cholecalciferol	N	S	Unknown	Not Reported
Fructose;Glycerol;Sodium Chloride	N	S	Oral	Not Reported
Atropine Sulfate\Diphenoxylate Hydrochloride	N	S	Unknown	Not Reported
Neomycin Sulfate	N	S	Unknown	Not Reported
Neomycin	N	S	Unknown	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Not Reported
Polyethylene Glycol 4000	N	S	Endocervical	Not Reported
Benzydamine Hydrochloride	N	S	Unknown	Not Reported
Macrogol;Potassium Chloride; Sodium Bicarbonate;Sodium Chloride	N	S	Unknown	Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown	Not Reported
Fluocinolone Acetonide; Neomycin Sulfate;Polymyxin B Sulfate	N	S	Unknown	Not Reported
Ichthammol;Zinc Oxide	N	S	Unknown	Not Reported
Pantoprazole Sodium	N	S	Unknown	Not Reported
Nicotinamide	N	S	Unknown	Not Reported
Vitamin D [Ergocalciferol]	N	S	Unknown	Not Reported
Atropine Sulfate	N	S	Unknown	Not Reported
Atropine Sulfate	N	S	Oral	Not Reported
Calcium Citrate	N	S	Unknown	Not Reported
Difenoxin Hydrochloride	N	S	Unknown	Not Reported
Ambroxol Hydrochloride	N	S	Unknown	Not Reported
Calcium Gluconate	N	S	Unknown	Not Reported
Zinc Chloride	N	S	Unknown	Not Reported
Sodium Stearate	N	S	Oral	Not Reported
Mezavant	N	S	Unknown	Not Reported



		Mezava	nt		N	S	Unknown				Not Reported
		Simvast	atin		Ν	S	Unknown				Not Reported
		Simvast	atin		Ν	S	Unknown				Not Reported
		Glycero	;Ichthammol		Ν	S	Unknown				Not Reported
		Calcium	Carbonate/Vitamin D3		Ν	С	Unknown				Not Reported
		Valsarta	n		Ν	С	Unknown				Not Reported
		Vitamin	A [Retinol]		Ν	С	Unknown				Not Reported
			in Sulfate thoxazole\Trimethoprim			S S					Not Reported Not Reported
FDA Received Date	Case #	<u>#</u>	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Nov-2022	21640	103	EXPEDITED (15-DAY)	N		ОТ	US-ALLERG 2238234US	GAN-		Female	USA
Preferred Term		Produc	<u>t</u>	Comp.	OTO	Role	<u>Route</u>	Dosage Text	Duration		<u>Mfr</u>
Dry Eye; Glaucoma;		Refresh			Υ	S S					Allergan
Product Availability Iss Therapy Interrupted	sue;	Refresh	Optive Advanced		Υ	S					Allergan
	case #		Optive Advanced Case Type	<u>Health</u>	•	S Outcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	
Therapy Interrupted		<u>#</u>	•	<u>Health</u> Y	•		Mfr Contro CA-ABBVIE- 2688707-00	-19K-028-	Age	<u>Sex</u> Female	Allergan
FDA Received Date 28-Nov-2022	Case #	<u>#</u>	Case Type EXPEDITED (15-DAY)		•	Outcomes OT	CA-ABBVIE-	-19K-028-	Age Duration	Female	Allergan <u>Country</u>
Therapy Interrupted FDA Received Date 28-Nov-2022 Preferred Term Macular Degeneration	Case # 160389	<u>#</u> 950	Case Type EXPEDITED (15-DAY)	Y	Prof	Outcomes OT	CA-ABBVIE- 2688707-00	-19K-028-		Female	Allergan Country CAN
FDA Received Date 28-Nov-2022 Preferred Term Macular Degeneration Therapeutic Product E	Case # 160389	# 950 <u>Produc</u>	Case Type EXPEDITED (15-DAY)	Y	Prof OTC	Outcomes OT Role	CA-ABBVIE- 2688707-00 Route	-19K-028-		Female	Country CAN
Therapy Interrupted FDA Received Date 28-Nov-2022 Preferred Term Macular Degeneration Therapeutic Product E	Case # 160389	950 Produc Humira	Case Type EXPEDITED (15-DAY)	Y	Prof OTC	Outcomes OT Role S	CA-ABBVIE- 2688707-00 Route Subcutaneous	-19K-028-		Female	Country CAN Mfr Abbvie
Therapy Interrupted FDA Received Date 28-Nov-2022 Preferred Term Macular Degeneration Therapeutic Product E	Case # 160389	950 Produc Humira Humira	Case Type EXPEDITED (15-DAY)	Y	OTC N N	Outcomes OT Role S S	CA-ABBVIE- 2688707-00 Route Subcutaneous Subcutaneous	Dosage Text Solution Subcutaneous 0.025 + 2.5 Mg/ 1 Tablet Times A Day Or As		Female	Country CAN Mfr Abbvie Abbvie
Therapy Interrupted FDA Received Date 28-Nov-2022 Preferred Term Macular Degeneration Therapeutic Product E	Case # 160389	Produc Humira Humira Humira Humira Lomotil	Case Type EXPEDITED (15-DAY)	Y	Prof OTC N N N	Outcomes OT Role S S S S	CA-ABBVIE- 2688707-00 Route Subcutaneous Subcutaneous Unknown	Dosage Text Solution Subcutaneous 0.025 + 2.5 Mg/ 1 Tablet		Female	Country CAN Mfr Abbvie Abbvie Abbvie
Therapy Interrupted FDA Received Date 28-Nov-2022 Preferred Term Macular Degeneration Therapeutic Product E	Case # 160389	Produc Humira Humira Humira Humira Lomotil	Case Type EXPEDITED (15-DAY)	Y	Prof OTC N N N N	Outcomes OT Role S S S S S	CA-ABBVIE- 2688707-00 Route Subcutaneous Subcutaneous Unknown Oral	Dosage Text Solution Subcutaneous 0.025 + 2.5 Mg/ 1 Tablet Times A Day Or As		Female	Country CAN Mfr Abbvie Abbvie Abbvie Not Reported
Therapy Interrupted FDA Received Date	Case # 160389	Produc Humira Humira Humira Lomotil	Case Type EXPEDITED (15-DAY) t	Y	Prof N N N N	Outcomes OT Role S S S S S	CA-ABBVIE- 2688707-00 Route Subcutaneous Subcutaneous Unknown Oral	Dosage Text Solution Subcutaneous 0.025 + 2.5 Mg/ 1 Tablet Times A Day Or As		Female	Country CAN Mfr Abbvie Abbvie Abbvie Not Reported



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Apo Amoxi	N	S	Unknown		Not Reported
Statex	N	S	Unknown		Not Reported
Apo Nadol	N	S	Unknown		Not Reported
Atorvastatine	N	S	Unknown		Not Reported
Pregabalin	N	S	Unknown		Not Reported
Triamcinolone Acetonide	N	S	Unknown		Not Reported
M Cal	N	S	Unknown		Not Reported
Jamp Azithromycin	N	S	Unknown		Not Reported
Act Clarithromycin	N	S	Unknown		Not Reported
Avamys	N	S	Ophthalmic	Spray, Metered Dose	Not Reported
Prednisone	N	S	Subcutaneous	· ·	Not Reported
Prednisone	N	S	Unknown	Not Specified	Not Reported
Sodium Chloride	N	S	Endosinusial	•	Not Reported
Ms Ir	N	S	Unknown	Not Specified	Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown	•	Not Reported
Pentasa	N	S	Unknown	Not Specified	Not Reported
Entocort	N	S	Oral	·	Not Reported
Entocort	N	S	Unknown	Sustained Release	Not Reported
Bisacodyl	N	S	Unknown	Not Specified	Not Reported
Peglyte	N	S	Unknown	·	Not Reported
Polysporin	N	S	Unknown		Not Reported
D-Tabs	N	S	Unknown		Not Reported
Eurocal	N	S	Unknown		Not Reported
Kenalog	N	S	Intra-articular		Not Reported
Habitrol	N	S	Unknown		Not Reported
Thrive	N	S	Unknown		Not Reported
Taro-Mupirocin	N	S	Unknown		Not Reported
Metronidazole	N	S	Unknown		Not Reported
Ratio-Topisone	N	S	Unknown		Not Reported
			•		



Flovent	N	S	Unknown	Not Specified	Not Reported
Nicoderm	N	S	Unknown	Patch	Not Reported
Betaderm	N	S	Unknown		Not Reported
Alrex	N	S	Unknown		Not Reported
Refresh Tears	N	S	Ophthalmic	Drops Ophthalmic	Not Reported
Glycerine	N	S	Oral		Not Reported
Glycerine	N	S	Unknown		Not Reported
Biaxin XI	N	S	Unknown		Not Reported
Preservision Areds 2	N	S	Unknown		Not Reported
Dilaudid	N	S	Unknown		Not Reported
Sinus Rinse	N	S	Nasal		Not Reported
Sinus Rinse	N	S	Unknown	Solution Nasal	Not Reported
Bactroban	N	S	Unknown		Not Reported
Sulfamethoxazole	N	S	Unknown		Not Reported
Trimethoprim	N	S	Unknown		Not Reported
Morphine Sulfate	N	S	Unknown		Not Reported
Sodium Chloride	N	S	Nasal		Not Reported
Sodium Chloride	N	S	Unknown	Not Specified	Not Reported
Nicotine Polacrilex	N	S	Unknown		Not Reported
Mupirocin	N	S	Topical		Unknown
Macrogol	N	S	Unknown		Not Reported
Potassium Chloride	N	S	Unknown		Not Reported
Sodium Bicarbonate	N	S	Unknown		Not Reported
Chloride	N	S	Unknown		Unknown
Nadolol	N	S	Intra-articular		Not Reported
Nadolol	Ν	S	Unknown		Not Reported
Atropine Sulfate Diphenoxylate Hydrochloride	N	S	Oral		Unknown
Diphenoxylate Hydrochloride	N	S	Oral		Unknown
Diphenoxylate Hydrochloride	N	S	Unknown		Unknown



Nicotine	N	S	Unknown	Not Specified	Not Reported
Ertapenem Sodium	N	S	Nasal		Par
Ertapenem Sodium	N	S	Unknown		Par
Desonide	N	S	Unknown	Not Specified	Unknown
Amoxicillin	N	S	Unknown		Not Reported
Zinc Oxide	N	S	Unknown		Not Reported
Zeaxanthin	N	S	Unknown		Not Reported
Xantofyl Palmitate	N	S	Unknown		Unknown
Vitamin E	N	S	Unknown		Not Reported
Cupric Oxide	N	S	Unknown	Not Specified	Unknown
Clotrimazole	N	S	Unknown		Not Reported
Vitamin D3	N	S	Unknown		Not Reported
Vitamin D3	N	S	Unknown		Not Reported
Vitamin D3	N	S	Oral		Not Reported
Clarithromycin	N	S	Oral		Not Reported
Clarithromycin	N	S	Unknown		Not Reported
Magnesium Sulfate	N	S	Unknown	Not Specified	Not Reported
Calcium Carbonate	N	S	Unknown	Not Specified	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Not Specified	Not Reported
Betamethasone	N	S	Unknown		Not Reported
Azithromycin Dihydrate	N	S	Unknown		Not Reported
Calcium Carbonate/Vitamin D3	N	S	Unknown		Unknown
Betamethasone Valerate	N	S	Topical		Bausch And Lomb
Betamethasone Valerate	N	S	Unknown		Bausch And Lomb
Cetirizine Hydrochloride	N	S	Unknown		Mylan
Paracetamol	N	S	Unknown		Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown		Not Reported
Amoxicillin Trihydrate	N	S	Unknown		Not Reported
Triamcinolone	N	S	Intra-articular		Not Reported



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Bactrim	N	S	Unknown		Not Reported
Pms Azithromycin	N	S	Unknown		Not Reported
Atorvastatin Calcium	N	S	Unknown		Not Reported
Budesonide	N	S	Oral		Not Reported
Budesonide	N	S	Unknown		Not Reported
Budesonide	N	S	Other		Not Reported
Hydrochlorothiazide	N	S	Endocervical		Not Reported
Hydrochlorothiazide	N	S	Oral		Not Reported
Hydrochlorothiazide	N	S	Unknown		Not Reported
Mezavant	N	S	Unknown		Not Reported
Ergocalciferol	N	S	Unknown	Not Specified	Not Reported
Pantoprazole	N	S	Unknown	Not Specified	Not Reported
Riva-Pantoprazole	N	S	Unknown		Not Reported
Prednisone Teva	N	S	Unknown		Not Reported
Pulmicort	N	S	Respiratory (inhalation)	Pulmicort Nebuamp	Not Reported
Pulmicort	N	S	Unknown	Not Specified	Not Reported
Loperamide Hydrochloride	N	S	Oral		Not Reported
Polyethylene Glycol	N	S	Unknown		Not Reported
Hydromorphone Hydrochloride	N	S	Unknown		Not Reported
Fluticasone Furoate	N	S	Ophthalmic		Unknown
Fluticasone Furoate	N	S	Unknown		Unknown
Calcium Carbonate;Calcium Gluconate;Vitamin D Nos	N	S	Unknown	Not Specified	Unknown
Azithromycin	N	S	Unknown		Not Reported
Azithromycin	N	S	Oral	Not Specified	Not Reported
Cetrizine	N	S	Unknown		Not Reported
DI-Alpha Tocopheryl Acetate	N	S	Unknown		Unknown
Gramicidin	N	S	Unknown		Unknown
Neomycin Sulfate	N	S	Unknown		Not Reported



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Polymyxin B Sulfate	N	S	Unknown		Not Reported
Acetylsalicylic Acid	N	S	Unknown		Not Reported
Mesalamine	N	S	Unknown		Unknown
Benzydamine Hydrochloride	N	S	Unknown		Unknown
Cholecalciferol	N	S	Unknown		Not Reported
Zinc	N	S	Unknown		Not Reported
Dulcolax	N	S	Unknown		Not Reported
Simvastatin	N	S	Unknown		Not Reported
Acetaminophen	N	S	Unknown		Not Reported
Alprazolam	N	S	Oral		Not Reported
Alprazolam	N	S	Unknown		Not Reported
Glycerol	N	S	Oral		Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Dosage Form: Suspension Intraarticular	Not Reported
D-Alpha Tocopherol	N	S	Unknown		Unknown
Fluticasone	N	S	Unknown		Unknown
Hydromorphone	N	S	Unknown	Not Specified	Unknown
Sulfamethoxazole And	N	S	Unknown		Unknown
Trimethoprim Neomycin B Sulfate	N	S	Unknown		Unknown
Ertapenem	N	S	Intramuscular	Vial	Not Reported
Moviprep	N	S	Oral		Not Reported
Pseudoephedrin Hydrochloride	N	S	Unknown		Not Reported
Neomycin	N	S	Unknown		Not Reported
Macrogol 3350;Potassium Chloride;Sodium Chloride; Sodium Sulfate	N	S	Unknown		Unknown
Vitamin C	N	S	Unknown		Not Reported
Valsartan	N	S	Unknown		Not Reported
Valsartan	N	S	Intracardiac	Not Specified	Not Reported
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;	N	S	Unknown	,	Unknown



se #	Case Type	Health Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
	ulfamethoxazole\Trimethoprim eomycin Sulfate		S S					Not Reported Not Reported
	nc Chloride	N	S	Unknown				Unknown
	dalimumab	N	S	Subcutaneous	Solution Subcutaneous			Unknown
Va	alsartan	N	С	Unknown				Not Reported
In	flectra	N	С	Intravenous (not otherwise specified)				Not Reported
Ni	cotinamide	N	S	Unknown				Not Reported
So	odium Stearate	N	S	Oral				Unknown
_	hloride mbroxol Hydrochloride	N	S	Unknown				Not Reported
	ructose;Glycerol;Sodium	N	S	Oral				Unknown
Pa	antoprazole Sodium	N	S	Unknown				Not Reported
Po	olyethylene Glycol 4000	N	S	Unknown				Unknown
So	odium Sulfate uticasone Propionate	N	S	Unknown Unknown				Unknown
	otassium;Sodium Bicarbonate;	N	S	Topical	Dihydrate			Not Reported
H	ropine Sulfate\Diphenoxylate ydrochloride upirocin Calcium	N N	s s	Unknown	Dihardrata			Unknown Glenmark
So	odium Bicarbonate alcium Carbonate And Vitamin	N	S	Unknown				Unknown
	acrogol;Potassium Chloride;	N	S	Unknown Unknown				Unknown
	itric Acid;Sodium Bicarbonate	N	S	Oral				Unknown
	ifenoxin Hydrochloride	N	S	Ophthalmic	Eye Drops			Unknown
	odium Carboxymethylcellulose	N	S	Unknown	Not Specified			Unknown
	ropine Sulphate	N N	S	Oral	N . O			Not Reported
	odium Chloride tropine Sulphate	N	S					Not Reported

FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country
29-Nov-2022 17921729 EXPEDITED (15-DAY) Y OT CA-APOTEX2020AP012302 Female CAN



Preferred Term	Product	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular	Alprazolam		N	S	Unknown	Unk		Apotex
Degeneration	Acetaminophen		Υ	S	Unknown	Unk		Apotex
	Amoxicillin		N	S	Unknown	Unk		Not Reported
	Apo-Hydro		N	S	Endocervical	Unk		Apotex
	Apo-Hydro		N	S	Unknown	Unk		Apotex
	Atorvastatin		N	S	Unknown	Unk		Apotex
	Azithromycin		N	S	Unknown	Unk		Apotex
	Bisacodyl		N	S	Unknown	Unk		Not Reported
	Bisacodyl		N	S	Transplacental	Unk		Not Reported
	Cetirizine		N	S	Unknown	Unk		Apotex
	Cetirizine Clarithromycin		N N	S S	Unknown	Unk		Apotex Apotex
	Diphenhydramine		Υ	S	Unknown	Unk		Apotex
	Nadolol		N	S	Unknown	Unk		Not Reported
	Metronidazole		N	S	Unknown	Unk		Not Reported
	Pantoprazole		N	S	Unknown	Unk		Apotex
	Prednisone		N	S	Unknown	Unk		Not Reported
	Pregabalin		N	S	Unknown	Unk		Apotex
	Trimethoprim/Sulfamethoxazole		N	S	Unknown	Unk		Apotex
	Triamcinolone		N	S	Unknown	Unk		Apotex
	Calcium Carbonate		N	S	Intra-articular	Unk		Not Reported
	Nicotine		N	S	Transdermal	Unk		Apotex
	Nicotine		N	S	Unknown	Unk		Apotex
	Nicotine		N	S	Other	Unk		Apotex
	Loperamide		N	S	Oral	Unk, Qid		Apotex
	Loperamide		N	S	Oral	1 Dosage Form, 1 Every Hours	6	Apotex
	Loperamide		N	S	Oral	1 Dosage Form, Cyclical		Apotex



				opo		
Loperamide	N	S	Oral	4 Dosage Form, Qd		Apotex
Loperamide	N	S	Oral	Unk, Q.M.T.		Apotex
Loperamide	N	S	Oral	Unk (1 Every Four Weeks)		Apotex
Acetylsalicylic Acid	N	S	Unknown	Unk		Not Reported
Hydromorphone	N	S	Unknown	Unk		Not Reported
Potassium Chloride	N	S	Unknown	Unk		Apotex
Fluticasone	N	S	Unknown	Unk		Apotex
Hydrochlorothiazide	N	S	Unknown	100 Milligram		Apotex
Hydrochlorothiazide	N	S	Unknown	Unk		Apotex
Simvastatin	N	S	Unknown	Unk		Not Reported
Valsartan	N	S	Unknown	Unk		Apotex
Trimethoprim	N	S	Unknown	Unk		Not Reported
Avamys	N	S	Unknown	Unk (Metered Dose)		Not Reported
Betaderm [Betamethasone]	N	S	Unknown	Unk		Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk		Not Reported
Betamethasone Dipropionate	N	S	Topical	Unk		Not Reported
Biaxin XI	N	S	Unknown	Unk		Not Reported
Clotrimazole	N	S	Unknown	Unk		Not Reported
Desonide	N	S	Unknown	Unk		Not Reported
Dilaudid	N	S	Unknown	Unk		Not Reported
Entocort	N	S	Oral	Unk		Not Reported
Entocort	N	S	Unknown	Unk		Not Reported
Ertapenem Sodium	N	S	Unknown	Unk		Not Reported
Flovent	N	S	Unknown	Unk		Not Reported
Glycerine	N	S	Oral	Unk		Not Reported
Humira	N	S	Subcutaneous	Unk	6 YR	Not Reported
Humira	N	S	Unknown	Unk		Not Reported
Kenalog /00031902/	N	S	Intra-articular	Unk		Not Reported
Lomotil [Loperamide Hydrochloride]	N	S	Oral	Unk, Qid		Not Reported



Ms Ir	N	S	Unknown	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Mupirocin	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Transdermal	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S		Unk	Not Reported
Pulmicort	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Refresh Tears	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Nasal	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Sinus Rinse	N	S	Nasal	Unk	Not Reported
Sinus Rinse	N	S	Other	Unk	Not Reported
Calcium Carbonate; Colecalciferol;Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D3	N	S	Unknown	Unk	Not Reported
Habitrol [Nicotine]	N	S	Unknown	Unk	Not Reported
Bactroban [Mupirocin]	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Nasal	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intraocular	Unk	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	4 Dosage Form, Qd	Not Reported



				•	
Atropine Sulfate;Diphenoxylate	N	S	Oral	Unk Unk, Qid	Not Reported
Hydrochloride Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
DI-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Nasal	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Other	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Bactrim	N	S	Unknown	Unk	Not Reported
Alka-Seltzer	N	S	Unknown	Unk	Not Reported
Cholecalciferol	N	S	Unknown	Unk	Not Reported
Pms Azithromycin	N	S	Unknown	Unk	Not Reported
Triamcinolone	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Glycerol	N	S	Oral	Unk	Not Reported
Glycerol	N	S	Unknown	Unk	Not Reported
Vitamin-E [Tocopheryl Acetate]	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Oral	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Multivitamines And Minerals	N	S	Unknown	Unk	Not Reported
Niquitin Mint	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol;Potassium Chloride;Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported



Vitamin D3	N	S	Unknown	Unk	Not Reported
Adalimumab	Ν	S	Subcutaneous	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Macrogol;Potassium Chloride; Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Macrogol	N	S	Urethral	Unk	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Neomycin Sulfate	N	S	Unknown	Unk	Not Reported
Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Vitamin E [Vitamin E Nos]	N	S	Unknown	Unk	Not Reported
Isoniazid;Pyridoxine Hydrochloride; Sulfamethoxazole;Trimethoprim	N	S	Unknown	Unk	Not Reported
Mezavant	N	S	Unknown	Unk (Delayed And Extended Release Tablet)	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Glycerinum	N	S	Unknown	Unk (Glob, 1xc1000)	Not Reported
Gramicidin;Polymyxin B	N	S	Unknown	,	Not Reported
Vitamins Nos	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
Acetaminophen; Pseudoephedrine	N	S	Unknown	Unk	Not Reported
Dulcolax [Bisacodyl]	N	S	Unknown	Unk	Not Reported
Mesalamine	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
Budesonide	N	S		Unk	Not Reported
Benzydamine	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium Anhydrous	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Cutaneous	Unk	Not Reported
Prednisone	N	S	Subcutaneous	Unk	Not Reported
Betamethasone;Mupirocin	N	S	Topical	Unk	Not Reported



				•	
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Fructose;Glycerol;Sodium Chloride	N	S	Oral	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Unk	Not Reported
Vitamin E Natural [Tocopheryl Acetate]	N	S	Unknown	Unk	Not Reported
Acetaminophen; Dextropropoxyphene	N	S	Unknown	Unk	Not Reported
Vitamin D Nos	N	S	Unknown	Unk	Not Reported
Atropine	N	S	Oral	Unk	Not Reported
Betamethasone Sodium Phosphate	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Bromhexine;Clorprenaline; Sulfamethoxazole;Trimethoprim	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Imodium	N	S	Unknown	Unk	Not Reported
Mupirocin Calcium	N	S	Unknown	Unk	Not Reported
Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Glyceryl Trinitrate	N	S	Oral	Unk	Not Reported
Nicomorphine	N	S	Unknown	Unk	Not Reported
Pseudoephedrine	N	S	Unknown	Unk	Not Reported
Vitamin D [Colecalciferol]	N	S	Unknown	Unk	Not Reported
Calcium Carbonate;Calcium Gluconate;Vitamin D Nos	N	S	Unknown	Unk	Not Reported
Ambroxol;Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Calcium Carbonate; Ergocalciferol	N	S	Unknown	Unk	Not Reported
Atropine Sulfate	N	S	Oral	Unk	Not Reported
Glycerol;Sodium Stearate	N	S	Oral	Unk	Not Reported
Gramicidin;Neomycin	N	S	Unknown	Unk	Not Reported
Valsartan	N	S	Intracardiac	Unk	Not Reported



		Calcium Carbonate; Colecalciferol			N	С	Unknown	Unk			ı	Not Reported
		Valsarta			N	С	Unknown	Unk			ı	Not Reported
		Valsartan			Ν	С	Vaginal	Unk			1	Not Reported
			n Carbonate W/Vitamin D m Carbonate;		N	С	Unknown	Unk			ı	Not Reported
			nlorothiazide		Ν	С	Unknown	Unk			ı	Not Reported
		Calcium D	Carbonate And Vitamin		N	С	Unknown	Unk			ı	Not Reported
		Vitamin	D3		Ν	С	Unknown	Unk			ı	Not Reported
		Sulfame	ethoxazole\Trimethoprim			S					ľ	Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contr	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Nov-2022	197086	23	EXPEDITED (15-DAY)	Y		ОТ	CA-AstraZe 2021A6745				Female	CAN
Preferred Term		Produc	<u>t</u>	Comp.	OTO	Role	Route	<u>Dosag</u>	e Text	Duration	<u>N</u>	<u>lfr</u>
Drug Ineffective; Macu	ılar	Budeso	nide		N	S	Unknown				,	Astrazeneca
Degeneration		Acetam	inophen		Ν	S	Unknown				1	Not Reported
		Adalimu	ımab		Ν	S	Subcutaneous				ı	Not Reported
		Alprazo	lam		Ν	S	Unknown				ı	Not Reported
		Amoxici	illin Trihydrate		Ν	S	Unknown				ı	Not Reported
		Atorvas	tatin Calcium		Ν	S	Unknown				ı	Not Reported
		Avamys	3		Ν	S	Ophthalmic				ı	Not Reported
		Benzyda	amine Hydrochloride		Ν	S	Unknown				1	Not Reported
		Betame	thasone Dipropionate		Ν	S	Unknown				1	Not Reported
		Betame	thasone Valerate		Ν	S	Unknown				ı	Not Reported
		Cetirizin	ne Hydrochloride		Ν	S	Unknown				ı	Not Reported
		Clarithro	omycin		Ν	S	Unknown				ı	Not Reported
Clotrimazole		azole		N	S	Unknown				ı	Not Reported	
		Desonic	de		N	S	Unknown				ı	Not Reported
		Diphenh	nydramine		N	S	Unknown				1	Not Reported



	Dulcola	ax		N	S	Unknown			N	ot Reported
	Ergoca	alciferol		Ν	S	Unknown			N	ot Reported
	Ertape	nem Sodium		N	S	Unknown			N	ot Reported
	Floven	t		N	S	Unknown			N	ot Reported
	Glycer	ine		Ν	S	Oral			N	ot Reported
	Humira	a		Ν	S	Subcutaneous			N	ot Reported
	Hydrod	chlorothiazide		Ν	S	Unknown			N	ot Reported
		gol Potassium/Sodium de/Sodium Bicarbonate		N	S	Unknown			N	ot Reported
	Mesala	azine		Ν	S	Unknown			N	ot Reported
	Metron	nidazole		N	S	Unknown			N	ot Reported
	Morphi	ine Sulfate		N	S	Unknown			N	ot Reported
	Mupiro	ocin		N	S	Unknown			N	ot Reported
	Nadolo	ol		N	S	Intra-articular			N	ot Reported
	Nicode	erm		Ν	S	Unknown			N	ot Reported
	Nicotin	ne Polacrilex		Ν	S	Unknown			N	ot Reported
	Pms-A	zithromycin		Ν	S	Unknown			N	ot Reported
	Predni	sone		Ν	S	Subcutaneous			N	ot Reported
	Pregab	oalin		N	S	Topical			N	ot Reported
	Refres	h Tears		N	S	Ophthalmic			N	ot Reported
	Triamo	cinolone Acetonide		N	S	Intra-articular			N	ot Reported
	Valsari	tan		N	S	Unknown			N	ot Reported
	Valsari	tan		N	С	Unknown			N	ot Reported
	Sulfam	nethoxazole\Trimethoprim			S				N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Dec-2022	21675228	EXPEDITED (15-DAY)	Υ		HO, OT	CA-AstraZeneo 2022A204396	ca-	71 YR	Female	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	OTO	Role	Route	Dosage Text	Duration	Mf	<u>fr</u>
Chronic Sinusitis; Drug	Budes	onide		N	S	Nasal			N	ot Reported



Neomycin

Sulfate/Gramicidin/Polymyxin B

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Not Reported

Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported

Not Reported
Not Reported
Not Reported
Not Reported
Not Reported
Not Reported
Not Reported
Not Reported
Not Reported
Not Reported
Not Reported
Not Reported
Not Reported
Not Reported
Not Reported
Not Reported
Not Reported
Not Reported

Not Reported

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Ineffective; Dyspepsia; Infusion Related Reaction; Macular Degeneration; Malaise; Nausea; Off Label Use; Pain; Paraesthesia Oral; Procedural Pain; Pyrexia; Therapeutic Product Effect Incomplete; Weight Decreased

			•
Nicoderm	N	S	Unknown
Nicotine	N	S	Unknown
Nicotine	N	S	Unknown
Paracetamol	N	S	Unknown
Cetirizine Hydrochloride	N	S	Unknown
Diphenhydramine Hydrochloride	N	S	Unknown
Infliximab, Recombinant	N	S	Intravenous (not otherwise specified)
Zinc Oxide	N	S	Unknown
Imodium	N	S	Unknown
Adalimumab	N	S	Subcutaneous
Amoxicillin Trihydrate	N	S	Unknown
Atorvastatin Calcium	N	S	Unknown
Alprazolam	N	S	Unknown
Diphenoxylate Hydrochloride/Atropine Sulfate	N	S	Oral
Azithromycin	N	S	Unknown
Betamethasone	N	S	Unknown
Betamethasone Valerate	Ν	S	Unknown
Bisacodyl	N	S	Unknown
Calcium Carbonate	N	S	Unknown
Clarithromycin	N	S	Unknown
Clotrimazole	N	S	Unknown
Cupric Oxide	N	S	Unknown
Desonide	N	S	Unknown
Ertapenem Sodium	N	S	Unknown
Fluticasone Furoate	N	S	Unknown
Fluticasone Propionate	N	S	Unknown
Glycerol	N	S	Oral
A.1		_	

Date - Time: 11-Apr-2023 10:56:54 AM EST Note: If the field is blank, there is no data.

S

Unknown

Ν



Sulfate Hydromorphone Hydrochloride	N	S	Endocervical	Not Reported
Macrogol	N	S	Unknown	Not Reported
Magnesium Sulfate	N	S	Unknown	Not Reported
Mesalazine	N	S	Unknown	Not Reported
Metronidazole	N	S	Unknown	Not Reported
Vitamin E Mixed Tocopherols	N	S	Unknown	Not Reported
Morphine Sulfate	N	S	Unknown	Not Reported
Mupirocin	N	S	Unknown	Not Reported
Nadolol	N	S	Unknown	Not Reported
Pantoprazole	N	S	Unknown	Not Reported
Potassium Chloride	N	S	Unknown	Not Reported
Prednisone	N	S	Unknown	Not Reported
Pregabalin	Ν	S	Unknown	Not Reported
Sodium Bicarbonate	Ν	S	Unknown	Not Reported
Sodium Carboxymethyl Cellulose	Ν	S	Unknown	Not Reported
Sodium Chloride	N	S	Unknown	Not Reported
Sulfamethoxazole/Trimethoprim	N	S	Unknown	Not Reported
Triamcinolone	N	S	Intra-articular	Not Reported
Vitamin D3	N	S	Unknown	Not Reported
Xantofyl Palmitate	N	S	Unknown	Not Reported
Zeaxanthin	N	S	Unknown	Not Reported
Calcium & Vitamin D3	N	S	Unknown	Not Reported
Acetaminophen	Ν	S	Unknown	Not Reported
Loperamide	Ν	S	Unknown	Not Reported
Nicotine Polacrilex	N	S	Unknown	Not Reported
Calcium Citrate	N	S		Not Reported
Sodium Sulfate/Macrogol 3350/Sodium Chloride/Sodium	N	S		Not Reported
Bicarbonate/Potassium Chloride		_		
Hydrochlorothiazide	N	S		Not Reported



Date - Time: 11-Apr-2023 10:56:54 AM EST

Preferred Term	Prod	luct	Comp.	отс	Role Role	Route		<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>M</u>	<u>lfr</u>
05-Dec-2022	21172982	EXPEDITED (15-DAY)	Υ		HO, OT		A-SSP-)22SA30212	5AA		71 YR	Female	CAN
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	N	fr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
	Calci	ium		N	С	Unknow	n				١	Not Reported
	Calci	um & Ergocalciferol		Ν	С							Not Reported
		calciferol/Calcium onate		N	С						N	Not Reported
	Valsa			N	С	Unknow	n					Not Reported
		•										
		ocnioridej clopramide Hydrochloride		N	С	Unknow	n				N	Not Reported
		adryl [Diphenhydramine ochloride]		N	С	Unknow	n				N	Not Reported
		tinamide		N	S							Not Reported
		ramide Hydrochloride		Ν	S							Not Reported
		ethoprim		Ν	S							Not Reported
		ncinolone		N	S							Not Reported
		s Rinse		N	S							Not Reported
		rastatin		N	S							Not Reported
		niciain nesium Oxide		N N	S S							Not Reported Not Reported
	Glyce	erine nicidin		N	S							Not Reported
		onate/Zinc		N.	0							let Demented
		triol/Calcium		Ν	S						N	Not Reported
		ochloride										
		ochloride/Cetirizine										•
	Amb			Ν	S						N	Not Reported
	hene			. •	Ü						'	ioi rioportoa
		aminophen/Dextropropoxyp		N	S							Not Reported
	Lomo			N	S							Not Reported
		ncinolone Acetonide		N	S							Not Reported
	Ento Pulm			N N	S S							Not Reported Not Reported
	Biaxi			N	S							Not Reported
		oha Tocopherol		N	S							Not Reported
	/Trim	ethoprim										
		ochloride/Sulfamethoxazole			-						·	
		azid/Pyridoxine		N	S							Not Reported
	Natu	ral Vitamin E		Ν	S						N	Not Reported



Chronic Sinusitis; Drug Ineffective; Dyspepsia; Infusion Related Reaction; Macular Degeneration; Malaise; Nausea; Off Label Use; Pain; Paraesthesia Oral; Procedural Pain; Pyrexia; Therapeutic Product Effect Incomplete; Weight Decreased

			Dotalioa Ito	od Nopoli			
Ergocalciferol	N	S	Unknown	Unk			
Alprazolam	N	S	Unknown	0.25 Mg			
Atorvastatin	N	S	Unknown	Unk			
Atropine Sulfate	N	S	Oral	Unk			
Atropine Sulfate	N	S	Oral	4 Df			
Atropine Sulfate	N	S	Oral	1 Df			
Atropine Sulfate	N	S	Unknown	Unk			
Fluticasone Furoate	N	S	Unknown	Metered Dose			
Betamethasone Dipropionate	N	S	Unknown	Unk			
Betamethasone Valerate	N	S	Unknown	Unk			
Bisacodyl	N	S	Unknown	Unk			
Budesonide	N	S	Oral	Unk			
Budesonide	N	S	Respiratory (inhalation)	Unk			
Budesonide	N	S	Unknown	Unk			
Cetirizine Hydrochloride	N	S	Unknown	Unk			
Clarithromycin	N	S	Unknown	Unk			
Clotrimazole	N	S	Unknown	Unk			
Desonide	N	S	Unknown	Unk			
Diphenhydramine Hydrochloride	N	S	Oral	50 Mg			
Glycerine	N	S	Oral	Unk			
Hydrochlorothiazide	N	S	Endocervical	Unk			
Hydromorphone Hydrochloride	N	S	Unknown	Unk			
Mesalazine	N	S	Unknown	Unk			
Metronidazole	N	S	Unknown	Unk			
Morphine Sulfate	N	S	Unknown	Unk			
Mupirocin	N	S	Unknown	Unk			
Mupirocin	N	S	Topical	Unk			
		_					

Ν

S

Unknown

40 Mg

Nadolol

Not Reported

Sanofi

Not Reported

Not Reported

Not Reported

Not Reported

Not Reported

Not Reported

Not Reported Not Reported Not Reported Sanofi Not Reported Not Reported

Not Reported
Not Reported
Not Reported
Not Reported
Not Reported
Sanofi
Not Reported
Not Reported
Not Reported
Sanofi
Sanofi
Sanofi
Not Reported
Sanofi
Not Reported
Not Reported
Not Reported
Not Reported
Not Reported



				•	
Nicoderm	N	S	Unknown	Unk	Sanofi
Nicotine	N	S	Unknown	Unk	Sanofi
Pantoprazole	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Unknown	150 Mg	Not Reported
Carmellose Sodium	N	S	Ophthalmic	Unk	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole	N	S	Oral	200 Mg, Qd	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Sanofi
Triamcinolone Acetonide	N	S	Unknown	Unk	Sanofi
Triamcinolone Acetonide	N	S	Unknown	Unk	Sanofi
Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Sanofi
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Intramuscular	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Benzydamine Hydrochloride	N	S	Unknown	Unk	Not Reported
Macrogol	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk	Not Reported
Glyceryl Trinitrate	N	S	Unknown	Unk	Sanofi



Glycerol	N	S	Oral	Unk	Not Reported
Trimethoprim	N	S	Oral	1 Df	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole/Trimethoprim	N	S	Unknown	Unk	Not Reported
Paracetamol	N	S	Unknown	Unk	Not Reported
Azithromycin Dihydrate	N	S	Unknown	Unk	Not Reported
Calcitriol	N	S	Intra-articular	Unk	Not Reported
Acetaminophen	N	S	Unknown	Unk	Not Reported
Acetaminophen	N	S	Unknown	Unk	Not Reported
Adalimumab	N	S	Subcutaneous	Unk	Not Reported
Adalimumab	N	S			Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Ertapenem Sodium	N	S	Respiratory (inhalation)	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Oral	Unk	Not Reported
Zinc Chloride	N	S	Unknown	Unk	Not Reported
Salinex [Sodium Chloride]	N	S	Nasal	Unk	Not Reported
Sinus Rinse	N	S	Nasal	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Mentha Arvensis	N	S	Unknown	Unk	Not Reported
Nicomorphine	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Imodium	N	S	Unknown	Unk	Not Reported
Habitrol [Nicotine Polacrilex]	N	S	Unknown	Unk	Not Reported
Infliximab	N	S	Intravenous (not otherwise specified)	Unk	Not Reported



Fluticasone Propionate	N	S	Unknown	Unk		Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk		Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk		Not Reported
Cupric Oxide	N	S	Unknown	Unk		Not Reported
Entocort	N	S	Unknown	Unk		Not Reported
Humira	N	S	Unknown	Unk		Not Reported
Humira	N	S	Subcutaneous	Unk	6 YR	Not Reported
Humira	N	S	Subcutaneous	Unk	6 YR	Not Reported
Flovent	N	S	Unknown	Unk		Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown	Unk		Not Reported
Cupric Oxide;Folic Acid;Nicotinic Acid;Zinc	N	S	Unknown	Unk		Not Reported
Glycerol;Sodium Stearate	N	S	Unknown	Unk		Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown	Unk		Not Reported
Gramicidin;Polymyxin B	N	S	Unknown	Unk		Not Reported
Isoniazid/Pyridoxine Hydrochloride/Sulfamethoxazole /Trimethoprim	N	S	Unknown	Unk		Not Reported
Pantoprazole Sodium Anhydrous	N	S	Unknown	Unk		Not Reported
Pantoprazole Sodium	N	S	Unknown	Unk		Not Reported
Valsartan	N	С		Unk		Not Reported
Amoxicillin	N	С		Unk		Not Reported
Amoxicillin Trihydrate	N	С		Unk		Not Reported
Neomycin Sulfate	N	С		Unk		Not Reported
Sodium Stearate	N	С		Unk		Not Reported
Calcium Carbonate And Vitamin D3	N	С		Unk		Not Reported
Diphenhydramine Hydrochloride	N	С		Unk		Not Reported
Mupirocin Calcium	N	С		Unk		Not Reported
Acetylsalicylic Acid	N	S		Unk		Not Reported
Calcium Citrate	N	S		Unk		Not Reported



		Diphenhydramine		N	S		Unk				Sanofi
		Lomotil [Loperamide		N	S	Oral	Unk				Not Reported
		Hydrochloride] Tocopherol		N	S		Unk				Not Reported
		Vitamin E Nos		N	S		Unk				Not Reported
		Potassium Chloride		N	S		Unk				Not Reported
		Pulmicort		N	S	Respiratory (inhalation)	Unk				Not Reported
		Sodium Bicarbonate		N	S	,	Unk				Not Reported
		Metoclopramide Hydrochloride		N	С	Oral	Unk				Not Reported
FDA Received Date	Case #	Case Type	Health	Prof (<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Dec-2022	216901	82 EXPEDITED (15-DAY)	N	(TC	US-ALLER 2239648U				Male	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	Duration		<u>Mfr</u>
Cataract		Refresh Optive Mega-3		Υ	S		Unk				Allergan
FDA Received Date	Case #	Case Type	Health	Prof (Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Dec-2022	207106	71 EXPEDITED (15-DAY)	Υ	(TC	CA-JNJFO 202204193				Female	CAN
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>		<u>Mfr</u>
Drug Ineffective; Macu	ular	Imodium		N	S	Unknown					Not Reported
Degeneration		Cetirizine Hydrochloride		N	S	Unknown					Not Reported
		Diphenhydramine Hydrochloride		Υ	S	Unknown					Not Reported
		Nicoderm Unspecified		N	S	Transdermal					Not Reported
		Acetaminophen		N	S	Unknown					Not Reported
		Alprazolam		N	S	Unknown					Not Reported
		Amoxicillin Trihydrate		N	S	Unknown					Not Reported
		7 tilloxionini Tilliyarato									
		Hydrochlorothiazide		N	S	Unknown					Not Reported



			<u>.</u>	
Diphenoxylate Hydrochloride And Atropine Sulfate	N	S	Unknown	Not Reported
Arid Atropine Suifate Azithromycin Dihydrate	N	S	Unknown	Not Reported
Betamethasone	N	S	Unknown	Not Reported
Daivobet [Betamethasone Dipropionate;Calcipotriol]	N	S	Unknown	Not Reported
Bisacodyl	N	S	Unknown	Not Reported
Budesonide	N	S	Unknown	Not Reported
Calcium Carbonate/Vitamin D3	N	S	Unknown	Not Reported
Clarithromycin	N	S	Unknown	Not Reported
Clotrimazole	N	S	Unknown	Not Reported
Cupric Oxide	N	S	Unknown	Not Reported
Desonide	N	S	Unknown	Not Reported
Dilaudid	N	S	Unknown	Not Reported
Entocort	N	S	Unknown	Not Reported
Ertapenem Sodium	N	S	Unknown	Not Reported
Flovent	N	S	Unknown	Not Reported
Fluticasone Furoate	N	S	Unknown	Not Reported
Glycerol	N	S	Unknown	Not Reported
Humira	N	S	Subcutaneous	Not Reported
Magnesium Oxide	N	S	Unknown	Not Reported
Magnesium Sulfate	N	S	Unknown	Not Reported
Morphine Sulfate	N	S	Unknown	Not Reported
Mupirocin	N	S	Topical	Not Reported
Nadolol	N	S	Unknown	Not Reported
Nicotine Polacrilex	N	S	Unknown	Not Reported
Pantoprazole	N	S	Unknown	Not Reported
Pentasa	N	S	Unknown	Not Reported
Prednisone	N	S	Unknown	Not Reported
Pregabalin	N	S	Unknown	Not Reported



	Re	fresh Tears Plus		N	S	Ophthalmic			N	lot Reported
		nus Rinse dium Chloride		N N	S S	Unknown				lot Reported lot Reported
	Or	iprim		Ν	S	Unknown			N	lot Reported
	Tri	amcinolone Acetonide		Ν	S	Intra-articular			N	lot Reported
	Vit	amin D3		Ν	S	Unknown			N	lot Reported
	Xa	ntofyl Palmitate		Ν	S	Unknown			N	lot Reported
	Ze	axanthin		Ν	S	Unknown			N	lot Reported
	Zir	nc Oxide		Ν	S	Unknown			N	lot Reported
	Me	etronidazole		Ν	S	Unknown			N	lot Reported
	Va	Isartan		N	С	Unknown			N	lot Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Dec-2022	21698534	EXPEDITED (15-DAY)	Y		ОТ	FR-JNJFOC- 20221216183		44 YR	Male	FRA
Preferred Term	Pr	oduct	Comp.	OTC	Role	Route	Dosage Text	Duration	<u>M</u>	<u>fr</u>
Leukopenia; Neutrope	nia Tra	amadol Hydrochloride		Ν	S	Oral	Unk		Ν	lot Reported
	Ce	lluvisc [Carmellose Sodium]		Ν	S		1 Drop, 4/Day		N	lot Reported
	Pa	racetamol		N	S	Oral	1 Dosage Form, 4/Day		N	lot Reported
	La	roxyl		N	S	Oral	5 Drop, 5/Day		N	lot Reported
	Ga	bapentine		N	S	Oral	1200 Milligram, 1/Day		N	lot Reported
	Су	anocobalamin		Ν	S		1 Drop, 4/Day		N	lot Reported
	Dι	loxetine		Ν	S	Unknown	60 Milligram, 1/Day		N	lot Reported
	Lo	venox [Enoxaparin Sodium]		Ν	S	Subcutaneous	Unk		N	lot Reported
	Le	vothyrox		N	S	Oral	1 Dosage Form, 1/Day		N	lot Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Dec-2022	21309147	EXPEDITED (15-DAY)	Υ		но, от	CA- GLAXOSMITHI CACH2022AMF			Unknown	CAN
Preferred Term	Dr	oduct	Comp.	OTC	Role	Route	Dosage Text	Duration	M	e

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Note: If the field is blank, there is no data.



Azithromycin Dihydrate

Clotrimazole

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) **Detailed Report**

Abdominal Pain; Anaemia; Chronic Sinusitis; Colitis; Colitis Ulcerative; Constipation; Drug Ineffective; Dyspepsia; Erythema; Female Genital Tract Fistula; Frequent Bowel Movements; Haematochezia; Headache; Infusion Related Reaction; Macular Degeneration; Malaise; Nausea; Off Label Use; Oral Candidiasis; Pain; Paraesthesia Oral; Procedural Pain; Proctitis; Pyrexia; Radiculopathy; Rectal Haemorrhage; Therapeutic Product Effect Incomplete; Vaginal Discharge; Vaginal
•
200100000

· KATTON	Detailed Report							
Calcium Carbonate, Cholecalciferol	N	S		Unk				
Habitrol	N	S		Unk				
Nicotine	N	S		Unk				
Nicoderm	N	S		Unk				
Nicotine Polacrilex	N	S		Unk				
Pantoprazole	N	S		Unk				
Diphenhydramine	N	S		Unk				
Multivitamins	N	S		Unk				
Zinc Oxide	Υ	S		Unk				
Acetaminophen + Pseudoephedrine	N	S		Unk				
Sodium Chloride	N	S		Unk				
Magnesium Sulfate	N	S		Unk				
D-Alpha Tocopherol	N	S		Unk				
Niquitin 4 Mg Mint Lozenge	N	S		Unk				
Magnesium Oxide Magnesium Sulfate Inj	N N	S S		Unk				
Vitamin E	N	S		Unk				
Nicotinamide Magnesium Hydroxide Acetaminophen	N N Y	S S S		Unk				
Bactroban (Mupirocin)	N	S		Unk				
Fluticasone Propionate	N	S		Unk				
Magnesium (Magnesium Salt)	N	S		Unk				
Empracet Cetirizine Hydrochloride	N N	S S	Unknown	Unk				
Cetirizine Hydrochloride	N	S	Unknown	Unk				
Cetirizine Hydrochloride	N	S	Unknown	Unk				
Cetirizine Hydrochloride	N	S	Unknown	Unk				

S

S

Unk

Ν

Ν

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Glaxosmithkline

Glaxosmithkline

Glaxosmithkline Glaxosmithkline

Not Reported Not Reported

Glaxosmithkline

Glaxosmithkline

Not Reported

Not Reported Not Reported

Glaxosmithkline

Glaxosmithkline Not Reported

Not Reported Glaxosmithkline

Not Reported

Not Reported Glaxosmithkline

Not Reported Glaxosmithkline

Not Reported



Metronidazole	N	S		Unk	Not Reported
Alprazolam Tablet	N	S		0.25 Mg	Not Reported
Biaxin XI Clarithromycin	N N	S S		Unk	Not Reported Not Reported
Desonide	N	S		Unk	Not Reported
Ertapenem Sodium	N	S		Unk	Not Reported
Glycerine Humira	N N	S S		Unk	Not Reported Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Prednisone	N	S		Unk	Not Reported
Pregabalin Capsule	N	S		150 Mg	Not Reported
Refresh Tears	N	S		Unk	Not Reported
Sinus Rinse	N	S		Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Budesonide Mesalazine	N N	S S		Unk	Not Reported Not Reported
Morphine Sulfate	N	S		Unk	Not Reported
Sulfamethoxazole + Tmp	N	S		200 Mg	Not Reported
Kenalog (Triamcinolone Acetonide)	N	S		Unk	Not Reported
Loperamide Hydrochloride	N	S		Unk	Not Reported
Zeaxanthin Xantofyl Palmitate	N N	S S			Not Reported Not Reported



Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S		Unk	Not Reported
Cupric Oxide + Folic Acid + Nicotinamide + Zinc	N	S		Unk	Not Reported
Amoxicillin Trihydrate	N	S		Unk	Not Reported
Glyceryl Trinitrate	N	S		Unk	Not Reported
Calcium Carbonate + Colecalciferol + Zinc Oxide	N	S			Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Subcutaneous	Unk	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Dulcolax (Bisacodyl)	N	S		Unk	Not Reported
Gramicidin/Neomycin Sulfate/Polymyxin B Sulfate	N	S		Unk	Not Reported
Vitamin D3	N	S		Unk	Not Reported
Magnesium Carbonate	N	S		Unk	Not Reported
Diphenhydramine Hydrochloride	N	S		Unk	Not Reported
Dextropropoxyphene + Acetaminophen	N	S		Unk	Not Reported
Benzydamine	N	S			Not Reported
Atropine Sulphate + Diphenoxylate Hydrochloride	N	S		Unk	Not Reported
Magnesium Sulfate	N	S		Unk	Not Reported
Statex (Morphine Sulfate)	N	S	Unknown	Unk	Not Reported
Isoniazid + Pyridoxine Hydrochloride + Sulfamethoxazole + Trimethoprim	N	S		Unk	Not Reported
Alka-Seltzer (Acetylsalicylic Acid + Citric Acid + Sodium Bicarbonate)	N	S		Unk	Not Reported
Potassium Chloride	N	S		Unk	Not Reported
Ubidecarenone	N	S		Unk	Not Reported



			-	
Glycerol Macrogol 3350 + Potassium	N N	S S	Hal	Not Reported Not Reported
Chloride + Sodium Bicarbonate + Sodium Chlor	IN	3	Unk	not reported
Sodium Carboxymethyl Cellulose	N	S	Unk	Not Reported
Acetylsalicylic Acid	N	S	Unk	Not Reported
Calcitriol + Calcium Carbonate + Zinc	N	S	Unk	Not Reported
Acetic Acid + Triamcinolone Acetonide	N 	S	Unk	Not Reported
Fluconazole	N	S	Unk	Not Reported
Methylprednisolone Sodium Succinate	N 	S	Unk	Not Reported
Midazolam	N	S	Unk	Not Reported
Bifidobacterium Infantis	N	S	Unk	Not Reported
Hydrocortisone	N	S	Unk	Not Reported
Zopiclone	N	S	Unk	Not Reported
Sucralfate	N	S	Unk	Not Reported
Oxybutynin Hydrochloride	N	S	Unk	Not Reported
Fentanyl Citrate	N	S	Unk	Not Reported
Ciprofloxacin Hydrochloride	N	S	Unk	Not Reported
Vedolizumab	N	S		Not Reported
Fructose Solu Medrol	N N	S S	Unk	Not Reported Not Reported
Align	N	S	-	Not Reported
Ciprofloxacin	N	S	Unk	Not Reported
Oxybutynin Hydrochloride	N	S	Unk	Not Reported
Cortenema	N	S	Unk	Not Reported
Framycetin Sulfate	N	S	Unk	Not Reported
Pyridoxine	N	S	Unk	Not Reported
Simvastatin	N	S	Unk	Not Reported
Benzydamine Hydrochloride	N	S	Unk	Not Reported



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FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Dec-2022	217084	55 NON-EXPEDITED	N			US-UNITED THERAPEUTIO 2022-025556	CS-UNT-		Female	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	,	<u>Mfr</u>
Dermatitis Contact; De	evice	Remodulin Sq		N	S	Subcutaneous	Unk, Continuing			Not Reported
Allergy		Remodulin Sq		N	S	Subcutaneous	0.150 Mg/Kg, Continuing			Not Reported
		Remodulin Sq		N	S	Subcutaneous	Unk, Continuing			Not Reported
		Carboxymethylcellulose Sodium\Gelatin\Pectin		N	S	Unknown	Unk			Not Reported
		Eliquis		N	С	Unknown	Unk			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof C	<u>outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Dec-2022	2172223	34 EXPEDITED (15-DAY) Y	C	T	FR-MYLANLAI 2022M113734		44 YR	Male	FRA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Leukopenia; Neutrope	nia	Duloxetine		N	S	Unknown	60 Milligram, Qd (60 Mg/Day)			Not Reported
		Tramadol		N	S	Oral	Unk			Not Reported
		Gabapentin		N	S	Oral	1200 Milligram, Qd (1200 Mg/Day)			Not Reported
		Celluvisc		N	S		1 Drop 2 To 4 Times A Day			Not Reported
		Dafalgan		N	S	Oral	1 Dosage Form, Qid (1 Tablets 4 Times A Day)			Not Reported
		Laroxyl		N	S	Oral	5 Drops 5 Times A Day			Not Reported
		Vitamine B12 Chauvin		N	S		1 Drop 3 To 4 Times A Day			Not Reported
		Lovenox		N	S	Subcutaneous	Unk			Not Reported
		Levothyrox		N	S	Oral	1 Dosage Form, Qd (1 Tablet Daily)			Not Reported

Note: If the field is blank, there is no data.



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FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control a	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Dec-2022	217249	26 EXPEDITED (15-DAY)	Υ	ОТ		FR-SA-2022SA504550		44 YR	Male	FRA
Preferred Term		<u>Product</u>	Comp.	OTO	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Leukopenia; Neutrope	enia	Paracetamol		N	S	Oral	Unk, 1 Tablet 4 Times A Day			Not Reported
		Amitriptyline Hydrochloride		N	S	Oral	Unk, 5 Drops 5 Times A Day			Not Reported
		Gabapentin		Ν	S	Oral	1200 Mg, Qd			Not Reported
		Duloxetine Hydrochloride		N	S		60 Mg, Qd			Not Reported
		Lovenox		Ν	S	Subcutaneous	Unk			Sanofi
		Levothyroxine Sodium		Ν	S	Oral	Unk, Qd			Not Reported
		Tramadol Hydrochloride		Ν	S	Oral	Unk			Not Reported
		Vitamine B12 Chauvin		N	S	Intraocular	Unk, 1 Drop 3 To 4 Times A Day			Not Reported
		Celluvisc [Carmellose Sodium]		N	S	Intraocular	Unk, 1 Drop 2 To 4 Times A Day			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Dec-2022	217437	55 EXPEDITED (15-DAY)	Υ		ОТ	FR-AUROBINE APL-2022-0529		44 YR	Male	FRA
Preferred Term		Product	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		Mfr
_eukopenia; Neutropenia		Duloxetine		N	S	Unknown	60 Milligram, Once A Day (60 Mg/Day)			Aurobindo
		Gabapentin		N	S	Oral	1200 Milligram, Once A Day (1200mg/Day)			Aurobindo
		Tramadol		Ν	S	Oral	Unk			Aurobindo
		Celluvisc		N	S		1 Drop 2 To 4 Times A Day			Not Reported
		Dafalgan		N	S	Oral	1 Dosage Form, Four Times/Day (1 Tablet 4 Times A Day)			Not Reported

Note: If the field is blank, there is no data.



		Laroxyl			Ν	S	Oral	5 Drops 5 Times A Day			Not Reported
		Lovenox	(Ν	S	Subcutaneous	Unk			Not Reported
		Levothy	rox		N	S	Oral	1 Dosage Form, Once A Day (1 Tablet/Day)			Not Reported
		Vitamine	e B12 Chauvin		N	S		1 Drop 3 To 4 Times A Day			Not Reported
FDA Received Date	Case #	<u>#</u>	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Dec-2022	20487	629	EXPEDITED (15-DAY)	Υ		HO, OT	CA-ABBVIE-22 4281888-00	2K-028-	71 YR	Female	e CAN
Preferred Term		Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Chronic Sinusitis; Drug		Humira			N	S	Subcutaneous				Abbvie
Ineffective; Dyspepsia; Infusion Related Reac Macular Degeneration	tion;	Pulmico	rt		N	S	Respiratory (inhalation)				Not Reported
Malaise; Nausea; Off Label Use; Pain;	,	Inflixima	b		N	S	Intravenous (not otherwise specified)			Not Reported
Paraesthesia Oral; Procedural Pain; Pyrex	via:	Mupiroc	in		Ν	S	Topical				Not Reported
Therapeutic Product E		Atorvast	atin Calcium		N	S	Unknown				Not Reported
Incomplete; Weight Decreased		Bactrim			N	S	Unknown				Not Reported
Decreased		Cetirizin	e Hydrochloride		N	S	Unknown				Not Reported
		Choleca	lciferol		N	S	Unknown				Not Reported
		Cupric C	Oxide		N	S	Unknown				Not Reported
		Dilaudid			N	S	Unknown				Not Reported
		Diphenh	ydramine Hydrochloride		N	S	Unknown				Not Reported
		Flovent			N	S	Unknown				Not Reported
		Bicarbor			N	S	Unknown				Not Reported
		-	ium Sulfate		N	S	Unknown				Not Reported
		Nadolol			N	S	Oral				Not Reported
		Pantopr			N	S	Unknown				Not Reported
		Predniso	one		N	S	Unknown				Not Reported



				•	
Pregabalin	N	S	Oral		Not Reported
Triamcinolone Acetonide	N	S	Intra-articular		Not Reported
Zeaxanthin	N	S	Unknown		Not Reported
Refresh Tears	N	S	Ophthalmic		Not Reported
D-Alpha Tocopherol	N	S	Unknown		Not Reported
Pms Azithromycin	N	S	Unknown		Not Reported
Nicotine	N	S	Unknown		Not Reported
Sodium Chloride	N	S	Unknown		Not Reported
Acetaminophen	N	S	Unknown		Not Reported
Biaxin XI	N	S	Oral		Not Reported
Calcium Carbonate	N	S	Unknown		Not Reported
Entocort	N	S	Oral		Not Reported
Amoxicillin Trihydrate	N	S	Unknown		Not Reported
Avamys	N	S	Unknown	Spray, Metered Dose	Not Reported
Benadryl	N	S	Oral		Not Reported
Bisacodyl	N	S	Unknown		Not Reported
Clarithromycin	N	S	Unknown		Not Reported
Clotrimazole	N	S	Unknown		Not Reported
Desonide	N	S	Unknown		Not Reported
Ertapenem Sodium	N	S	Unknown		Not Reported
Glycerol	N	S	Oral		Not Reported
Gramicidin;Neomycin Sulfate;	N	S	Unknown		Not Reported
Polymyxin B Sulfate Hydromorphone Hydrochloride	N	S	Endocervical		Not Reported
Metronidazole	N	S	Unknown		Not Reported
Nicoderm	N	S	Unknown		Not Reported
Pentasa	N	S	Unknown		Not Reported
Isoniazid/Pyridoxine	N	S	Unknown		Not Reported
Hydrochloride/Sulfamethoxazole	• •	-	GIRHOWH		
/Trimethoprim Xantofyl Palmitate	N	S	Linknows		Not Reported
Admory i allimate	14		Unknown		



Zinc Oxide	N	S	Unknown		Not Reported
Lomotil	N	S	Unknown		Not Reported
Nicotine Polacrilex	N	S	Unknown		Not Reported
Acetaminophen; Dextropropoxyphene	N	S	Unknown		Not Reported
Alprazolam	N	S	Unknown		Not Reported
Simvastatin	N	S	Unknown		Not Reported
Betamethasone Dipropionate	N	S	Unknown		Not Reported
Nicotinamide	N	S	Unknown		Not Reported
Budesonide	N	S	Unknown		Not Reported
Fluticasone Furoate	N	S	Unknown		Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral		Not Reported
Loperamide Hydrochloride	N	S	Oral		Not Reported
Calcium Carbonate W/Vitamin D [Calcium Carbonate; Ergocalciferol]	N	S	Unknown		Not Reported
Ambroxol Hydrochloride; Cetirizine Hydrochloride	N	S	Unknown		Not Reported
Azithromycin Dihydrate	N	S	Unknown		Not Reported
Vitamin D3	N	S	Unknown		Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic		Not Reported
Cupric Oxide;Folic Acid;Nicotinic Acid;Zinc	N	S	Unknown		Not Reported
Hydrochlorothiazide	N	S	Unknown		Not Reported
Polyethylene Glycol 4000	N	S	Unknown		Not Reported
Morphine Sulfate	N	S	Unknown		Not Reported
Calcitriol;Calcium Carbonate; Zinc	N	S	Unknown		Not Reported
Glycerine	N	S	Oral	Liquid	Not Reported
Mesalazine	N	S	Unknown		Not Reported
Magnesium Oxide	Ν	S	Unknown		Not Reported
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;	N	S	Unknown	Sodium Sulfate	Not Reported



		Sodium Chloride											
		Pantoprazole Sodium Anhy	drous		N	S	Unknown						Not Reported
		Glycerol;Sodium Stearate			N	S	Unknown						Not Reported
		Sinus Rinse			Ν	S	Unknown						Not Reported
		Loperamide Metoclopramide Hydrochlo	ride		N N	C C	Oral						Not Reported Not Reported
		Calcium Carbonate And Vi D3	amin		N	С							Not Reported
		Valsartan Sodium Stearate			N N	C C							Not Reported Not Reported
FDA Received Date	Case #	Case Type		<u>Health</u>	<u>Prof</u>	Outcomes	Mfr	Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Dec-2022	217638	86 EXPEDITED (15-	DAY)	Y		ОТ	PH/ IND	SUN ARMACEUTIC USTRIES LTI 2RR-369620			44 YR	Male	FRA
Preferred Term		Product		Comp.	OTC	Role	Route	<u>D</u>	<u> Oosage</u>	<u>Text</u>	Duration		<u>Mfr</u>
Leukopenia; Neutrope	nia	Gabapentine			N	S	Oral		1200 M	illigram			Sun
		Celluvisc			N	S	Ophthalm	ic	Unk				Not Reported
		Dafalgan			N	S	Oral		Unk				Not Reported
		Laroxyl			N	S	Oral		Unk				Not Reported
		Vitamine B12 Chauvin			N	S	Ophthalm	ic	Unk				Not Reported
		Duloxetine Base			N	S	Unknown		60 Milli	gram			Not Reported
		Lovenox			N	S	Subcutan		Unk				Not Reported
		Levothyrox			Ν	S	Oral		Unk				Not Reported
		Tramadol Base			N	S	Oral		Unk				Not Reported
FDA Received Date	Case #	Case Type		<u>Health</u>	<u>Prof</u>	Outcomes	Mfr	Control #		503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Dec-2022	217644	28 EXPEDITED (15-	DAY)	Υ		ОТ		TEVA-2022-F 7071	R-		44 YR	Male	FRA
Preferred Term		Product		Comp.	OTO	Role	Route	<u>D</u>	osage	<u>Text</u>	Duration		Mfr
Leukopenia; Neutrope	nia	Gabapentin			N	S				illigram Daily; g/Day , Therapy			Ivax



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					End Date : Nask			
	Duloxetine	N	S		60 Milligram Daily; 60mg/Day , Therapy End Date : Nask		Tev	/a
	Tramadol Base	N	S		Therapy End Date : Nask		Tev	/a
	Celluvisc	N	S		1 Drop 2 To 4 Times A Day, 4 Mg/0.4 MI, Eye Drops In A Single-Dose Container ,Therapy End Date: N		Not	t Reported
	Dafalgan	N	S		4 Dosage Forms Daily; 1 Tablet 4 Times A Day , Form Strength : 1 Gram , Therapy Start Date : Asku		Not	t Reported
	Laroxyl	N	S		25 Gtt Daily; 5 Drops 5 Times A Day , Form Strength : 40 Mg/Ml , Therapy End Date : Nask		Not	t Reported
	Vitamine B12 Chauvin	N	S		1 Drop 3 To 4 Times A Day, 0.2 Mg/0.4 MI Eye Drops, Solution In Single- Dose Container, Therapy E		Not	t Reported
	Lovenox	N	S		Therapy End Date : Nask		Not	t Reported
	Levothyrox	N	S		1 Dosage Forms Daily; 1 Tablet/Day , Therapy End Date : Nask		Not	t Reported
FDA Received Date Case	<u>Case Type</u>	Health Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Dec-2022 2176	7074 DIRECT						Unknown	USA
Preferred Term	Product	Comp. OT	C Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Refresh Tears	N	S				Not	Reported



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							- 1			
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Dec-2022	217671	44 DIRECT							Unknown	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Orug Ineffective		Refresh Relieva		N	S				No	t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Dec-2022	217685	662 EXPEDITED (15-DA)	() N	1	ОТ	US-ALLERG 2241714US	GAN-		Female	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	Duration	<u>Mfr</u>	
Cataract; Impaired Hea	aling	Refresh Optive Mega-3		Υ	S				Alle	ergan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Dec-2022	212979	993 EXPEDITED (15-DA)	() Y		HO, OT	CA-AstraZer 2022A29928		71 YR	Female	CAN
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	Duration	<u>Mfr</u>	
Chronic Sinusitis; Drug		Budesonide		N	S	Unknown			Ast	razeneca
neffective; Dyspepsia; nfusion Related Reac		Budesonide		N	S	Unknown			No	t Reported
Macular Degeneration:	,	Entocort		N	S	Unknown			No	t Reported
Malaise; Nausea; Off _abel Use; Pain;		Paracetamol/Dextropropoxyph	en	N	S	Unknown			No	t Reported
Paraesthesia Oral;		e Acetaminophen		N	S	Unknown			No	t Reported
Procedural Pain; Pyrex Therapeutic Product E ncomplete; Weight		Adalimumab Alprazolam		N N	S S	Unknown				t Reported t Reported
Decreased		Atorvastatin Calcium		N	S	Unknown			No	t Reported
		Diphenoxylate		N	S	Oral			No	t Reported
		Hydrochloride/Atropine Sulfate Azithromycin		N	S	Unknown			No	t Reported
		Betamethasone Dipropionate		N	S	Unknown			No	t Reported
		Betamethasone Dipropionate		N	S	Unknown			No	t Reported
		Betamethasone Valerate		N	S	Unknown			No	t Reported

Note: If the field is blank, there is no data.



Calcium Carbonate	N	S	Unknown	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Not Reported
Clarithromycin	N	S		Not Reported
Clotrimazole	N	S	Unknown	Not Reported
Magnesium Sulfate Mesalazine	N N	S S	Halmanna	Not Reported Not Reported
Metronidazole	N	S	Unknown	Not Reported
		_	Unknown	·
Morphine Sulfate	N	S	Unknown	Not Reported
Mupirocin	N	S	Topical	Not Reported
Nadolol	N	S	Unknown	Not Reported
Nicoderm	N	S	Unknown	Not Reported
Nicotine Polacrilex	N	S	Unknown	Not Reported
Nicotine Polacrilex	N	S	Unknown	Not Reported
Pantoprazole	N	S	Unknown	Not Reported
Potassium Chloride	N	S	Unknown	Not Reported
Prednisone	N	S	Unknown	Not Reported
Pregabalin	N	S	Unknown	Not Reported
Sodium Carboximethyl Cellulose	N	S	Unknown	Not Reported
Sodium Chloride	N	S	Respiratory (inhalation)	Not Reported
Sulfamethoxazole/Trimethoprim	N	S	Unknown	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Not Reported
Vitamin D3	N	S	Unknown	Not Reported
Xantofyl Palmitate	N	S	Unknown	Not Reported
Zeaxanthin	N	S	Unknown	Not Reported
Zinc Oxide	N	S	Unknown	Not Reported
Calcium Carbonate/Vitamin D3	N	S	Unknown	Not Reported
Cupric Oxide	N	S	Unknown	Not Reported
D-Alpha Tocopherol	N	S		Not Reported
Desonide	N	S	Unknown	Not Reported



				<u> </u>	
Diphenhydramine Hydrochloride	N	S	Unknown		Not Reported
Ertapenem Sodium	N	S	Unknown		Not Reported
Fluticasone Furoate	N	S	Unknown		Not Reported
Glycerin	N	S	Unknown		Not Reported
Neomycin Sulfate/Gramicidin/Polymyxin B Sulfate	N	S	Unknown		Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical		Not Reported
Hydromorphone Hydrochloride	N	S	Unknown		Not Reported
Infliximab	N	S	Intravenous (not otherwise specified	l)	Not Reported
Loperamide	N	S	Unknown		Not Reported
Fluticasone Propionate	N	S	Unknown		Not Reported
Amoxicillin Trihydrate	N	S	Unknown		Not Reported
Ambroxol Hydrochloride	N	S	Unknown		Not Reported
Ambroxol/Cetirizine	N	S	Unknown		Not Reported
Hydrochloride Sodium Citrate/Diphenhydramine Hydrochloride/Ammonium	N	S	Unknown	1.0df Unknown	Not Reported
Chloride Sodium Citrate/Diphenhydramine Hydrochloride/Ammonium Chloride	N	S	Oral	Unknown	Not Reported
Sodium Citrate/Diphenhydramine Hydrochloride/Ammonium Chloride	N	S	Oral	Unknown	Not Reported
Azithromycin Dihydrate	N	S	Unknown		Not Reported
Biaxin XI	N	S	Unknown		Not Reported
Bisacodyl	N	S	Unknown		Not Reported
Calcitriol/Calcium	N	S	Unknown		Not Reported
Carbonate/Zinc Ergocalciferol/Calcium Carbonate	N	S	Unknown		Not Reported

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Note: If the field is blank, there is no data.



Calcium Carbonate/Vitamin D3	N	S	Unknown	Not Reported
Nicotinic Acid/Cupric Oxide/Folic Acid/Zinc	N	S	Unknown	Not Reported
Desonide	N	S	Unknown	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Not Reported
Ergocalciferol	N	S	Unknown	Not Reported
Flovent	N	S	Unknown	Not Reported
Fluticasone Furoate	N	S	Unknown	Not Reported
Fluticasone Propionate	N	S	Unknown	Not Reported
Glycerin	N	S	Unknown	Not Reported
Glycerin	N	S	Unknown	Not Reported
Gramicidin	N	S	Unknown	Not Reported
Humira	N	S	Unknown	Not Reported
Humira	N	S	Unknown	Not Reported
Hydrochlorothiazide	N	S	Unknown	Not Reported
Isoniazid	N	S	Unknown	Not Reported
Isoniazid/Pyridoxine Hydrochloride/Sulfamethoxazole /Trimethoprim	N	S	Unknown	Not Reported
Loperamide Hydrochloride	N	S	Unknown	Not Reported
Macrogol	N	S	Unknown	Not Reported
Sodium Sulfate/Macrogol 3350/Sodium Ascorbate/Sodium Chloride/Potassium Chloride/Ascorbic Acid	N	S	Unknown	Not Reported
Sodium Bicarbonate/Macrogol/Potassiu m Chloride	N	S	Unknown	Not Reported
Polyethylene Glycol\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride	N	S	Unknown	Not Reported
Magnesium Oxide	N	S	Unknown	Not Reported
Mixed Tocopherols	N	S	Unknown	Not Reported



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Mupirocin Calcium Dihydrate

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Unknown

		Neomyc	in Sulfate		N	S	Unknown					Not Reported
		Nicoderr	n		N	S	Unknown					Not Reported
		Nicotina	mide		N	S	Unknown					Not Reported
		Polyethy	lene Glycol 4000		N	S	Unknown					Not Reported
		Refresh	Tears		N	S	Unknown					Not Reported
		Simvasta	atin		Ν	S	Unknown					Not Reported
		Sinus Ri	nse		Ν	S	Unknown					Not Reported
		Sodium	Bicarbonate		Ν	S	Unknown					Not Reported
		Sodium	Stearate		N	S	Unknown					Not Reported
		Sulfame	thoxazole/Tri Methoprim		Ν	S	Unknown					Not Reported
		Triamcin	olone		Ν	S	Unknown					Not Reported
		Trimetho	pprim		Ν	S	Unknown					Not Reported
		Bactrim			Ν	S	Unknown					Not Reported
		Metoclop	oramide Hydrochloride		Ν	С	Unknown					Not Reported
		Benadry	I		Ν	С	Unknown					Not Reported
		Valsarta	n		Ν	С	Unknown					Not Reported
		Lomotil			Ν	С	Unknown					Not Reported
		Calcium Lactate/l Phospha	Ergocalciferol/Calcium ate		N	С	Unknown					Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Dec-2022	217900	71	EXPEDITED (15-DAY)	Υ		HO, OT	CA-Astr 2022A4	aZeneca- 12818		71 YR	Female	CAN
Preferred Term		Product	i	Comp.	OTO	Role	Route	Dos	sage Text	<u>Duration</u>		<u>Mfr</u>
Chronic Sinusitis; Drug		Budesor	nide		Ν	S	Unknown					Astrazeneca
Ineffective; Dyspepsia; Infusion Related React		Entocort			Ν	S	Unknown					Not Reported
Macular Degeneration;		Clarithro	mycin		Ν	S	Unknown					Not Reported
Malaise; Nausea; Off Label Use; Pain;		Hydroch	lorothiazide		N	S	Unknown					Not Reported

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Not Reported



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Paraesthesia Oral; Procedural Pain; Pyrexia; Therapeutic Product Effect Incomplete; Weight Decreased

			Detailed Report	
Amoxicillin Trihydrate	N	S	Unknown	Not Reported
Acetaminophen	N	S	Unknown	Not Reported
Alprazolam	N	S	Unknown	Not Reported
Adalimumab	N	S	Subcutaneous	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Not Reported
Atorvastatin	N	S	Unknown	Not Reported
Atropine Sulfate	N	S	Oral	Not Reported
Atropine Sulfate	N	S	Oral	Not Reported
Atropine Sulfate	N	S	Oral	Not Reported
Atropine Sulfate	N	S	Unknown	Not Reported
Azithromycin Dihydrate	N	S	Unknown	Not Reported
Benzydamine Hydrochloride	N	S	Unknown	Not Reported
Betamethasone	N	S	Unknown	Not Reported
Betamethasone Valerate	N	S	Unknown	Not Reported
Biaxin XI	N	S	Unknown	Not Reported
Bisacodyl	N	S	Unknown	Not Reported
Calcitriol	N	S	Intra-articular	Not Reported
Calcium Carbonate	N	S	Unknown	Not Reported
Cupric Oxide	N	S	Unknown	Not Reported
Clotrimazole	N	S	Unknown	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Not Reported
Desonide	Ν	S	Unknown	Not Reported
Diphenhydramine	N	S	Unknown	Not Reported
Nicotinic Acid/Cupric Oxide/Folic Acid/Zinc	N	S	Unknown	Not Reported
Ergocalciferol	N	S	Unknown	Not Reported
Ertapenem Sodium	N	S	Unknown	Not Reported
Flovent	N	S	Unknown	Not Reported
Fluticasone Furoate	N	S	Unknown	Not Reported
Glycerine	N	S	Oral	Not Reported



Glycerol	N	S	Oral	Not Reported
Glyceryl Trinitrate	N	S	Unknown	Not Reported
Sodium Stearate/Glycerol	N	S	Unknown	Not Reported
Gramicidin	N	S	Unknown	Not Reported
Humira	N	S	Subcutaneous	Not Reported
Gramicidin/Polymyxin B	N	S	Unknown	Not Reported
Imodium	N	S	Unknown	Not Reported
Cefixime	N	S	Dental	Not Reported
Isoniazid/Pyridoxine	N	S	Unknown	Not Reported
Loperamide	N	S	Unknown	Not Reported
Loperamide	N	S	Oral	Not Reported
Macrogol	N	S	Unknown	Not Reported
Magnesium Oxide	N	S	Unknown	Not Reported
Magnesium Sulfate	N	S	Intramuscular	Not Reported
Mentha Arvensis	N	S	Unknown	Not Reported
Mesalazine	N	S	Unknown	Not Reported
Metronidazole	N	S	Unknown	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Not Reported
Cetrizine Hydrochloride	N	S	Unknown	Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown	Not Reported
Neomycin Sulfate/Gramicidin/Polymyxin B Sulfate	N	S	Unknown	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Not Reported
Infliximab	N	S	Unknown	Not Reported
Morphine Sulfate	N	S	Unknown	Not Reported
Mupirocin	N	S	Topical	Not Reported
Mupirocin	N	S	Unknown	Not Reported
Nadolol	N	S	Unknown	Not Reported
Neomycin Sulfate	N	S	Unknown	Not Reported



Nicoderm	N	S	Transdermal	Not Reported
Nicomorphine	N	S	Unknown	Not Reported
Nicotinamide	N	S	Unknown	Not Reported
Nicotine	N	S	Unknown	Not Reported
Nicotine Polacrilex	N	S	Unknown	Not Reported
Pantoprazole	N	S	Unknown	Not Reported
Pantoprazole Sodium	N	S	Unknown	Not Reported
Pantoprazole Sodium Anhydrous	N	S	Unknown	Not Reported
Polyethylene Glycol	N	S	Unknown	Not Reported
Prednisone	N	S	Unknown	Not Reported
Pregabalin	N	S	Unknown	Not Reported
Salinex	N	S	Nasal	Not Reported
Simvastatin	N	S	Unknown	Not Reported
Sinus Rinse	N	S	Nasal	Not Reported
Sodium Chloride	N	S	Unknown	Not Reported
Sodium Carboxymethyl	N	S	Ophthalmic	Not Reported
Cellulose Sodium Carboxymethyl	N	S	On hith plants	Not Reported
Cellulose			Ophthalmic	•
Sodium Stearate	N	S	Unknown	Not Reported
Sulfamethoxazole	N	S	Unknown	Not Reported
Sodium Carboxymethyl Cellulose	N	S	Unknown	Not Reported
Sulfamethoxazole/Tetryzoline	N	S	Unknown	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Not Reported
Trimethoprim	N	S	Unknown	Not Reported
Vitamin D3	N	S	Unknown	Not Reported
Xantofyl Palmitate	N	S	Unknown	Not Reported
Zeaxanthin	N	S	Oral	Not Reported
Zinc Chloride	N	S	Unknown	Not Reported



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		Zinc Oxide		N	S	Unknown				Not Reported
		Diphenhydramine Hydrochloride		N	С					Not Reported
		Calcium Carbonate And Vitamin D3		N	С					Not Reported
		Amoxicillin		N	С	Unknown				Not Reported
		Valsartan		N	С	Unknown				Not Reported
FDA Received Date	Case #	<u>Case Type</u>	Health	Prof	<u>Outcomes</u>	Mfr Co	ntrol # 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jan-2023	218107	768 DIRECT			DS			76 YR	Male	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Keratitis		Refresh Digital Pf Multi Vitamin Mineral		Υ	S C					Allergan Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Co	ntrol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Jan-2023	204997	EXPEDITED (15-DAY)	Y		HO, OT		ROBINDO-AUR- 22-004685	71 YR	Female	e CAN
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	Duration		Mfr
Chronic Sinusitis; Drug		Atorvastatin		N	S	Unknown	Unk			Not Reported
neffective; Dyspepsia Infusion Related Reac		Amoxicillin		Ν	S	Unknown	Unk			Aurobindo
Macular Degeneration		Atorvastatin Tablets		Ν	S	Unknown	Unk			Not Reported
Malaise; Nausea; Off		Azithromycin		Ν	S	Unknown	Unk			Eugia Pharma
Label Use; Pain; Paraesthesia Oral;		Ertapenem		Ν	S	Unknown	Unk			Eugia Pharma
Procedural Pain; Pyre		Metronidazole		Ν	S	Unknown	Unk			Aurobindo
Therapeutic Product E ncomplete; Weight	ttect	Pantoprazole		Ν	S	Unknown	Unk			Aurobindo
Decreased		Pregabalin Capsules		Ν	S	Oral	150 Milligram			Not Reported
		Sulfamethoxazole+Trimethoprim		Ν	S	Unknown	200 Milligram			Aurobindo
		Simvastatin Tablet		Ν	S	Unknown	Unk			Aurobindo
		Acetaminophen		Ν	S	Unknown	Unk			Not Reported
		Acetaminophen		N	S	Unknown	Unk			Not Reported
		Acetaminophen; Dextropropoxyphene		N	S	Unknown	Unk			Not Reported

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Adalimumab	N	S	Subcutaneous	Unk	Not Reported					
Alprazolam	N	S	Oral	0.25 Milligram	Not Reported					
Alprazolam	N	S		Unk	Not Reported					
Ambroxol Hydrochloride; Cetirizine	N	S	Unknown	Unk	Not Reported					
Avamys	N	S	Unknown	Unk	Not Reported					
Benadryl	N	S	Oral	50 Milligram	Not Reported					
Betamethasone	N	S	Unknown	Unk	Not Reported					
Betamethasone Valerate	N	S	Topical	0.122 Gram	Not Reported					
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported					
Biaxin XI	N	S	Unknown	Unk	Not Reported					
Budesonide	N	S	Unknown	Unk	Not Reported					
Calcitriol;Calcium Carbonate; Zinc Sulfate	N	S	Unknown	Unk	Not Reported					
Bisacodyl	N	S	Unknown	Unk	Not Reported					
Calcium Carbonate	N	S	Unknown	Unk	Not Reported					
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported					
Calcium;Ergocalciferol	N	S	Unknown	Unk	Not Reported					
Cholecalciferol	N	S	Unknown	Unk	Not Reported					
Cupric Oxide;Folic Acid; Nicotinamide;Zinc	N	S	Unknown	Unk	Not Reported					
Clarithromycin	N	S	Unknown	Unk	Not Reported					
Clotrimazole	Ν	S	Unknown	Unk	Not Reported					
Cupric Oxide	N	S	Unknown	Unk	Not Reported					
Calcium & Vitamin D3	N	S	Unknown	Unk	Not Reported					
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported					
Diphenoxylate Hydrochloride And Atropine Sulfate	N	S	Oral	Unk	Not Reported					
Diphenoxylate Hydrochloride And Atropine Sulfate	N	S	Unknown	1 Dosage Form	Not Reported					
Diphenoxylate Hydrochloride And Atropine Sulfate	N	S	Unknown	Unk	Not Reported					
Desonide	N	S	Unknown	Unk	Not Reported					



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Dilaudid	N	S	Endocervical	Unk	Not Reported
Diphenhydramine Hydrochloride; Zinc Oxide	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Oral	50 Milligram	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Entocort	N	S	Oral	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Flovent	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate Glycerol	N N	S S	Oral	Unk	Not Reported Not Reported
Gramicidin;Polymyxin B Glycerol;Sodium Stearate	N N	S S	Unknown	Unk	Not Reported Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Humira	N	S	Subcutaneous	Unk	Not Reported
Hydromorphone	N	S	Unknown	Unk	Not Reported
Hydromorphone	N	S	Endocervical	Unk	Not Reported
Hydrochlorothiazide	N	S	Oral	Unk	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
Infliximab	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Isoniazid/Pyridoxine Hydrochloride/Sulfamethoxazole /Trimethoprim	N	S	Unknown	Unk	Not Reported
Loperamide Hcl	N	S	Oral	Unk	Not Reported
Lomotil	N	S	Oral	Unk	Not Reported
Loperamide	N	S	Oral	4 Dosage Form, Once A Day	Not Reported
Macrogol;Potassium Chloride; Sodium Bicarbonate;Sodium Chloride	N	S	Unknown	Unk	Not Reported



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Metoclopramide Hydrochloride	N	S	Oral	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Macrogol	N	S	Unknown	Unk	Not Reported
Macrogol 3350;Magnesium Sulfate;Potassium Chloride; Potassium Sulfate;S	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Oral	40 Milligram	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Pms-Azithromycin	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S		Unk	Not Reported
Potassium Chloride	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Sodium Chloride	N	S	Nasal	Unk	Not Reported
Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Sodium Carboxymethylcellulose Sinus Rinse	N N	S S	Unknown	Unk	Not Reported Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-arterial	Unk	Not Reported
Vitamin D3	N	S	Oral	Unk	Not Reported



		Pantoprazole		Ν	S	Unknown	Unk				Aurobindo
		Pregabalin Capsules		N	S	Unknown	Unk				Not Reported
		Metronidazole		N	S	Unknown	Unk				Aurobindo
		Azithromycin		N	S	Oral	Unk				Eugia Pharma
		Azithromycin		N	S	Unknown	Unk				Eugia Pharma
		Azithromycin		N	S	Oral	Unk				Eugia Pharma
		Atorvastatin		N	S	Unknown	Unk				Not Reported
		Atorvastatin		N	S	Unknown	Unk				Not Reported
		Atorvastatin		N	S	Unknown	Unk				Not Reported
Degeneration		Atorvastatin		N	S	Unknown	Unk				Not Reported
Drug Ineffective; Macu	lar	Amoxicillin		N	S	Unknown	Unk				Aurobindo
Preferred Term		<u>Product</u>	Comp	<u>. OTC</u>	Role	Route	Dosage Text		<u>Duration</u>	ı	<u>Mfr</u>
03-Jan-2023	211650	EXPEDITED (15-	DAY) Y	(DΤ		JROBINDO-AUR- 2022-029356			Female	CAN
FDA Received Date	Case #	Case Type	<u>Heal</u>	th Prof (Outcomes	Mfr (Control # 503E	3 Facility	<u>Age</u>	<u>Sex</u>	Country
		Valsartan		N	С	Oral	4 Dosage Fo Day	orm, Once A			Not Reported
		Sodium Stearate		N	С	Unknown	Unk				Not Reported
		Neomycin Sulfate		Ν	С	Unknown	Unk				Not Reported
		Phosphate; Ergocal ciferol Diphenoxylate Hydrochloric	de	N	С	Unknown	Unk				Not Reported
		Calcium Lactate;Calcium		Ν	С	Unknown	Unk				Not Reported
		Calcium		N	С	Unknown	Unk				Not Reported
		Calcium Carbonate/Vitamir	n D3	N	С	Unknown	Unk				Not Reported
		Benadryl		N	С	Unknown	Unk				Not Reported
		Zinc Oxide		N	S	Unknown	Unk				Not Reported
		Zeaxanthin		N	S	Unknown	Unk				Not Reported
		Xantofyl Palmitate		N	S	Unknown	Unk				Not Reported
		Vitamin E Mixed Tocopher	ols	N	S	Unknown	Unk				Not Reported



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Pantoprazole	N	S	Unknown	Unk	Aurobindo
Pantoprazole	N	S	Unknown	Unk	Aurobindo
Pantoprazole	N	S	Unknown	Unk	Aurobindo
Sulfamethoxazole+Trimethoprim	N	S	Unknown	Unk	Aurobindo
Simvastatin Tablet	N	S	Unknown	Unk	Aurobindo
Valsartan	N	S	Unknown	Unk	Aurobindo
Alprazolam	N	S	Unknown	Unk	Not Reported
Acetaminophen	N	S	Unknown	Unk	Not Reported
Acetaminophen	N	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid	N	S	Oral	Unk	Not Reported
Adalimumab	N	S	Subcutaneous	Unk	Not Reported
Atropine Sulfate	N	S	Oral	Unk	Not Reported
Atropine Sulfate	N	S	Unknown	Unk	Not Reported
Atropine Sulfate	N	S	Unknown	Unk	Not Reported
Ambroxol Hydrochloride	N	S	Unknown	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Avamys	N	S	Unknown	Unk	Not Reported
Atorvastatin	N	S	Unknown	Unk	Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Bactrim	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Budesonide	N	S		Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported



Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Intra-articular	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Calcium Carbonate And Vitamin D3	N	S	Unknown	Unk	Not Reported
Calcium Carbonate And Vitamin D3	N	S	Unknown	Unk	Not Reported
Calcium Carbonate And Vitamin D3	N	S	Unknown	Unk	Not Reported
Calcium Citrate	N	S	Unknown	Unk	Not Reported
Calcium Gluconate	N	S	Unknown	Unk	Not Reported
Cetirizine	N	S	Unknown	Unk	Not Reported
Cholecalciferol	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Difenoxin Hydrochloride	N	S	Unknown	1 Unk	Not Reported
Diladid	N	S	Unknown	Unk	Not Reported
Diphenhydramine	N	S	Unknown	Unk	Not Reported
Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown	Unk	Not Reported
Entocort	N	S	Unknown	Unk	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported



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Flovent	N	S	Unknown	Unk	Not Reported
Fluocinolone Acetonide; Neomycin Sulfate;Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Fructose;Glycerol;Sodium Chloride	N	S	Oral	Unk	Not Reported
Glycerol	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B	N	S	Unknown	Unk	Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B	N	S	Unknown	Unk	Not Reported
Glycerin	N	S	Oral	Unk	Not Reported
Glycerin	N	S	Unknown	Unk	Not Reported
Humira	N	S	Unknown	Unk	Not Reported
Hydromorphone Hcl	N	S	Endocervical	Unk	Not Reported
Hydromorphone Hcl	N	S	Unknown	Unk	Not Reported
Humira	N	S	Subcutaneous	Unk	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Ichthammol;Zinc Oxide	N	S	Unknown	Unk	Not Reported
Ichthammol;Zinc Oxide	N	S	Unknown	Unk	Not Reported
Kenalog	N	S	Intra-articular	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk Unk, Once A Day	Not Reported
Macrogol;Potassium;Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Macrogol;Potassium;Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unknown	Not Reported
Mezavant	N	S	Unknown	Unknown	Not Reported



Ms Ir	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Macrogol 3350;Potassium; Sodium Bicarbonate;Sodium Chloride	N	S	Unknown	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Neomycin	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	С	Unknown	Unk	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Endocervical	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S		Unk	Not Reported
Pulmicort	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Sodium Chloride	N	S	Endosinusial		Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Sinus Rinse	N	S	Endosinusial	Unk	Not Reported



Cataract	Refres	sh Optive Mega-3		Υ	S		Unk Unk, Qid		All	ergan
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
05-Jan-2023	21824734	EXPEDITED (15-DAY)	N		ОТ	US-ALLERGAN 2242813US	l-		Female	USA
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
	Vitami	ne A		N	С	Unknown	Unk		No	t Reported
	Valsar	tan		N	С	Intracardiac	Unk		No	t Reported
	Valsar			N	С	Vaginal	Unk			t Reported
	Calciu	m		N	С	Unknown	Unk			t Reported
	Zinc C	hloride		N	S	Unknown	Unk		No	t Reported
	Zeaxa	nthin		N	S	Unknown	Unk		No	t Reported
	Zeaxa	nthin		N	S	Unknown	Unk		No	t Reported
	Potass	sium Chloride		N	S	Unknown	Unknown		No	t Reported
	Zinc C	xide		N	S	Unknown	Unk		No	t Reported
	Xantof	fyl Palmitate		N	S	Unknown	Unk		No	t Reported
	Xantof	fyl Palmitate		N	S	Unknown	Unk		No	t Reported
	Vitami	n E		Ν	S	Unknown	Unknown		No	t Reported
	Vitami	n D3		N	S	Unknown	Unk		No	t Reported
	Vitami	n D		N	S	Unknown	Unk		No	t Reported
	Triamo	cinolone Acetonide		N	S	Intra-articular	Unk		No	t Reported
	Trimet	hoprim		N	S	Unknown	Unk		No	t Reported
	Triamo	cinolone Acetonide		N	S	Intra-articular	Unk		No	t Reported
	Triamo	cinolone Acetonide		N	S	Unknown	Unk			t Reported
	Sodiur	m Chloride		N	S	Nasal	Unk		No	t Reported
	Sodiur	m Stearate		N	S	Oral	Unk			t Reported
	Sodiur	m Stearate		N	S	Unknown	Unk			t Reported
	Sinus	Rinse		N	S	Unknown	Unk		No	t Reported



FDA Received Date	Case #		Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Jan-2023	206985	77	EXPEDITED (15-DAY)	Υ		ОТ	NVSC20220	CA080548			Female	USA
Preferred Term		Produc	<u>:t</u>	Comp.	ОТС	Role	Route	Dosag	ge Text	<u>Duration</u>	<u>N</u>	<u>Nfr</u>
Drug Ineffective; Macu	ular	Adalimu	ımab		N	S	Subcutaneous	Unk			ı	Novartis
Degeneration		Hydrom	orphone		Ν	S	Unknown	Unk,	Qw		1	Not Reported
		Hydrom	orphone		Ν	S	Unknown	Unk			ļ	Not Reported
		Atorvas	tatin Calcium		Ν	S	Unknown	Unk			ļ	Novartis
		Atorvas	tatin Calcium		Ν	S	Unknown	Unk			I	Novartis
		Atorvas	tatin Calcium		Ν	S	Unknown	Unk			I	Novartis
		Atorvas	tatin Calcium		Ν	S	Unknown	Unk			I	Novartis
		Azithror	mycin		Ν	S	Oral	Unk			1	Novartis
		Valsarta	an		Ν	S	Intracardiac	Unk			1	Novartis
		Ergocal	ciferol		Ν	S	Unknown	Unk			1	Not Reported
		Clarithro	omycin		Ν	S	Unknown	Unk			1	Novartis
		Morphin	ne Sulfate		Ν	S	Unknown	Unk			1	Not Reported
		Amoxici	illin		Ν	S	Unknown	Unk			1	Novartis
		Diphenh	nydramine Hydrochloride		Ν	S	Unknown	Unk			I	Not Reported
		Pantopr	azole		Ν	S	Unknown	Unk			1	Novartis
		Pantopr	azole		Ν	S	Unknown	Unk			1	Novartis
		Potassi	um Chloride		Ν	S	Unknown	Unk			l	Not Reported
		Pregaba	alin		Ν	S	Unknown	Unk			l	Not Reported
		Magnes	sium Sulfate		Ν	S	Unknown	Unk			I	Not Reported
		Sodium	Bicarbonate		N	S	Unknown	Unk			I	Not Reported
		Pantopr	azole Sodium		Ν	S	Unknown	Unk				Novartis
		Pantopr	azole Sodium		Ν	S	Unknown	Unk			I	Novartis
		Pantopr	azole Sodium		Ν	S	Unknown	Unk			1	Novartis
		Pantopr	azole Sodium		Ν	S	Unknown	Unk			1	Novartis
		Atropine	e Sulfate		N	S	Unknown	Unk			1	Not Reported



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Acetaminophen	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Ambroxol Hydrochloride	N	S	Unknown	Unk	Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Bactrim	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Budesonide	N	S		Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D3	N	S	Unknown	Unk	Not Reported
Calcium Gluconate	N	S	Unknown	Unk	Not Reported
Cetirizine	N	S	Unknown	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Diladid	N	S	Unknown	Unk	Not Reported
Entocort	N	S	Unknown	Unk	Not Reported
Flovent	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Humira	N	S	Subcutaneous	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Macrogol	N	S	Unknown	Unk	Not Reported
Ms Ir	N	S	Unknown	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
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Nadolol	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S		Unk	Not Reported
Pulmicort	N	S		Unk	Not Reported
Sinus Rinse	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk, Other	Not Reported
Sodium Stearate	N	S	Oral	Unk	Not Reported
Sulfamethoxazole And Trimethoprim	N	S	Unknown	Unk	Not Reported
Triamcinolone	N	S	Intra-articular	Unk	Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported



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Diphenoxylate Hydrochloride	N	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid	N	S	Oral	Unk	Not Reported
Zinc Chloride	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Avamys	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Dilaudid	N	S	Unknown	Unk	Not Reported
Vitamin B Complex Nos	N	S	Unknown	Unk	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Glycerol	N	S	Oral	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk Unk, Qw	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Mupirocin Calcium	N	S	Topical	Unk	Not Reported
Neomycin Sulfate	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Diphenoxylate Hcl And Atropine Sulfate	N	S	Oral	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Ichthammol And Zinc Oxide	N	S	Unknown	Unk	Not Reported
Ichthammol And Zinc Oxide	N	S	Unknown	Unk	Not Reported
Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Mezavant	N	S	Unknown	Unk	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Cupric Oxide;Folic Acid; Nicotinamide;Zinc	N	S	Unknown	Unk	Not Reported



FDA Received Date	Case #		Case Type	Health	<u>Prof</u>	Outcomes	Mfr Contro	l#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Jan-2023	2183800	09	EXPEDITED (15-DAY)	N		ОТ	ALC2023CA	000442			Female	CAN
Preferred Term		Product	<u> </u>	Comp.	отс	Role	Route	Dosage	e Text	<u>Duration</u>	Mf	<u>r</u>
Drug Ineffective; Macu	ular .	Atropine	Sulfate		N	S	Oral	Unk			А	con
Degeneration		Acetami	nophen		Ν	S	Unknown				N	ot Reported
		Acetami	nophen		Ν	S	Unknown	Unk			N	ot Reported
		Adalimu	mab		Ν	S	Subcutaneous	Unk			N	ot Reported
		Alprazol	am		Ν	S	Unknown	Unk			N	ot Reported
		Amoxicil	lin Trihydrate		Ν	S	Unknown				N	ot Reported
		Apo-Hyd	Irochlorothiazide		Ν	S	Unknown				N	ot Reported
		Atorvast	atin Calcium		Ν	S	Unknown				N	ot Reported
			Sulfate;Diphenoxylate		N	S	Unknown	Unk			N	ot Reported
		Hydroch Avamys	loride		N	S	Unknown				N	ot Reported
		Azithron	nycin		N	S	Unknown				N	ot Reported
		Azithron	nycin		N	S	Unknown				N	ot Reported
		Bactrim			Ν	S	Unknown	Unk			N	ot Reported
		Betamet	hasone Dipropionate		Ν	S	Unknown				N	ot Reported
		Betamet	hasone Valerate		N	S	Unknown				N	ot Reported
		Biaxin X	I		N	S	Unknown	Unk			N	ot Reported
		Bisacod	yl		Ν	S	Unknown	Unk			N	ot Reported
		Bisacod	yl		Ν	S	Unknown	Unk			N	ot Reported
		Budesor	nide		Ν	S	Unknown				N	ot Reported
		Calcium	Carbonate		N	S	Intra-articular	Unk			N	ot Reported
		Cetirizin	e Hydrochloride		Ν	S	Unknown	Unk			N	ot Reported
		Clarithro	mycin		Ν	S	Unknown				N	ot Reported
		Clotrima	zole		Ν	S	Unknown	Unk			N	ot Reported
		Desonid	е		Ν	S	Unknown	Unk			N	ot Reported



				- 1	
Dilaudid	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown		Not Reported
Entocort	N	S	Unknown		Not Reported
Ergocalciferol	N	S	Unknown		Not Reported
Ertapenem Sodium	N	S	Unknown		Not Reported
Flovent	N	S	Unknown		Not Reported
Fluticasone Furoate	N	S	Unknown		Not Reported
Glycerine	N	S	Oral		Not Reported
Gramicidin;Neomycin	N	S	Unknown		Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown		Not Reported
Humira	N	S	Unknown		Not Reported
Hydrochlorothiazide	N	S	Unknown		Not Reported
Hydromorphone Hydrochloride	N	S	Unknown		Not Reported
Mesalazine	N	S	Unknown		Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Mezavant	N	S	Unknown		Not Reported
Morphine Sulfate	N	S	Unknown		Not Reported
Mupirocin	N	S	Topical		Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown		Not Reported
Nicotine	N	S	Unknown		Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Unknown		Not Reported
Pulmicort	N	S	Unknown		Not Reported
Refresh Tears	N	S	Ophthalmic		Not Reported
Simvastatin	N	S	Unknown		Not Reported
Sinus Rinse	N	S	Unknown		Not Reported



		Sodium	Chloride		N	S	Unknowr					Not Reported
		Sulfame	thoxazole;Trimethoprim		Ν	S	Unknown	Unk				Not Reported
		Triamcin	olone Acetonide		Ν	S	Intra-artic	cular				Not Reported
		Vitamin	D3		Ν	S	Unknown					Not Reported
		Vitamin	E Nos		Ν	S	Unknown					Not Reported
		Xantofyl	Palmitate		Ν	S	Unknown	Unk				Not Reported
		Zeaxant	hin		Ν	S	Unknown					Not Reported
		Zinc Oxi	de		Ν	S	Unknown					Not Reported
		Valsarta	n		N	С	Vaginal					Not Reported
FDA Received Date	Case #	<u> </u>	Case Type	Health	<u>Prof</u>	Outcomes	Mf	r Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jan-2023	218440)15	EXPEDITED (15-DAY)	N		ОТ		-ALLERGAN- 36274US			Female	USA
Preferred Term		Product	<u>I</u>	Comp.	OTO	Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>		<u>Mfr</u>
Drug Hypersensitivity;	Eye	Refresh	Relieva Pf		Υ	S	Ophthaln	nic 2 Gt	t			Allergan
Pruritus; Retinal Haemorrhage		Coenzyr	me Q10		Ν	S		Unk				Not Reported
nacmonnage		Refresh	Optive Mega-3		N	С		Unk				Not Reported
		Genteal	[Hypromellose]		Ν	С		Unk				Not Reported
		Similasa	n		Ν	С		Unk				Not Reported
		Calcium			Ν	С		Unk				Not Reported
		Magnesi	ium		N	С		Unk				Not Reported
		Vitamin	D [Colecalciferol]		N	С		Unk				Not Reported
FDA Received Date	Case #	<u> </u>	Case Type	Health	Prof	Outcomes	Mf	r Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Jan-2023	218451	115	EXPEDITED (15-DAY)	N		ОТ		-BAXTER- 23BAX010003			Female	CAN
Preferred Term		Product	<u>t</u>	Comp.	OTO	Role Role	Route	<u>Dosa</u>	ge Text	<u>Duration</u>		Mfr
Drug Ineffective; Macu Degeneration	lar	Sodium	Chloride		N	S	Unknowr		sage Form: Not cified)			Baxter
		Metronic	lI-		Ν	S	Unknown		sage Form: Not			Baxter

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				Specified)	
Acetaminophen	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
Adalimumab	N	S	Subcutaneous	(Dosage Form: Solution Subcutaneous)	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
Atropine Sulfate	N	S	Oral	(Dosage Form: Not Specified)	Not Reported
Diphenoxylate Hydrochloride And Atropine Sulfate	N	S	Unknown	Unk	Not Reported
Avamys	N	S	Unknown	(Dosage Form: Spray, Metered Dose)	Not Reported
Azithromycin	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
Bactrim	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
Betamethasone Dipropionate	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	(Dosage Form: Tablet (Extended-Release))	Not Reported
Bisacodyl	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
Budesonide	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
Calcium Carbonate	N	S	Intra-articular	(Dosage Form: Not Specified)	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported



Discrimazole					<u> </u>	
Dilaudid N S Unknown (Dosage Form: Not Specified) Diphenhydramine Hydrochloride N S Unknown Unk Not Reported Specified Entocort N S Unknown (Dosage Form: Capsule, Soustained-Release) Ergocalciferol N S Unknown (Dosage Form: Not Specified) Ertapenem Sodium N S Unknown Unk Not Reported Specified) Ertapenem Sodium N S Unknown (Dosage Form: Not Specified) Ertapenem Sodium N S Unknown Unk Not Reported Specified) Fluticasone Furoate N S Unknown Unk Not Reported Glycerine N S Oral (Dosage Form: Liquid Oral) Gramicidin; Neomycin N S Unknown Unk Not Reported Oral) Gramicidin; Neomycin Sulfate; N S Unknown Unk Not Reported Gramicidin; Neomycin Sulfate Humira N S Unknown Unk Not Reported Not Reported Oral) Hydrochlorothiazide N S Unknown Unk Not Reported Subcutaneous) Hydrochlorothiazide N S Unknown Unk Not Reported Oral Subcutaneous) Hydrochlorothiazide N S Unknown Unk Not Reported Not Reported Oral Subcutaneous) Mesalazine N S Unknown Unk Not Reported Not Reported Oral Specified) Mezavant N S Unknown (Dosage Form: Not Specified) Mupirocin N S Unknown (Dosage Form: Not Specified) Mupirocin N S Unknown (Dosage Form: Not Specified) Not Reported Not Reported Not Reported Not Reported Opsage Form: Tablet (Delayed And Extended Release) Mupirocin N S Unknown (Dosage Form: Not Specified) Mupirocin N N S Unknown (Dosage Form: Not Specified) Not Reported Not Reported Opsage Form: Ointment Topical)	Clotrimazole	N	S	Unknown		Not Reported
Diphenhydramine Hydrochloride Entocort N S Unknown Diphenhydramine Hydrochloride N S Diphenhydramine Hydrochl	Desonide	N	S	Unknown		Not Reported
Entocort N S Unknown (Dosage Form: Capsule, Sustained-Release) Ergocalciferol N S Unknown (Dosage Form: Not Specified) Ertapenem Sodium N S Unknown Unk Not Reported Specified) Fluticasone Furoate N S Unknown Unk Not Reported Specified) Fluticasone Furoate N S Unknown Unk Not Reported Specified) Fluticasone Furoate N S Unknown Unk Not Reported Glycerine N S Unknown Unk Not Reported Oral) Gramicidin; Neomycin N S Unknown Unk Not Reported Oral) Gramicidin; Neomycin Sulfate; N S Unknown Unk Not Reported Unk Not Reported Delaymyrin B Sulfate Humira N S Unknown (Dosage Form: Solurion Subcutaneous) Hydrochlorothiazide N S Unknown Unk Not Reported Subcutaneous) Hydrochlorothiazide N S Unknown Unk Not Reported Not Reported Subcutaneous) Mezavant N S Unknown (Dosage Form: Not Specified) Morphine Sulfate Not Reported Release)) Morphine Sulfate Not Reported Not Reported Release)) Morphine Sulfate Not Reported Not Reported Release))	Dilaudid	N	S	Unknown		Not Reported
Ergocalciferol N S Unknown (Dosage Form: Not Specified) Ertapenem Sodium N S Unknown Unk Not Reported Specified) Flovent N S Unknown (Dosage Form: Not Specified) Fluticasone Furoate N S Unknown Unk Not Reported Specified) Fluticasone Furoate N S Unknown Unk Not Reported Glycerine N S Unknown Unk Not Reported Oral (Dosage Form: Liquid Oral) Gramicidin; Neomycin N S Unknown Unk Not Reported Gramicidin; Neomycin Sulfate; N S Unknown Unk Not Reported Gramicidin; Neomycin Sulfate; N S Unknown Unk Not Reported Humira N S Unknown (Dosage Form: Solurion Substate Humira N S Unknown Unk Not Reported Hydrochlorothiazide N S Unknown Unk Not Reported Hydromorphone Hydrochloride N S Unknown (Dosage Form: Solurion Subcutaneous) Mezavant N S Unknown (Dosage Form: Not Not Reported Not Reported Specified) Mezavant N S Unknown (Dosage Form: Tablet (Delayed And Extended Release)) Morphine Sulfate N S Topical (Dosage Form: Not Specified) Mupirocin N N S Topical (Dosage Form: Not Specified)	Diphenhydramine Hydrochloride	Ν	S	Unknown	Unk	Not Reported
Ertapenem Sodium N S Unknown Unk Not Reported Specified) Flovent N S Unknown (Dosage Form: Not Specified) Fluticasone Furoate N S Unknown Unk Not Reported Specified) Fluticasone Furoate N S Unknown Unk Not Reported Glycerine N S Unknown Unk Not Reported Oral) Gramicidin;Neomycin N S Unknown Unk Not Reported Gramicidin;Neomycin Sulfate; N S Unknown Unk Not Reported Gramicidin;Neomycin Sulfate; N S Unknown Unk Not Reported Humira N S Unknown Unk Not Reported Polymyxin B Sulfate Humira N S Unknown Unk Not Reported Subcutaneous) Hydrochlorothiazide N S Unknown Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Mesalazine N S Unknown (Dosage Form: Not Specified) Mezavant N S Unknown (Dosage Form: Tablet (Delayed And Extended Release)) Morphine Sulfate N S Unknown (Dosage Form: Not Specified) Mupirocin N S Topical (Dosage Form: Ointment Topical)	Entocort	N	S	Unknown		Not Reported
Flovent N S Unknown (Dosage Form: Not Specified) Fluticasone Furoate N S Unknown Unk Not Reported (Dosage Form: Liquid Oral) Gramicidin; Neomycin N S Unknown Unk Not Reported (Oral) Gramicidin; Neomycin Sulfate; N S Unknown Unk Not Reported (Dosage Form: Solurion Subcutaneous) Hydrochlorothiazide N S Unknown Unk Not Reported (Dosage Form: Solurion Subcutaneous) Hydrochlorothiazide N S Unknown Unk Not Reported (Dosage Form: Not Specified) Mezavant N S Unknown (Dosage Form: Not Specified) Morphine Sulfate N S Unknown (Dosage Form: Not Specified) Morphine Sulfate N S Unknown (Dosage Form: Not Specified) Morphine Sulfate N S Unknown (Dosage Form: Tablet (Delayed And Extended Release)) Morphine Sulfate N S Unknown (Dosage Form: Not Specified) Mupirocin N S Topical (Dosage Form: Not Specified)	Ergocalciferol	N	S	Unknown		Not Reported
Fluticasone Furoate N Specified) Fluticasone Furoate N Specified) Not Reported Oral) Gramicidin; Neomycin N S Unknown Unk Not Reported Oral) Gramicidin; Neomycin Sulfate; N S Unknown Unk Not Reported Oral) Gramicidin; Neomycin Sulfate; N S Unknown Unk Not Reported Polymyxin B Sulfate Humira N S Unknown (Dosage Form: Solurion Subcutaneous) Hydrochlorothiazide N S Unknown Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Mesalazine N S Unknown (Dosage Form: Not Specified) Mezavant N S Unknown (Dosage Form: Not Specified) Morphine Sulfate N S Unknown (Dosage Form: Tablet (Delayed And Extended Release)) Morphine Sulfate N S Unknown (Dosage Form: Not Specified) Mupirocin N S Topical (Dosage Form: Ointment Topical)	Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Glycerine N S Oral (Dosage Form: Liquid Oral) Gramicidin;Neomycin N S Unknown Unk Not Reported Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate Humira N S Unknown (Dosage Form: Solurion Subcutaneous) Hydrochlorothiazide N S Unknown Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Mesalazine N S Unknown (Dosage Form: Not Specified) Mezavant N S Unknown (Dosage Form: Tablet (Delayed And Extended Release)) Morphine Sulfate N S Unknown (Dosage Form: Not Specified) Mupirocin Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Oral)	Flovent	N	S	Unknown		Not Reported
Gramicidin;Neomycin N S Unknown Unk Not Reported Oral) Gramicidin;Neomycin Sulfate; N S Unknown Unk Not Reported Polymyxin B Sulfate Humira N S Unknown (Dosage Form: Solurion Subcutaneous) Hydrochlorothiazide N S Unknown Unk Not Reported Subcutaneous) Hydromorphone Hydrochloride N S Unknown Unk Not Reported Mesalazine N S Unknown (Dosage Form: Not Specified) Mezavant N S Unknown (Dosage Form: Tablet (Delayed And Extended Release)) Morphine Sulfate N S Unknown (Dosage Form: Not Specified) Mupirocin N S Topical (Dosage Form: Ointment Topical)	Fluticasone Furoate	Ν	S	Unknown	Unk	Not Reported
Gramicidin; Neomycin Sulfate; Polymyxin B Sulfate Humira N S Unknown (Dosage Form: Solurion Subcutaneous) Hydrochlorothiazide N S Unknown Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Mesalazine N S Unknown Unk Not Reported Specified) Mezavant N S Unknown (Dosage Form: Not Specified) Morphine Sulfate N S Unknown (Dosage Form: Tablet (Delayed And Extended Release)) Morphine Sulfate N S Unknown (Dosage Form: Not Specified) Mupirocin N S Topical (Dosage Form: Ointment Topical)	Glycerine	N	S	Oral		Not Reported
Polymyxin B Sulfate Humira N S Unknown (Dosage Form: Solurion Subcutaneous) Not Reported (Dosage Form: Tablet (Delayed And Extended Release)) Morphine Sulfate Not Reported Not Reported Not Reported (Dosage Form: Not Specified) Not Reported (Dosage Form: Not Specified) Not Reported Not Reported (Dosage Form: Ointment Topical)	Gramicidin;Neomycin	Ν	S	Unknown	Unk	Not Reported
Hydrochlorothiazide N S Unknown Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Mesalazine N S Unknown (Dosage Form: Not Specified) Not Reported Specified) Mezavant N S Unknown (Dosage Form: Tablet (Delayed And Extended Release)) Morphine Sulfate N S Unknown (Dosage Form: Not Specified) Mupirocin N S Topical (Dosage Form: Ointment Topical)		N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride N S Unknown (Dosage Form: Not Specified) Mezavant Not Reported Not Reported Not Reported (Dosage Form: Tablet (Delayed And Extended Release)) Morphine Sulfate N S Unknown (Dosage Form: Tablet (Delayed And Extended Release)) Morphine Sulfate N S Unknown (Dosage Form: Not Specified) Not Reported (Dosage Form: Ointment Topical)	Humira	N	S	Unknown		Not Reported
Mesalazine N S Unknown (Dosage Form: Not Specified) Not Reported Mezavant N S Unknown (Dosage Form: Tablet (Delayed And Extended Release)) Not Reported Morphine Sulfate N S Unknown (Dosage Form: Not Specified) Not Reported Mupirocin N S Topical (Dosage Form: Ointment Topical) Not Reported	Hydrochlorothiazide	Ν	S	Unknown	Unk	Not Reported
Mezavant N S Unknown (Dosage Form: Tablet (Delayed And Extended Release)) Morphine Sulfate N S Unknown (Dosage Form: Not Specified) Mupirocin N S Topical (Dosage Form: Ointment Topical)	Hydromorphone Hydrochloride	Ν	S	Unknown	Unk	Not Reported
Morphine Sulfate N S Unknown (Delayed And Extended Release)) Morphine Sulfate N S Unknown (Dosage Form: Not Specified) Mupirocin N S Topical (Dosage Form: Ointment Topical)	Mesalazine	N	S	Unknown		Not Reported
Mupirocin N S Topical (Dosage Form: Ointment Topical) Not Reported Topical)	Mezavant	N	S	Unknown	(Delayed And Extended	Not Reported
Topical)	Morphine Sulfate	N	S	Unknown		Not Reported
Nadolol N S Unknown Unk Not Reported	Mupirocin	N	S	Topical		Not Reported
	Nadolol	N	S	Unknown	Unk	Not Reported

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Note: If the field is blank, there is no data.



se #	Case Type	Health Prof	<u>Outcomes</u>	Mfr Control #	503B Facility Age	<u>Sex</u>	Country
\	√alsartan	N	С	Vaginal	(Dosage Form: Not Specified)		Not Reported
2	Zinc Oxide	N	S	Unknown	(Dosage Form: Not Specified)		Not Reported
	Zeaxanthin	N	S	Unknown	Unk		Not Reported
	Xantofyl Palmitate	N	S	Unknown	Unk		Not Reported
'	Vitamin E Nos	N	S	Unknown	Unk		Not Reported
'	Vitamin D3	N	S	Unknown	Unk		Not Reported
-	Triamcinolone Acetonide	N	S	Intra-articular	(Dosage Form: Suspension Intra-Articular)		Not Reported
,	Sulfamethoxazole;Trimethoprim	N	S	Unknown	(Dosage Form: Not Specified)		Not Reported
	Sinus Rinse	N	S	Unknown	(Dosage Form: Solution Nasal		Not Reported
	Simvastatin	N	S	Unknown	Unk		Not Reported
	Refresh Tears	N	S	Ophthalmic	(Dosage Form: Drops Ophthalmic)		Not Reported
ı	Pulmicort	N	S	Unknown	(Dosage Form: Not Specified)		Not Reported
	Pregabalin	N	S	Unknown	Unk		Not Reported
ſ	Prednisone	N	S	Unknown	(Dosage Form: Not Specified)		Not Reported
ı	Pentasa	N	S	Unknown	(Dosage Form: Not Specified)		Not Reported
I	Pantoprazole	N	S	Unknown	(Dosage Form: Not Specified)		Not Reported
1	Nicotine	N	S	Unknown	(Dosage Form: Not Specified)		Not Reported
	Nicoderm	N	S	Unknown	Unk		Not Reported

FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country

11-Jan-2023 21849449 DIRECT 64 YR Female USA



Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	Duration		Mfr
Drug Ineffective	Refre	sh Solution Nos		N	S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jan-2023	21284458	EXPEDITED (15-DAY)	Y		ОТ	FR-BRISTOL-N SQUIBB COMF 2022-099280		76 YR	Male	FRA
Preferred Term	Produ	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	Duration		<u>Mfr</u>
Mouth Ulceration	Istoda	ax		N	S	Intravenous drip				Not Reported
	Lasilix	([Furosemide]		Ν	S	Oral	One Tablet In The Morning	g		Not Reported
	Hydro	cortisone		N	S	Oral	Two In The Morning			Not Reported
	Januv	ria		N	S	Oral	Once In The Morning			Not Reported
	Vitam	ine B12		N	S	Oral	Two Ampoules Weekly, 1000 Microg / 2 Ml Oral Solution			Not Reported
	Venla	faxine		Ν	S	Oral	Once In The Morning			Not Reported
	Clopic	dogrel		N	S	Oral	Once In The Morning			Not Reported
	Diffu I	<		N	S	Oral	Two Tablets In The Morning, One At Midday			Not Reported
		line oxymethylpenicillin athine]		N	S	Oral	1000000 lu			Not Reported
	Levot	-		N	S	Oral	Once In The Morning			Not Reported
	Atorva	astatine		N	S	Oral	Once In The Evening			Not Reported
	Parac	etamol		Ν	S	Oral	1 G, One Tablet Every 8 H	ł		Not Reported
	Brond	hodual		N	S	Respiratory (inhalation)	50 Microg / 20 Microg Per Dose (Inns: Fenoterol Hydrobromide / Ipratropium Bromide) Two Puffs In The			Not Reported
	Bisop	rolol		N	S	Oral	One Tablet In The Morning	g		Not Reported
	Zyma	d		N	S	Oral	In Ampoules			Not Reported
	Amlor			Ν	S	Oral	Once In The Morning			Not Reported

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		Dexeryl [Glycerol;Paraffin, Liquid;White Soft Paraffin]		N	S		One Daily Application On The Whole Body, 2 Tubes Weekly.	1		Not Reported
		Optive		N	S		Lubricating And Osmoprotective Ocular Solution 1-2 Drops Per Day Depending On Discomfort			Not Reported
		Clarelux		N	С		2 Tubes Weekly: One Weekly Application On The Whole Body, Space Out Applications For Few Days, Even			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Jan-2023	218616	690 EXPEDITED (15-DAY)) N		OT	US-ALLERGAN 2300183US	1 -		Female	USA
Preferred Term		<u>Product</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Allergy To Chemicals;		Refresh Plus		Υ	S	Ophthalmic	4-5 Times Daily			Not Reported
Cataract; Conjunctiviti Cough; Covid-19; Eye		Children'S Chewable Complete Multivitamins		N	С					Not Reported
Contusion; Eye Irritation Incorrect Dose Administered; Ocular Hyperaemia; Photopho		Tums [Calcium Carbonate]		N	С		Unk			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Jan-2023	218735	EXPEDITED (15-DAY)) N		DS	US-ALLERGAN 2300539US	٧-		Male	USA
Preferred Term		<u>Product</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Condition Aggravated; Disability; Expired Pro Administered; Eye Inju Eye Irritation; Gait Inability; Vision Blurred Visual Impairment	duct ıry;	Refresh Optive		Y	S	Ophthalmic	2 Drop Per Eye			Allergan



Date - Time: 11-Apr-2023 10:56:54 AM EST

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Conti	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Jan-2023	21880256	EXPEDITED (15-DAY)	N		ОТ	US-ALLER 2300879U				Female	USA
Preferred Term	Pr	oduct	Comp.	OTO	Role	Route	Dosage	<u> Text</u>	Duration	<u>Mf</u>	<u>r</u>
Cataract; Expired Prod Administered	duct Re	fresh Tears		Υ	S		Unk			N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jan-2023	20213444	EXPEDITED (15-DAY)	N		ОТ	CA-PFIZEF 202101810				Female	CAN
Preferred Term	Pr	oduct	Comp.	OTO	Role	Route	<u>Dosage</u>	<u> Text</u>	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Drug Ineffective; Macu	ular Alp	orazolam Mylan		Ν	S	Unknown	Unk			М	ylan
Degeneration	Pre	egabalin Mylan		N	S	Unknown	Unk			М	ylan
	Ato	orvastatin Calcium		Ν	S	Unknown	Unk			M	ylan
	Pa	ntoprazole		Ν	S	Unknown	Unk			N	ot Reported
	Am	noxicillin Trihydrate		Ν	S	Unknown	Unk			N	ot Reported
	Me	etronidazole		N	S	Unknown	Unk			N	ot Reported
	Az	ithromycin		N	S	Unknown	Unk			N	ot Reported
	So	dium Chloride Bacteriostatic		N	S	Unknown	Unk			N	ot Reported
	Tri	amcinolone Acetonide		N	S	Unknown	Unk			N	ot Reported
	Tri	amcinolone Acetonide		N	S	Intra-arterial	Unk			N	ot Reported
	Mo	orphine Sulfate		Ν	S	Unknown	Unk			N	ot Reported
	Ну	dromorphone Hydrochloride		N	S	Unknown	Unk			N	ot Reported
	Dip	phenhydramine Hcl		Ν	S	Unknown	Unk				ot Reported
		lcium Carbonate		N	S	Unknown	Unk				ot Reported
	Atr	opine Sulfate		N	S	Oral	Unk				ot Reported
	Ad	alimumab		N	S	Subcutaneous	Unk			N	ot Reported
	Me	ezavant		Ν	S	Unknown	Unk			N	ot Reported
	Pe	ntasa		Ν	S	Unknown	Unk			N	ot Reported

Note: If the field is blank, there is no data.



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Acetaminophen	N	S	Unknown	Unk	Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Avamys	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Humira	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Vitamine D3	N	S	Unknown	Unk	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Mupirocin	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
Cetirizine	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Subcutaneous	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Sinus Rinse	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole	N	S	Unknown	Unk	Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Valsartan	N	С	Unknown	Unk	Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jan-2023	20378873	EXPEDITED (15-DAY)	N		ОТ	CA-PFIZER 2022001224				Female	CAN
Preferred Term	Proc	duct	Comp.	OTO	Role	Route	Dosage	e Text	<u>Duration</u>		<u>Mfr</u>
Drug Ineffective; Macu	ılar Alpra	azolam Mylan		N	S	Unknown	Unk				Mylan
Degeneration	Atory	vastatin Calcium		Ν	S	Unknown	Unk				Mylan
	Preg	abalin Mylan		N	S	Unknown	Unk				Mylan
	Pant	oprazole		N	S	Unknown	Unk				Not Reported
	Amo	xicillin Trihydrate		Ν	S	Unknown	Unk				Not Reported
	Metr	onidazole		Ν	S	Unknown	Unk				Not Reported
	Calc	ium Carbonate		Ν	S	Unknown	Unk				Not Reported
	Atrop Hcl	oine Sulfate, Diphenoxylate		N	S	Unknown	Unk				Not Reported
		pine Sulfate, Diphenoxylate		N	S	Oral	Unk				Not Reported
		nromycin		Ν	S	Unknown	Unk				Not Reported
	Morp	ohine Sulfate		Ν	S	Unknown	Unk				Not Reported
	Para	cetamol		Ν	S	Unknown	Unk				Not Reported
	Adal	imumab		Ν	S	Subcutaneous	Unk				Not Reported
	Dilau	udid		Ν	S	Unknown	Unk				Not Reported
	Mesa	alazine		Ν	S	Unknown	Unk				Not Reported
	Pred	Inisone		Ν	S	Unknown	Unk				Not Reported
	Triar Acet	ncinolone Acetonide ate		N	S	Intra-articular	Unk				Not Reported
	Bact			Ν	S	Unknown	Unk				Not Reported
	Beta	methasone Dipropionate		Ν	S	Unknown	Unk				Not Reported
	Beta	methasone Valerate		Ν	S	Unknown	Unk				Not Reported
	Biax	in XI		Ν	S	Unknown	Unk				Not Reported
	Bisa	codyl		Ν	S	Unknown	Unk				Not Reported
	Ergo	calciferol		N	S	Unknown	Unk				Not Reported



	C	Cetirizine	e Hydrochloride		N	S	Unknown	Unk				Not Reported	
	C	Clarithro	mycin		N	S	Unknown	Unk				Not Reported	
	C	Clotrimaz	zole		N	S	Unknown	Unk				Not Reported	
		Desonide)		N	S	Unknown	Unk				Not Reported	
		Diphenhy	dramine Hydrochloride		N	S	Unknown	Unk				Not Reported	
	E	Entocort			N	S	Oral	Unk				Not Reported	
	E	Ertapene	m Sodium		N	S	Unknown	Unk				Not Reported	
	F	Fluticaso	ne Furoate		N	S	Unknown	Unk				Not Reported	
	C	Slycerine)		N	S	Unknown	Unk				Not Reported	
	C	Slycerine)		N	S	Oral	Unk				Not Reported	
	C	Gramicid	in;Neomycin		N	S	Unknown	Unk				Not Reported	
	H	Hydrochl	orothiazide		N	S	Subcutaneous	Unk				Not Reported	
	N	Mupirocii	า		N	S	Topical	Unk				Not Reported	
	N	Nadolol			N	S	Unknown	Unk				Not Reported	
	١	Nicodern	า		N	S	Unknown	Unk				Not Reported	
	N	Vicotine	Polacrilex		N	S	Unknown	Unk				Not Reported	
	F	Pulmicor	t		N	S	Unknown	Unk				Not Reported	
	F	Refresh [*]	Tears		N	S	Ophthalmic	Unk				Not Reported	
	S	Sinus Rir	nse		N	S	Nasal	Unk				Not Reported	
	\	/itamin [03		N	S	Unknown	Unk				Not Reported	
	\	/alsartar	1		N	С	Unknown	Unk				Not Reported	
FDA Received Date	Case #		Case Type	Health	<u>Prof</u>	Outcomes	Mfr Control	<u> 503</u>	BB Facility	<u>Age</u>	<u>Sex</u>	Country	
19-Jan-2023	2188672	1	EXPEDITED (15-DAY)	N		ОТ	CA-PFIZER II 20220092017				Female	CAN	
Preferred Term	E	Product		Comp.	OTC	Role	Route	Dosage Tex	<u>t</u>	<u>Duration</u>		<u>Mfr</u>	
Drug Ineffective; Macu	lar F	Pregabal	in Mylan		N	S	Unknown	Unk				Mylan	
Degeneration	A	Alprazola	am Mylan		N	S	Unknown	Unk				Mylan	
	A	Atorvasta	atin Calcium		N	S	Unknown	Unk				Mylan	



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Pantoprazole	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Intra-articular	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
Azithromycin	N	S	Unknown	Unk	Not Reported
Paracetamol	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Diphenhydramine Hcl	N	S	Unknown	Unk	Not Reported
Atropine Sulfate	N	S	Oral	Unk	Not Reported
Adalimumab	N	S	Subcutaneous	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Avamys	N	S	Unknown	Unk	Not Reported
Sinus Rinse	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Entocort	N	S	Unknown	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Entocort	N	S	Unknown		Not Repo



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Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Flovent	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Pms Azithromycin	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Bactrim	N	S	Unknown	Unk	Not Reported
Dilaudid	N	S	Unknown	Unk	Not Reported
Humira	N	S	Unknown	Unk	Not Reported
Dulcolax [Bisacodyl]	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Vitamin E Nos	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Mezavant	N	S	Unknown	Unk	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Gramicidin; Neomycin Sulfate;	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate Diphenoxylate Hydrochloride And Atropine Sulfate	N	S	Unknown	Unk	Not Reported



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Calcium Carbonate;

Colecalciferol Acetylsalicylic Acid

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Unknown

Unknown

Unk

Unk

Not Reported

Not Reported

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		Ambrox	ol Hydrochloride		Ν	S	Unknown	Unk				Not Reported
		Calcium	Gluconate		Ν	S	Unknown	Unk				Not Reported
		Cupric C	Oxide		N	S	Unknown	Unk				Not Reported
		Fructose)		N	S	Unknown	Unk				Not Reported
		Magnes	ium Sulfate		N	S	Unknown	Unk				Not Reported
		Polyethy	lene Glycol 4000		Ν	S	Unknown	Unk				Not Reported
		Trimetho	pprim		Ν	S	Unknown	Unk				Not Reported
		Atropine Hydroch	Sulfate;Difenoxin loride		N	S	Unknown	Unk				Not Reported
		Calcium	Citrate		N	S	Unknown	Unk				Not Reported
			olone Acetonide; in Sulfate;Polymyxin B		N	S	Unknown	Unk				Not Reported
			mol;Zinc Oxide		Ν	S	Unknown	Unk				Not Reported
			bl;Potassium Chloride;		Ν	S	Unknown	Unk				Not Reported
			Bicarbonate Carboxymethylcellulose		N	S	Unknown	Unk				Not Reported
		Valsarta	n		Ν	С	Vaginal	Unk				Not Reported
FDA Received Date	Case #		Case Type	Health	<u>Prof</u>	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jan-2023	218867	'94	EXPEDITED (15-DAY)	N		HO, OT	US-ALLEI 2300805L				Male	USA
Preferred Term		Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosa	ge Text	Duration		<u>Mfr</u>
Amnesia; Disease		Refresh	Relieva Pf		Υ	S	Ophthalmic					Allergan
Recurrence; Eye Discharge; Transient		Refresh	Optive		Ν	S	Ophthalmic	1 Dı	op Each Eye			Allergan
Ischaemic Attack; Visional Blurred	on	Refresh Metform			N N	S C						Allergan Not Reported
FDA Received Date	Case #		Case Type	Health	Prof	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
19-Jan-2023	218868	805	EXPEDITED (15-DAY)	N		ОТ	US-ALLEI 2300675L				Female	USA

Note: If the field is blank, there is no data.

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Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosage Text	Duration		<u>Mfr</u>
Cataract; Swelling Of Eyelid	Refre	sh Liquigel Ophthalmic		Υ	S	Ophthalmic	Unk			Allergan
FDA Received Date	Case #	Case Type	Health	Prof C	<u> Dutcomes</u>	Mfr Contr	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jan-2023	21314309	EXPEDITED (15-DAY)	Υ	(T	NVSC2022	FR200301	76 YR	Male	FRA
Preferred Term	Prod	<u>uct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Mouth Ulceration	Atorva	astatin		N	S	Oral	40 Mg, Qd			Novartis
	Furos	semide		N	S	Oral	40 Mg, Qd			Not Reported
	Parac	cetamol		N	S	Oral	1 Dosage Form, Prn			Novartis
	Bisop	rolol Fumarate		N	S	Oral	5 Mg, Qd			Novartis
	Venla	faxine		Ν	S	Oral	75 Mg, Qd			Not Reported
	Amloo	dipine		N	S	Oral	5 Mg, Qd			Novartis
	Vit B1	12		N	S	Oral	2 Dosage Form, Qw			Not Reported
	Diffu I	K		N	S	Oral	1800 Mg, Qd (Two Table In The Morning, One At Midday)	ts		Not Reported
	Hydro	ocortisone		N	S	Oral	20 Mg, Qd (Two In The Morning)			Not Reported
	Levot	hyrox		N	S	Oral	Once In The Morning			Not Reported
	Oracil	lline		N	S	Oral	2 Dosage Form, Qd (Strength: 1 000 000 U.I. /10 MI)			Not Reported
	Brond	chodual		N	S		50 Microg / 20 Microg Pe Dose (Inns: Fenoterol Hydrobromide / Ipratropium Bromide) Two Puffs In The			Not Reported
	Januv	<i>v</i> ia		N	S	Oral	1000 Mg, Qd			Not Reported
	Januv	<i>i</i> ia		N	S	Oral	100 Mg, Qd (Once In The Morning)	e		Not Reported
	Istoda	ax		Ν	S	Intravenous (not	53.1 Mg, Qmo			Not Reported

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Note: If the field is blank, there is no data.



						otherwise specified)				
	Zymad			N	S	Oral	1 Dosage Form, Qmo (Strength: 50 000 Ui)		Not	Reported
	Clopido	grel		Ν	S	Oral	75 Mg, Qd		Not	Reported
	Clopido	grel		N	S	Oral	75 Mg, Qd (Once In The Morning)		Not	Reported
	Atorvas	tatine		N	S	Oral	40 Mg, Qd (Once In The Evening)		Not	Reported
	Optive			N	S	Unknown	Unk (Lubricating And Osmoprotective Ocular Solution 1-2 Drops Per Day Depending On Discomfort)		Not	Reported
	Bisopro	lol		N	S	Oral	5 Mg, Qd (One Tablet In The Morning)		Not	Reported
	Amlor			N	S	Oral	5 Mg, Qd (Once In The Morning)		Not	Reported
	Vitamin	B12		N	S	Oral	2 Dosage Form, Qw (Two Ampoules Weekly, 1000 Microg / 2 Ml Oral Solution)		Not	Reported
	Lasilix			N	S	Oral	40 Mg, Qd (One Tablet In The Morning)		Not	Reported
	Glycerir	\Mineral Oil\Petrolatum		N	S	Unknown	One Daily Application On The Whole Body, 2 Tubes Weekly.		Not	Reported
	Clarelux	(N	С	Unknown	2 Tubes Weekly: One Weekly Application On The Whole Body, Space Out Applications For Few Days, Even		Not	Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jan-2023	21890963	EXPEDITED (15-DAY)	Y		ОТ	CA-009507513- 2301CAN00685			Female	CAN
Preferred Term	Produc	<u>t</u>	Comp.	OTO	<u>Role</u>	Route	<u>Dosage Text</u>	Duration	Mfr	

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Drug Ineffective; Macular Degeneration

Invanz	N	S	Unknown	Unk	Merck
Simvastatin	N	S	Unknown	Unk	Merck
Acetaminophene	N	S	Unknown		Not Reported
Adalimumab	N	S	Subcutaneous	Unk	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Ambroxol Hydrochloride	N	S	Unknown	Unk	Not Reported
Amoxicillin Trihydrate	N	S	Unknown		Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown		Not Reported
Atorvastatin Calcium	N	S	Unknown		Not Reported
Atropine	N	S	Oral		Not Reported
Avamys	N	S	Unknown		Not Reported
Azithromycin	N	S	Oral		Not Reported
Azithromycin Dihydrate	N	S	Unknown		Not Reported
Azithromycin Dihydrate	N	S	Oral	Unk	Not Reported
Bactrim	N	S	Unknown		Not Reported
Betamethasone	N	S			Not Reported
Betamethasone Valerate	N	S	Unknown		Not Reported
Biaxin XI	N	S	Unknown		Not Reported
Bisacodyl	N	S	Unknown		Not Reported
Budesonide	N	S	Unknown		Not Reported
Calcium Carbonate	N	S	Unknown		Not Reported
Calcium Gluconate	N	S	Unknown		Not Reported
Calcium Gluconate	N	S	Unknown		Not Reported
Cetirizine	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown		Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
Cupric Oxide;Folic Acid;Nicotinic Acid;Zinc Oxide	N	S	Unknown	Unk	Not Reported



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D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Dilaudid	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown	Unk	Not Reported
DI-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
Entocort	N	S	Unknown	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Flovent	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Fructose;Glycerol;Sodium Chloride	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Humira	N	S	Subcutaneous	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Kenalog [Triamcinolone Acetonide]	N	S	Intra-articular	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk	Not Reported
Loperamide Hydrochloride; Simeticone	N	S	Oral	Unk	Not Reported
Macrogol 3350;Potassium; Sodium Bicarbonate;Sodium Chloride	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Metronidazole Hydrochloride	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Ms Ir	N	S	Unknown	Unk	Not Reported
Mupirocin Calcium Hydrate	N	S	Unknown		Not Reported



Mupirocin Calcium Hydrate	N	S	Unknown	Unk	Not Reported
Mupirocin Calcium Hydrate	N	S	Topical	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Salinex Seawater	N	S	Endosinusial	Unk	Not Reported
Sinus Rinse	N	S	Endosinusial	Unk	Not Reported
Sodium Carboxymethyl Starch	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethyl Starch	N	S	Ophthalmic	Unk	Not Reported
Sodium Chloride	N	S	Endosinusial	Unk	Not Reported
Sodium Stearate	N	S	Oral	Unk	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	Unk	Not Reported
Triamcinolone	N	S	Intra-articular	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported
Valsartan	N	S	Intracardiac	Unk	Not Reported
Valsartan	N	S	Unknown	Unk	Not Reported
Vitamin-C	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Zinc Chloride	N	S	Unknown	Unk	Not Reported



							- 0 ta	a itopoit				
		Zinc Oxide			N	S	Unknown	Unk				ot Reported
		Calcium			N	С	Unknown				N	ot Reported
FDA Received Date	Case #	<u>Case T</u>	<u>ype</u>	<u>Health</u>	Prof	Outcomes	Mfr C	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Jan-2023	21897	598 DIREC	Γ								Unknown	USA
Preferred Term		<u>Product</u>		Comp.	OTC	Role	Route	<u>Dosag</u>	<u>e Text</u>	<u>Duration</u>	Mf	<u>ir</u>
Drug Ineffective		Refresh Eye Dro	ps		N	S					N	ot Reported
FDA Received Date	Case #	<u>Case T</u>	<u>ype</u>	Health	Prof	Outcomes	Mfr C	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jan-2023	16797	741 EXPED	ITED (15-DAY)	N		HO, OT	CA-TE 110479	VA-2019-CA- 90			Female	CAN
Preferred Term		<u>Product</u>		Comp.	OTC	Role	Route	Dosage	e Text	Duration	<u>Mf</u>	<u>ir</u>
Chronic Sinusitis; Drug		Azithromycin			N	S	Unknown				N	ot Reported
neffective; Dyspepsia; nfusion Related Reaction		Azithromycin			Ν	S	Unknown				N	ot Reported
Macular Degeneration;		Azithromycin			Ν	S	Unknown				N	ot Reported
Malaise; Nausea; Off Label Use; Pain;		Azithromycin			Ν	S	Unknown				N	ot Reported
Paraesthesia Oral;		Acetaminophen			Ν	S	Unknown				N	ot Reported
Procedural Pain; Pyrex		Acetaminophen			Ν	S	Unknown				N	ot Reported
Therapeutic Product Et Incomplete; Weight	пест	Acetaminophen			Ν	S	Unknown				N	ot Reported
Decreased		Acetaminophen			Ν	S	Unknown				N	ot Reported
		Acetaminophen			Ν	S	Unknown				N	ot Reported
		Acetaminophen			Ν	S	Unknown				N	ot Reported
		Alprazolam			Ν	S	Unknown				A	ctavis
		Alprazolam			Ν	S	Unknown				A	ctavis
		Alprazolam			Ν	S	Unknown				A	ctavis
		Alprazolam			N	S	Unknown				A	ctavis
		Amoxicillin Trihyo	drate		N	S	Unknown				Te	eva
		Atorvastatin Calo	ium		N	S	Unknown				Te	eva
		Atorvastatin Calo	ium		Ν	S	Unknown				Te	eva

Date - Time: 11-Apr-2023 10:56:54 AM EST Note: If the field is blank, there is no data.

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Budesonide	N	S	Unknown	Ivax
Azithromycin Dihydrate	N	S	Unknown	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Actavis
Betamethasone Dipropionate	N	S	Unknown	Actavis
Clarithromycin	N	S	Unknown	Actavis
Clarithromycin	N	S	Unknown	Actavis
Calcium	N	S	Unknown	Not Reported
Carbonate/Ergocalciferol Calcium Carbonate/Ergocalciferol	N	S	Unknown	Not Reported
Calcium	N	S	Unknown	Not Reported
Carbonate/Ergocalciferol Calcium Carbonate/Ergocalciferol	N	S	Unknown	Not Reported
Mesalazine	N	S	Unknown	Teva
Mesalazine	N	S	Unknown	Teva
Diphenhydramine Hydrochloride	N	S	Unknown	Not Reported
Nicotine	N	S	Unknown	Not Reported
Nicotine	N	S	Unknown	Not Reported
Morphine Sulfate	N	S	Unknown	Actavis
Morphine Sulfate	N	S	Unknown	Actavis
Morphine Sulfate	N	S	Unknown	Actavis
Metronidazole	N	S	Unknown	Actavis
Metronidazole	N	S	Unknown	Actavis
Hydrochlorothiazide	N	S	Unknown	Ivax
Hydrochlorothiazide	N	S	Unknown	Ivax
Hydrochlorothiazide	N	S	Unknown	Ivax
Hydrochlorothiazide	N	S	Unknown	Ivax
Hydrochlorothiazide	N	S	Endocervical	Ivax
Valsartan	N	S	Unknown	Actavis
Fluticasone Propionate	N	S	Unknown	Teva
Nicotine Polacrilex	N	S	Unknown	Not Reported



Acetylsalicylic Acid	N	S	Unknown	Not Reported
Pantoprazole	N	S	Unknown	Teva
Calcium Carbonate	N	S	Unknown	Not Reported
Calcium Carbonate	N	S	Unknown	Not Reported
Calcium Carbonate	N	S	Unknown	Not Reported
Calcium Carbonate	N	S	Unknown	Not Reported
Calcium Carbonate	N	S	Unknown	Not Reported
Calcium Carbonate	N	S	Unknown	Not Reported
Calcium Carbonate	N	S	Unknown	Not Reported
Betamethasone Valerate	N	S	Unknown	Actavis
Betamethasone Valerate	N	S	Unknown	Actavis
Betamethasone Valerate	N	S	Unknown	Actavis
Betamethasone Valerate	N	S	Unknown	Actavis
Betamethasone Valerate	N	S	Unknown	Actavis
Betamethasone Valerate	N	S	Unknown	Actavis
Betamethasone Valerate	N	S	Unknown	Actavis
Nicotine	N	S	Unknown	Not Reported
Nicotine	N	S	Unknown	Not Reported
Atorvastatin Calcium	N	S	Unknown	Teva
Atorvastatin Calcium	N	S	Unknown	Teva
Magnesium Sulfate	N	S	Unknown	Not Reported
Prednisone	N	S	Unknown	Actavis
Prednisone	N	S	Unknown	Actavis
Prednisone	N	S	Unknown	Actavis
Prednisone	N	S	Unknown	Actavis
Prednisone	N	S	Unknown	Actavis
Prednisone	N	S	Unknown	Actavis
Pregabalin	N	S	Unknown	Teva
Pregabalin	N	S	Unknown	Teva



Pregabalin	N	S	Unknown		Teva
Pregabalin	N	S	Unknown		Teva
Pregabalin	N	S	Unknown		Teva
Pregabalin	N	S	Unknown		Teva
Pregabalin	N	S	Unknown		Teva
Pregabalin	N	S	Unknown		Teva
Loperamide Hydrochloride	N	S	Oral	4 Dosage Forms Daily;	Not Reported
Loperamide Hydrochloride	N	S	Oral	4 Dosage Forms Daily;	Not Reported
Loperamide Hydrochloride	N	S	Oral		Not Reported
Zinc Oxide	N	S	Unknown		Teva
Sodium Chloride	N	S	Unknown		Not Reported
Hydromorphone Hydrochloride	N	S	Unknown		Actavis
Hydromorphone Hydrochloride	N	S	Unknown		Actavis
Hydromorphone Hydrochloride	N	S	Unknown		Actavis
Sulfamethoxazole	N	S	Unknown		Teva
W/Trimethoprim Sulfamethoxazole	N	S	Unknown		Teva
W/Trimethoprim			UNKNOWN		
Sulfamethoxazole W/Trimethoprim	N	S	Unknown		Teva
Sulfamethoxazole	N	S	Unknown		Teva
W/Trimethoprim	N.I.				Teva
Sulfamethoxazole W/Trimethoprim	N	S	Unknown		reva
Sulfamethoxazole	N	S	Unknown		Teva
W/Trimethoprim Sulfamethoxazole	N	S	Unknown		Teva
W/Trimethoprim			OTIKITOWIT		
Sulfamethoxazole W/Trimethoprim	N	S	Unknown		Teva
Fluticasone Furoate	N	S	Unknown		Teva
Calcium Carbonate/Vitamin D3	N	S	Unknown		Not Reported
Valsartan	N	S	Unknown		Actavis
Valsartan	N	S	Intracardiac		Actavis



Pantoprazole Sodium Anhydrous N S Unknown Teva Glycerine N S Unknown Not Reported Sodium Chloride N S Unknown Tova Clotrimazole N S Unknown Ivax Simvastatin N S Unknown Ivax Simvastatin N S Unknown Tova Apo-Hydrochlorothiazide N S Unknown Not Reported Apo-Hydrochlorothiazide N S Endocervical Not Reported Ayamys N S Unknown Not Reported Avamys N S Unknown Not Reported Bactroban N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Calcium Carbonate/Nagnesium N					•	
Sodium Chloride N S Unknown Not Reported Clotrimazole N S Unknown Teva Simvastatin N S Unknown Ivax Simvastatin N S Unknown Ivax Simvastatin N S Unknown Ivax Mesalamine N S Unknown Not Reported Apo-Hydrochlorothiazide N S Unknown Not Reported Apo-Hydrochlorothiazide N S Endocervical Not Reported Ayamys N S Unknown Not Reported Avamys N S Unknown Not Reported Bactoban N S Unknown Not Reported Bactoban N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Galcium Carbonate/Magnesium N S <td>F</td> <td>Pantoprazole Sodium Anhydrous</td> <td>N</td> <td>S</td> <td>Unknown</td> <td>Teva</td>	F	Pantoprazole Sodium Anhydrous	N	S	Unknown	Teva
Clotrimazole	C	Glycerine	N	S	Unknown	Not Reported
Simvastatin N S Unknown Ivax Simvastatin N S Unknown Ivax Simvastatin N S Unknown Ivax Mesalamine N S Unknown Teva Apo-Hydrochlorothiazide N S Endocervical Not Reported Apo-Hydrochlorothiazide N S Endocervical Not Reported Avamys N S Unknown Not Reported Avamys N S Unknown Not Reported Bactroban N S Unknown Not Reported Betaderm N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Calcium Carbonate/Magnesium N S Unknown Not Reported Cetirizine N S	5	Sodium Chloride	N	S	Unknown	Not Reported
Simvastatin N S Unknown Ivax Simvastatin N S Unknown Ivax Mesalamine N S Unknown Teva Apo-Hydrochlorothiazide N S Unknown Not Reported Apo-Hydrochlorothiazide N S Endocervical Not Reported Apo-Hydrochlorothiazide N S Endocervical Not Reported Avamys N S Unknown Not Reported Avamys N S Unknown Not Reported Bactroban N S Unknown Not Reported Betaderm N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Calcium Carbonate/Magnesium N S Unknown Not Reported Sulfate/Vitamin D3 N S Unknown Not Reported Calcium Carbonate/Vitamin D3 N S Unknown Not Reported Celtrizine N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cottrizine N S Unknown Not Reported	C	Clotrimazole	N	S	Unknown	Teva
Simvastatin N S Unknown Teva Mesalamine N S Unknown Teva Apo-Hydrochlorothiazide N S Unknown Not Reported Apo-Hydrochlorothiazide N S Endocervical Not Reported Apo-Hydrochlorothiazide N S Endocervical Not Reported Apo-Hydrochlorothiazide N S Endocervical Not Reported Apo-Hydrochlorothiazide N S Unknown Not Reported Avamys N S Unknown Not Reported Avamys N S Unknown Not Reported Bactroban N S Unknown Not Reported Betaderm N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Calcium Carbonate/Magnesium N S Unknown Not Reported Calcium Carbonate/Vitamin D3 Calcium Carbonate/Vitamin D3 N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cupric Oxide/DI-Alpha N S Unknown Not Reported Cupric Oxide/DI-Alpha N S Unknown Not Reported Tocopheryl Acetate/Vitamin C / Xantofyl Palmitat Desonide N S Unknown Not Reported Dilaudid N S Unknown Not Reported Entocort N S Oral Not Reported	5	Simvastatin	N	S	Unknown	Ivax
Mesalamine N S Unknown Teva Apo-Hydrochlorothiazide N S Unknown Not Reported Apo-Hydrochlorothiazide N S Endocervical Not Reported Apo-Hydrochlorothiazide N S Endocervical Not Reported Apo-Hydrochlorothiazide N S Endocervical Not Reported Avamys N S Unknown Not Reported Avamys N S Unknown Not Reported Avamys N S Unknown Not Reported Bactroban N S Unknown Not Reported Betaderm N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Calcium Carbonate/Magnesium N S Unknown Not Reported Calcium Carbonate/Magnesium N S Unknown Not Reported Calcium Carbonate/Vitamin D3 N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cutrico Cxide/DI-Alpha N S Unknown Not Reported Cupric Oxide/DI-Alpha N S Unknown Not Reported Cupric Oxide/DI-Alpha N S Unknown Not Reported Dilaudid N S Unknown Not Reported Dilaudid N S Unknown Not Reported Entocort N S Unknown Not Reported Dilaudid N S Unknown Not Reported Entocort N S Unknown Not Reported Entocort N S Unknown Not Reported Dilaudid N S Unknown Not Reported Entocort N S Oral	5	Simvastatin	N	S	Unknown	Ivax
Apo-Hydrochlorothiazide N S Unknown Not Reported Apo-Hydrochlorothiazide N S Endocervical Not Reported Avamys N S Unknown Not Reported Avamys N S Unknown Not Reported Bactroban N S Unknown Not Reported Betaderm N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Calcium Carbonate/Magnesium N S Unknown Not Reported Calcium Carbonate/Magnesium N S Unknown Not Reported Calcium Carbonate/Vitamin D3 N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cotirimazole N S Unknown Not Reported	5	Simvastatin	N	S	Unknown	Ivax
Apo-Hydrochlorothiazide N S Endocervical Not Reported Apo-Hydrochlorothiazide N S Endocervical Not Reported Avamys N S Unknown Not Reported Avamys N S Unknown Not Reported Bactroban N S Unknown Not Reported Betaderm N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Calcium Carbonate/Magnesium N S Unknown Not Reported Sulfate/Vitamin D3 Calcium Carbonate/Vitamin D3 N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cetirizine N S Unknown Not Reported Clotrimazole N S Unknown Not Reported Cupric Oxide/DI-Alpha N S Unknown Not Reported Cupric Oxide/DI-Alpha N S Unknown Not Reported Dilaudid N S Unknown Not Reported Entocort N S Unknown Not Reported Cetirizaline N S Unknown Not Reported Cupric Oxide/DI-Alpha N S Unknown Not Reported Dilaudid N S Unknown Not Reported Cetirizaline N S Unknown Not Reported Cupric Oxide/DI-Alpha N S Unknown Not Reported	Ν	Mesalamine	N	S	Unknown	Teva
Apo-Hydrochlorothiazide N S Endocervical Not Reported Avamys N S Unknown Not Reported Avamys N S Unknown Not Reported Bactroban N S Unknown Not Reported Betaderm N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Calcium Carbonate/Magnesium Sulfate/Vitamin D3 N S Unknown Not Reported Calcium Carbonate/Magnesium Sulfate/Vitamin D3 N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cetirizine N S Unknown Not Reported Clotrimazole N S Unknown Not Reported Cupric Oxide/DI-Alpha N S Unknown Not Reported <	A	Apo-Hydrochlorothiazide	N	S	Unknown	Not Reported
Avamys N S Unknown Not Reported Avamys N S Unknown Not Reported Bactroban N S Unknown Not Reported Betaderm N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Calcium Carbonate/Magnesium N S Unknown Not Reported Calcium Carbonate/Magnesium N S Unknown Not Reported Calcium Carbonate/Vitamin D3 N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cottrianacole N S Unknown Not Reported Cottrianacole N S Unknown Not Reported Cupric Oxide/DI-Alpha Not Reported Cupric Oxide/DI-Alpha Not Reported Tocopheryl Acetate/Vitamin C / Xantofyl Palmitat Desonide N S Unknown Not Reported Dilaudid N S Unknown Not Reported Entocort N S Oral Not Reported	A	Apo-Hydrochlorothiazide	N	S	Endocervical	Not Reported
Avamys N S Unknown Not Reported Bactroban N S Unknown Not Reported Betaderm N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Calcium Carbonate/Magnesium N S Unknown Not Reported Sulfate/Vitamin D3 N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cotrimazole N S Unknown Not Reported Cupric Oxide/DI-Alpha N S Unknown Not Reported Dilaudid N S Unknown Not Reported Dilaudid N S Unknown Not Reported Entocort N S Oral	A	Apo-Hydrochlorothiazide	N	S	Endocervical	Not Reported
Bactroban N S Unknown Not Reported Betaderm N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Calcium Carbonate/Magnesium N S Unknown Not Reported Calcium Carbonate/Magnesium N S Unknown Not Reported Calcium Carbonate/Vitamin D3 N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cetirizine N S Unknown Not Reported Clotrimazole N S Unknown Not Reported Clotrimazole N S Unknown Not Reported Cupric Oxide/DI-Alpha N S Unknown Not Reported Cupric Oxide/DI-Alpha N S Unknown Not Reported Dilaudid N S Unknown Not Reported Dilaudid N S Unknown Not Reported Entocort N S Oral Not Reported	A	Avamys	N	S	Unknown	Not Reported
Betaderm N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Calcium Carbonate/Magnesium N S Unknown Not Reported Calcium Carbonate/Magnesium N S Unknown Not Reported Calcium Carbonate/Vitamin D3 Calcium Carbonate/Vitamin D3 N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cetirizine N S Unknown Not Reported Clotrimazole N S Unknown Not Reported Clotrimazole N S Unknown Not Reported Cupric Oxide/DI-Alpha N S Unknown Not Reported Tocopheryl Acetate/Vitamin C / Xantofyl Palmitat Desonide N S Unknown Not Reported Dilaudid N S Unknown Not Reported Entocort N S Oral	A	Avamys	N	S	Unknown	Not Reported
Biaxin XI Biaxin XI N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Biaxin XI N S Unknown Not Reported Calcium Carbonate/Magnesium Sulfate/Vitamin D3 Calcium Carbonate/Vitamin D3 N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cetirizine N S Unknown Not Reported Coupric Oxide/DI-Alpha N S Unknown Not Reported Cupric Oxide/DI-Alpha N S Unknown Not Reported Cupric Oxide/DI-Alpha N S Unknown Not Reported Cupric Oxide/DI-Alpha N S Unknown Not Reported Diaudid N S Unknown Not Reported Not Reported Not Reported Diaudid N S Unknown Not Reported Not Reported Not Reported Not Reported	Е	Bactroban	N	S	Unknown	Not Reported
Biaxin XI Biaxin XI N S Unknown Not Reported Not Reported Calcium Carbonate/Magnesium Sulfate/Vitamin D3 Calcium Carbonate/Vitamin D3 Calcium Carbonate/Vitamin D3 N S Unknown Not Reported Not Reported Cetrizine N S Unknown Not Reported Cetrizine N S Unknown Not Reported Cetrizine N S Unknown Not Reported Clotrimazole Clotrimazole Cupric Oxide/DI-Alpha N S Unknown Not Reported Cupric Oxide/DI-Alpha N S Unknown Not Reported Cupric Oxide/DI-Alpha N S Unknown Not Reported Diaudid N S Unknown Not Reported	Е	Betaderm	N	S	Unknown	Not Reported
Biaxin XI N S Unknown Calcium Carbonate/Magnesium Sulfate/Vitamin D3 Calcium Carbonate/Vitamin D3 N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cetirizine N S Unknown Not Reported Clotrimazole Clotrimazole Cupric Oxide/DI-Alpha Tocopheryl Acetate/Vitamin C / Xantofyl Palmitat Desonide N S Unknown Not Reported	Е	Biaxin XI	N	S	Unknown	Not Reported
Calcium Carbonate/Magnesium Sulfate/Vitamin D3 N S Unknown Not Reported Sulfate/Vitamin D3 N S Unknown Not Reported Calcium Carbonate/Vitamin D3 N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cetirizine N S Unknown Not Reported Clotrimazole N S Unknown Not Reported Cupric Oxide/DI-Alpha N S Unknown Not Reported Cupric Oxide/DI-Alpha N S Unknown Not Reported Tocopheryl Acetate/Vitamin C / Xantofyl Palmitat Desonide N S Unknown Not Reported Dilaudid N S Unknown Not Reported Cupric Oxide/DI-Alpha N S Unknown Not Reported	Е	Biaxin XI	N	S	Unknown	Not Reported
Sulfate/Vitamin D3 Calcium Carbonate/Vitamin D3 N S Unknown Not Reported Cetirizine N S Unknown Not Reported Cetirizine N S Unknown Not Reported Clotrimazole Cupric Oxide/DI-Alpha Tocopheryl Acetate/Vitamin C / Xantofyl Palmitat Desonide N S Unknown Not Reported Vitamin C / Vantofyl Palmitat Desonide N S Unknown Not Reported N N S Unknown Not Reported	Е	Biaxin XI	N	S	Unknown	Not Reported
Calcium Carbonate/Vitamin D3 N S Unknown Cetirizine N S Unknown Cetirizine N S Unknown Cotrimazole N S Unknown Cupric Oxide/DI-Alpha Tocopheryl Acetate/Vitamin C / Xantofyl Palmitat Desonide N S Unknown Not Reported		Calcium Carbonate/Magnesium	N	S	Unknown	Not Reported
Cetirizine N S Unknown Not Reported Cetirizine N S Unknown Not Reported Clotrimazole N S Unknown Not Reported Cupric Oxide/DI-Alpha N S Unknown Cupric Oxide/DI-Alpha Not Reported Tocopheryl Acetate/Vitamin C / Xantofyl Palmitat Desonide N S Unknown Not Reported Dilaudid N S Unknown Not Reported Entocort N S Oral			N	S	Unknown	Not Reported
Cetirizine N S Unknown Not Reported Clotrimazole N S Unknown Not Reported Cupric Oxide/DI-Alpha N S Unknown Not Reported Tocopheryl Acetate/Vitamin C / Xantofyl Palmitat Desonide N S Unknown Not Reported Dilaudid N S Unknown Not Reported Entocort N S Oral	C	Cetirizine	N	S		Not Reported
Cupric Oxide/DI-Alpha N S Unknown Not Reported Tocopheryl Acetate/Vitamin C / Xantofyl Palmitat Desonide N S Unknown Not Reported Dilaudid N S Unknown Not Reported Entocort N S Oral Not Reported	C	Cetirizine	N	S		Not Reported
Tocopheryl Acetate/Vitamin C / Xantofyl Palmitat Desonide N S Unknown Dilaudid N S Unknown Entocort N S Oral Not Reported Not Reported	C	Clotrimazole	N	S	Unknown	Not Reported
Desonide N S Unknown Not Reported Dilaudid N S Unknown Not Reported Entocort N S Oral Not Reported	Т	ocopheryl Acetate/Vitamin C /	N	S		Not Reported
Dilaudid N S Unknown Not Reported Entocort N S Oral Not Reported			N	S	Unknown	Not Reported
Entocort N S Oral Not Reported	Ε	Dilaudid	N	S		Not Reported
	Е	Entocort	N	S		Not Reported
	E	Entocort	N	S	Unknown	Not Reported



			•		
Entocort	N	S	Unknown		Not Reported
Entocort	N	S	Unknown		Not Reported
Ertapenem For Injection	N	S	Unknown		Not Reported
Ertapenem For Injection	N	S	Unknown		Not Reported
Flovent	N	S	Unknown		Not Reported
Flovent	N	S	Unknown		Not Reported
Flovent	N	S	Oral		Not Reported
Glycerine	N	S	Unknown		Not Reported
Glycerine	N	S	Oral		Not Reported
Glycerine	N	S	Unknown		Not Reported
Gramicidin/Neomycin Sulfate/Polymyxin B Sulfate	N	S	Unknown		Not Reported
Habitrol	N	S	Unknown		Not Reported
Humira	N	S	Subcutaneous	6 YR	Not Reported
Humira	N	S	Subcutaneous	6 YR	Not Reported
Humira	N	S	Subcutaneous	6 YR	Not Reported
Kenalog	N	S	Unknown		Not Reported
Lomotil	N	S	Oral		Not Reported
Lomotil	N	S	Oral		Not Reported
Macrogol 3350/Potassium Chloride/Sodium Bicarbonate/Sodium Chloride/So	N	S	Unknown		Not Reported
Ms Ir	N	S	Unknown		Not Reported
Mupirocin	N	S	Topical		Not Reported
Mupirocin	N	S	Unknown		Not Reported
Mupirocin	N	S	Topical		Not Reported
Mupirocin	N	S	Unknown		Not Reported
Nicoderm	N	S	Unknown		Not Reported
Nicoderm	N	S	Unknown		Not Reported
Nicoderm	N	S	Unknown		Not Reported
Nicoderm	N	S	Unknown		Not Reported



			<u> </u>	
Pentasa	N	S	Unknown	Not Reported
Pulmicort	N	S	Unknown	Not Reported
Pulmicort	N	S	Respiratory (inhalation)	Not Reported
Refresh Tears	N	S	Ophthalmic	Not Reported
Refresh Tears	N	S	Ophthalmic	Not Reported
Refresh Tears	N	S	Unknown	Not Reported
Sodium Chloride	N	S	Unknown	Not Reported
Sinus Rinse	N	S	Other	Not Reported
Statex	N	S	Unknown	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Not Reported
Vitamin D3	N	S	Unknown	Not Reported
Vitamin D3	N	S	Unknown	Not Reported
Vitamin D3	N	S	Unknown	Not Reported
Multivitamine (S)	N	S	Unknown	Not Reported
Apo Hydro	N	S	Unknown	Not Reported
Apo Hydro	N	S	Unknown	Not Reported
Atropine/Difenoxin Hydrochloride	N	S	Unknown	Not Reported
Avamys	N	S	Unknown	Not Reported
Avamys	N	S	Unknown	Not Reported
Bactrim	N	S	Unknown	Not Reported
Bisacodyl	N	S	Unknown	Not Reported
Kenalog	N	S	Intra-articular	Not Reported
Metronidazole	N	S	Unknown	Not Reported



			-	
Nadolol	N	S	Unknown	Not Reported
Nadolol	N	S	Unknown	Not Reported
Nadolol	N	S	Unknown	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Not Reported
Ergocalciferol	N	S	Unknown	Not Reported
Ertapenem Sodium	N	S	Unknown	Not Reported
Apo Amoxi	N	S	Unknown	Not Reported
Adalimumab	N	S	Subcutaneous	Not Reported
Adalimumab	N	S	Subcutaneous	Not Reported
Sodium Chloride	N	S	Nasal	Not Reported
Sodium Chloride	N	S	Unknown	Not Reported
Sodium Chloride	N	S	Other	Not Reported
Sodium Carboxymethyl Cellulose	N	S	Ophthalmic	Not Reported
Bisacodyl	N	S	Unknown	Not Reported
Nadolol	N	S	Unknown	Not Reported
Acetaminophen/Pseudoephedrin e	N	S	Unknown	Not Reported
Cupric Oxide	N	S	Unknown	Not Reported
D-Alpha Tocopheryl Acetate	N	S	Unknown	Not Reported
Vitamin E	N	S	Unknown	Not Reported
Zeaxanthin	N	S	Unknown	Not Reported
Xantofyl Palmitate	N	S	Unknown	Not Reported
Atropine/Diphenoxylate Hydrochloride	N	S	Oral	Not Reported
Atropine/Diphenoxylate Hydrochloride	N	S	Unknown	Not Reported
Atropine/Diphenoxylate Hydrochloride	N	S	Oral	Not Reported
Gramicidin And Polymyxin B	N	S	Unknown	Not Reported



Vitamins Nos	N	S	Unknown	Not Reported
Mezavant Also Known As Mesalamine	N	S	Unknown	Not Reported
Gramicidin	N	S	Unknown	Not Reported
Gramicidin	N	S	Unknown	Not Reported
Pms-Azithromycin	N	S	Unknown	Not Reported
Budesonide	N	S	Oral	Not Reported
Budesonide	N	S	Cutaneous	Not Reported
Budesonide	N	S	Subcutaneous	Not Reported
Budesonide	N	S	Oral	Not Reported
Glycerol	N	S	Oral	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Not Reported
Macrogol	N	S	Unknown	Not Reported
Neomycin Sulfate	N	S	Unknown	Not Reported
Potassium Chloride	N	S	Unknown	Not Reported
Nicotine Polacrilex	N	S	Unknown	Not Reported
Sodium Bicarbonate	N	S	Unknown	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Not Reported
Acetylsalicylic Acid/Citric Acid/Sodium Bicarbonate	N	S	Unknown	Not Reported
Atropine/Difenoxinhydrochloride	N	S	Oral	Not Reported
Calcium Carbonate/Sodium/Vitamin D3	N	S	Unknown	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Not Reported
Vitamin E	N	S	Unknown	Not Reported
Mupirocin Calcium Dihydrate	N	S	Unknown	Not Reported
Ambroxol/Cetirizine Hydrochloride	N	S	Unknown	Not Reported
Glycerol/Sodium Stearate	N	S	Oral	Not Reported
Imodium	N	S	Unknown	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Not Reported



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Moviprep	N	S	Unknown	Not Reported
Calcitriol/Calcium	N	S	Intra-articular	Not Reported
Carbonate/Zinc Calcitriol/Calcium Carbonate/Zinc	N	S	Intra-articular	Not Reported
Sulfamethoxazole	N	S	Unknown	Not Reported
Sulfamethoxazole	N	S	Unknown	Not Reported
Sulfamethoxazole	N	S	Unknown	Not Reported
Atropine Sulfate	N	S	Oral	Not Reported
Citric Acid/Sodium Bicarbonate	N	S	Unknown	Not Reported
Difenoxin Hydrochloride	N	S	Oral	Not Reported
Macrogol/Potassium Chloride/Sodium Bicarbonate	N	S	Unknown	Not Reported
Benzydamine Hydrochloride	N	S	Unknown	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Not Reported
Prednisone	N	S	Subcutaneous	Not Reported
Pregabalin	N	S	Topical	Not Reported
Potassium/Sodium Bicarbonate/Sodium Sulfate	N	S	Unknown	Not Reported
Glycerine	N	S	Oral	Not Reported
Gramicidin/Neomycin	N	S	Unknown	Not Reported
Calcium/Magnesium Oxide/Vitamin D3	N	S	Unknown	Not Reported
Clarithromycin	N	S	Unknown	Not Reported
Minerals\Vitamins	N	S	Unknown	Not Reported
Macrogol 3350/Potassium/Sodium Bicarbonate/Sodium Sulfate	N	S	Unknown	Not Reported
Zinc Oxide	N	S	Unknown	Not Reported
Macrogol 3350/Potassium Chloride/Sodium Ascorbate/Sodium Chloride/Sodi	N	S	Unknown	Not Reported
Cholecalciferol	N	S	Unknown	Not Reported
Pseudoephedrine Hydrochloride	N	S	Unknown	Not Reported



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Dulcolax	N	S	Unknown	Not Reported
Macrogol/Potassium Chloride/Sodium Bicarbonate/Sodium Chloride	N	S	Unknown	Not Reported
Acetic Acid/Triamcinolone	N	S	Unknown	Not Reported
Acetaminophen/Dextropropoxyp hene	N	S	Unknown	Not Reported
Minerals	N	S	Unknown	Not Reported
Macrogol/Propylene Glycol/Sodium Chloride	N	S	Unknown	Not Reported
Fructose/Glycerol/Sodium Chloride	N	S	Oral	Not Reported
Calcium Carbonate/Vitamin D/Zinc	N	S	Intra-articular	Not Reported
Ambroxol Hydrochloride	N	S	Unknown	Not Reported
Betamethasone Dipropionate/Betamethasone Sodium Phosphate	N	S	Unknown	Not Reported
Betamethasone/Mupirocin	N	S	Topical	Not Reported
Bromhexinehydrochloride/Sulfa methoxazole/Trimethoprim	N	S	Unknown	Not Reported
Butanediol/Dexpanthenol/Dimeth ylsulfoxide/Glycerol	N	S	Oral	Not Reported
Calcium Gluconate	N	S	Unknown	Not Reported
Calcium Carbonate\Calcium Citrate\Calcium Phosphate\Cholecalciferol\Vitam in D	N	S	Unknown	Not Reported
Clobetasol Propionate/Clotrimazole	N	S	Unknown	Not Reported
D-Alpha Tocopherol/Vitamin C	N	S	Unknown	Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown	Not Reported
Gramicidin/Neomycin/Nystatin/Tr iamcinolon	N	S	Unknown	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Not Reported
Isoniazid/Pyridoxine Hydrochloride/Sulfamethoxazole /Trimethoprim	N	S	Unknown	Not Reported



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Gramicidin/Neomycin/Nystatin/Tr iamcinolone	N	S	Unknown	Not Reported
Cefixime	N	S	Unknown	Not Reported
Infliximab	N	S	Intravenous (not otherwise specified)	Not Reported
Macrogol/Potassium Chloride/Sodium Bicarbonate	N	S	Unknown	Not Reported
Mentha Arvensis	N	S	Unknown	Not Reported
Nicotinamide	N	S	Unknown	Not Reported
Potassium Chloride	N	S	Unknown	Not Reported
Polyethylene Glycol 4000\Potassium Chloride\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate	N	S	Unknown	Not Reported
Sodium Stearate	N	S	Oral	Not Reported
Trimethoprim	N	S	Unknown	Not Reported
Valsartan	N	S	Unknown	Not Reported
Vitamin D	N	S	Unknown	Not Reported
Zinc Chloride	N	S	Unknown	Not Reported
Calcium Citrate	N	S	Unknown	Not Reported
Fluocinolone Acetonide/Neomycin Sulfate/Polymyxin B Sulfate	N	S	Unknown	Not Reported
Ichthammol/Zinc Oxide	N	S	Unknown	Not Reported
Atropine Sulfate\Diphenoxylate Hydrochloride	N	S	Unknown	Not Reported
Sodium Bicarbonate/Sodium Chloride	N	S	Unknown	Not Reported
Butanediol/Dexpanthenol/Dimeth ylsulfoxide/Glycerol	N	S	Oral	Not Reported
Calcium Carbonate/Calcium Citrate/Calcium Phosphate/Cellulose - Microc	N	S	Unknown	Not Reported
Antipyrine	N	S	Unknown	Not Reported
Bromhexine	N	S	Unknown	Not Reported



		Hydroch /	oride/Clorprenaline oride/Sulfamethoxazole		NI	c						Not Deposted
		Calcium Carbona Valsarta	te/Ergocalciferol า		N N	s C	Unknown Unknown					Not Reported Not Reported
			te/Colecalciferol Carbonate; Vitamin D		N N	C C	Unknown					Not Reported Not Reported
		Benadry			N	С	Unknown					Not Reported
		Calcium	& Ergocalciferol		N	С	Unknown					Not Reported
		Lomotil			N	С	Unknown					Not Reported
		Metoclop	ramide Hydrochloride		N	С	Unknown					Not Reported
		Clotrima Vitamin			N N	C C	Unknown					Not Reported Not Reported
		Hydroch	orothiazide		N	С						Not Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol# <u>503</u>	B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jan-2023	206961	93	EXPEDITED (15-DAY)	Υ	С	Т	ALC2022CA	001692			Female	CAN
Preferred Term		Product		Comp.	OTC	Role	Route	Dosage Tex	<u>t</u>	<u>Duration</u>		<u>Mfr</u>
Drug Ineffective; Macul	lar	Atropine	Sulfate		N	S	Unknown	Unk				Alcon
Degeneration		Atropine	Sulfate		N	S	Oral					Not Reported
		Acetamii	nophen		N	S	Unknown	Unk				Not Reported
		Acetylsa	licylic Acid		N	S	Oral	Unk				Not Reported
		Adalimu	mab		N	S	Subcutaneous	Solution Su	bcutaneous			Not Reported
		Alprazola	am		N	S	Unknown	Unk				Not Reported
		Ambroxo	l Hydrochloride		N	S	Unknown	Unk				Not Reported
		Amoxicil	in		N	S	Unknown	Unk				Not Reported
		Apo-Hyd	rochlorothiazide		N	S	Unknown	Unk				Not Reported
		Atorvast	atin Calcium		N	S	Unknown	Unk				Not Reported
		Atorvast	atin Calcium		N	S	Unknown	Unk				Not Reported



Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Avamys	N	S	Unknown	Unk	Not Reported
Azithromycin	N	S	Oral	Unk	Not Reported
Bactrim	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Respiratory (inhalation)	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D3	N	S	Unknown	Unk	Not Reported
Calcium Gluconate	N	S	Unknown	Unk	Not Reported
Cetirizine	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown		Not Reported
Dilaudid	N	S	Unknown		Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown	Unk	Not Reported
Vitamins	N	S	Unknown		Not Reported
Entocort	N	S	Unknown	Unk	Not Reported
Ergocalciferol	N	S	Unknown		Not Reported



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Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Flovent	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Unknown	Unk	Not Reported
Glycerol	N	S	Oral	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Gramicidin;Neomycin Sulfate; Polymycin B	N	S	Unknown	Unk	Not Reported
Humira	Ν	S	Subcutaneous	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Hydromorphone	N	S	Unknown	Unk, One Every One Week	Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Every 1 Week	Not Reported
Macrogol	N	S	Unknown	Unk	Not Reported
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate; Sodium Chloride	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Mesalazine	Ν	S	Unknown	Unk	Not Reported
Metronidazole	Ν	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Ms Ir	Ν	S	Unknown	Unk	Not Reported
Mupirocin	Ν	S	Topical	Unk	Not Reported
Mupirocin Calcium	Ν	S	Topical	Unk	Not Reported
Nadolol	N	S	Unknown		Not Reported
Neomycin Sulfate	Ν	S	Unknown		Not Reported
Nicoderm	N	S	Unknown	Patch	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported



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Nicotine	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Pentasa	N	S	Unknown		Not Reported
Polymyxin B Sulfate	N	S	Unknown		Not Reported
Potassium Chloride	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Unknown		Not Reported
Pulmicort	N	S	Respiratory (inhalation)	Unk	Not Reported
Pulmicort	N	S	Respiratory (inhalation)	Unk	Not Reported
Sinus Rinse	N	S	Unknown	Solution Nasal	Not Reported
Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Sodium Chloride	N	S	Other	Unk	Not Reported
Sodium Stearate	N	S	Oral	Unk	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	Unk	Not Reported
Triamcinolone	N	S	Intra-articular	Unk	Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Zinc Chloride	N	S	Unknown	Unk	Not Reported



	Zinc Oxide		N	S	Unknown	Unk			١	lot Reported
	Valsartan		N	С	Intracardiac	Unk			١	lot Reported
	Biaxin XI		N	S	Unknown	Unk			١	lot Reported
	Fructose;Glycerol;Sodium Chloride		N	S	Unknown	Unk			١	lot Reported
	Ichthammol;Zinc Oxide		N	S	Unknown	Unk			١	lot Reported
	Ichthammol;Zinc Oxide		N	S	Unknown	Unk			١	lot Reported
	Magnesium Oxide		N	S	Unknown	Unk			١	lot Reported
	Pantoprazole Sodium		N	S	Unknown	Unk			١	lot Reported
	Pantoprazole Sodium		N	S	Unknown	Unk			١	lot Reported
	Pantoprazole Sodium		N	S	Unknown	Unk			١	lot Reported
	Pantoprazole Sodium		N	S	Unknown	Unk			١	lot Reported
	Refresh Tears		N	S	Ophthalmic	Unk			١	lot Reported
	Sodium Carboxymethylcellulose		N	S	Unknown	Unk			١	lot Reported
	Sodium Carboxymethylcellulose		Ν	S	Unknown	Unk			N	lot Reported
	Mezavant		Ν	S	Unknown				N	lot Reported
	Simvastatin		Ν	S	Unknown	Unk			N	lot Reported
	Zeaxanthin Forte		Ν	S	Unknown	Unk			N	lot Reported
	Triamcinolone Acetonide		Ν	S	Intra-articular	Unk			N	lot Reported
	Cupric Oxide;Folic Acid;Nicotinic Acid;Zinc Oxide		N	S	Unknown	Unk			١	lot Reported
	Hydromorphone Hydrochloride		N	S	Unknown	Unk			١	lot Reported
FDA Received Date Case	# Case Type	<u>Health</u>	Prof	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Jan-2023 21905	EXPEDITED (15-DAY)	Υ		HO, OT	CA-BAUS 000835	CH-BL-2023-		65 YR	Female	CAN
Preferred Term	Product	Comp.	OTO	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>M</u>	<u>fr</u>
Abdominal Pain; Anaemia;	Budesonide		N	S	Unknown				5	Santarus
Chronic Sinusitis; Colitis; Colitis Ulcerative;	Glyceryl Trinitrate		Ν	S	Unknown				١	lot Reported
Constipation; Drug	Mesalazine		Ν	S	Unknown				\	'aleant
Ineffective; Dyspepsia;										



Erythema; Female Genital Tract Fistula; Frequent Bowel Movements:
Haematochezia;
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Headache; Infusion
Related Reaction; Macular
Degeneration; Malaise;
Nausea; Off Label Use;
Oral Candidiasis; Pain;
Paraesthesia Oral;
Procedural Pain; Proctitis;
Pyrexia; Radiculopathy;
Rectal Haemorrhage;
Therapeutic Product Effect
Incomplete; Vaginal
Discharge; Vaginal
Flatulence; Weight
Decreased

Hydrocortisone	N	S	Unknown		Not Reported
Triamcinolone Acetonide	N	S	Unknown		Not Reported
Triamcinolone Acetonide	N	S	Unknown	Suspension Intra- Articular	Not Reported
Acetaminophen	N	S	Unknown	·	Not Reported
Acetaminophen;	N	S	Unknown		Not Reported
Dextropropoxyphene Acetaminophen; Pseudoephedrine	N	S	Unknown		Not Reported
Acetic Acid;Triamcinolone Acetonide	N	S	Unknown		Not Reported
Acetylsalicylic Acid	N	S	Unknown		Not Reported
Align	N	S	Unknown		Not Reported
Amoxicillin Trihydrate	N	S	Unknown		Not Reported
Apo-Alpraz	N	S	Unknown		Not Reported
Apo Pregabalin	N	S	Unknown		Not Reported
Atorvastatin Calcium	N	S	Unknown		Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Unknown		Not Reported
Azithromycin	N	S	Unknown		Not Reported
Benzydamine	N	S	Unknown		Not Reported
Betamethasone Valerate	N	S	Unknown		Not Reported
Biaxin XI	N	S	Unknown	Tablet (Extended- Release)	Not Reported
Bifidobacterium Longum	N	S	Unknown	Bifidobacterium Longum Subsp. Infantis	Not Reported
Bisacodyl	N	S	Unknown		Not Reported
Calcitriol;Calcium Carbonate; Zinc	N	S	Unknown		Not Reported
Calcium & Vitamin D [Calcium; Colecalciferol]	N	S	Unknown		Not Reported
Cetirizine Hydrochloride	N	S	Unknown		Not Reported
Ciprofloxacin	N	S	Unknown		Not Reported

Date - Time: 11-Apr-2023 10:56:54 AM EST Note: If the field is blank, there is no data.

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Unknown

Ciprofloxacin Hydrochloride

Not Reported



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Clarithromycin	N	S	Unknown		Not Reported
Cortenema	N	S	Unknown	Cortenema Suspension	Not Reported
Cupric Oxide;Folic Acid; Nicotinamide;Zinc	N	S	Unknown	·	Not Reported
Desonide	N	S	Unknown		Not Reported
Diphenhydramine	N	S	Unknown		Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown		Not Reported
Empracet [Paracetamol]	N	S	Unknown		Not Reported
Entyvio	N	S	Unknown	Powder For Solution Intravenous	Not Reported
Ertapenem Sodium	N	S	Unknown		Not Reported
Fentanyl	N	S	Unknown		Not Reported
Fentanyl Citrate	N	S	Unknown		Not Reported
Fluconazole	N	S	Unknown		Not Reported
Fluticasone Propionate	N	S	Unknown		Not Reported
Fructose	N	S	Unknown		Not Reported
Glycerine	N	S	Unknown		Not Reported
Glycerol	N	S	Unknown		Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown		Not Reported
Habitrol [Nicotine]	N	S	Unknown	Patch	Not Reported
Humira	N	S	Unknown	Solution Subcutaneous	Not Reported
Hydrochlorothiazide	N	S	Unknown	Solution Subcutaneous	Not Reported
Hydrochlorothiazide	N	S	Subcutaneous	Solution Subcutaneous	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Solution Subcutaneous	Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Prolonged-Release Tablet	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown		Not Reported
Isoniazid;Pyridoxine Hydrochloride;	N	S	Endocervical	Prolonged-Release Tablet	Not Reported
Sulfamethoxazole;Trimethoprim Isoniazid;Pyridoxine Hydrochloride;	N	S	Unknown		Not Reported



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Sulfamethoxazole;Trimethoprim Loperamide Hydrochloride	N	S	l la la avva		Not Reported
Magnesium	N	S	Unknown		Not Reported
Magnesium Carbonate	N	S	Unknown		Not Reported
Magnesium Hydroxide	N	S	Unknown		Not Reported
Magnesium Oxide	N	S	Unknown		Not Reported
•			Unknown		•
Magnesium Sulfate	N	S	Unknown		Not Reported
Methylprednisolone Sodium Succinate	N	S	Unknown		Not Reported
Midazolam	N	S	Unknown		Not Reported
Morphine Sulfate	N	S	Unknown		Not Reported
Mupirocin	N	S	Unknown		Not Reported
Nadolol	N	S	Unknown		Not Reported
Macrogol;Potassium;Sodium Bicarbonate;Sodium Chloride	N	S	Unknown		Not Reported
Nicoderm	N	S	Unknown	Patch	Not Reported
Nicotinamide	N	S	Unknown		Not Reported
Nicotine	N	S	Unknown		Not Reported
Oxybutynin Hydrochloride	N	S	Unknown		Not Reported
Pantoprazole	N	S	Unknown		Not Reported
Potassium Chloride	N	S	Unknown		Not Reported
Prednisone	N	S	Unknown		Not Reported
Refresh Tears	N	S	Unknown		Not Reported
Salinex [Furosemide]	N	S	Unknown		Not Reported
Sinus Rinse	N	S	Unknown	Solution Nasal	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown		Not Reported
Sucralfate	N	S	Unknown		Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown		Not Reported
Ubidecarenone	N	S	Unknown		Not Reported
Vitamin D3	N	S	Unknown		Not Reported
Xantofyl Palmitate	N	S	Unknown		Not Reported



		Zeaxanthin		N	S	Unknown					Not Reported
		Zinc Oxide		N	S	Unknown					Not Reported
		Zopiclone		N	S	Unknown					Not Reported
		Acetylsalicylic Acid;Citric Acid;		Ν	S	Unknown					Not Reported
		Sodium Bicarbonate Apo Pregabalin		N	S	Unknown					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcome	s Mfr	Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
25-Jan-2023	193300	EXPEDITED (15-DAY)	Y		ОТ		TAKEDA- TUS033851			Female	CAN
Preferred Term		Product	Comp.	OTO	Rol	Route	Dosage	e Text	Duration		<u>Mfr</u>
Drug Ineffective; Macu	ılar	476 (Mesalazine/Mesalamine)		N	S	Unknown	Unk				Takeda
Degeneration		Pentasa		Ν	S	Unknown	Unk				Takeda
		Pantoprazole		Ν	S	Unknown	Unk				Not Reported
		Pantoprazole Sodium		Ν	S	Unknown	Unk				Not Reported
		Calcium Carbonate		Ν	S	Unknown	Unk				Not Reported
		Calcium Carbonate, Cholecalciferol		N	S	Unknown	Unk				Not Reported
		Amoxicillin		Ν	S	Unknown	Unk				Not Reported
		Amoxicillin Trihydrate		Ν	S	Unknown	Unk				Not Reported
		Metronidazole		Ν	S	Unknown	Unk				Not Reported
		Acetylsalicylic Acid		Ν	S	Unknown	Unk				Not Reported
		Macrogol		N	S	Unknown	Unk				Not Reported
		Calcium Citrate		N	S	Unknown	Unk				Not Reported
		Atorvastatin		N	S	Unknown	Unk				Not Reported
		Cholecalciferol		N	S	Unknown	Unk				Not Reported
		Zinc Oxide		N	S	Unknown	Unk				Not Reported
		Moviprep		N	S	Unknown	Unk				Not Reported
		Morphine Sulfate		Ν	S	Unknown	Unk				Not Reported
		Acetaminophen		Ν	S	Unknown	Unk				Not Reported
		Alprazolam		N	S	Respirator	y Unk				Not Reported

Date - Time: 11-Apr-2023 10:56:54 AM EST N

Note: If the field is blank, there is no data.



			(inhalation)		
Alprazolam	N	S	Unknown	Unk	Not Reported
Azithromycin	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Transplacental	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Lomotil	N	S	Oral	Unk	Not Reported
Ertapenem	N	S	Nasal	Unk	Not Reported
Ertapenem	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Ophthalmic	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Glycerol	N	S	Oral	Unk	Not Reported
Glycerol	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Humira	N	S	Subcutaneous	Unk	Not Reported
Humira	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk, 1/Week	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Mupirocin	Ν	S	Unknown	Unk	Not Reported



				-	
Nadolol	N	S	Intra-articular	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Neomycin B Sulfate	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Potassium Chloride	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Subcutaneous	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Topical	Unk	Not Reported
Pregabalin	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Refresh Tears	N	S	Unknown	Unk	Not Reported
Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole And	N	S	Unknown	Unk	Not Reported
Trimethoprim Triamcinolone	N	S	Unknown	Unk	Not Reported
Triamcinolone	N	S	Intra-articular	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Vitamin E Natural	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Flovent	N	S	Unknown	Unk	Not Reported
Bactroban	N	S	Unknown	Unk	Not Reported
Bactroban	N	S	Topical	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	N	S	Unknown	Unk	Not Reported
Ocean Nasal	N	S	Nasal	Unk	Not Reported



Calcium Phosphate Dibasic; Colecalciferol	N	S	Unknown		Not Reported
Ichthammol And Zinc Oxide	N	S	Unknown		Not Reported
Macrogol;Potassium Chloride; Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Neomycin	N	S	Unknown		Not Reported
Sodium Chloride	N	S	Other	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk	Not Reported
Vitamin D	N	S	Unknown		Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Neomycin Sulfate	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Avamys	N	S	Ophthalmic	Unk	Not Reported
Dilaudid	N	S	Unknown	Unk	Not Reported
Diphenhydramine	N	S	Unknown		Not Reported
Entocort	N	S	Unknown	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown		Not Reported
Magnesium Oxide	N	S	Unknown		Not Reported
Mupirocin Calcium	N	S	Topical	Unk	Not Reported
Prednisone Acetate	N	S	Unknown		Not Reported
Pulmicort	N	S	Respiratory (inhalation)	Unk	Not Reported
Sinus Rinse	N	S	Nasal	Unk	Not Reported



Valsartan	N	S	Intracardiac	Unk	Not Reported
Macrogol 3350	N	S	Unknown	Unk	Not Reported
Pms Azithromycin	N	S	Unknown	Unk	Not Reported
Macrogol 3350;Potassium Chloride;Sodium Chloride; Sodium Sulfate	N	S	Unknown		Not Reported
Adalimumab	N	S	Subcutaneous	Unk	Not Reported
Glycerol;Sodium Stearate	N	S	Oral	Unk	Not Reported
Ambroxol;Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Bactrim	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Fluticasone Propionate	N	S	Unknown		Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Difenoxin Hydrochloride	N	S	Unknown		Not Reported
Vitamin A	N	S	Unknown		Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk Unk, 1/Week	Not Reported
Zinc Chloride	N	S	Unknown	Unk	Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown	Unk	Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported
Sodium Stearate	N	S	Oral	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Ms Ir	N	S	Unknown	Unk	Not Reported
Calcium Gluconate	N	S	Unknown	Unk	Not Reported
Ambroxol Hydrochloride	N	S	Unknown	Unk	Not Reported
Atropine Sulphate	N	S	Unknown	Unk	Not Reported
Vitamin C	N	S	Unknown	Unk	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Endosinusial	Unk	Not Reported



		ose;Glycerol;Sodium		N	S	Unknown	Unk			Not Reported
	Chlori Loper	ide amide Hydrochloride;		N	S	Unknown	Unk			Not Reported
	Simet Kenal	ticone log		N	S	Intra-articular	Unk			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	Sex	Country
25-Jan-2023	21327001	EXPEDITED (15-DAY)	Υ	(ЭТ	FR-AUROBIND APL-2022-0356		76 YR	Male	FRA
Preferred Term	Prod	<u>uct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		Mfr
Mouth Ulceration	Amloo	dipine		N	S	Oral	5 Milligram, Once A Day			Aurobindo
	Atorva	astatin		N	S	Oral	40 Milligram, Once A Day (Once In The Evening)			Not Reported
	Bisop	rolol Film-Coated Tablets		Ν	S	Oral	5 Milligram, Once A Day			Aurobindo
	Clopic	dogrel		Ν	S	Oral	75 Milligram, Once A Day			Aurobindo
	Furos	semide		Ν	S	Oral	40 Milligram, Once A Day			Eugia Pharma
	Parac	cetamol Tablet		N	S	Oral	1 Dosage Form, As Necessary			Aurobindo
	Venla	ıfaxine		N	S	Oral	75 Milligram, Once A Day (Once In The Morning)			Aurobindo
	Amlor	r		N	S	Oral	5 Milligram, Once A Day (Once In The Morning)			Not Reported
	Brond	chodual		N	S		1 Dosage Form, Once A Day			Not Reported
	Glyce	rin\Mineral Oil\Petrolatum		N	S	Unknown	One Daily Application On The Whole Body, 2 Tubes Weekly	i		Not Reported
	Diffu I	K		N	S	Oral	1800 Milligram, Once A Day			Not Reported
	Hydro	ocortisone		Ν	S	Oral	20 Milligram, Once A Day			Not Reported
	Istoda	ах		N	S	Intravenous (not otherwise specified)	53.1 Milligram 1 Month			Not Reported
	Lasilix	x		N	S	Oral	40 Milligram, Once A Day (One Tablet In The			Not Reported



		Levothyr	οx		N	S	Oral		Morning) 1 Dosage Form, Once A			Not Re	eported
						· ·	Olai		Day				,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
		Januvia			N	S	Oral		1000 Milligram, Once A Day			Not Re	eported
		Januvia			N	S	Oral		100 Milligram, Once A Day (Once In The Morning)	,		Not Re	eported
		Optive			N	S	Unknown		Lubricating And Osmoprotective Ocular Solution 1-2 Drops Per Day Depending On Discomfort			Not Re	eported
		Oracilline	•		N	S	Oral		2 Dosage Form, Once A Day			Not Re	eported
		Vitamine	B12		N	S	Oral		2 Dosage Form, Every Week			Not Re	eported
		Zymad			N	S	Oral		1 Dosage Form (Every Month)			Not Re	eported
		Clarelux			N	С	Unknown		2 Tubes Weekly: One Weekly Application On The Whole Body, Space Out Applications For Few Days, Even			Not Re	eported
FDA Received Date	Case #	<u>ŧ</u>	Case Type	Health I	Prof C	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>C</u>	Country
25-Jan-2023	219073	338	EXPEDITED (15-DAY)	Υ	C	T	CA-ORC 023010		44		Female	L	JSA
Preferred Term		Product		Comp.	<u>OTC</u>	<u>Role</u>	Route	1	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>	
Drug Ineffective; Macul	lar	Zocor			N	S	Unknown		Unk			Organ	on
Degeneration		Invanz			N	S	Unknown		Unk			Not Re	eported
		Acetamir	nophene		N	S	Unknown		Unk			Not Re	eported
		Adalimur	nab		N	S	Subcutaneous	S	Unk, Solution Subcutaneous			Not Re	eported
		Alprazola	am		N	S	Unknown		Unk			Not Re	eported



				•	
Ambroxol Hydrochloride	N	S	Unknown	Unk	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Atropine	N	S	Oral	Unk	Not Reported
Avamys	N	S	Unknown	Unk	Not Reported
Azithromycin	N	S	Oral	Unk	Not Reported
Azithromycin Dihydrate	N	S	Unknown	Unk	Not Reported
Azithromycin Dihydrate	N	S	Oral	Unk	Not Reported
Bactrim	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Calcium Gluconate	N	S	Unknown	Unk	Not Reported
Calcium Gluconate	N	S	Unknown	Unk	Not Reported
Cetirizine	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
Cupric Oxide;Folic Acid;Nicotinic Acid;Zinc Oxide	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Dilaudid	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown	Unk	Not Reported
DI-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported



				•	
Entocort	N	S	Unknown	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Flovent	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Fructose;Glycerol;Sodium Chloride	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Humira	N	S	Subcutaneous	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Kenalog [Triamcinolone Acetonide]	N	S	Intra-articular	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk	Not Reported
Loperamide Hydrochloride; Simeticone	N	S	Oral	Unk	Not Reported
Macrogol 3350;Potassium; Sodium Bicarbonate;Sodium Chloride	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Metronidazole Hydrochloride	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Ms Ir	N	S	Unknown	Unk	Not Reported
Mupirocin Calcium Hydrate	N	S	Unknown	Unk	Not Reported
Mupirocin Calcium Hydrate	N	S	Unknown	Unk	Not Reported
Mupirocin Calcium Hydrate	N	S	Topical	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk, Patch	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported



<u>e #</u>	Case Type	Health Prof	<u>Outcomes</u>	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
Calcium	1	N	С	Unknown	Unk			Not Reported
Zinc Ox	ide	N	S	Unknown	Unk			Not Reported
Zinc Ch		N	S	Unknown	Unk			Not Reported
Zeaxant	thin	N	S	Unknown	Unk			Not Reported
Xantofyl	l Palmitate	N	S	Unknown	Unk			Not Reported
Vitamin	D3	N	S	Unknown	Unk			Not Reported
Vitamin-	-C	N	S	Unknown	Unk			Not Reported
Valsarta	an	N	S	Unknown	Unk			Not Reported
Valsarta	an	N	S	Intracardiac	Unk			Not Reported
Trimetho	oprim	N	S	Unknown	Unk			Not Reported
Triamcir	nolone Acetonide	N	S	Intra-articular	Unk			Not Reported
Triamcir	nolone	N	S	Intra-articular	Unk			Not Reported
Sulfame	ethoxazole;Trimethoprim	N	S	Unknown	Unk			Not Reported
Sodium	Stearate	N	S	Oral	Unk			Not Reported
Sodium	Chloride	N	S	Endosinusial	Unk			Not Reported
Sodium	Carboxymethyl Starch	N	S	Ophthalmic	Unk			Not Reported
Sodium	Carboxymethyl Starch	N	S	Unknown	Unk			Not Reported
Sinus R	inse	N	S	Endosinusial	Unk			Not Reported
Salinex	Seawater	N	S	Endosinusial	Unk, Nasal Solution			Not Reported
Refresh	Tears	N	S	Ophthalmic	Unk			Not Reported
Pulmico	ort	N	S	Unknown	Unk			Not Reported
Pregaba	alin	N	S	Unknown	Unk			Not Reported
Prednise	one	N	S	Unknown	Unk			Not Reported
Pentasa	ì	N	S	Unknown	Unk			Not Reported
Pantopr	azole	N	S	Unknown	Unk			Not Reported
Nicotine	Polacrilex	N	S	Unknown	Unk			Not Reported

FDA Received Date Case # Case Type Health Prof Outcomes Mfr Control # 503B Facility Age Sex Country

25-Jan-2023 21911968 NON-EXPEDITED N US-ALLERGAN-2230989US Female USA



Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Asthenopia; Burning	Botox (Cosmetic		N	S		Unk Unk, Single	1 DAY	А	llergan
Sensation; Dry Eye; Dysarthria; Dysphagia	. Botox (Cosmetic		N	S		Unk Unk, Single	1 DAY	А	llergan
Eye Disorder; Facial	Botox (Cosmetic		N	S		Unk Unk, Single	1 DAY	А	llergan
Paresis; Headache; Ja	DUIUX (Cosmetic		N	S		1.5 Units, Single	1 DAY	А	llergan
Clicking; Jaw Disorder Malocclusion; Muscle	Botox (Cosmetic		N	S		2 Units, Single	1 DAY	А	llergan
Atrophy; Off Label Use Pruritus; Tongue Diso Vision Blurred; Visual Impairment		h Tears		N	S	Ophthalmic	Unk		А	llergan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jan-2023	21928058	EXPEDITED (15-DAY)	N	0.	Γ	US-ALLERGA 2302183US	AN-		Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Cataract	Refres	h Tears		Υ	S	Ophthalmic	Unk		А	llergan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jan-2023	21928067	EXPEDITED (15-DAY)	N	0.	Γ	US-ALLERGA 2213826US	AN-		Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Blepharitis; Cataract; Epiretinal Membrane; Lacrimation Increased		h Tears		Y	S		Unk		A	llergan
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Contro	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
30-Jan-2023	21928088	EXPEDITED (15-DAY)	N	0.	Γ	US-ALLERGA 2302237US	AN-		Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosage Text	<u>Duration</u>	<u>M</u> :	<u>fr</u>
Cataract	Refres	h Tears		Υ	S				N	lot Reported



FDA Received Date	Case #	Case Type	Health	Prof Ou	itcomes	Mfr Contro	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jan-2023	21931693	EXPEDITED (15-DAY)	Υ	ОТ	-	CA-JNJFOC 2023015355				Female	CAN
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosag	<u>je Text</u>	<u>Duration</u>	Mf	<u>r</u>
Drug Ineffective; Macu	ular Bu	desonide		N	S	Unknown				No	ot Reported
Degeneration	Nic	coderm		N	S	Unknown				No	ot Reported
	Nic	cotine		N	S	Unknown				No	ot Reported
	Nic	cotine		N	S	Other				No	ot Reported
	Ce	tirizine Hydrochloride		N	S	Unknown				No	ot Reported
	Dip	henhydramine Hydrochloride		N	S	Unknown				No	ot Reported
	Lop	peramide Hydrochloride		N	S	Unknown				No	ot Reported
	Lop	peramide/Simethicone		N	S	Oral				No	ot Reported
	Zin	c Oxide		N	S	Unknown				No	ot Reported
	Pai	racetamol		N	S	Unknown				No	ot Reported
	Ada	alimumab		N	S	Subcutaneous				No	ot Reported
	Alp	orazolam		N	S	Unknown				No	ot Reported
	Am	broxol Hydrochloride		N	S	Unknown				No	ot Reported
	Am	noxicillin Trihydrate		N	S	Unknown				No	ot Reported
	Apo	o-Hydrochlorothiazide		N	S	Unknown				No	ot Reported
	Ato	orvastatin Calcium		N	S	Unknown				No	ot Reported
	Ato	orvastatin Calcium		N	S	Unknown				No	ot Reported
	Atr	opine		N	S	Unknown				No	ot Reported
	Atr	opine		N	S	Oral				No	ot Reported
	Ava	amys		N	S	Unknown				No	ot Reported
	Bet	tamethasone		N	S	Unknown				No	ot Reported
	Bet	tamethasone Valerate		N	S	Unknown				No	ot Reported
	Bia	ixin XI		N	S	Unknown				No	ot Reported
	Bis	acodyl		N	S	Unknown				No	ot Reported
	Cal	Icium Carbonate		N	S	Unknown				No	ot Reported



Calcium Gluconate N S Unknown Not Reported Clarithromycin N S Unknown Not Reported Clotrimazole N S Unknown Not Reported Cupric Oxide N S Unknown Not Reported Cupric Oxide Folic Acid;Nicotinic Acid;Zinc Oxide N S Unknown Not Reported Acid;Zinc Oxide N S Unknown Not Reported Acid;Zinc Oxide N S Unknown Not Reported Dilaudid N S Unknown Not Reported Dil-Alpha Tocopheryl Acetate N S Unknown Not Reported Dil-Alpha Tocopheryl Acetate N S Unknown Not Reported Ertocort N S Unknown Not Reported Ertocort N S Unknown Not Reported Ertopcalciferol N S Unknown Not Reported Ertopcalciferol N S Unknown Not Reported Ertapenem Sodium N S Unknown Not Reported Filovent N S Unknown Not Reported Magnesium Sulfate N S Unknown Not Reported Mesiazine N S Unknown Not Reported Morphine Sulfate N S Unknown Not Reported Morphine Sul				•	
Clotrimazole N S Unknown Not Reported Cupric Oxide N S Unknown Not Reported Cupric Oxide N S Unknown Not Reported D-Alpha Tocopherol N S Unknown Not Reported Dilaudid N S Unknown Not Reported Diphenoxylate Hydrochloride N S Unknown Not Reported DI-Alpha Tocopheryl Acetate N S Unknown Not Reported Entocort N S Unknown Not Reported Ertopcalciferol N S Unknown Not Reported Ertapenem Sodium N S Unknown Not Reported Flovent N S Unknown Not Reported Fluctoses Glycerol; Sodium N S Unknown Not Reported Fluctoses Glycerol; Sodium N S Unknown Not Reported Glycerine N S Unknown Not Reported	Calcium Gluconate	N	S	Unknown	Not Reported
Cupric Oxide N S Unknown Not Reported Cupric Oxide: Folic Acid: Nicotinic Acid: Zinc Oxide N S Unknown Not Reported D-Alpha Tocopherol N S Unknown Not Reported Diladudid N S Unknown Not Reported Di-Alpha Tocopheryl Acetate N S Unknown Not Reported Entocort N S Unknown Not Reported Ergocalciferol N S Unknown Not Reported Erapenem Sodium N S Unknown Not Reported Flovent N S Unknown Not Reported Fluctose, Glycerol; Sodium N S Unknown Not Reported Fructose, Glycerol; Sodium N S Unknown Not Reported Gramicidin N S Unknown Not Reported Gramicidin; Neomycin Sulfate; N S Unknown Not Reported Hydromorphone Hydrochloride N S <	Clarithromycin	N	S	Unknown	Not Reported
Cupric Oxide; Folic Acid; Nicotinic Acid; Zinc Oxide Di-Alpha Tocopherol N S Unknown Not Reported Dilaudid N S Unknown Not Reported Diphenoxylate Hydrochloride N S Unknown Not Reported Di-Alpha Tocopheryl Acetate N S Unknown Not Reported Entocort N S Unknown Not Reported Erapocalciferol N S Unknown Not Reported Flovent N S Unknown Not Reported Flovent N S Unknown Not Reported Fluticasone Furoate N S Unknown Not Reported Fluticasone Furoate N S Unknown Not Reported Fructose; Glycerol; Sodium N S Unknown Not Reported Glycerine N S Unknown Not Reported Gramicidin; Neomycin Sulfate; N S Unknown Not Reported Gramicidin; Neomycin Sulfate; N S Unknown Not Reported Humira N S Subcutaneous Not Reported Hydrochlorothiazide N S Unknown Not Reported Hydromorphone Hydrochloride N S Unknown Not Reported Hydromorphone Hydrochloride N S Unknown Not Reported Acetonide] Magnesium Sulfate N S Unknown Not Reported Mesalazine N S Unknown Not Reported Mesalazine N S Unknown Not Reported Metronidazole Hydrochloride N S Unknown Not Reported Metronidazole Hydrochloride N S Unknown Not Reported Morphine Sulfate N S Unknown Not Reported Metronidazole Hydrochloride N S Unknown Not Reported Metronidazole Hydrochloride N S Unknown Not Reported Metronidazole Hydrochloride N S Unknown Not Reported Morphine Sulfate N S Unknown Not Reported	Clotrimazole	N	S	Unknown	Not Reported
Acid.Zinc Oxide D-Alpha Tocopherol N S Unknown Not Reported Diphenoxylate Hydrochloride N S Unknown Not Reported Diphenoxylate Hydrochloride N S Unknown Not Reported Di-Alpha Tocopheryl Acetate N S Unknown Not Reported Ertocort Ertocort N S Unknown Not Reported Ergocalciferol N S Unknown Not Reported Ertapenem Sodium Riovent N S Unknown Not Reported Flovent N S Unknown Not Reported Fluticasone Furoate N S Unknown Not Reported Fructose; Glycerol; Sodium Chloride Glycerine N S Unknown Not Reported N S Unknown Not Reported Gramicidin; Neomycin Sulfate; Polymyxin B Sulfate Humira N S Unknown Not Reported Hydrochlorothiazide N S Unknown Not Reported Hydrochlorothiazide N S Unknown Not Reported Hydromorphone Hydrochloride N S Unknown Not Reported Hydromorphone Hydrochloride N S Unknown Not Reported Not Reported Hydromorphone Hydrochloride N S Unknown Not Reported Megnesium Sulfate N S Unknown Not Reported Mesalazine N S Unknown Not Reported Metronicazole Hydrochloride N S Unknown Not Reported Morphine Sulfate N S Unknown N N S Unknown N N S Unknown N N N N S Unknown N N N N S Unknown N N N N N N N N N N N N N	Cupric Oxide	N	S	Unknown	Not Reported
Dilaudid N S Unknown Not Reported Diphenoxylate Hydrochloride N S Unknown Not Reported DI-Alpha Tocopheryl Acetate N S Unknown Not Reported Ertocort N S Unknown Not Reported Ergocalciferol N S Unknown Not Reported Ergocalciferol N S Unknown Not Reported Ertapenem Sodium N S Unknown Not Reported Flovent N S Unknown Not Reported Flovent N S Unknown Not Reported Fluticasone Furoate N S Unknown Not Reported Glycerine N S Unknown Not Reported Glycerine N S Unknown Not Reported Glycerine N S Unknown Not Reported Gramicidin N S Unknown Not Reported Gramicidin N S Unknown Not Reported Humira N S Subcutaneous Not Reported Humira N S Unknown Not Reported Hydrochloride N S Unknown Not Reported Hydromorphone Hydrochloride N S Unknown Not Reported Hydromorphone Hydrochloride N S Unknown Not Reported Acetonide] Not Reported Not Reported Magnesium Sulfate N S Unknown Not Reported Mesalazine N S Unknown Not Reported Mesalazine N S Unknown Not Reported Metronidazole Hydrochloride N S Unknown Not Reported Morphine Sulfate N S Unknown Not Reported Not Reported Morphine Sulfate N S Unknown Not Reported Not Reported Not Reported Not Reported Not	Acid;Zinc Oxide	N		Unknown	•
Diphenoxylate Hydrochloride N S Unknown Not Reported DI-Alpha Tocopheryl Acetate N S Unknown Not Reported Entocort N S Unknown Not Reported Ergocalciferol N S Unknown Not Reported Ergocalciferol N S Unknown Not Reported Ertapenem Sodium N S Unknown Not Reported Ertapenem Sodium N S Unknown Not Reported Flovent N S Unknown Not Reported Fluticasone Furoate N S Unknown Not Reported Glycerol; Sodium Not Reported Chloride N S Unknown Not Reported Glycerine N S Unknown Not Reported Glycerine N S Unknown Not Reported Gramicidin Not N S Unknown Not Reported Gramicidin Not N S Unknown Not Reported Gramicidin; Neomycin Sulfate; N S Unknown Not Reported Hydrochloridazide N S Subcutaneous Not Reported Hydrochloridazide N S Unknown Not Reported Hydromorphone Hydrochloride N S Unknown Not Reported Kenalog [Triamcinolone N S Unknown Not Reported Acetonide] Not Reported Not Reported Magnesium Sulfate N S Unknown Not Reported Mesalazine N S Unknown Not Reported Mesalazine N S Unknown Not Reported Metronidazole Hydrochloride N S Unknown Not Reported Morphine Sulfate N S Unknown Not Reported Not Reported Morphine Sulfate N S Unknown Not Reported Morphine S	D-Alpha Tocopherol	N	S	Unknown	Not Reported
Di-Alpha Tocopheryl Acetate N S Unknown Not Reported Entocort N S Unknown Not Reported Ergocalciferol N S Unknown Not Reported Ergocalciferol N S Unknown Not Reported Ertapenem Sodium N S Unknown Not Reported Ertapenem Sodium N S Unknown Not Reported Flovent N S Unknown Not Reported Fluticasone Furoate N S Unknown Not Reported Fructose; Glycerol; Sodium Chloride Pructose; Glycerol; Sodium N S Unknown Not Reported Glycerine N S Oral Not Reported Glycerine N S Unknown Not Reported Gramicidin; Neomycin Sulfate; N S Unknown Not Reported Gramicidin; Neomycin Sulfate; N S Unknown Not Reported Humira N S Subcutaneous Not Reported Humira N S Subcutaneous Not Reported Hydrochlorothiazide N S Unknown Not Reported Hydromorphone Hydrochloride N S Unknown Not Reported Kenalog [Triamcinolone N S Unknown Not Reported Acetonide] N S Unknown Not Reported Magnesium Sulfate N S Unknown Not Reported Mesalazine N S Unknown Not Reported Mesalazine N S Unknown Not Reported Metronidazole Hydrochloride N S Unknown Not Reported Morphine Sulfate N S Unknown Not Reported Not Reported Morphine Sulfate N S Unknown Not Reported Not Reported Morphine Sulfate N S Unknown Not Reported Not Rep	Dilaudid	N	S	Unknown	Not Reported
Entocort N S Unknown Not Reported Ergocalciferol N S Unknown Not Reported Ertapenem Sodium N S Unknown Not Reported Flovent N S Unknown Not Reported Fluticasone Furoate N S Unknown Not Reported Fructose; Glycerol; Sodium Chloride N S Unknown Not Reported Growing Glycerol; Sodium Chloride N S Unknown Not Reported Glycerine N S Unknown Not Reported Gramicidin N S Unknown Not Reported Gramicidin; Neomycin Sulfate; Polymyxin B Sulfate N S Unknown Not Reported Hydrochlorothiazide N S Subcutaneous Not Reported Hydrochlorothiazide N S Unknown Not Reported Hydromorphone Hydrochloride N S Unknown Not Reported Kenalog [Triamcinolone Actonide] N	Diphenoxylate Hydrochloride	N	S	Unknown	Not Reported
Ergocalciferol N S Unknown Not Reported Ertapenem Sodium N S Unknown Not Reported Flovent N S Unknown Not Reported Flovent N S Unknown Not Reported Fluticasone Furoate N S Unknown Not Reported Fructose; Glycerol; Sodium N S Unknown Not Reported Chloride Glycerine N S Oral Not Reported Gramicidin; Neomycin Sulfate; N S Unknown Not Reported Gramicidin; Neomycin Sulfate; N S Unknown Not Reported Polymyxin B Sulfate N S Subcutaneous Not Reported Humira N S Subcutaneous Not Reported Hydrochlorothiazide N S Unknown Not Reported Hydromorphone Hydrochloride N S Unknown Not Reported Kenalog [Triamcinolone N S Unknown Not Reported Kenalog [Triamcinolone N S Unknown Not Reported Magnesium Sulfate N S Unknown Not Reported Mesalazine N S Unknown Not Reported Metronidazole Hydrochloride N S Unknown Not Reported Morphine Sulfate N S Unknown Not Reported Morphine Sulfate N S Unknown Not Reported Morphine Sulfate N S Unknown Not Reported Not Reported Morphine Sulfate N S Unknown Not Reported Not Reported Morphine Sulfate N S Unknown Not Reported Not Repo	DI-Alpha Tocopheryl Acetate	N	S	Unknown	Not Reported
Ertapenem Sodium N S Unknown Not Reported Flovent N S Unknown Not Reported Flovent N S Unknown Not Reported Fluticasone Furoate N S Unknown Not Reported Fructose; Glycerol; Sodium N S Unknown Not Reported Chloride Glycerine N S Oral Not Reported Gramicidin; Neomycin Sulfate; N S Unknown Not Reported Gramicidin; Neomycin Sulfate; N S Unknown Not Reported Polymyxin B Sulfate Humira N S Subcutaneous Not Reported Hydrochlorothiazide N S Unknown Not Reported Hydromorphone Hydrochloride N S Unknown Not Reported Kenalog [Triamcinolone Acetonide] N S Unknown Not Reported Magnesium Sulfate N S Unknown Not Reported Mesalazine N S Unknown Not Reported Metronidazole Hydrochloride N S Unknown Not Reported Morphine Sulfate N S Unknown Not Reported	Entocort	N	S	Unknown	Not Reported
Flovent N S Unknown Not Reported Fluticasone Furoate N S Unknown Not Reported Fructose; Glycerol; Sodium N S Unknown Not Reported Chloride Glycerine N S Oral Not Reported Gramicidin; Neomycin Sulfate; N S Unknown Not Reported Gramicidin; Neomycin Sulfate; N S Unknown Not Reported Humira N S Subcutaneous Not Reported Hydrochlorothiazide N S Unknown Not Reported Hydromorphone Hydrochloride N S Unknown Not Reported Kenalog [Triamcinolone N S Unknown Not Reported Acetonide] Magnesium Sulfate N S Unknown Not Reported Mesalazine N S Unknown Not Reported Metronidazole Hydrochloride N S Unknown Not Reported Metronidazole Hydrochloride N S Unknown Not Reported Metronidazole Hydrochloride N S Unknown Not Reported Morphine Sulfate N S Unknown Not Reported	Ergocalciferol	N	S	Unknown	Not Reported
Fluticasone Furoate N S Unknown Not Reported Fructose; Glycerol; Sodium N S Unknown Not Reported Chloride Glycerine N S Oral Not Reported Gramicidin N S Unknown Not Reported Gramicidin; Neomycin Sulfate; Polymyxin B Sulfate Humira N S Subcutaneous Not Reported Hydrochlorothiazide N S Unknown Not Reported Hydromorphone Hydrochloride N S Unknown Not Reported Kenalog [Triamcinolone N S Unknown Not Reported Acetonide] Magnesium Sulfate N S Unknown Not Reported Mesalazine N S Unknown Not Reported Metronidazole Hydrochloride N S Unknown Not Reported Morphine Sulfate N S Unknown Not Reported Morphine Sulfate N S Unknown Not Reported Morphine Sulfate N S Unknown Not Reported Ms Ir N S Unknown Not Reported	Ertapenem Sodium	N	S	Unknown	Not Reported
Fructose; Glycerol; Sodium N S Unknown Not Reported Chloride Glycerine N S Oral Not Reported Glycerine N S Unknown Not Reported Gramicidin N S Unknown Not Reported Gramicidin; Neomycin Sulfate; N S Unknown Not Reported Polymyxin B Sulfate Humira N S Subcutaneous Not Reported Hydrochlorothiazide N S Unknown Not Reported Hydromorphone Hydrochloride N S Unknown Not Reported Kenalog [Triamcinolone N S Intra-articular Not Reported Acetonide] Magnesium Sulfate N S Unknown Not Reported Mesalazine N S Unknown Not Reported Metronidazole Hydrochloride N S Unknown Not Reported Metronidazole Hydrochloride N S Unknown Not Reported Morphine Sulfate N S Unknown Not Reported	Flovent	N	S	Unknown	Not Reported
Chloride Glycerine N S Oral Not Reported Gramicidin N S Unknown Not Reported Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate Humira N S Subcutaneous Not Reported Hydrochlorothiazide N S Unknown Not Reported Hydromorphone Hydrochloride N S Unknown Not Reported Kenalog [Triamcinolone Acetonide] Magnesium Sulfate N S Unknown Not Reported Mesalazine N S Unknown Not Reported Metronidazole Hydrochloride N S Unknown Not Reported	Fluticasone Furoate	N	S	Unknown	Not Reported
Gramicidin N S Unknown Not Reported Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate Humira N S Subcutaneous Not Reported Hydrochlorothiazide N S Unknown Not Reported Hydromorphone Hydrochloride N S Unknown Not Reported Kenalog [Triamcinolone N S Intra-articular Not Reported Acetonide] Magnesium Sulfate N S Unknown Not Reported Mesalazine N S Unknown Not Reported Metronidazole Hydrochloride N S Unknown Not Reported Morphine Sulfate N S Unknown Not Reported		N	S	Unknown	Not Reported
Gramicidin; Neomycin Sulfate; Polymyxin B Sulfate Humira N S Subcutaneous Not Reported Hydrochlorothiazide N S Unknown Not Reported Hydromorphone Hydrochloride N S Unknown Not Reported Kenalog [Triamcinolone Acetonide] Magnesium Sulfate N S Unknown Not Reported Mesalazine N S Unknown Not Reported Metronidazole Hydrochloride N S Unknown Not Reported Morphine Sulfate N S Unknown Not Reported	Glycerine	N	S	Oral	Not Reported
Polymyxin B Sulfate Humira N S Subcutaneous Not Reported Hydrochlorothiazide N S Unknown Not Reported Hydromorphone Hydrochloride N S Unknown Not Reported Kenalog [Triamcinolone N S Intra-articular Acetonide] Magnesium Sulfate N S Unknown Not Reported Mesalazine N S Unknown Not Reported Metronidazole Hydrochloride N S Unknown Not Reported Morphine Sulfate N S Unknown Not Reported	Gramicidin	N	S	Unknown	Not Reported
HydrochlorothiazideNSUnknownNot ReportedHydromorphone HydrochlorideNSUnknownNot ReportedKenalog [Triamcinolone Acetonide]NSIntra-articularNot ReportedMagnesium SulfateNSUnknownNot ReportedMesalazineNSUnknownNot ReportedMetronidazole HydrochlorideNSUnknownNot ReportedMorphine SulfateNSUnknownNot ReportedMs IrNSUnknownNot ReportedMs IrNSUnknownNot Reported	Polymyxin B Sulfate	N		Unknown	
Hydromorphone HydrochlorideNSUnknownNot ReportedKenalog [Triamcinolone Acetonide]NSIntra-articularNot ReportedMagnesium SulfateNSUnknownNot ReportedMesalazineNSUnknownNot ReportedMetronidazole HydrochlorideNSUnknownNot ReportedMorphine SulfateNSUnknownNot ReportedMs IrNSUnknownNot ReportedMs IrNSUnknownNot Reported	Humira	N		Subcutaneous	•
Kenalog [Triamcinolone	Hydrochlorothiazide	N	S	Unknown	Not Reported
Acetonide] Magnesium Sulfate N S Unknown Mesalazine Not Reported Metronidazole Hydrochloride N S Unknown Not Reported Not Reported Not Reported Not Reported Morphine Sulfate N S Unknown Not Reported	Hydromorphone Hydrochloride	N	S	Unknown	Not Reported
MesalazineNSUnknownNot ReportedMetronidazole HydrochlorideNSUnknownNot ReportedMorphine SulfateNSUnknownNot ReportedMs IrNSUnknownNot Reported	Acetonide]	N		Intra-articular	•
Metronidazole HydrochlorideNSUnknownNot ReportedMorphine SulfateNSUnknownNot ReportedMs IrNSUnknownNot Reported	Magnesium Sulfate	N	S	Unknown	Not Reported
Morphine Sulfate N S Unknown Not Reported Ms Ir N S Unknown Not Reported	Mesalazine	N	S	Unknown	Not Reported
Ms Ir N S Unknown Not Reported	Metronidazole Hydrochloride	N	S	Unknown	Not Reported
	Morphine Sulfate	N	S	Unknown	Not Reported
Mupirocin Calcium Hydrate N S Unknown Not Reported	Ms Ir	N	S	Unknown	Not Reported
	Mupirocin Calcium Hydrate	N	S	Unknown	Not Reported



	Mup	pirocin Calcium Hydrate	N	S	Topical			N	ot Reported
	Nad	olol	N	S	Unknown			N	ot Reported
	Pan	toprazole	N	S	Unknown			N	ot Reported
	Pen	tasa	N	S	Unknown			N	ot Reported
	Pred	dnisone	N	S	Unknown			N	ot Reported
	Preg	gabalin	N	S	Unknown			N	ot Reported
	Pulr	micort	N	S	Unknown			N	ot Reported
	Refr	esh Tears	N	S	Ophthalmic			N	ot Reported
	Glyd	nex [Macrogol;Propylene col;Sodium Chloride]	N	S	Endosinusial				ot Reported
		vastatin	N	S	Unknown			N	ot Reported
	Sinu	us Rinse	N	S	Endosinusial			N	ot Reported
		mellose Sodium	N	S	Unknown			N	ot Reported
	Carı	mellose Sodium	N	S	Ophthalmic			N	ot Reported
	Sod	ium Chloride	N	S	Endosinusial			N	ot Reported
	Sod	ium Stearate	N	S	Oral			N	ot Reported
	Sulf	amethoxazole;Trimethoprim	N	S	Unknown			N	ot Reported
	Tria	mcinolone	N	S	Intra-articular			N	ot Reported
	Tria	mcinolone Acetonide	N	S	Intra-articular			N	ot Reported
	Trim	nethoprim	N	S	Unknown			N	ot Reported
	Vals	sartan	N	S	Intracardiac			N	ot Reported
	Vita	min C [Ascorbic Acid]	N	S	Unknown			N	ot Reported
	Vita	min D3	N	S	Unknown			N	ot Reported
	Xan	tofyl Palmitate	N	S	Unknown			N	ot Reported
	Zea	xanthin	N	S	Unknown			N	ot Reported
	Zinc	: Chloride	N	S	Unknown			N	ot Reported
	Cald	cium	N	С	Unknown			N	ot Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jan-2023	21932378	EXPEDITED (15-DAY)	Υ	HO, OT	CA-AstraZeneca- 2023A023914		65 YR	Female	CAN



Preferred Term	<u>Product</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosa	age Text	Duration	<u>Mfr</u>
Abdominal Pain; Anaemia;	Budesonide		N	S					Not Reported
Chronic Sinusitis; Colitis;	Acetaminophen		N	S					Not Reported
Colitis Ulcerative;	Paracetamol/Dextropropoxyphen	1	N	S					Not Reported
Constipation; Drug	е								
Ineffective; Dyspepsia;	Pseudoephedrine/Paracetamol		N	S					Not Reported
Erythema; Female Genital	Triamcinolone Acetonide/Acetic		N	S					Not Reported
Tract Fistula; Frequent	Acid			_					
Bowel Movements;	Acetylsalicylic Acid		N	S					Not Reported
Haematochezia;	Acetylsalicylic Acid/Sodium		N	S					Not Reported
Headache; Infusion	Bicarbonate/Citric Acid			0					N (B)
Related Reaction; Macular	Align		N	S S					Not Reported
Degeneration; Malaise;	Amoxicillin Trihydrate		N	S					Not Reported
Nausea; Off Label Use; Oral Candidiasis; Pain;	Apo-Alpraz		N			0.25	5 Milligram		Not Reported
Paraesthesia Oral;	Apo-Pregabalin		N	S		150) Milligram		Not Reported
Procedural Pain; Proctitis;	Atorvastatin Calcium		N	S					Not Reported
Pyrexia; Radiculopathy;	Diphenoxylate		N	S					Not Reported
Rectal Haemorrhage;	Hydrochloride/Atropine Sulfate								
Therapeutic Product Effect	Azithromycin		N	S					Not Reported
Incomplete; Vaginal	Benzydamine		N	S					Not Reported
Discharge; Vaginal	Betamethasonevalerate		N	S					Not Reported
Flatulence; Weight	Biaxin XI		N	S					Not Reported
Decreased	Bifidobacterium Spp.		N	S					Not Reported
	Bisacodyl		N	S					Not Reported
	Calcitriol/Calcium		N	S					Not Reported
	Carbonate/Zinc								
	Calcium & Vitamin D		N	S					Not Reported
	Calcium Carbonate/Vitamin		N	S					Not Reported
	D3/Zinc Oxide								
	Cetirizine Hydrochloride		N	S					Not Reported
	Ciprofloxacin		N	S					Not Reported
	Ciprofloxacin Hydrochloride		N	S					Not Reported
	Clarithromycin		N	S					Not Reported
	Clotrimazole		N	S					Not Reported
	Cortenema Suspension		N	S					Not Reported
	Nicotinamide/Cupric Oxide/Folic		N	S					Not Reported
	Acid/Zinc								
	Desonide		N	S					Not Reported
	Diphenhydramine		N	S					Not Reported
	Diphenhydramine Hydrochloride		N	S					Not Reported



Empracet N S S Not Reported Entryvio N S S Not Reported Fentanyl Citrate N S S Not Reported Funcionazole N S S Not Reported Not Reported Funciose N N S Not Reported Not Reported Silvering Not Reported Not Reported Silvering Not Reported Not Reported Silvering Not Reported Not Reported Silvering Not Reported Not Repo				•	
Ertapenem Sodium	Empracet	N			Not Reported
Fentanyl Citrate N S Not Reported Fentanyl Citrate N S Not Reported Fluctorazole N S Not Reported Fluctose N S Not Reported Glycerin N S Not Reported Glyceryl Trinitrate N S Not Reported Neomycin/Gramicidin/Polymyxin N S Not Reported Neomycin/Gramicidin/Polymyxin N S Not Reported B Sulfate N S Not Reported Hubitrol N S Not Reported Hydrochlorothiazide N S Not Reported Hydrochlorothiazide N S Endocervical Not Reported Hydrochlorothiazide N S Endocervical Not Reported Hydrochlorida/Sulfa N S Endocervical Not Reported Hydrochloride/Sulfa N S Not Reported Methoxazole/Trimethoprin Loperamide Hydrochloride N S	Entyvio	N	S		Not Reported
Fentanyl Citrate	Ertapenem Sodium	N			Not Reported
Fluticasone N S Not Reported Fluticasone Propionate N S Not Reported Fluticasone Propionate N S Not Reported No	Fentanyl	N	S		Not Reported
Fluticasone Propionate	Fentanyl Citrate	N	S		Not Reported
Fluticasone Propionate	Fluconazole	N	S		Not Reported
Glycerin	Fluticasone Propionate	N	S		
Silverol	Fructose	N	S		Not Reported
Silverol	Glycerin	N	S		Not Reported
Glyceryl Trinitrate N S S Not Reported Not Reported Neomycin/Gramicidin/Polymyxin N S S Not Reported B Sulfate Habitrol N S S Not Reported Humira N S Not Reported Humira N S Not Reported Hydrochlorothiazide N S Subcutaneous Not Reported Hydrochlorothiazide N S Subcutaneous Not Reported Hydrochlorothiazide N S Subcutaneous Not Reported Hydrochlorothiazide N S Endocervical Not Reported Hydrochloride N S Endocervical Not Reported Not Reported Hydrochloride/Sulfa Not Reported Not Reported Hydrochloride/Sulfa Not Reported Not Reported Hydrochloride/Sulfa Not Reported Not Reported Not Reported Macrogol 3350/Sodium N S Not Reported Not Reported Magnesium Carbonate N S Not Reported Magnesium Hydroxide N S Not Reported Magnesium Hydroxide N S Not Reported Magnesium Hydroxide N S Not Reported Magnesium Oxide N S Not Reported Magnesium Oxide N S Not Reported Magnesium Oxide N S Not Reported Not Reported Magnesium Oxide N S Not Reported Not Reported Mesalazine N S Not Reported Not Reported Mesalazine N S Not Reported Methylprednisolone Sodium N S Not Reported Methylprednisolone Sodium N S Not Reported Not Reported Methylprednisolone Sodium N S Not Reported Midazolam N S Not Reported Not Reported Midazolam N S Not Reported Not Reported Not Reported Midazolam N S Not Reported Not Reported Not Reported Midazolam N S Not Reported N		N	S		
Neomycin/Gramicidin/Polymyxin B S S Indate B Sulfate Habitrol N S Not Reported Humira N S Not Reported Hydrochlorothiazide N S Subcutaneous Not Reported Hydrochlorothiazide N S Endocervical Not Reported Hydrochloride/Soulfa Methoxazole/Trimethoprim Loperamide Hydrochloride N S N S Not Reported Macrogol 3350/Sodium N S Not Reported Magnesium Carbonate N S N S Not Reported Magnesium Carbonate N S N S Not Reported Magnesium Hydroxide N S N S Not Reported Magnesium Oxide N S N S Not Reported Magnesium Oxide N S N S Not Reported Magnesium Sulfate N S N S Not Reported Mesalazine N S N S Not Reported Mesalazine N S N S Not Reported Methoridazole N S N S Not Reported Methoridazole N S N S Not Reported Methoridazole N S N S Not Reported Midazolam Not Reported Midazolam Not Reported Morphine Sulfate N S N S Not Reported Morphine Sulfate N S S Not Reported		N	S		
B Sulfate		N			
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Mupirocin N S Not Reported					
Nadolol N S Not Reported					
	Nadolol	N	S		Not Reported



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		Nicoderm		N	S						ot Reported
		Nicotinamide		N	S						ot Reported
		Nicotine		N	S						ot Reported
		Oxybutynin Hydrochloride		N	S						ot Reported
		Pantoprazole		N	S						ot Reported
		Potassium Chloride		N	S						ot Reported
		Prednisone		N	S						ot Reported
		Refresh Tears		Ν	S						ot Reported
		Polyethylene Glycol\Propylene		N	S					N	ot Reported
		Glycol\Sodium Chloride									
		Sinus Rinse		N	S						ot Reported
		Sodium Carboxymethyl		N	S					N	ot Reported
		Cellulose Sucralfate		N	S					N	ot Reported
		Sulfamethoxazole/Trimethoprim		N	Š		200 Milli	gram			ot Reported
		Triamcinolone Acetonide		N	S						ot Reported
		Ubidecarenone		N	S						ot Reported
		Vitamin D3		Ν	S						ot Reported
		Xantofyl Palmitate		N	S						ot Reported
		Zeaxanthin		Ν	S						ot Reported
		Zinc Oxide		Ν	S						ot Reported
		Zopiclone		N	S					N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Jan-2023	219329	28 EXPEDITED (15-DAY)	N	(ОТ	US-ALLERGA 2302484US	AN-			Female	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage 1	<u> Text</u>	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Skin Cancer		Refresh Tears		Υ	S	Ophthalmic				N	ot Reported
						<u> </u>					•
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Contro	l #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Feb-2023	212648	73 EXPEDITED (15-DAY)	Υ	I	но, от	CA-Accord-2	75681		71 YR	Female	CAN
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage 1	<u> Fext</u>	<u>Duration</u>	<u>M</u> 1	<u>ir</u>
Chronic Sinusitis; Drug	a	Atorvastatin		N	S	Unknown				N	ot Reported
Ineffective; Dyspepsia	ι;			N	S						ot Reported
Infusion Related Read	ction;	Pregabalin		IN	3	Unknown					•
Macular Degeneration Malaise; Nausea; Pair	ı;	Pantoprazole		N	S	Unknown				N	ot Reported



FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Paraesthesia Oral; Procedural Pain; Pyrexia; Therapeutic Product Effect Incomplete; Weight Decreased

			Dotalioa 110	port	
Simvastatin Acetaminophen	N N	S S	Unknown		Accord Not Reported
Adalimumab	N	S	Subcutaneous		Not Reported
Alprazolam	N	S	Unknown		Not Reported
Amoxicillin	N	S	Unknown		Not Reported
Atropine W/Diphenoxylate	N	S	Oral		Not Reported
Azithromycin	N	S	Unknown		Not Reported
Betamethasone	N	S	Unknown		Not Reported
Biaxin XI	N	S	Unknown	Tablet (Extended- Release)	Not Reported
Bisacodyl	N	S	Unknown		Not Reported
Budesonide	N	S	Oral		Not Reported
Calcium W/Colecalciferol	N	S	Unknown		Not Reported
Calcium Carbonate	N	S	Unknown		Not Reported
Cetirizine Hydrochloride	N	S	Unknown		Not Reported
Clarithromycin	N	S	Unknown		Not Reported
Clotrimazole	N	S	Unknown		Not Reported
Cupric Oxide	N	S	Unknown		Not Reported
Tocopherol	N	S	Unknown		Not Reported
Desonide	N	S	Unknown		Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown		Not Reported
Entocort	N	S	Oral	Capsule, Sustained Release	Not Reported
Ertapenem Sodium	N	S	Unknown		Not Reported
Fluticasone	N	S	Unknown		Not Reported
Glycerin	N	S	Oral		Not Reported
Gramicidin W/Neomycin/Polymyxin B	N	S	Unknown	Ointment Dental	Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical		Not Reported
Infliximab	N	S	Intravenous (not otherwise specified)		Not Reported

Note: If the field is blank, there is no data.



				<u> </u>	
Isoniazid W/Pyridoxine	N	S	Unknown		Not Reported
Lomotil	N	S	Oral		Not Reported
Magnesium Sulfate	N	S	Intramuscular		Not Reported
Mesalazine	N	S	Unknown		Not Reported
Metronidazole	N	S	Unknown		Not Reported
Morphine Sulfate	N	S	Unknown		Not Reported
Mupirocin	N	S	Unknown	Route-Topical	Not Reported
Nadolol	N	S	Unknown	·	Not Reported
Nicoderm	N	S	Transdermal		Not Reported
Nicotine	N	S	Unknown		Not Reported
Nicotine Polacrilex	N	S	Unknown		Not Reported
Potassium Chloride	N	S	Unknown		Not Reported
Prednisone	N	S	Unknown		Not Reported
Pulmicort	N	S		Inhalation	Not Reported
Carboxymethylcellulose Sodium	N	S	Unknown	Ophthalmic	Not Reported
Sodium Chloride	N	S	Unknown	Intra-Nasal, Inhalation	Not Reported
Sulfamethoxazole	N	S	Unknown		Not Reported
W/Trimethoprim Triamcinolone Acetonide	N	S	latra articular		Not Reported
Vitamin D3	N	S	Intra-articular		Not Reported
Xantofyl Palmitate	N	S	Unknown		Not Reported
Zeaxanthin	N	S	Unknown		Not Reported
Macrogol	N	S	Unknown		Not Reported
Sodium Bicarbonate	N	S			Not Reported
Zinc Oxide	N	S	Unknown		Not Reported
Loperamide	N	S	Oral		Not Reported
Acetaminophen	N	S			Not Reported
W/Dextropropoxyphene Ambroxol,Cetirizine	N	S			Not Reported
Hydrochloride	14				·
Calcitriol, Calcium Carbonate,	N	S			Not Reported
Zinc					

Date - Time: 11-Apr-2023 10:56:54 AM EST

Note: If the field is blank, there is no data.



				•	
Hydrochlorothiazide Humira	N N	S S	Subcutaneous	Solution Subcutaneous	Not Reported Not Reported
Sodium Hydrogen Carbonate, Potassium Chloride, Mac	N	S			Not Reported
Flovent	N	S			Not Reported
Nicotinamide	N	S			Not Reported
Polyethylene Glycol	N	S			Not Reported
Refresh Tears	N	S		Opthalmic	Not Reported
Trimethoprim	N	S			Not Reported
Atropine Sulfate	N	S	Oral		Not Reported
Benzydamine Hydrochloride	N	S			Not Reported
Calcitriol	N	S	Intra-articular		Not Reported
Gramicidin	N	S			Not Reported
Imodium	N	S			Not Reported
Nicomorphine Hydrochoride	N	S			Not Reported
Glycerol	N	S	Oral		Not Reported
Sulfamethoxazol	N	S			Not Reported
Calcium	N	С			Not Reported
Neomycin	N	С			Not Reported
Metoclopramide Hydrochloride	N	С	Oral		Not Reported
Calcium	N	С			Not Reported
Valsartan	N	С	Oral	1 Every 1 Days	Not Reported
Calcium And Ergocalciferol	N	С	Unknown		Not Reported
Amoxicillin	N	C			Not Reported
Calcium Gluconate	N	С			Not Reported
Calcium W/Colecalciferol	N	С			Not Reported
Diphenhydramine Hydrochloride Mupirocin Calcium	N N	C C			Not Reported Not Reported
Sodium	N	Ċ			Not Reported
Benadryl	N	Č			Not Reported
Atropine W/Diphenoxylate	N	Š			Not Reported
Betamethasone	N	S	Unknown		Not Reported
Diphenhydramine Hydrochloride	N	S	Oral		Not Reported
Hydromorphone Hydrochloride	N	S			Not Reported
Sulfamethoxazole	Ν	S	Unknown		Not Reported
W/Trimethoprim		_			N . 5
Sulfamethoxazole W/Trimethoprim	N	S	Oral		Not Reported



	FI	uticasone		N	S	Unknown					Not Reported
	At	ropine Sulfate		N	S	Oral				I	Not Reported
	At	ropine Sulfate		N	S	Oral				!	Not Reported
		ropine Sulfate alsartan		N N	S C	Oral					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Contro	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
01-Feb-2023	21886070	EXPEDITED (15-DAY)	N	0	Γ	CA-PFIZER 2021018245				Female	CAN
Preferred Term	<u>P</u> 1	roduct	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>N</u>	<u>Nfr</u>
Drug Ineffective; Macul Degeneration	ılar Al	prazolam		N	S	Unknown	Unk			I	Not Reported
	At	orvastatin		N	S	Unknown	Unk			1	Not Reported
	Pr	egabalin Mylan		N	S	Unknown	Unk			1	Mylan
	Se	ertraline Hcl		N	S	Unknown	25 Millig	gram, Qd		1	Mylan
	Ar	mlodipine Besilate		N	S	Unknown	5 Milligr	am, Qd		1	Mylan
	Pa	antoprazole		N	S	Unknown	40 Millig	gram, Qd		1	Not Reported
	Pa	antoprazole		N	S	Unknown	Unk			1	Not Reported
	Ar	moxicillin Trihydrate		N	S	Unknown	Unk			1	Not Reported
	Az	zithromycin		N	S	Unknown	Unk			ļ	Not Reported
	At	ropine Sulfate		N	S	Oral	Unk			I	Not Reported
	Hy	ydromorphone Hydrochloride		N	S	Unknown	Unk			I	Not Reported
	M	orphine Sulfate		N	S	Unknown	Unk				Not Reported
	Sc	odium Bicarbonate		N	S	Unknown	Unk			I	Not Reported
	Sc	odium Chloride		N	S	Unknown	Unk			I	Not Reported
	Po	otassium Chloride		N	S	Unknown	Unk				Not Reported
	At Ho	ropine Sulfate, Diphenoxylate		N	S	Oral	Unk			1	Not Reported
	Bi	soprolol Fumarate		N	S	Unknown	5 Milligr	am, Qd		1	Not Reported
	Tr	iamcinolone Acetonide		N	S	Intra-articular	Unk			1	Not Reported
	Ad	dalimumab		N	S	Subcutaneous	Unk			1	Not Reported



Mesalazine	N	S	Unknown	Unk	Not Reported
Metronidazole Benzoate	N	S	Unknown	Unk	Not Reported
Acetaminophen	N	S	Unknown	Unk	Not Reported
Avamys	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Respiratory (inhalation)	Unk	Not Reported
Cetirizine [Cetirizine Hydrochloride]	N	S	Unknown	Unk	Not Reported
Clarithromycin	Ν	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	Ν	S	Unknown	Unk	Not Reported
Ertapenem Sodium	Ν	S	Unknown	Unk	Not Reported
Flovent	N	S	Unknown	Unk	Not Reported
Glycerine Ichtyol	N	S	Unknown	Unk	Not Reported
Gramicidin;Neomycin;Polymyxin B	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	Ν	S	Oral	1 Dosage Form, Q6hr	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Nadololum	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Sinus Rinse	N	S	Nasal	Unk	Not Reported
Sulfamethoxazole And Trimethoprim	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Nicoderm	Ν	S	Topical	Unk	Not Reported



			201404 . 10	P	
Nicoderm	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Doxazocin	N	S	Unknown	2 Milligram, Qd	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid	N	S	Oral	Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Azithromycin Monohydrate	N	S	Unknown	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Neomycin Sulfate	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Vitamin B 12 [Cyanocobalamin]	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Vitamin E Nos	N	S	Intracardiac	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Calcium Carbonate W/Vitamin D [Calcium Carbonate; Ergocalciferol]	N	S	Unknown	Unk	Not Reported
Isoniazid;Pyridoxine Hydrochloride; Sulfamethoxazole;Trimethoprim	N	S	Unknown	Unk	Not Reported
Amoxicillin	N	S	Unknown	Unk	Not Reported
Mupirocin Calcium	N	S	Unknown	Unk	Not Reported



			= = = = = = = = = = = = = = = = = = = =	<u> </u>	
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Salbutamol	N	S	Unknown	Unk	Not Reported
Mepolizumab	N	S	Intravenous (not otherwise specified)	100 Milligram	Not Reported
Irbesartan	N	S	Unknown	75 Milligram, Qd	Not Reported
Formoterol Fumarate	N	S	Unknown	Unk	Not Reported
Clopidogrel Bisulfate	N	S	Unknown	25 Milligram, Qd	Not Reported
Rosuvastatin Calcium	N	S	Unknown	10 Milligram, Qd	Not Reported
Valsartan	N	S	Unknown	Unk	Not Reported
Calcium Gluconate	N	S	Unknown	Unk	Not Reported
Calcium Carbonate; Colecalciferol	N	S	Unknown	Unk	Not Reported
Triamcinolone	N	S	Unknown	Unk	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Entocort	N	S	Unknown	Unk	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Gramicidine	N	S	Unknown	Unk	Not Reported
Humira	N	S	Unknown	Unk	Not Reported
Macrogol	N	S	Unknown	Unk	Not Reported
Ms Ir	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S	Unknown	Unk	Not Reported
Refresh Tears Lubricant	N	S	Unknown	Unk	Not Reported
Trimethoprime	N	S	Unknown	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported



	Gramicidin Polymyxin	;Neomycin Sulfate;		N	S	Unknown	Unk		1	Not Reported
	Glycerol	D Sullate		N	S	Unknown	Unk		ı	Not Reported
	Sodium Ste	earate		N	S	Unknown	Unk		1	Not Reported
	Dilaudid			N	S	Unknown	Unk		1	Not Reported
	Bactrim			N	S	Unknown	Unk		1	Not Reported
	Ambroxol			N	S	Unknown	Unk		1	Not Reported
	Diphenoxy	late Hydrochloride		N	S	Unknown	Unk		1	Not Reported
	D-Alpha To	ocopherol		N	S	Unknown	Unk		1	Not Reported
		3350;Potassium odium Bicarbonate; oloride		N	S	Unknown	Unk		1	Not Reported
	Magnesiun			N	S	Unknown	Unk		1	Not Reported
	Zinc Chlori	de		N	S	Unknown	Unk		1	Not Reported
	Vitamin E			N	S	Unknown	Unk		1	Not Reported
	Calcium Ca	arbonate/Vitamin D3		N	С	Unknown	Unk		1	Not Reported
FDA Received Date Ca	nse# C	ase Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Co	ontrol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
02-Feb-2023 19	362106 E	XPEDITED (15-DAY)	Υ	(DΤ	CA-PFI 202161	ZER INC- 9805		Female	CAN
Preferred Term	Product		Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>N</u>	<u>Mfr</u>
Drug Ineffective; Macular	Pantoprazo	ole		N	S	Unknown	Unk		ı	Unknown
Degeneration	Pantoprazo	ole		N	S	Unknown	Unk		ı	Unknown
	Alprazolam	1		N	S	Respiratory	Unk		ſ	Pfizer
						(inhalation)				
	Alprazolam	1		N	S	(innalation) Unknown	Unk		ŀ	Pfizer
	Alprazolam Azithromyo			N N	s s	•	Unk Unk			Pfizer Pfizer
	•					Unknown			ſ	
	Azithromyo Lomotil			N	S	Unknown Unknown	Unk		; ;	Pfizer Pfizer Pfizer
	Azithromyo Lomotil	ohone Hydrochloride n Sulfate		N N	s s	Unknown Unknown Oral	Unk Unk		; ; ;	Pfizer Pfizer



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Neomycin Sulfate	N	S	Unknown	Unk	Pfizer
Potassium Chloride	N	S	Unknown	Unk	Pfizer
Pregabalin	N	S	Topical	Unk	Pfizer
Pregabalin	N	S	Unknown	Unk	Pfizer
Sodium Bicarbonate	N	S	Unknown	Unk	Pfizer
Triamcinolone	N	S	Unknown	Unk, Suspension	Pfizer
Triamcinolone	N	S	Intra-articular	Unk, Suspension	Pfizer
Amoxicillin	N	S	Unknown	Unk	Pfizer
Amoxicillin	N	S	Unknown	Unk	Pfizer
Atorvastatin Calcium	N	S	Unknown	Unk	Pfizer
Atorvastatin Calcium	N	S	Unknown	Unk	Pfizer
Morphine Sulfate	N	S	Unknown	Unk	Pfizer
Atropine Sulfate/Diphenoxylate	N	S	Oral	Unk	Pfizer
Hydrochloride Atropine Sulfate/Diphenoxylate Hydrochloride	N	S	Unknown	Unk	Pfizer
Atropine Sulfate	Ν	S	Unknown	Unk	Pfizer
Calcium Carbonate	Ν	S	Unknown	Unk	Not Reported
Calcium Gluconate	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk	Not Reported
Sodium Chloride	Ν	S	Other	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Adalimumab	N	S	Subcutaneous	Unk	Not Reported
Gramicidin;Neomycin Sulfate; Polymycin B	N	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Unk	Not Reported
Ocean Nasal	N	S	Nasal	Unk	Not Reported
Mesalamine	N	S	Unknown	Unk	Not Reported
Mesalamine	N	S	Unknown	Unk	Not Reported
Moviprep [Ascorbic Acid; Macrogol 3350;Potassium	N	S	Unknown	Unk	Not Reported



Chloride;Sodium Ascorb Acetaminophen	N	s			Not Reported
•			Unknown	Unk	•
Betamethasone	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Transplacental	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
Humira	N	S	Subcutaneous	Unk	Not Reported
Humira	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
And Atropine Sulfate Ertapenem [Ertapenem Sodium]	N	S	Nasal	Unk	Not Reported
Ertapenem [Ertapenem Sodium]	N	S	Unknown	Unk	Not Reported
Ertapenem [Ertapenem Sodium]	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Ophthalmic	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Glycerol	N	S	Oral	Unk	Not Reported
Glycerol	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Mupirocin	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Intra-articular	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
			CHRIOWII	OTIK	•



Nicoderm	N	S	Unknown	Unk (Formulation: Patch)	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Subcutaneous	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Refresh Tears	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole And Trimethoprim	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Vitamin E Natural [Tocopheryl Acetate]	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Cholecalciferol	N	S	Unknown	Unk	Not Reported
Macrogol/Potassium Chloride/Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Flovent	N	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	N	S	Unknown	Unk	Not Reported
Bactroban [Mupirocin Calcium]	N	S	Unknown	Unk	Not Reported
Bactroban [Mupirocin Calcium]	N	S	Topical	Unk	Not Reported
Pulmicort	N	S	Respiratory (inhalation)	Unk	Not Reported
Statex [Morphine Sulfate]	N	S		Unk	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Vitamin D [Colecalciferol]	N	S	Unknown	Unk	Not Reported



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D-Alpha Tocopheryl Acetate	N	S	Intracardiac	Unk	Not Reported
D-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
Ichthammol And Zinc Oxide	N	S	Unknown	Unk	Not Reported
Calcium Phosphate Dibasic/Colecalciferol	N	S	Unknown	Unk	Not Reported
Calcium Citrate	N	S	Unknown	Unk	Not Reported
Valsartan	N	S	Intracardiac	Unk	Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Avamys	N	S	Ophthalmic	Unk,(Spray (Except Inhalation))	Not Reported
Dilaudid	N	S	Unknown	Unk	Not Reported
Entocort	N	S	Unknown	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Oral	Unk (Liquid)	Not Reported
Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Mupirocin Calcium	N	S	Topical	Unk	Not Reported
Prednisone Acetate	N	S	Unknown	Unk	Not Reported
Sinus Rinse	N	S	Nasal	Unk	Not Reported
Macrogol 3350	N	S	Unknown	Unk	Not Reported
Pms Azithromycin	N	S	Unknown	Unk	Not Reported
Macrogol 3350/Potassium Chloride/Sodium Chloride/Sodium Sulfate	N	S	Unknown	Unk	Not Reported
Glycerol/Sodium Stearate	N	S	Oral	Unk	Not Reported
Ambroxol/Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Bactrim	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Fluticasone Propionate	N	S	Unknown	Unk	Not Reported
Benzydamine Hydrochloride	N	S	Unknown	Unk	Not Reported
Dulcolax [Bisacodyl]	N	S	Unknown	Unk	Not Reported
Calcium Carbonate W/Vitamin D	N	S	Unknown	Unk	Not Reported



	Vita Sim	eramide Hydrochloride min C [Ascorbic Acid] vastatin		N N N	s s s	Unknown Unknown Unknown	Unk Unk Unk			Not Reported Not Reported Not Reported	
	Fruc Chlo	nex [Sodium Chloride] stose/Glycerol/Sodium oride		N N	S S	Endosinusial Unknown	Unk Unk			Not Reported Not Reported	
	Hyd Ken Ace Frud	eramide rochloride/Simeticone alog [Triamcinolone tonide] ctose eticone		N N N N	s s s	Unknown Intra-articular	Unk Unk			Not Reported Not Reported Not Reported Not Reported	
	Lope	eramide		N	S					Not Reported	
FDA Received Date 02-Feb-2023	<u>Case #</u> 21945525	Case Type EXPEDITED (15-DAY)	<u>Health</u> Y	Prof O	utcomes T	Mfr Contro CA-AstraZer	neca-	<u>Age</u>	<u>Sex</u> Female	<u>Country</u> USA	
	0.3020		•	Ü	•	2023A02647			· Smare		
Preferred Term	<u>Pro</u>	<u>duct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration		<u>Mfr</u>	
Drug Ineffective; Macul Degeneration	lar Bud Pulr	esonide		N N	S S					Not Reported Astrazeneca	



Entocort Nicoderm	N N	S S	Unknown	Not Reported Not Reported
Nicotine	N	S	Unknown	Not Reported
Nicotine	N	S	Other	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Not Reported
Loperamide Hydrochloride	N	S	Unknown	Not Reported
Dimethicone\Loperamide	N	S	Oral	Not Reported
Zinc Oxide	N	S	Unknown	Not Reported
Paracetamol	N	S	Unknown	Not Reported
Adalimumab	N	S	Subcutaneous	Not Reported
Alprazolam	N	S	Unknown	Not Reported
Ambroxol Hydrochloride	N	S	Unknown	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown	Not Reported
Atorvastatin Calcium	N	S	Unknown	Not Reported
Atropine	N	S	Unknown	Not Reported
Avamys	N	S	Unknown	Not Reported
Betamethasone	N	S	Unknown	Not Reported
Betamethasone Valerate	N	S	Unknown	Not Reported
Biaxin XI	N	S	Unknown	Not Reported
Bisacodyl	N	S	Unknown	Not Reported
Calcium Carbonate	N	S	Unknown	Not Reported
Calcium Gluconate	N	S	Unknown	Not Reported
Clarithromycin	N	S	Unknown	Not Reported
Clotrimazole	N	S	Unknown	Not Reported
Cupric Oxide	N	S	Unknown	Not Reported
Nicotinic Acid/Cupric Oxide/Folic Acid/Zinc Oxide	N	S	Unknown	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Not Reported



Dilaudid	N	S	Unknown	Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown	Not Reported
DI-Alpha Tocopheryl Acetate	N	S	Unknown	Not Reported
Ergocalciferol	N	S	Unknown	Not Reported
Ertapenem Sodium	N	S	Unknown	Not Reported
Flovent	N	S	Unknown	Not Reported
Fluticasone Furoate	N	S	Unknown	Not Reported
Sodium Chloride/Glycerol/Fructose	N	S	Unknown	Not Reported
Glycerine	N	S	Oral	Not Reported
Gramicidin	N	S	Unknown	Not Reported
Neomycin Sulfate/Gramicidin/Polymyxin B Sulfate	N	S	Unknown	Not Reported
Humira	N	S	Subcutaneous	Not Reported
Hydrochlorothiazide	N	S	Unknown	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Not Reported
Kenalog [Triamcinolone Acetonide]	N	S	Intra-articular	Not Reported
Magnesium Sulfate	N	S	Unknown	Not Reported
Mesalazine	N	S	Unknown	Not Reported
Metronidazole Hydrochloride	N	S	Unknown	Not Reported
Morphine Sulfate	N	S	Unknown	Not Reported
Ms Ir	N	S	Unknown	Not Reported
Mupirocin Calcium Hydrate	N	S	Unknown	Not Reported
Nadolol	N	S	Unknown	Not Reported
Pantoprazole	N	S	Unknown	Not Reported
Pentasa	N	S	Unknown	Not Reported
Prednisone	N	S	Unknown	Not Reported
Pregabalin	N	S	Unknown	Not Reported
Refresh Tears	N	S	Ophthalmic	Not Reported



Salinex [Macrogol;Propylene

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

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		-	-						-		-
03-Feb-2023	219506	39	DIRECT			RI			76 YR	Female	USA
FDA Received Date	Case #		Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Erythema Of Eyelid; Eyelids Pruritus; Swell Of Eyelid; Therapy No Responder			Tears Lubricant Eye Carboxymethylcellulose)		Υ	S	Ophthalmic	Frequency : Every 12 Hours;		E	zricare
Preferred Term		Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
02-Feb-2023	219466	648	DIRECT			DS, RI			67 YR	Male	USA
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
		Calcium			N	С	Unknown			No	ot Reported
		Zinc Ch	loride		N	S	Unknown			No	ot Reported
		Zeaxant	thin		Ν	S	Unknown			No	ot Reported
		Xantofy	Palmitate		Ν	S	Unknown			No	ot Reported
		Vitamin	D3		Ν	S	Unknown			No	ot Reported
		Vitamin	C [Ascorbic Acid]		Ν	S	Unknown			No	ot Reported
		Valsarta	ın		Ν	S	Intracardiac			No	ot Reported
		Trimeth	oprim		N	S	Unknown				ot Reported
			nolone Acetonide		N	S	Intra-articular				ot Reported
		Triamcir	•		N	S	Intra-articular				ot Reported
			ethoxazole/Trimethoprim		N	S	Oral Unknown				ot Reported
			Stearate		N	S	Endosinusial				ot Reported
			Chloride		N	S	Ophthalmic				ot Reported
			ose Sodium		N N	S	Unknown				ot Reported
		Sinus R	inse ose Sodium		N	S S	Endosinusial				ot Reported ot Reported
		Simvast			N	S	Unknown				ot Reported
			Sodium Chloride]			0	Liidosiiidsiai			. 1	-t Demonto d

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Not Reported



FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	Proc	<u>luct</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage	Text	Duration	Mf	
Eye Infection; Nausea; Recalled Product Administered	; Refr	esh Liquigel		Y	S					Ur	nknown
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Feb-2023	21950640	DIRECT		D	S, RI				66 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>Mf</u>	<u>.</u>
Conjunctivitis; Instillation Site Reaction; Recalled Product Administered		oxymethylcellulose Sodium		Y	S	Ophthalmic		Quantity : 2 Drop(\$ ency : As Needed;	5);	De	elsam Pharm
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Feb-2023	21951661	DIRECT	N	0	Т				46 YR	Female	USA
Preferred Term	Proc	luct	Comp.	OTC	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Blindness; Eye Irritatio Eye Pruritus; Foreign Body Sensation In Eye Ocular Hyperaemia; Periorbital Swelling; Therapy Cessation; Vis Impairment	Drop es; Sodi	cial Tears Lubricant Eye s (Carboxymethylcellulose um)		Y	S					Ez	rricare
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Feb-2023	21951668	DIRECT		0	Т				57 YR	Female	USA
Preferred Term	Proc	luct	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>Text</u>	<u>Duration</u>	<u>Mf</u> ı	<u>.</u>
Bladder Pain; Erythem Eyelid; Micturition Urgency; Photophobia Pollakiuria; Recalled Product Administered; Renal Disorder; Renal Pain; Swelling Of Eyeli	Drop ; Sodi	cial Tears Lubricant Eye s (Carboxymethylcellulose um)		Y	S	Ophthalmic		Quantity : 1 Drop(\$ ency : Every 6	S);6 WEEK	Ez	rricare

Note: If the field is blank, there is no data.



FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Urinary Tract Infection											
FDA Received Date	Case #	<u>#</u>	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Feb-2023	219569	998	DIRECT		DS	3			53 YR	Female	USA
Preferred Term		Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Anxiety; Drug Ineffective Eye Discharge; Eyelid Margin Crusting;			Tears Lubricant Eye Carboxymethylcellulose		Υ	S	Ophthalmic	Frequency : Every 4 Hours;		E	Ezricare
Headache; Lacrimation Increased; Memory Impairment; Nervousn Ocular Hyperaemia; V Impairment	ess;	Lumify Systane Artificial	Tears Lubricant Eye Carboxymethylcellulose			S S S				1	Not Reported Not Reported Not Reported
FDA Received Date	Case #	<u>#</u>	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Feb-2023	21957	012	DIRECT		0	Γ			67 YR	Female	USA
Preferred Term		Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Blepharitis; Conjunctiv Haemorrhage; Hypertension; Keratitis		Carboxy Lisinopr Areds	methylcellulose Sodium		Y N N	S C C	Ophthalmic	Frequency : As Needed;		1	Delsam Pharm Not Reported Not Reported
FDA Received Date	Case #	<u>#</u>	Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Feb-2023	21957	079	DIRECT		DS	S, OT			46 YR	Female	USA
Preferred Term		Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Arthralgia; Chest Pain; Chills; Cough; Dyspno Ear Pain; Ear Pruritus; Eye Pain; Eye Pruritus Fatigue; Headache; Lo Of Personal Independe In Daily Activities; Mala Nausea; Pelvic Pain; Pyrexia; Viral Infection	ea; s; oss ence aise;		Tears Lubricant Eye Carboxymethylcellulose)		Y	S	Ophthalmic	2 Drop(S) As Needed			Global Pharmaceuticals

Note: If the field is blank, there is no data.



Vision Blurred											
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	<u> </u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Feb-2023	21957980	DIRECT	N							Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage To	<u>ext</u>	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Eye Irritation	Dro	ficial Tears Lubricant Eye pps (Carboxymethylcellulose dium)		N	S						Not Reported
FDA Received Date	Case #	Case Type	Health	Prof O	utcomes	Mfr Control #	<u> </u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Feb-2023	21958512	DIRECT	N	0	т				57 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage To	<u>ext</u>	<u>Duration</u>	!	<u>VIfr</u>
Blindness; Corneal Transplant; Endophthalmitis; Ulcerative Keratitis	Dro	ficial Tears Lubricant Eye ops (Carboxymethylcellulose dium)		Υ	S						Ezricare
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	<u> </u>	03B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Feb-2023	21961577	DIRECT		0	T				54 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage To	<u>ext</u>	<u>Duration</u>	<u>!</u>	<u>Mfr</u>
Conjunctivitis; Eye Infection; Eye Pain; Feeling Abnormal; Pro Contamination; Recall	Ado duct Dul ed Vita	rboxymethylcellulose Sodium derall loxetine amin And Mineral		N N N	S C C C						Not Reported Not Reported Not Reported Not Reported
Product Administered	Vita Net	oplements amin B1 ttle Tea		N N	C C						Not Reported Not Reported
	Ext	ck Walnut And Wormwood ract		N	С						Not Reported
	R-A	ino Acids Alpha Lipoic Acid		N N N	000						Not Reported Not Reported Not Reported
		berine I Oil		N N	C C						Not Reported Not Reported



		Dim 7-Keto Adrenal (Ptobiotics	Glandular & Adaptogens		N N N	C C C				No No	t Reported t Reported t Reported t Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Feb-2023	219617	54	DIRECT			RI			63 YR	Male	USA
Preferred Term		Product		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Adverse Event; Recall Product Administered	ed		Fears Lubricant Eye arboxymethylcellulose		Υ	S	Ophthalmic	Frequency : As Needed;		Ez	ricare
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Feb-2023	219617	'80	DIRECT			RI			24 YR	Female	USA
Preferred Term		Product		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Eye Infection			Fears Lubricant Eye arboxymethylcellulose		Υ	S	Ophthalmic	Other Quantity : 2 Drop(S) Frequency : As Needed;);	Ez	ricare
FDA Received Date	Case #		Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Feb-2023	219617	'96	DIRECT						63 YR	Female	USA
Preferred Term		Product		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Eyelid Margin Crusting Vision Blurred) ;		Fears Lubricant Eye arboxymethylcellulose		Y	S	Ophthalmic	Other Quantity : 2 Drop(S) Other Frequency : As Needed;);2 MTH	Ez	ricare
FDA Received Date	Case #		Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
04-Feb-2023	219617	97	DIRECT			НО			58 YR	Female	USA
Preferred Term		Product		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Pneumonia; Recalled		Artificial 7	Гears Lubricant Eye		Υ	S	Ophthalmic			Ez	ricare



							- 1			
Product Administered		s (Carboxymethylcellulose								
	Sodii Proza			N	С					Not Reported
	Albut			N	č					Not Reported
	Zetia			N	Ċ					Not Reported
	Cetir	izine		N	С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Feb-2023	21962804	DIRECT			ОТ			50 YR	Male	USA
Preferred Term	Prod	<u>luct</u>	Comp.	ото	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Instillation Site Burn; Product Contamination Recalled Product; Visio	n; Drop on Sodiu			Y	S	Ophthalmic	Frequency : At Bedtime;	90 DAY		Not Reported
Blurred	Armo	or Throid		N	С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Feb-2023	21962923	DIRECT			ОТ			51 YR	Female	e USA
Preferred Term	Prod	<u>luct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Eye Discharge; Eye Irritation; Eye Irritation; Visual Impairment		oxymethylcellulose Sodium		Y	S	Ophthalmic	Other Quantity : 1 Drop(S) Frequency : As Needed;);10 DAY		Delsam Pharm
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Feb-2023	21449961	EXPEDITED (15-DAY)	Υ		ОТ	FR-MYLANLA 2022M111353		76 YR	Male	FRA
Preferred Term	Prod	<u>luct</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Mouth Ulceration	Atorv	vastatin		N	S	Oral	40 Milligram, Qd, Once In The Evening			Not Reported
	Bisop	prolol		N	S	Oral	5 Milligram, Qd, One Tablet In The Morning			Not Reported
	Para	cetamol		N	S	Oral	1 Df, As Necessary (1 G, One Tablet Every 8 H)			Not Reported
		afaxine		Ν	S	Oral	75 Milligram, Qd, Once In			Not Reported



						The Morning			
	Amlodip	pine	N	S	Oral	5 Milligram, Qd, Once In The Morning		١	Not Reported
	Clopido	grel Bisulfate	N	S	Oral	75 Milligram, Qd, Once In The Morning		١	Not Reported
	Lasilix		N	S	Oral	40 Milligram, Qd, One Tablet In The Morning		١	Not Reported
	Levothy	rox	N	S	Oral	1 Dosage Form, Qd, Once In The Morning		1	Not Reported
	Istodax		N	S	Intravenous (not otherwise specified)	53.1 Milligram, Monthly		1	Not Reported
	Bronch	odual	N	S		1 Dosage Form,Qd,50 Microg / 20 Microg Per Dose		1	Not Reported
	Hydroc	ortisone	N	S	Oral	20 Milligram, Qd, Two In The Morning		1	Not Reported
	Januvia	ı	N	S	Oral	100 Milligram, Qd, Once In The Morning	ı	1	Not Reported
	Oracillir	ne	N	S	Oral	2 Dosage Form, Qd, 1 000 000 U.I./10 MI		1	Not Reported
	Diffu K		N	S	Oral	1800 Mg, Qd, Two In The Morning, One At Midday		1	Not Reported
	Vitamin	e B12	N	S	Oral	2 Df Qw, Two Ampoules Weekly, 1000 Microg / 2 MI		١	Not Reported
	Optive		N	S	Unknown	1-2 Drops Per Day Depending On Discomfort		1	Not Reported
	Glycerii	n\Mineral Oil\Petrolatum	N	S	Unknown	One Daily Application On The Whole Body		1	Not Reported
	Clarelu	x	N	С	Unknown	2 Tubes Weekly: One Weekly Application		1	Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Feb-2023	21956498	EXPEDITED (15-DAY)	Υ	HO, OT	CA-Accord-2983	352	65 YR	Female	CAN

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Note: If the field is blank, there is no data.



Preferred Term	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Anaemia;	Atorvastatin		N	S				Not Reported
Chronic Sinusitis; Colitis;	Hydrochlorothiazide		N	S				Not Reported
Colitis Ulcerative;	Oxybutynin Hydrochloride		N	S				Not Reported
Constipation; Drug	Pantoprazole		N	S				Not Reported
Ineffective; Dyspepsia;	Pregabalin		N	S				Not Reported
Erythema; Female Genital	Simvastatin		N	S				Accord
Tract Fistula; Frequent	Acetaminophen		N	S				Not Reported
Bowel Movements;	Acetaminophen		N	S				Not Reported
Haematochezia;	W/Dextropropoxyphene							
Headache; Infusion	Acetaminophen		N	S				Not Reported
Related Reaction; Macular	W/Pseudoephedrine							
Degeneration; Malaise;	Acetic Acid W/Triamcinolone		Ν	S				Not Reported
Nausea; Oral Candidiasis;	Acetoni							
Pain; Paraesthesia Oral;	Acetylsalicylic Acid		N	S				Not Reported
Procedural Pain; Proctitis;	Acetylsalicylic Acid, Sodium		Ν	S				Not Reported
Pyrexia; Radiculopathy;	Bicarbonate, Anhydrous Citric							
Rectal Haemorrhage;	Acid							
Therapeutic Product Effect	Alprazolam		N	S				Not Reported
Incomplete; Vaginal	Amoxicillin		N	S				Not Reported
Discharge; Vaginal	Atropine Sulfate		N	S	Oral	4 Every 1 Days		Not Reported
Flatulence; Weight	W/Diphenoxylate Hy			_				
Decreased	Azithromycin		N	S	Oral			Not Reported
	Benzydamine		N	S				Not Reported
	Betamethasone Valerate		N	S				Not Reported
	Biaxin XI		N	S				Not Reported
	Bifidobacterium Longum		N	S				Not Reported
	Bisacodyl		N	S				Not Reported
	Budesonide		Ν	S		Route: Inhalation		Not Reported
	Calcitriol, Calcium Carbonate,		N	S				Not Reported
	Zinc							1
	Calcium Vit D		N	S				Not Reported
	Calcium Carbonate		N	S				Not Reported
	W/Colecalciferol							•
	Cetirizine		N	S				Not Reported
	Ciprofloxacin		N	S				Not Reported
	Clarithromycin		N	S				Not Reported
	Clotrimazole		N	S				Not Reported
	Cupric Oxide		N	S				Not Reported
	Tocopheryl Acetate		N	S				Not Reported



			Dotanoa i	oport	
Desonide Disodium Phosphate Dexpanthenol Diphenhydramine Vedolizumab	N N N N	S S S S		For I.V Infusion, Powder For Solution Intravenous	Not Reported Not Reported Not Reported Not Reported
Ertapenem	N	S		Intra-Nasal	Not Reported
Fentanyl Citrate Flovent Fluconazole Fluticasone Propionate Fluticasone Propionate W/Salmeterol	N N N N N	S S S S S			Not Reported Not Reported Not Reported Not Reported Not Reported
Glycerin Glycerol	N N	S S	Oral		Not Reported Not Reported
Glyceryl Trinitrate	N	S	Oral		Not Reported
Gramicidin W/Neomycin Sulfate/Polym	Ν	S			Not Reported
Habitrol Humira	N N	S S	Subcutaneous	Solution Subcutaneous 2190 DAY	Not Reported Not Reported
Hydrocortisone Hydromorphone Hydrochloride Isoniazid W/Pyridoxine Loperamide	N N N	S S S	Oral		Not Reported Not Reported Not Reported Not Reported
Sodium Hydrogen Carbonate, Potassium Chloride, Mac	Ν	S	Ordi		Not Reported
Magnesium Mesalazine Methylprednisolone Metronidazole Midazolam Morphine Sulfate	N N N N N	S S S S S S			Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
Mupirocin Calcium Nadolol	N	S S		Topical	Not Reported
Nicoderm	N N	S		Topical	Not Reported Not Reported
Nicotinamide Nicotine Potassium Chloride Prednisone	N N N	S S S S			Not Reported Not Reported Not Reported Not Reported



				<u> </u>	
Refresh Tears	N	S		Drops Ophthalmic, Ophthalmic	Not Reported
Sodium Chloride	N	S		Solution Nasal, Intra-Nasal	Not Reported
Povidone Iodine	N	S		Solution Nasal, Intra Nasal	Not Reported
Carboxymethylcellulose Sodium Sucralfate Sulfamethoxazole W/Trimethoprim	N N N	S S S		,	Not Reported Not Reported Not Reported
Triamcinolone Acetonide Ubidecarenone Vitamin D3 Xantofyl Palmitate	N N N N	S S S	Oral		Not Reported Not Reported Not Reported Not Reported
Zeaxanthin	N	S	Oral		Not Reported
Zinc Oxide Zopiclone Pregabalin Cortenema	N N N N	\$ \$ \$ \$		Suspension	Not Reported Not Reported Not Reported Not Reported
Empracet Fructose Nadolol Metronidazole Hydrochlorothiazide Loperamide Loperamide	N N N N N N N N N N N N N N N N N N N	S S S S S S S	Oral	4 Every 1 Days	Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
Loperamide	N	S	Oral	1 Every 1 Days	Not Reported
Loperamide	N	S	Oral	1 Every 1 Days	Not Reported
Alprazolam Atropine Sulfate W/Diphenoxylate Hy	N N	S S	Oral		Not Reported Not Reported
Atropine Sulfate W/Diphenoxylate Hy	N	S	Oral	1 Every 1 Days	Not Reported
Atropine Sulfate W/Diphenoxylate Hy	N	S	Oral		Not Reported
Budesonide	N	S	Oral		Not Reported
Clarithromycin Diphenhydramine	N N	S S	Oral		Not Reported Not Reported
Ertapenem	N	S	Intramuscular		Not Reported



		Glycerin			Ν	S	Oral				N	lot Reported	
		Azithron Biaxin X			N N	S S			Tablet (Extended-Release)			lot Reported lot Reported	
		Mesalaz Metronio Morphin Refresh	lazole e Sulfate		N N N N	\$ \$ \$ \$			Eye Drops		N N	lot Reported lot Reported lot Reported lot Reported	
		Magnes Magnes Magnes Magnes Triamcir	ium ium		N N N N	\$ \$ \$ \$ \$ \$	Intra-articular		•		N N	lot Reported lot Reported lot Reported lot Reported lot Reported	
		Triamcir	olone Acetonide		Ν	S			Suspension Intra- Articula	r	N	lot Reported	
		Pregaba Magnes			N N	S S			50 %, Liquid Intramuscula	ır		lot Reported lot Reported	
		Budesor Pantopra Sulfame W/Trime	azole thoxazole		N N N	S S S					N	lot Reported lot Reported lot Reported	
		Zinc Oxi Nicoderi Triamcir Hydrom	de		N N N N	S S S S S S			Endocervical		N N	lot Reported lot Reported lot Reported lot Reported lot Reported	
		Humira			N	S	Subcutaneous				N	lot Reported	
FDA Received Date	Case #		Case Type	Health	Prof	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country	_
06-Feb-2023	219595	82	EXPEDITED (15-DAY)	N		ОТ	US-ALLE 23029720		-		Female	USA	
Preferred Term		Produc	<u>t</u>	Comp.	OTC	Role	<u>Route</u>		Dosage Text	Duration	<u>M</u>	<u>fr</u>	
Coeliac Disease; Spina Cord Injury; Stress			Optive Advanced ative-Free		Y	S			Unk		А	llergan	
FDA Received Date	Case #		Case Type	Health	Prof	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country	_
06-Feb-2023	219669	56	DIRECT			RI				36 YR	Female	USA	



						Dotalloa I	орон			
Preferred Term	<u>F</u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Blindness; Condition Aggravated; Eye Disord		Refresh Tears		N	S				N	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Feb-2023	2196695	8 DIRECT			DS, RI, OT			26 YR	Female	USA
Preferred Term	<u> </u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Eye Discharge; Eye Infection Bacterial; Ocu Hyperaemia; Periorbita Swelling; Product Contamination Microbia Product Quality Issue; Product Quality Issue; Respiratory Tract Congestion; Respirator Tract Infection; Sinusiti Skin Discolouration; Suspected Product Tampering	ular C al S al;	ortificial Tears Lubricant Eye Orops (Carboxymethylcellulose Godium)	е	Y	S	Ophthalmic	Frequency : As Needed;		E	zricare
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Feb-2023	2196696	8 DIRECT			ОТ			43 YR	Female	USA
Preferred Term	<u> </u>	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Eye Irritation; Eyelid Function Disorder; Ocu Hyperaemia		Carboxymethylcellulose Sodiu	m	Y	S				D	elsam Pharm
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Feb-2023	2196739	4 DIRECT						63 YR	Female	USA
Preferred Term	E	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Dermatitis Contact; Documented	F	Refresh Tears		N	S			3 YR	Al	lergan

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Note: If the field is blank, there is no data.

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Frequency: Twice A Day; 4 MTH

503B Facility

Hypersensitivity To Administered Product; Drug Ineffective; Eye Infection; Insomnia; Reading Disorder; Sinusitis		Optive Gel Drops		N N N	S C C				No	t Reported t Reported t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Feb-2023	21969485	DIRECT			ОТ			51 YR	Female	USA
Preferred Term	Produc	<u>:t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation	Carbox	ymethylcellulose Sodium		Υ	S				De	Isam Pharm
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Feb-2023	21968555	DIRECT			RI, OT			54 YR	Female	USA
Preferred Term	Produc	<u>:t</u>	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	Mfr	
Eye Disorder; Visual Impairment		Tears Lubricant Eye Carboxymethylcellulose)		Y	S	Ophthalmic	Frequency : Twice A Day;		Ezı	ricare
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Contro	I# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Feb-2023	21968556	DIRECT			RI, OT			42 YR	Male	USA
Preferred Term	Produc	<u>:t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	

Preferred Term Product OTC Dosage Text Duration <u>Mfr</u> Comp. <u>Role</u> Route Υ S **Delsam Pharm** Eye Pain; Eye Pain; Carboxymethylcellulose Sodium Ophthalmic Frequency: As Needed; Ocular Discomfort; Ocular

S

Ophthalmic

Mfr Control #

Υ

Health Prof Outcomes

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21968575

Dry Skin; Eye Infection

Product Administered

FDA Received Date Case #

Bacterial; Recalled

07-Feb-2023

Artificial Tears Lubricant Eye

Sodium)

Drops (Carboxymethylcellulose

Case Type

DIRECT

Note: If the field is blank, there is no data.

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Ezricare

Country

USA

<u>Sex</u>

Female

<u>Age</u>

66 YR



FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Hyperaemia				N N N N	C C C					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Feb-2023	21937837	EXPEDITED (15-DAY)	N		DS, HO, OT	US-ALLERGAN 2302217US	N-		Male	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Atrial Fibrillation;	Refrest	n Plus		Υ	S	Ophthalmic	Unk, Qd			Not Reported
Blindness Unilateral; Cardiac Ablation; Chor Melanoma; Heart Rate Increased; Macular Degeneration; Poor Quality Product Administered; Product Quality Issue; Visual Impairment	•			N	С		Unk			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Feb-2023	21968756	EXPEDITED (15-DAY)	N		ОТ	US-ALLERGAN 2127468US	N-		Male	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Dry Eye; Eyelid Opera Eyelid Ptosis; Poor Qu Product Administered		n Celluvisc Solution		Υ	S		Unk			Allergan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	Sex	Country
08-Feb-2023	21968785	EXPEDITED (15-DAY)	N		ОТ	US-ALLERGAN 2303292US	N-		Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Cataract; Dry Eye; Dry Eye; Eye Discharge; E	ye	n Relieva		Υ	S	Ophthalmic	1-3 Drops In Each Eye At Day Time			Not Reported
Disorder; Eye Infection Eye Pain; Eye Pain; Foreign Body Sensation	Kellesi	n Tears		N	S	Ophthalmic	1-2 Drops In Each Eye, Night Time Only			Not Reported

Note: If the field is blank, there is no data.



								•			
Eyes; Foreign Body		Unspecifie	ed Ingredient		N	S		Unk			Not Reported
Sensation In Eyes		Unspecifie	ed Ingredient		N	S		Unk			Not Reported
		Atenolol			N	С		Unk			Not Reported
		Gabapent	in		N	С		Unk			Not Reported
		Buspirone	•		N	С		Unk			Not Reported
		Aspirin [A	cetylsalicylic Acid]		N	С		Unk			Not Reported
		Ibuprofen			N	С		Unk Unk, Prn			Not Reported
FDA Received Date	Case #	<u>ŧ</u> 9	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	Sex	Country
08-Feb-2023	219725	567	DIRECT			ОТ			43 YR	Male	USA
Preferred Term		Product		Comp.	отс	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Vision Blurred			ears Lubricant Eye arboxymethylcellulose		N	S	Endocervical	Frequency : Twice A Day	;		Not Reported
		Atorvasta			N	С					Not Reported
		Multivitam Calcium	nin		N N	C C					Not Reported Not Reported
		Vitamin D			N	C					Not Reported
		Vitamin B	12		N	С					Not Reported
FDA Received Date	Case #	<u>ŧ</u> 9	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Feb-2023	219740	001	DIRECT						54 YR	Male	USA
Preferred Term		Product		Comp.	ОТС	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Eye Infection; Eye Irritation; Product Qual Issue; Visual Impairme			ears Lubricant Eye arboxymethylcellulose		Y	S	Ophthalmic		30 DAY		Ezricare
issue, visuai impairme	5111	Crestor	ıy Men'S Vitamin		N N	C C					Not Reported Not Reported
		01107120	.,								
FDA Received Date	Case #		Case Type	Health	<u>Prof</u>	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country



							•			
Preferred Term	Product	i	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u> ı	
Eye Pain; Periorbital Swelling; Product Quality Issue; Vision Blurred; Visual Impairment		Tears Lubricant Eye Carboxymethylcellulose		Y	S	Ophthalmic	Other Quantity : 2 Drop(S Frequency : Twice A Day;		Ez	rricare
FDA Received Date Ca	ıse#	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Feb-2023 21	974006	DIRECT			DS, RI			39 YR	Female	USA
Preferred Term	Product	<u>.</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfı</u>	ŗ
Blindness; Impaired Driving Ability; Impaired Work Ability; Middle Insomnia; Ocular Hyperaemia; Periorbital Pain; Vision Blurred		Tears Lubricant Eye Carboxymethylcellulose		Y	S			60 DAY	Ur	nknown Manufacture
FDA Received Date Ca	ise #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Feb-2023 21	974228	DIRECT			ОТ			80 YR	Female	USA
Preferred Term	Product	<u>.</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfı</u>	t.
Central Vision Loss; Erythema Of Eyelid; Eye Pruritus; Lacrimation Increased; Ocular Hyperaemia; Therapy Cessation; Vision Blurred		Tears Lubricant Eye Carboxymethylcellulose		Y	S	Ophthalmic	Frequency : As Needed;		Ez	rricare
FDA Received Date Ca	ise#	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Feb-2023 21	974229	DIRECT			DS, RI, OT			32 YR	Female	USA
Preferred Term	Product	1	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfı</u>	[
Bacterial Infection; Conjunctivitis; Corneal Disorder; Eye Infection Bacterial; Eye		Tears Lubricant Eye Carboxymethylcellulose		Y	S	Ophthalmic	Frequency : Every 4 Hours;		Ez	rricare



FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Inflammation; Retinal Scar; Therapy Cessation; Visual Impairment

FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2023	21974230	DIRECT			RI			56 YR	Female	USA
Preferred Term	Proc	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Conjunctivitis		icial Tears Lubricant Eye os (Carboxymethylcellulose ium)		Y	S				E	Ezricare
	Zyrte	,		N	С				١	Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Feb-2023	21974388	DIRECT			ОТ			64 YR	Male	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Eye Irritation; Instillation Site Foreign Body Sensation		icial Tears Lubricant Eye os (Carboxymethylcellulose ium)		Y	S	Ophthalmic	Other Quantity : 1 Drop(S) Frequency : As Needed;);	E	Ezricare
	Lata	noprost Palmetto			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Feb-2023	21974415	DIRECT			ОТ				Male	USA
Preferred Term	Pro	duct	Comp.	OTC	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Eye Pruritus; Recalled Product Administered; Vision Blurred		icial Tears Lubricant Eye os (Carboxymethylcellulose ium)		Y	S	Ophthalmic	Frequency : As Needed;		E	Ezricare
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Feb-2023	21974424	DIRECT			DS			58 YR	Female	USA
Preferred Term	Proc	<u>duct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>lfr</u>

Note: If the field is blank, there is no data.



Eye Pruritus; Product Contamination; Recalled Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium) S Ophthalmic

Υ

Frequency: As Needed;

Global Pharmaceuticals

Product Administered; Vision Blurred; Visual Impairment	Sodiur	n)								
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Feb-2023	21974425	DIRECT			ОТ			76 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	!	<u>Mfr</u>
Eye Irritation; Hordeolu Recalled Product Administered		al Tears Lubricant Eye (Carboxymethylcellulose n)		Y	S	Ophthalmic	Frequency : As Needed;			Ezricare
	Gemfil	prozil		Ν	С					Not Reported
		an Hctz		N	С					Not Reported
	Pantor Atrova	orazole		N N	C C					Not Reported Not Reported
	Meloxi			N	C					Not Reported
	Propra			N	Č					Not Reported
	Co Q 1			N	Ċ					Not Reported
	Refres	h Eye Drops For Contacts		N	С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Feb-2023	21974454	DIRECT			DS				Male	USA
Preferred Term	<u>Produ</u>	<u>ct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	1	<u>Mfr</u>
Eye Infection; Recalled Product Administered		al Tears Lubricant Eye (Carboxymethylcellulose		Y	S					Not Reported
	Multivi Fish O	tamin			C C					Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Feb-2023	21974629	DIRECT						54 YR	Female	USA
Preferred Term	Produ	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	J	<u>Mfr</u>

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Eye Pruritus; Thermal Burns Of Eye; Vision Blurred			Tears Lubricant Eye Carboxymethylcellulose)		Y	S	Ophthalmic				Ezricare
FDA Received Date	Case #	<u>ŧ</u>	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Feb-2023	21974	673	DIRECT	Υ		DS, HO, LT	, RI		83 YR	Female	USA
Preferred Term		Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Cellulitis Orbital; Corne Perforation; Endophthalmitis; Oper Globe Injury;		Drops (G Sodium	Tears Lubricant Eye Carboxymethylcellulose) n Eye Drops		Y N	s C	Ophthalmic				Ezricare Not Reported
Pseudomonas Test Positive			olone Eye Drops an Eye Drops		N N	C C					Not Reported Not Reported
FDA Received Date	Case #	<u> </u>	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Feb-2023	219746	681	DIRECT			RI			49 YR	Male	USA
Preferred Term		Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Eye Infection			Tears Lubricant Eye Carboxymethylcellulose)		Υ	S	Ophthalmic	Frequency : As Needed;			Not Reported
FDA Received Date	Case #	<u>ŧ</u>	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
08-Feb-2023	219746	685	DIRECT			DS			45 YR	Male	USA
Preferred Term		Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Conjunctivitis; Dry Eye Eye Discharge; Eye P Illness; Liquid Product	ain;		Tears Lubricant Eye Carboxymethylcellulose)		Y	S	Ophthalmic	Other Quantity: 30 Drop (S); Frequency: As Needed;			Ezricare
Physical Issue; Recall Product Administered; Vision Blurred		Armour	Thyroid			С					Not Reported



FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #		Case Type	Health	Prof Ou	tcomes	Mfr Control #	<u> </u>	03B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2023	207252	230	EXPEDITED (15-DAY)	N	НО), OT	NVSC2022CA0)89948		71 YR	Female	USA
Preferred Term		Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage T	<u>'ext</u>	<u>Duration</u>		<u>Mfr</u>
Abdominal Pain; Anaei		Adalimu	ımab		N	S	Subcutaneous	Unk				Novartis
Chronic Sinusitis; Colit Colitis Ulcerative;	tis;	Pregaba	alin		N	S	Unknown	150 Mg				Not Reported
Constipation; Drug		Pregaba	alin		N	S	Unknown	Unk				Not Reported
Ineffective; Dyspepsia; Erythema; Female Ger Tract Fistula; Frequent	nital	Inflixima	ab		N	S	Intravenous (not otherwise specified)	Unk				Not Reported
Bowel Movements;	L	Methotr	exate		N	S	Unknown	Unk				Novartis
Haematochezia; Headache; Infusion		Pantopr	azole		N	S	Unknown	Unk				Novartis
Related Reaction; Mac	cular	Triamcii	nolone Acetonide		N	S	Intra-articular	Unk				Novartis
Degeneration; Malaise		Triamcii	nolone Acetonide		N	S	Unknown	Unk				Novartis
Nausea; Off Label Use Oral Candidiasis; Pain;		Amoxici	llin		N	S	Unknown	Unk				Novartis
Paraesthesia Oral;		Sodium	Bicarbonate		N	S	Unknown	Unk				Not Reported
Procedural Pain; Proct Pyrexia; Radiculopathy		Atorvas	tatin Calcium		N	S	Unknown	Unk				Novartis
Rectal Haemorrhage; Therapeutic Product E		Atorvas	tatin Calcium		N	S	Unknown	Formulation Capsule	tion: Hard , Unk			Novartis
Incomplete; Vaginal Discharge; Vaginal Flatulence; Weight		Fentany	/I		N	S	Intravenous (not otherwise specified)	Unk				Not Reported
Decreased		Fentany	d.		N	S	Intravenous (not otherwise specified)	Unk				Not Reported
		Magnes	ium Sulfate		N	S	Intramuscular	Unk				Not Reported
		Ciproflo	xacin Hydrochloride		N	S	Intravenous (not otherwise specified)	Unk				Novartis
		Ciproflo	xacin Hydrochloride		N	S	Unknown	Unk				Novartis
		Hydrom	orphone Hydrochloride		N	S	Unknown	Unk				Not Reported
		Hydrom	orphone Hydrochloride		N	S	Endocervical	Unk				Not Reported
		Calcium	Carbonate		N	S	Unknown	Unk				Not Reported
		Calcium	n Carbonate		N	S	Unknown	Unk				Not Reported

Note: If the field is blank, there is no data.



Nitroglycerin	N	S	Oral	Unk	Novartis
Glyceryl Trinitrate	N	S	Oral	Unk	Novartis
Azithromycin Dihydrate	N	S	Unknown	Unk	Novartis
Azithromycin Dihydrate	N	S	Oral	Unk	Novartis
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Potassium Chloride	N	S	Unknown	Unk	Not Reported
Potassium Chloride	N	S	Unknown	Unk	Not Reported
Colecalciferol	N	S	Intra-articular	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Oral	50 Mg	Not Reported
Azithromycin	N	S	Unknown	Unk	Novartis
Azithromycin	N	S	Oral	Unk	Novartis
Midazolam Hydrochloride	N	S	Unknown	2 Dosage Form	Not Reported
Midazolam Hydrochloride	N	S	Unknown	2 Dosage Form, Pre Filled Syringe	Not Reported
Midazolam Hydrochloride	N	S	Unknown	Unk	Not Reported
Morphine	N	S	Unknown	Unk	Not Reported
Morphine	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole And	N	S	Unknown	200 Mg	Not Reported
Trimethoprim Sulfamethoxazole And Trimethoprim	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole And Trimethoprim	N	S	Unknown	1 Dosage Form	Not Reported
Oxybutynin Hydrochloride	N	S	Unknown	Unk	Not Reported
Oxybutynin Hydrochloride	N	S	Unknown	Unk	Not Reported
Inflectra	N	S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks	Not Reported
Inflectra	N	S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks	Not Reported



				Dotalica No	55. 0		
Inf	flectra	N	S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks		Not Reported
Inf	flectra	N	S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks		Not Reported
Inf	flectra	N	S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks		Not Reported
Inf	flectra	N	S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks		Not Reported
Inf	ilectra	N	S	Intravenous (not otherwise specified)	10 Mg/Kg, Every 6 Weeks		Not Reported
Inf	ilectra	N	S	Intravenous (not otherwise specified)	10 Mg/Kg, Every 6 Weeks	132 DAY	Not Reported
Bit	fidobacterium Infantis	N	S	Unknown	Unk		Not Reported
Me	etronidazole	N	S	Unknown	Unk		Not Reported
Me	etronidazole	N	S	Unknown	Unk	7 DAY	Not Reported
Zo	ppiclone	N	S	Unknown	Unk		Not Reported
Zo	ppiclone	N	S	Unknown	Unk		Not Reported
Αl	prazolam	N	S	Unknown	0.25 Mg		Not Reported
Alı	prazolam	N	S		Unk		Not Reported
Ap	oo Hydromorphone	N	S	Endocervical	Unk		Not Reported
Sc	odium Chloride	N	S	Nasal	Unk, (Formulation:Pellet)		Not Reported
Sc	odium Chloride	N	S	Nasal	Unk		Not Reported
Sc	odium Chloride	N	S		Unk		Not Reported
Sc	odium Chloride	N	S	Unknown	Unk		Not Reported
Αv	ramys	N	S	Unknown	Unk(Spray Metered Dose)		Not Reported
Me	esalazine	N	S	Unknown	Unk		Not Reported
Me	esalazine	N	S	Unknown	Unk		Not Reported
Me	esalazine	N	S	Unknown	Unk		Not Reported
Gl	ycerine	N	S	Oral	Unk		Not Reported
Gl	ycerine	N	S	Unknown	Unk		Not Reported
Ac	cetaminophen	N	S	Unknown	Unk		Not Reported

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Note: If the field is blank, there is no data.



Acetaminophen	N	S	Unknown	Unk	Not Reported
Diphenoxylate/Atropine	N	S	Oral	Unk	Not Reported
Diphenoxylate/Atropine	N	S	Oral	1 Dosage Form	Not Reported
Diphenoxylate/Atropine	N	S	Unknown	4 Dosage Form, Qd	Not Reported
Diphenoxylate/Atropine	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Oral	Unk	Not Reported
Budesonide	N	S	Cutaneous	Unk	Not Reported
Budesonide	N	S	Other	Unk	Not Reported
Budesonide	N	S	Subcutaneous	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Oral	1 Dosage Form	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
Fluticasone Propionate	N	S	Unknown	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Nadolol	N	S	Unknown	40 Mg	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Methylprednisolone Sodium Succinate	Ν	S	Intravenous (not otherwise specified)	Unk	Not Reported
Methylprednisolone Sodium Succinate	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported



				<u> </u>	
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Oral	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	0.122 G	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Loperamide Chlorhydrate	N	S	Unknown	Unk	Not Reported
Tocopherols Mixed	N	S	Unknown	Unk	Not Reported
Glycerol	N	S	Oral	Unk	Not Reported
Macrogol	N	S	Unknown	Unk	Not Reported
Macrogol	N	S	Urethral	Unk	Not Reported
Diflucan	N	S	Unknown	Unk	Not Reported
Solu-Medrol	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Pronutrients Calcium + D	N	S	Unknown	Unk	Not Reported
Bactrim	N	S	Unknown	Unk	Not Reported
Bactrim	N	S	Nasal	Unk	Not Reported
Refresh Tears	N	S	Intraocular	Unk	Not Reported
Refresh Tears	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk (Ophthalmic Insert)	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Dextropropoxyphene	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk (Extended Release)	Not Reported



				<u> </u>		
Dilaudid	N	S	Unknown	Unk		Not Reported
Dilaudid	N	S	Unknown	1 Dosage Form		Not Reported
Dilaudid	N	S	Unknown	1 Dosage Form, Bid		Not Reported
Entocort	N	S	Unknown	Unk (Extended)		Not Reported
Entocort	N	S	Oral	Unk		Not Reported
Ertapenem Sodium	N	S		Unk		Not Reported
Flovent	N	S	Unknown	Unk		Not Reported
Humira	N	S	Subcutaneous	Unk (Solution (Except Syrup))	2190 DAY	Not Reported
Humira	N	S	Subcutaneous	Unk	2190 DAY	Not Reported
Nicoderm	N	S	Transdermal	Unk		Not Reported
Nicoderm	N	S	Unknown	Unk		Not Reported
Pulmicort	N	S		Unk		Not Reported
Pulmicort	N	S	Oral	Unk		Not Reported
Glycerinum	N	S	Oral	Unk		Not Reported
Difenoxin Hydrochloride	N	S	Unknown	Unk		Not Reported
Ms Ir	N	S	Unknown	Unk		Not Reported
Mupirocin Calcium	N	S	Topical	Unk		Not Reported
Sinus Rinse	N	S	Nasal	Unk		Not Reported
Sinus Rinse	N	S	Other	Unk		Not Reported
Bactroban	N	S	Unknown	Unk		Not Reported
Habitrol	N	S	Other	Unk		Not Reported
Kenalog	N	S	Intra-articular	Unk		Not Reported
Statex	N	S	Unknown	Unk		Not Reported
Acetylsalicylic Acid	N	S	Unknown	Unk		Not Reported
Betaderm	N	S	Unknown	Unk		Not Reported
Simvastatin	N	S	Unknown	Unk		Not Reported
Zinc	N	S	Intra-articular	Unk		Not Reported
Sulfamethoxazole	N	S	Unknown	Unk		Not Reported



				•	
Cetirizine	N	S	Unknown	Unk	Not Reported
Pms Azithromycin	N	S	Unknown	Unk	Not Reported
Nicomorphine	N	S	Unknown	Unk	Not Reported
Clorprenaline Hydrochloride	N	S	Unknown	Unk	Not Reported
Vitamin D	N	S	Unknown	Unk	Not Reported
Pseudoephedrine	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Nasal	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Neomycin Sulphate	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	N	S	Ophthalmic	Unk	Not Reported
Dexpanthenol	N	S	Unknown	Unk	Not Reported
Dulcolax	N	S	Unknown	Unk	Not Reported
Sulfatrim	N	S	Unknown	Unk	Not Reported
Apo-Hydrochlorothiazide	N	S	Endocervical	100 Mg	Not Reported
Salix Alba Extract	N	S	Intramuscular	Unk, Solution (Except Syrup)	Not Reported
Dimethyl Sulfoxide	N	S	Unknown	Unk	Not Reported
Caltrate + D	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Transplacental	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Cortenema	N	S	Unknown	Unk (Suspension)	Not Reported
Empracet	N	S	Unknown	Unk	Not Reported
Flagyl	N	S	Unknown	Unk	Not Reported
Imovan	N	S	Unknown	Unk	Not Reported
Isoniazid	N	S	Unknown	Unk	Not Reported
Entyvio	N	S	Unknown	200 Mg, Tid	Not Reported
Vitamin E	N	S	Unknown	Unk	Not Reported



Versed	N	S	Unknown	2 Dosage Form		Not Reported
Mesalamine	N	S	Unknown	Unk, Tid	11 DAY	Not Reported
Mesalamine	N	S	Unknown	Unk		Not Reported
Ditropan	N	S	Unknown	Unk		Not Reported
Ambroxol	N	S	Unknown	Unk		Not Reported
Acetaminophene	N	S	Unknown	Unk		Not Reported
Calcium & Vitamin D3	N	S	Unknown	Unk		Not Reported
Calcitriol	N	S	Unknown	Unk		Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk		Not Reported
Align	N	S	Unknown	Unk		Not Reported
Align	N	S	Unknown	Unk		Not Reported
Lomotil	N	S	Oral	Unk, Qid		Not Reported
Lomotil	N	S	Oral	4 Dosage Form, Qd		Not Reported
Lomotil	N	S	Oral	Unk		Not Reported
Sulcrate	N	S	Unknown	Unk		Not Reported
Sulcrate	N	S	Unknown	Unk		Not Reported
Hydrochlorothiazide	N	S	Unknown	100 Mg		Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk		Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk		Not Reported
Hydrochlorothiazide	N	S	Subcutaneous	Unk		Not Reported
Trimethoprim	N	S	Unknown	Unk		Not Reported
Vedolizumab	N	S	Unknown	200 Mg, Tid		Not Reported
Vedolizumab	N	S	Unknown	600 Mg		Not Reported
Acetaminophen And Codeine Phosphate	N	S	Unknown	Unk		Not Reported
Triamcinolone	N	S	Unknown	Unk		Not Reported
Triamcinolone	N	S	Intra-articular	Unk		Not Reported
Triamcinolone	N	S	Unknown	Unk		Not Reported
Triamcinolone	N	S	Intra-articular	Unk		Not Reported
Calcium Citrate	N	S	Unknown	Unk		Not Reported



Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Macrogol	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Dosage Form	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	4 Dosage Form, Qd	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Atorvastatin	N	S	Unknown	Unk	Not Reported
DI-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
Macrogol	N	S	Urethral	Unk	Not Reported
Ambroxol;Cetirizine	N	S	Unknown	Unk	Not Reported
Moviprep	N	S	Unknown	Unk (Powder For Oral Solution)	Not Reported
Cupric Oxide;Folic Acid;Nicotinic Acid;Zinc	N	S	Unknown	Unk	Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Remicade	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Calcium Amino Acid Chelate	N	S	Unknown	Unk	Not Reported
Acetaminophen	N	S	Unknown	Unk	Not Reported
Acetaminophen	N	S	Unknown	Unk	Not Reported
Acetaminophen	N	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium Anhydrous	N	S	Unknown	Unk	Not Reported
Atropine Sulfate	N	S	Unknown	Unk	Not Reported



			<u> </u>	•		
Benzydamine	N	S	Unknown	Unk		Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk		Not Reported
Betamethasone Sodium	N	S	Unknown	Unk		Not Reported
Phosphate Betamethasone	N	S	Topical	Unk		Not Reported
Bromhexine Hydrochloride/Sulfa	N	S	Unknown	Unk		Not Reported
Methoxazole/Trimethoprim Imodium	N	S	Unknown	Unk		Not Reported
Calcium	N	S	Unknown	Unk		Not Reported
Fructose	N	S	Unknown	Unk		Not Reported
Gramicidin	N	S	Unknown	Unk		Not Reported
Magnesium Clofibrate	N	S	Unknown	Unk		Not Reported
Mentha Arvensis	N	S	Unknown	Unk		Not Reported
Polysporin	N	S	Unknown	Unk		Not Reported
Sulfamethoxazole And	N	S	Unknown	Unk		Not Reported
Trimethoprim Sulfamethoxazole And Trimethoprim	N	S	Oral	1 Dosage Form		Not Reported
Sulfamethoxazole And Trimethoprim	N	S	Unknown	200 Mg		Not Reported
Ubidecarenone	N	S	Unknown	Unk		Not Reported
Zinc Chloride	N	S	Unknown	Unk		Not Reported
Cipro	N	S	Intravenous (not otherwise specified)	Unk	7 DAY	Not Reported
Hydrocortisone Butyrate	N	S	Unknown	Unk		Not Reported
Calcium	N	С	Unknown	Unk		Not Reported
Metoclopramide Hydrochloride	N	С	Oral	Unk		Not Reported
Maxeron	N	С	Unknown	Unk		Not Reported
Benadryl Allergy	N	С	Unknown	Unk		Not Reported
Calcium And Ergocalciferol	N	С	Unknown	Unk		Not Reported
Sodium Stearate	N	С	Unknown	Unk		Not Reported
Benadryl	N	С	Unknown	Unk		Not Reported



FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Vitami	in D Nos		N	С	Unknown	Unk			Not Reported
	Valsaı	rtan		N	С	Oral	40 Mg, Qd			Not Reported
	Valsaı	rtan		Ν	С	Oral	4 Dosage Form, Qd			Not Reported
	Valsaı	rtan		Ν	С	Intracardiac	Unk			Not Reported
	Lopera	amide		Ν	С	Oral	4 Dosage Form, Qd			Not Reported
	Lopera	amide		Ν	С	Oral	1 Dosage Form, Q6h			Not Reported
	Amoxi	cillin Trihydrate		N	S	Unknown	Unk			Novartis
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Feb-2023	21322996	EXPEDITED (15-DAY)	Υ		ОТ	FR-US-Provell Pharmaceutical E2B_90088984		76 YR	Male	FRA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Mouth Ulceration	Levoth	nyrox		N	S	Oral	Once In Morning			Not Reported
	Bisopi	rolol		Ν	S	Oral	One Tablet In The Mornin	g		Not Reported
	Vitami	ine B12		N	S	Oral	Two Ampoules Weekly, 1000 Microg / 2 MI			Not Reported
	Diffu k	<		N	S	Oral	Two In The Morning, One At Midday			Not Reported
	Venla	faxine		Ν	S	Oral	Once In The Morning			Not Reported
	Amloc	lipine		Ν	S	Oral	Once In The Morning			Not Reported
	Hydro	cortisone		N	S	Oral	Two In The Morning			Not Reported
	Oracil [Phen	line oxymethylpenicillin]		N	S	Oral	1 000 000 U.I./10 MI, Suspension Buvable			Not Reported
	Lasilix	[Furosemide]		Ν	S	Oral	One Tablet In The Mornin	g		Not Reported
	Atorva	astatin		N	S	Oral	Once In The Evening			Not Reported
	Parac	etamol		N	S	Oral	(1 G, One Tablet Every 8 H)			Not Reported
	Bronc	hodual		N	S	Respiratory (inhalation)	100 Micrograms /40 Micrograms; 50 Micrograms /20 Micrograms Dose Two			Not Reported

Note: If the field is blank, there is no data.



							Puffs In Morning And Evening			_
	Jar	nuvia		Ν	S	Oral	Once In The Morning		1	Not Reported
	Isto	odax		N	S	Intravenous (not otherwise specified)	Ç		1	Not Reported
	Zyr	mad		N	S	Oral	50000 Ui; 50000 International Unit Oral Drinkable Solution In Ampoule			Not Reported
	Clo	pidogrel Bisulfate		Ν	S	Oral	Once In The Morning		1	Not Reported
	Op	tive		N	S	Unknown	Solution Lubricating And Osmoprotective Ocular Solution; 1-2 Drops Per Day Depending On Discomfort		I	Not Reported
		xeryl [Glycerol;Paraffin, uid;White Soft Paraffin]		N	S		Application On The Whole Body, 2 Tubes Weekly Via Unknown Route		1	Not Reported
	Cla	relux		N	С					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Feb-2023	21974458	EXPEDITED (15-DAY)	N		ОТ	US-ALLERGAN 2302977US	-		Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTO	Role Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Afr</u>
Retinal Oedema; Retin	nal Ref	fresh Optive Mega-3		Υ	S		Unk			Allergan
Tear	Ref	fresh Optive		N	S		Unk			Allergan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Feb-2023	21974491	EXPEDITED (15-DAY)	N		ОТ	US-ALLERGAN 2303342US	_		Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTO	Role Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Afr</u>
Cataract	Ref	fresh Plus		Υ	S					Allergan



FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Feb-2023	21977324	DIRECT						68 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTO	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>N</u>	<u>//fr</u>
Orug Ineffective; Endophthalmitis	D	rtificial Tears Lubricant Eye rops (Carboxymethylcellulose odium))	Y	S	Ophthalmic	Other Quantity: 1 Or 2 Drops; Frequency: As Needed;	2 DAY		Ezricare
		etoprolol estasis Eye Drops			C C		·			Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Feb-2023	21978271	DIRECT	N		DS, RI, OT			63 YR	Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTO	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>N</u>	<u>∕/fr</u>
Condition Aggravated; Crying; Eye Infection; Lung Disorder; Produc	D et S	rtificial Tears Lubricant Eye rops (Carboxymethylcellulose odium))	Y	S	Ophthalmic	Other Quantity : 1 Drop(S Other Frequency : As Needed	5)		Global Pharmaceuticals
Container Issue; Reca Product Administered; Sinusitis	Li M M P P Fi	uloxetine amotrigine emantine ontelukast ilocarpine regabalin amotidine			0000000					Not Reported
	R Tı Z <u>ı</u> B Fl	axalt-Mlt estasis ramadol yrtec reztri axsee Oil Glucosamine			000000					Not Reported
	M G M Tr	hondrotin agnesium lycinate ultivitamin umeric mino Acid			00000					Not Reported Not Reported Not Reported Not Reported Not Reported

Note: If the field is blank, there is no data.



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FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Feb-2023	21978273	DIRECT		D:	S, HO, LT T	, RI,		76 YR	Female	USA
Preferred Term	Pro	oduct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Blindness; Pseudomor Infection	Dro	ificial Tears Lubricant Eye ops (Carboxymethylcellulose dium)		N	S	Ophthalmic	Other Quantity : 0.5 Ound (S); Frequency : As Needed;	ce30 DAY	Ez	zricare
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Feb-2023	21978278	DIRECT		0	Т			78 YR	Male	USA
Preferred Term	Pr	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Corneal Oedema; Eye Disorder; Eye Irritation Eye Pain; Lacrimation Increased; Photophobi Product Container Sealssue	i; ia;	rboxymethylcellulose Sodium		Y	S	Ophthalmic	Frequency : At Bedtime;		Ne	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Feb-2023	21979040	DIRECT		0	Т			44 YR	Male	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>r</u>
Eye Irritation; Rash; Vi Blurred	Dro	ificial Tears Lubricant Eye ops (Carboxymethylcellulose dium)		Υ	S				Ne	ot Reported
		ympic			С				No	ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof O	<u>utcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2023	21979050	DIRECT		RI				63 YR	Female	USA
Preferred Term	Pro	<u>oduct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Hypersensitivity		ificial Tears Lubricant Eye		Υ	S			1 WEEK	Ez	zricare

Date - Time: 11-Apr-2023 10:56:54 AM EST

Note: If the field is blank, there is no data.

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		Sodium Valtrex Xanaex Clariten Dyrenni				0000					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	<u>ŧ</u>	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Feb-2023	219792	215	DIRECT	Υ		DS			74 YR	Female	USA
Preferred Term		Produc	<u>t</u>	Comp.	ОТС	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Bacterial Infection; Pseudomonas Test Positive; Ulcerative Keratitis			Tears Lubricant Eye Carboxymethylcellulose)		Y	S					Ezricare
FDA Received Date	Case #	<u>ŧ</u>	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
09-Feb-2023	219797	707	DIRECT			НО			66 YR	Male	USA
Preferred Term		Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Chemical Burns Of Eye Eye Pain; Instillation S Irritation; Instillation Sit	ite		Tears Lubricant Eye Carboxymethylcellulose)		Υ	S	Intraocular	Other Quantity: 1 Or 2 Drops; Frequency: As Needed;			Ezricare
Pain		Nitric Ox Aleve Lortab	xide		N N N	C C S		, i			Not Reported Not Reported Not Reported
FDA Received Date	Case #	<u>ŧ</u>	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Feb-2023	219773	334	EXPEDITED (15-DAY)	Y		HO, OT	CA-BAYER- 2023A013622		71 YR	Female	CAN
Preferred Term		Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Chronic Sinusitis; Drug Ineffective; Dyspepsia; Infusion Related Reac Macular Degeneration Malaise; Nausea; Off	; tion;		oprim d/Pyridoxine nloride/Sulfamethoxazole		N N N	S S S					Bayer Not Reported Not Reported
Label Use; Pain;		Acetam			N	S					Not Reported



Paraesthesia Oral; Procedural Pain; Pyrexia; Therapeutic Product Effect Incomplete; Weight Decreased

			•	
Gramicidin	N	S		Not Reported
Zeaxanthin	N	S		Not Reported
Xantofyl Palmitate	N	S		Not Reported
Nicomorphine	N	S		Not Reported
Budesonide	N	S		Not Reported
Metronidazole	N	S		Not Reported
Glyceryl Trinitrate	N	S		Not Reported
Ak-Spore [Gramicidin;Neomycin	N	S		Not Reported
Sulfate;Polymyxin B Sulfate]				•
Alprazolam	N	S		Not Reported
Atorvastatin	N	S		Not Reported
Atropine Sulfate	N	S		Not Reported
Betamethasone Dipropionate	N	S		Not Reported
Bisacodyl	N	S		Not Reported
Clarithromycin	N	S		Not Reported
Diphenhydramine	N	S		Not Reported
Hydromorphone Hydrochloride	N	S		Not Reported
Morphine Sulfate	N	S		Not Reported
Nadolol	N	S		Not Reported
Nicotine	N	S		Not Reported
Pregabalin	N	S		Not Reported
Sulfamethoxazole	N	S		Not Reported
Nicotine Polacrilex	N	S		Not Reported
Magnesium Oxide	N	S		Not Reported
Imodium	N	S		Not Reported
D-Alpha Tocopherol	N	S		Not Reported
Entocort	N	S		Not Reported
Flovent	N	S		Not Reported
Cupric Oxide; Folic Acid; Nicotinic	N	S		Not Reported
Acid;Zinc				·
Gramicidin;Polymyxin B	N	S		Not Reported
Pantoprazole Sodium	N	S		Not Reported
[Pantoprazole Sodium				•
Monohydrate]				
Benzydamine Hydrochloride	N	S		Not Reported
Valsartan	N	С	Unk	Not Reported
	NI		Olik	•
Amoxicillin	N	С		Not Reported
Sodium Stearate	N	C		Not Reported
Mupirocin Calcium Hydrate	N	S		Not Reported
Loperamide Hydrochloride	N	S		Not Reported
Sodium Carboxymethylcellulose	N	S		Not Reported
Biaxin XI	N	S		Not Reported



HumiraNSNot ReportedPantoprazole Sodium AnhydrousNSNot ReportedErgocalciferolNSNot ReportedClotrimazoleNSNot ReportedPantoprazoleNSNot ReportedNicotinamideNSNot Reported	
ErgocalciferolNSNot ReportedClotrimazoleNSNot ReportedPantoprazoleNSNot ReportedNicotinamideNSNot Reported	
Clotrimazole N S Not Reported Pantoprazole N S Not Reported Nicotinamide N S Not Reported Not Re	
Pantoprazole N S Not Reported Nicotinamide N S Not Reported	
Nicotinamide N S Not Reported	
Nicotinamide N S Not Reported	
Calcitriol N S Not Reported	
Triamcinolone Acetonide N S Not Reported	
Cetirizine Hydrochloride N S Not Reported	
Prednisone N S Not Reported	
Adalimumab N S Not Reported	
Infliximab N S Not Reported	
Sinus Rinse N S Not Reported	
Mupirocin N S Not Reported	
Loperamide Hydrochloride N S Not Reported	
Glycerol N S Not Reported	
Betamethasone N S Not Reported	
Calcium Carbonate N S Not Reported	
Azithromycin Dihydrate N S Unk Not Reported	
· · ·	
Zinc Chloride N S Not Reported	
Salinex [Sodium Chloride]NSNot ReportedMentha ArvensisNSNot Reported	
Polyethylene Glycol 4000 N S Not Reported	
Fluticasone Propionate N S Not Reported	
Diphenoxylate Hydrochloride N S Not Reported	
Glycerin N S Not Reported	
Isoniazid;Pyridoxine N S Not Reported	
Hydrochloride;	
Sulfamethoxazole;Trimethoprim	
Infa-3 [Gramicidin; Neomycin N S Not Reported	
Sulfate;Polymyxin B]	
Neomycin Sulfate N S Not Reported	
Diphenhydramine Hydrochloride N S Not Reported	
Mesalazine N S Not Reported	
Triamcinolone Acetonide N S Not Reported	
Sodium Chloride N S Not Reported	
Betamethasone Valerate N S Not Reported	
Fluticasone Furoate N S Not Reported	
Desonide N S Not Reported	
Glycerine N S Not Reported	



						Detailed Ne	port			
	Nicod Simva Amox Zinc C	istatin icillin Trihydrate		N N N N N N N	\$ \$ \$ \$ \$ \$					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Feb-2023	21979746	DIRECT						66 YR	Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Headache; Recalled Product Administered; Vision Blurred		al Tears Lubricant Eye (Carboxymethylcellulose m)		Y	S	Ophthalmic	Other Quantity : 2 Drop(S Frequency : Twice A Day;			Ezricare
Violett Blatted	Atorvi Fish C Vitam Turme Vitam	statin Dil in B eric		N N N N N	C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Feb-2023	21983779	DIRECT			ОТ				Unknow	n USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Dry Eye; Eye Colour Change; Eye Inflammation; Eye Pai Haemorrhage; Produc Contamination Microb Visual Impairment	n; t	tears Dry Eye Therapy		N	S		Other Quantity : 1 Ounce;			Akorn
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Feb-2023	21983780	DIRECT	N		DE, OT			74 YR	Male	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Bacterial Infection; Cardiac Failure;		al Tears Lubricant Eye (Carboxymethylcellulose		N	S		Other Quantity: 15			Ezricare

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Sodium)

21983783

Case Type

DIRECT

FDA Received Date Case #

11-Feb-2023

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) **Detailed Report**

Country USA

Country

Country

USA

USA

Sex

Unknown

Age

Clostridium Difficile Colitis: Sodium) Milliliters Bot: Decreased Appetite; Dehydration: Distributive Shock: Fluid Intake Reduced: Loss Of Consciousness; Myelodysplastic Syndrome: Pleural Effusion; Pseudomonas Infection; Pyrexia; Recalled Product Administered; Respiratory Failure; Urinary Incontinence: Urinary Retention; Urine Analysis Abnormal; Urine Odour Abnormal FDA Received Date Case # **Health Prof Outcomes** Mfr Control # 503B Facility Sex Case Type <u>Age</u> 10-Feb-2023 21984292 DIRECT 60 YR Female **Route** Preferred Term **Product** Comp. OTC Role **Dosage Text** Duration Mfr Therapy Cessation: Vision Artificial Tears Lubricant Eve Υ S Ezricare Ophthalmic Other Quantity: 2 Drop(S); Drops (Carboxymethylcellulose Blurred Frequency: As Needed; Sodium) С Multi Vitamins Ν Not Reported FDA Received Date Case # Case Type **Health Prof Outcomes** Mfr Control # 503B Facility Age Sex DIRECT DS. RI 32 YR 10-Feb-2023 21984314 Female **Preferred Term Product** Comp. OTC Role Route **Dosage Text** Duration Mfr Υ S Instillation Site Infection Artificial Tears Lubricant Eve Ezricare Ophthalmic Other Quantity: 1 Drop(S); Drops (Carboxymethylcellulose Frequency: At Bedtime;

Health Prof Outcomes

OT

Ν

Note: If the field is blank, there is no data. Page: 281 of 536 Date - Time: 11-Apr-2023 10:56:54 AM EST

Mfr Control #

503B Facility



FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Preferred Term	,	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Eye Irritation; Instillation Site Pruritus; Recalled Product Administered; Therapeutic Product E Incomplete	 	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		N	S				1	Not Reported
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Feb-2023	2198378	34 DIRECT			ОТ				Unknown	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Instillation Site Reaction Recalled Product	- , 	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		N	S					Global Pharmaceuticals
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Feb-2023	2198560	04 DIRECT			RI			54 YR	Female	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Eye Irritation; Ocular Hyperaemia; Product Quality Issue	1	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Other Quantity: 2 Ounce (S); Frequency: 4 Times A	\	l	Jnknown Manufacture
	l	Lisinopril		N	С				1	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
11-Feb-2023	2198562	26 DIRECT	N					77 YR	Male	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	l <u>fr</u>
Eye Pain; Vision Blurr	1	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	2 Drops As Needed Ophthalmic			Global Pharmaceuticals
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	Age	<u>Sex</u>	Country
11-Feb-2023	2198569	98 DIRECT			RI, OT			39 YR	Female	USA

Note: If the field is blank, there is no data.

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Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Eye Infection; Loss Of Personal Independence Daily Activities; Visual Impairment	e In	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Υ	S				Ez	rricare
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Feb-2023	219860	90 DIRECT			ОТ			67 YR	Female	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u> ı	1
Asthenopia; Headache Recalled Product Administered; Vision Blurred	,	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Υ	S	Ophthalmic	Frequency : As Needed;		Ez	cricare
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Feb-2023	219860	98 DIRECT			DS, RI, OT			58 YR	Female	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u> ı	1
Instillation Site Infection		Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Υ	S	Ophthalmic	Frequency : Twice A Day;		Ez	ricare
		Hydroxy Chloroquine Vitamin D		N N	C C					ot Reported ot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
12-Feb-2023	219861	09 DIRECT			ОТ			58 YR	Female	USA
Preferred Term		Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u> ı	
Lid Sulcus Deepened; Recalled Product; Visio Blurred	on	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Υ	S	Ophthalmic	Other Quantity: 30 Drop (S); Other Frequency: 6-7 Times Daily;		Ez	ricare



FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Feb-2023	21892436	6 EXPEDITED (15-DAY)	Y			FR-ALLER 2239708U				Female	FRA
Preferred Term	<u>P</u>	Product	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liquid Product Physical Issue; Ocular Discomfor	rt C	Optive		Υ	S	Ophthalmic	Unk			Alle	ergan
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof C	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Feb-2023	21982383	3 EXPEDITED (15-DAY)	Υ	ŀ	IO, OT	CA-GLENN PHARMAC 2023GMK	CEUTICALS-			Unknown	CAN
Preferred Term	<u>P</u>	Product	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	e Text	Duration	<u>Mfr</u>	
Chronic Sinusitis; Drug	M	1 upirocin		N	S	Unknown	Unk			Gle	enmark
Ineffective; Dyspepsia; Infusion Related Reaction Macular Degeneration;	on; N	Mupirocin		N	S	Topical	Unk (f Ointm	ormulation: ent)		Gle	enmark
Malaise; Nausea; Off	Α	cetaminophen		N	S	Unknown	Unk			No	t Reported
Label Use; Pain; Paraesthesia Oral;	Α	cetaminophen		N	S	Unknown	Unk			No	t Reported
Procedural Pain; Pyrexi Therapeutic Product Eff	a,	dalimumab		N	S	Unknown		Solution Itaneous)		No	t Reported
Incomplete; Weight Decreased	Α	lprazolam		N	S	Unknown	Unk			No	t Reported
Decreased	Α	moxicillin Trihydrate		N	S	Unknown	Unk			No	t Reported
	Α	torvastatin		N	S	Unknown	Unk			No	t Reported
	Α	tropine Sulfate		N	S	Oral	Unk			No	t Reported
	Α	tropine Sulfate		N	S	Oral	4 Dos	age Form		No	t Reported
	Α	tropine Sulfate		N	S	Oral	1 Dos	age Form			t Reported
		tropine Sulfate		N	S	Unknown	Unk				t Reported
		zithromycin Dihydrate		N	S	Unknown	Unk				t Reported
		Benzydamine Hydrochloride		N	S	Unknown	Unk				t Reported
		Betamethasone		N	S	Unknown	Unk				t Reported
		Setamethasone Dipropionate		N	S	Unknown	Unk				t Reported
	В	Setamethasone Valerate		N	S	Unknown	Unk			No	t Reported

Note: If the field is blank, there is no data.



				<u> </u>		
Biaxin XI	N	S	Unknown	Unk		Not Reported
Bisacodyl	N	S	Unknown	Unk		Not Reported
Budesonide	N	S	Unknown	Unk		Not Reported
Calcitriol	N	S	Intra-articular	Unk		Not Reported
Calcium Carbonate	N	S	Unknown	Unk		Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk		Not Reported
Clarithromycin	N	S	Unknown	Unk		Not Reported
Clotrimazole	N	S	Unknown	Unk		Not Reported
Cupric Oxide	N	S	Unknown	Unk		Not Reported
Cupric Oxide;Folic Acid;Nicotinic Acid;Zinc	N	S	Unknown	Unk		Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk		Not Reported
Desonide	N	S	Unknown	Unk		Not Reported
Diphenhydramine	N	S	Unknown	Unk		Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown	Unk		Not Reported
Entocort	N	S	Unknown	Unk		Not Reported
Ergocalciferol	N	S	Unknown	Unk		Not Reported
Ertapenem Sodium	N	S	Unknown	Unk		Not Reported
Flovent	N	S	Unknown	Unk		Not Reported
Fluticasone Furoate	N	S	Unknown	Unk		Not Reported
Fluticasone Propionate	N	S	Unknown	Unk		Not Reported
Glycerine	N	S	Unknown	Unk		Not Reported
Glycerol	N	S	Oral	Unk		Not Reported
Glycerol;Sodium Stearate	N	S	Unknown	Unk		Not Reported
Glyceryl Trinitrate	N	S	Unknown	Unk		Not Reported
Gramicidin	N	S	Unknown	Unk		Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown	Unk		Not Reported
Gramicidin;Polymyxin B Sulfate	N	S	Unknown	Unk		Not Reported
Humira	N	S	Unknown	Unk (Subcutaneous Solution)	6 YR	Not Reported



Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Imodium	N	S	Unknown	Unk	Not Reported
Infa-3 [Gramicidin;Neomycin Sulfate;Polymyxin B]	N	S	Unknown	Unk (Dental Ointment)	Not Reported
Infliximab	N	S	Unknown	Unk	Not Reported
Isoniazid/Pyridoxine Hydrochloride/Sulfamethoxazole /Trimethoprim	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk	Not Reported
Loperamide Hydrochloride	N	S	Unknown	Unk	Not Reported
Macrogol	N	S	Unknown	Unk	Not Reported
Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Intramuscular	Unk	Not Reported
Mentha Arvensis	N	S	Unknown	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Transdermal	Unk	Not Reported
Nicomorphine	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium Anhydrous	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Unknown	Unk	Not Reported
Salinex [Sodium Chloride]	N	S	Nasal	Unk (Nasal Solution)	Not Reported
				,	



		Simvast	tatin		N	S	Unknown	Unk			Not Re	ported
		Sinus R	inse		Ν	S	Nasal	Unk (Solution Nasal)			Not Re	ported
		Sodium	Carboxymethylcellulose		Ν	S	Ophthalmic	Unk			Not Re	ported
		Sodium	Carboxymethylcellulose		Ν	S	Ophthalmic	Unk			Not Re	eported
		Sodium	Chloride		Ν	S	Unknown	Unk			Not Re	eported
		Sulfame	ethoxazole		Ν	S	Unknown	Unk			Not Re	eported
		Sulfame	ethoxazole;Trimethoprim		Ν	S	Unknown	Unk			Not Re	eported
		Triamcii	nolone Acetonide		N	S	Intra-articular	Unk (Suspension Intra- Articular)			Not Re	eported
		Triamcii	nolone Acetonide		Ν	S	Unknown	Unk			Not Re	ported
		Trimeth	oprim		Ν	S	Unknown	Unk			Not Re	ported
		Vitamin	D3		Ν	S	Unknown	Unk			Not Re	ported
		Xantofy	l Palmitate		N	S	Unknown	Unk			Not Re	ported
		Zeaxan	thin		N	S	Oral	Unk			Not Re	ported
		Zinc Ch	loride		N	S	Unknown	Unk			Not Re	ported
		Zinc Ox	ide		N	S	Unknown	Unk			Not Re	ported
		Amoxici	llin		N	С	Unknown	Unk			Not Re	ported
		Diphenh	nydramine Hydrochloride		N	С	Unknown	Unk			Not Re	ported
		Mupiroc	in Calcium		N	С	Unknown	Unk			Not Re	ported
		Neomy	cin Sulfate		N	С	Unknown	Unk			Not Re	ported
		Sodium	Stearate		N	С	Unknown	Unk			Not Re	ported
-		Valsarta	an		N	С	Unknown	Unk			Not Re	ported
FDA Received Date	Case #		Case Type	Health	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>C</u>	Country
13-Feb-2023	219843	67	EXPEDITED (15-DAY)	Υ		HO, OT	CA-Allegis Pharmaceutica APL202302-00		65 YR	Female	; C	CAN
Preferred Term		Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosage Text	Duration		<u>Mfr</u>	
Abdominal Pain; Anae Chronic Sinusitis; Coli		Nitrogly	cerin		N	S		Unknown			Espero Pharm	aceuticals
Colitis Ulcerative; Constipation; Drug		Acetam	inophen		N	S		Unknown			Not Re	eported



Ineffective; Dyspepsia;
Erythema; Female Genital
Tract Fistula; Frequent
Bowel Movements;
Haematochezia;
Headache; Infusion
Related Reaction; Macular
Degeneration; Malaise;
Nausea; Off Label Use;
Oral Candidiasis; Pain;
Paraesthesia Oral;
Procedural Pain; Proctitis;
Pyrexia; Radiculopathy;
Rectal Haemorrhage;
Therapeutic Product Effect
Incomplete; Vaginal
Discharge; Vaginal
Flatulence; Weight
Decreased

		20100010	P	
Acetaminophen/Dextropropoxyphene	N	S	Unknown	Not Reported
Acetaminophen/Pseudoephedrin e Hydrochloride	N	S	Unknown	Not Reported
Acetic Acid/Triamcinolone Acetonide	N	S	Unknown	Not Reported
Acetylsalicylic Acid	Ν	S	Unknown	Not Reported
Acetylsalicylic Acid/Citric Acid/Sodium Bicarbonate	N	S	Unknown	Not Reported
Align	N	S	Unknown	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Not Reported
Apo-Alpraz Apo-Pregabalin Atorvastatin Calcium	N N N	S S S	Unknown	Not Reported Not Reported Not Reported
Atropine Sulfate/Diphenoxylate Hydrochloride	N	S	Unknown	Not Reported
Azithromycin	N	S	Unknown	Not Reported
Benzydamine	N	S	Unknown	Not Reported
Betamethasone Valerate	N	S	Unknown	Not Reported
Biaxin XI	Ν	S	Extended Release Tablets	Not Reported
Bifidobacterium Longum Subsp. Infantis	N	S	Unknown	Not Reported
Bisacodyl	N	S	Unknown	Not Reported
Budesonide	N	S	Unknown	Not Reported
Calcitriol/Calcium Carbonate/Zinc	N	S	Unknown	Not Reported
Calcium & Vitamin D	N	S	Unknown	Not Reported
Calcium Carbonate/Vitamin D3/Zinc Oxide	N	S	Unknown	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Not Reported
Ciprofloxacin	N	S	Unknown	Not Reported
Ciprofloxacin Hydrochloride	N	S	Unknown	Not Reported
Clarithromycin	N	S	Unknown	Not Reported
Clotrimazole	N	S	Unknown	Not Reported

Unknown

Ν

S

Cortenema Suspension

Not Reported



				·	
Cupric Oxide/Folic Acid/Nicotinamide/Zinc	N	S		Unknown	Not Reported
D-Alpha Tocopherol/DI-Alpha Tocopheryl Acetate	N	S		Unknown	Not Reported
Desonide	N	S		Unknown	Not Reported
Dexpanthenol/Ergocalciferol/Foli	N	S		Unknown	Not Reported
c Acid/Nicotinamide/Riboflavin/Thi amin					
Diphenhydramine	N	S		Unknown	Not Reported
Diphenhydramine Hydrochloride	N	S		Unknown	Not Reported
Empracet	N	S		Unknown	Not Reported
Entyvio For I.V. Infusion	N	S	Intravenous (not	Unknown	Not Reported
Ertapenem Sodium	N	S	otherwise specified)	Unknown	Not Reported
Fentanyl	N	S		Unknown	Not Reported
Fentanyl Citrate	N	S		Unknown	Not Reported
Fluconazole	N	S			Not Reported
Fluticasone Propionate	N	S		Unknown	Not Reported
Fructose		S		Unknown	·
	N			Unknown	Not Reported
Glycerin	N	S		Unknown	Not Reported
Gramicidin/Neomycin Sulfate/Polymyxin B Sulfate	N	S		Unknown	Not Reported
Habitrol	N	S		Unknown	Not Reported
Humira	N	S	Subcutaneous	Unknown	Not Reported
Hydrochlorothiazide	N	S		Unknown	Not Reported
Hydrocortisone	N	S		Unknown	Not Reported
Hydromorphone Hydrochloride	N	S		Unknown	Not Reported
Isoniazid/Pyridoxine	N	S		Unknown	Not Reported
Hydrochloride/Sulfa Methoxazole/Trimethoprim					
Loperamide Hydrochloride	N	S		Unknown	Not Reported
Macrogol/Potassium	N	S		Unknown	Not Reported
Chloride/Sodium					

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				_	
Bicarbonate/Sodium Chloride Magnesium	N	s		Unknown	Not Reported
Magnesium Carbonate	N	S			Not Reported
Magnesium Hydroxide	N	S		Unknown	Not Reported
Magnesium Oxide	N	S		Unknown	Not Reported
Magnesium Sulfate	N	S		Unknown	Not Reported
•		S		Unknown	· ·
Magnesium Sulfate Inj 50%	N		Intramuscular	Unknown	Not Reported
Mesalazine	N	S		Unknown	Not Reported
Methylprednisolone Sodium Succinate	N	S		Unknown	Not Reported
Metronidazole	N	S		Unknown	Not Reported
Midazolam	N	S		Unknown	Not Reported
Morphine Sulfate	N	S		Unknown	Not Reported
Mupirocin	N	S		Unknown	Not Reported
Nadolol	N	S		Unknown	Not Reported
Nicoderm	N	S		Unknown	Not Reported
Nicotinamide	N	S		Unknown	Not Reported
Nicotine	N	S		Unknown	Not Reported
Oxybutynin Hydrochloride	N	S		Unknown	Not Reported
Pantoprazole	N	S		Unknown	Not Reported
Potassium Chloride	N	S		Unknown	Not Reported
Prednisone	N	S		Unknown	Not Reported
Refresh Tears	N	S	Ophthalmic	Unknown	Not Reported
Sodium Chloride	N	S	Nasal	Unknown	Not Reported
Sinus Rinse	N	S	Nasal	Unknown	Not Reported
Sodium Carboxymethyl Cellulose	N	S		Unknown	Not Reported
Sucralfate	N	S		Unknown	Not Reported
Sulfamethoxazole/Trimethoprim	N	S			Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unknown	Not Reported
Ubidecarenone	N	S		Unknown	Not Reported



							•			
		Vitamin D3		N	S		Unknown			Not Reported
		Xantofyl Palmitate		N	S		Unknown			Not Reported
		Zeaxanthin		N	S		Unknown			Not Reported
		Zinc Oxide		Ν	S		Unknown			Not Reported
	Zopiclone			N S			Unknown			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Feb-2023	219845	69 EXPEDITED (15-DAY)	N		ОТ	ALC2023CA	A000920		Female	CAN
Preferred Term		Product	Comp.	<u>OT(</u>	Role	Route	<u>Dosage Text</u>	<u>Duration</u>	<u>N</u>	<u>Nfr</u>
Drug Ineffective; Macu	ular	Atropine		N	S	Unknown	Unk			Not Reported
Degeneration		Adalimumab		Ν	S	Subcutaneous	Unk			Not Reported
		Salinex [Sodium Chloride]		Ν	S	Nasal	Unk			Not Reported
		Atropine		Ν	S	Oral	Unk			Not Reported
		Morphine Sulfate		Ν	S	Unknown	Unk			Not Reported
		Amoxicillin		Ν	S	Unknown	Unk			Not Reported
		Atorvastatin		Ν	S	Unknown	Unk			Not Reported
		Clarithromycin		Ν	S	Unknown	Unk			Not Reported
		Magnesium Sulfate		Ν	S	Unknown	Unk			Not Reported
		Ertapenem Sodium		Ν	S	Unknown	Unk			Not Reported
		Zinc Oxide		Ν	S	Unknown	Unk			Not Reported
		Diphenhydramine Hydrochloride		Ν	S	Unknown	Unk			Not Reported
		Pregabalin		Ν	S	Unknown	Unk			Not Reported
		Pantoprazole		Ν	S	Unknown	Unk			Not Reported
		Colecalciferol		Ν	S	Unknown	Unk			Not Reported
		Prednisone		Ν	S	Unknown	Unk			Not Reported
		Cetirizine		Ν	S	Unknown	Unk			Not Reported
		Amoxicillin Trihydrate		Ν	S	Unknown	80 Mg			Not Reported
		Atorvastatin Calcium		Ν	S	Unknown	Unk			Not Reported



Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Atropine	N	S	Oral	Unk	Not Reported
Azithromycin	N	S	Oral	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Valsartan	N	S	Intracardiac	Unk	Not Reported
Valsartan	N	S	Unknown	Unk	Not Reported
Vitamin C [Ascorbic Acid]	N	S	Unknown	Unk	Not Reported
Acetaminophen	N	S	Unknown	Unk	Not Reported
Azithromycin Dihydrate	N	S	Oral	Unk	Not Reported
Azithromycin Dihydrate	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Macrogol 3350;Potassium Chloride;Sodium Chloride; Sodium Sulfate	N	S	Unknown	Unk	Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Transplacental	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Mupirocin	N	S	Unknown	Unk	Not Reported
Apo Hydro	N	S	Unknown	Unk	Not Reported
Avamys	N	S	Unknown	Unk (Metered Dose)	Not Reported
Bactroban [Mupirocin]	N	S	Unknown	Unk	Not Reported
Betaderm [Betamethasone]	N	S	Unknown	Unk	Not Reported



			Dotalica i	oport	
Biaxin XI	N	S	Unknown	Unk (Extended Release Tablet	Not Reported
Citirizine [Cetirizine Hydrochloride]	N	S	Unknown	Unk	Not Reported
Dilaudid	N	S	Unknown	Unk	Not Reported
Entocort	N	S	Unknown	Unk (Sustained Release)	Not Reported
Flovent	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Habitrol [Nicotine]	N	S	Unknown	Unk	Not Reported
Humira	N	S	Subcutaneous	Unk (Subcutaneous Solution)	Not Reported
Kenalog [Triamcinolone	N	S	Intra-articular	Unk	Not Reported
Acetonide] Lomotil [Loperamide Hydrochloride]	N	S	Oral	4 Ot, Qd	Not Reported
Ms Ir	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk (Patch)	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S	Unknown	Unk	Not Reported
Sinus Rinse	N	S	Nasal	Unk (Endosinusial)	Not Reported
Statex [Morphine Sulfate]	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Diphenhydramine	N	S	Unknown	Unk	Not Reported
Calcium & Vitamin D3	N	S	Unknown	Unk	Not Reported
Bactrim	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Vitamiin C	N	S	Unknown	Unk	Not Reported
DI-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported



Acetylsalicylic Acid	N	S	Intracardiac	Unk	Not Reported
Diphenoxylate Hydrochloride And Atropine Sulfate	N	S	Oral	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Un K	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Hydrochorothiazide	N	S	Endocervical	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk	Not Reported
Loperamide	N	S	Oral	Unk	Not Reported
Magnesium Clofibrate	N	S	Unknown	Unk	Not Reported
Mentha Arvensis	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
Sodium Chloride	N	S	Endosinusial	Unk (Intra Nasal)	Not Reported
Vitamin D Nos	N	S	Unknown	Unk	Not Reported
Ambroxol Hydrochloride	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Calcium Gluconate	N	S	Unknown	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
Cupric Oxide;Folic Acid;Nicotinic Acid;Zinc Oxide	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Fructose;Glycerol;Sodium Chloride	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride; Simeticone	N	S	Oral	Unk	Not Reported



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	L	operamide Hydrochloride		N	S	Oral	Unk			١	Not Reported
	M	letronidazole Hydrochloride		N	S	Unknown	Unk			١	Not Reported
	N	icotine		N	S	Unknown	Unk			١	Not Reported
	S	imvastatin		N	S	Unknown	Unk			١	Not Reported
	S	odium Stearate		N	S	Oral	Unk			١	Not Reported
	Т	riamcinolone		N	S	Intra-articular	Unk			١	Not Reported
	Т	rimethoprim		N	S	Unknown	Unk			١	Not Reported
	А	tropine		N	S	Oral	Unk			١	Not Reported
	Z	inc Chloride		N	S	Unknown	Unk			١	Not Reported
	Н	yrimoz [Adalimumab]		N	С	Unknown	Unk			١	Not Reported
	V	alsartan		N	С	Unknown	Unk			١	Not Reported
	С	alcium		N	С	Intracardiac	Unk			١	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2023	21987000	EXPEDITED (15-DAY)	N		ОТ	US-ALLER 2303414U				Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTO	Role	Route	Dosage	<u> Text</u>	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Eye Disorder; Eyelid Margin Crusting; Liquic	d R	efresh Relieva efresh Plus		Y N	S S		Unk				Not Reported Not Reported
Product Physical Issue	· R	efresh Plus		N	S		Unk			١	Not Reported
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2023	21987003	3 EXPEDITED (15-DAY)	N		OT	US-ALLER 2303508U				Female	USA
Preferred Term	<u>P</u>	roduct	Comp.	OTO	Role	Route	<u>Dosage</u>	<u>e Text</u>	<u>Duration</u>	<u>M</u>	<u>lfr</u>
Eye Pruritus; Macular Degeneration; Off Labe Use; Vitreous Floaters	el	efresh Tears		Y	S	Ophthalmic	3 To 4	Per Day		١	Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Cont	rol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Feb-2023	21987007	7 EXPEDITED (15-DAY)	N		ОТ	US-ALLER 2303696U	-			Male	USA



Preferred Term		Product		Comp.	OTC	Role	Route	Dosage Text	Duration	Mf	<u> </u>
Cataract; Vision Blurre	ed	Refresh	Tears		Υ	S	Ophthalmic	Unk		No	ot Reported
FDA Received Date	Case #		Case Type	Health	Prof (<u>Dutcomes</u>	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Feb-2023	219902	232	DIRECT		[OS, HO, OT			80 YR	Female	USA
Preferred Term		Product	<u>:</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mf	[
Eye Infection; Pseudomonas Infection			Tears Lubricant Eye Carboxymethylcellulose		Y	S	Ophthalmic	Other Quantity : 6 6; Frequency : As Needed;		Ez	rricare
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
13-Feb-2023	219916	555	DIRECT		F	રા			76 YR	Male	USA
Preferred Term		Product	:	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	[
Conjunctivitis; Culture Positive; Pathogen Resistance; Pseudomo			Tears Lubricant Eye Carboxymethylcellulose		Y	S	Ophthalmic	Other Quantity : Drop; Frequency : As Needed; Duration: Years		Ez	ricare
Infection		Nexium Losartan Victoza	1		N N N	C C C				No	ot Reported ot Reported ot Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof (<u>Dutcomes</u>	Mfr Contro	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Feb-2023	219730)17	EXPEDITED (15-DAY)	N	(TO	US-ALLERG 2303391US	AN-		Female	USA
Preferred Term		Product	:	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	1
Cataract		Refresh	Relieva Pf Ud		Υ	S		In The Morning And At Bedtime		All	ergan
FDA Received Date	Case #		Case Type	Health	Prof (<u> Dutcomes</u>	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Feb-2023	219907	'46	NON-EXPEDITED	N			US-SOMER: US-000002	SET-2023-	73 YR	Male	USA
Preferred Term		Product	:	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mf	



Retention; Urine Analysis Abnormal; Urine Odour

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Abnormal

						Detaile	u vehoi	L			
Dry Eye; Erythema; Eyelid Oedema; Photophobia	Solution, (ost Ophthalmic 0.005% Tears Moisture Drops		N N	S		1 D	rop Ou Qd			Somerset Not Reported
	Advil Tabl			N	Ċ	Oral					Not Reported
	Puritan'S	Pride Vitamin B-12		N	S	Oral					Not Reported
FDA Received Date Cas	se # (Case Type	Health	Prof	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Feb-2023 219	91840 I	EXPEDITED (15-DAY)	N		ОТ	US-ALL 230311	ERGAN- 2US			Female	USA
Preferred Term	Product		Comp.	<u>OTC</u>	Role	Route	Dosa	age Text	Duration	<u>N</u>	<u>lfr</u>
Cataract; Eye Inflammation; Lacrimation Increased	Refresh T	ears		Y	S	Ophthalmic				1	Not Reported
FDA Received Date Cas	se # (Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
14-Feb-2023 219	94131 [DIRECT			DE, HO				74 YR	Male	USA
Preferred Term	Product		Comp.	<u>OTC</u>	Role	Route	Dosa	age Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Cardiac Failure; Clostridium Difficile Colitis; Decreased Appetite; Dehydration; Distributive Shock; Fluid Intake Reduced; Multiple-Drug Resistance; Myelodysplastic Syndrome; Pseudomonas Infection; Pulmonary Oedema; Pyrexia; Recalled Product; Recalled Product Administered; Respiratory Failure; Syncope; Urinary Incontinence; Urinary		ears Lubricant Eye arboxymethylcellulose		N	S	Intraocular					Global Pharmaceuticals



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FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control :	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	Country
14-Feb-2023	21994602	DIRECT			ОТ			72 YR	Female	USA
Preferred Term	Pro	<u>duct</u>	Comp.	<u>OT(</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Headache	Drop	icial Tears Lubricant Eye os (Carboxymethylcellulose ium)		Y	S	Ophthalmic	Other Quantity: 1 Ounce (S); Frequency: As Needed;	4 DAY		Ezricare
	Sert Hyd Xelja Losa Rop Vit <i>P</i> Bioti Fish Lute	artan inerole A - D in I Oil ein nberry		N N N N N N N N N N N N N N N N N N N	000000000000					Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Control	# 503B Facility	<u>Age</u>	Sex	Country
15-Feb-2023	17484674	EXPEDITED (15-DAY)	N		ОТ	NVSC2020CA	058057		Female	CAN
Preferred Term	Pro	<u>duct</u>	Comp.	ото	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Drug Ineffective; Macu	ılar Ada	limumab		N	S	Subcutaneous	Unk			Novartis
Degeneration	Sod	ium Chloride		Ν	S	Nasal	Unk			Not Reported
	Atro	pine Sulfate		Ν	S	Oral	Unk			Not Reported
	Mor	phine Sulfate		Ν	S	Unknown	Unk			Not Reported
	Amo	oxicillin		Ν	S	Unknown	Unk			Novartis
	Ator	vastatin		Ν	S	Unknown	Unk (Not Specified)			Novartis
	Clar	ithromycin		Ν	S	Unknown	Unk			Novartis
	Mag	nesium Sulfate		Ν	S	Unknown	Unk			Not Reported
	Erta	penem Sodium		Ν	S	Unknown	Unk			Not Reported



				<u> </u>	
Zinc Oxide	N	S	Unknown	Unk	Novartis
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Novartis
Pregabalin	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Novartis
Colecalciferol	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Novartis
Cetirizine	N	S	Unknown	Unk	Novartis
Amoxicillin Trihydrate	N	S	Unknown	Unk (Not Specified)	Novartis
Atorvastatin Calcium	N	S	Unknown	Unk	Novartis
Atorvastatin Calcium	N	S	Unknown	Unk (Not Specified)	Novartis
Atropine	N	S	Unknown	Unk	Not Reported
Atropine	N	S	Oral	Unk	Not Reported
Azithromycin	N	S	Oral		Novartis
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Valsartan	N	S	Intracardiac	Unk	Novartis
Valsartan	N	S	Unknown	Unk	Novartis
Vitamin C	N	S	Unknown	Unk	Not Reported
Acetaminophen (Paracetamol)	N	S	Unknown	Unk	Novartis
Apo-Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Azithromycin Dihydrate	N	S	Unknown	Unk (Not Specified)	Novartis
Azithromycin Dihydrate	N	S	Oral	Unk	Novartis
Betamethasone Dipropionate	N	S	Unknown	Unk	Novartis
Betamethasone Dipropionate	N	S	Unknown	Unk	Novartis
Clotrimazole	N	S	Unknown	Unk	Novartis
Metronidazole	N	S	Unknown	Unk	Novartis
Macrogol 3350,Potassium Chloride,Sodium Chloride,	N	S	Unknown	Unk	Not Reported
Sodium Hydrogen Carbo Gramicidin,Neomycin Sulfate, Polymycin B Sulphate	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole, Trimethoprim	N	S	Unknown	Unk	Novartis



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Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Drops Ophthalmic	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk (Transplacental)	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Mupirocin	N	S	Unknown	Unk	Not Reported
Apo Hydro	N	S	Unknown	Unk	Not Reported
Avamys	N	S	Unknown	Unk (Metered Dose)	Not Reported
Bactroban	N	S	Unknown	Unk	Not Reported
Betaderm	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk (Extended Release Tablet)	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Dilaudid	N	S	Unknown	Unk	Not Reported
Entocort	N	S	Unknown	Unk (Sustained Release)	Not Reported
Flovent	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Habitrol	N	S	Unknown	Unk	Not Reported
Humira	N	S	Subcutaneous	Unk (Subcutaneous Solution)	Not Reported
Kenalog	N	S	Intra-articular	Unk	Not Reported
Lomotil	N	S	Oral	4 Ot, Qd	Not Reported
Ms Ir	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk (Patch)	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S	Unknown	Unk	Not Reported
Sinus Rinse	N	S	Nasal	Unk (Endosinusial)	Not Reported



S	Statex	N	S	Unknown	Unk	Not Reported
٧	/itamin D3	N	S	Unknown	Unk	Not Reported
D	Diphenhydramine	N	S	Unknown	Unk	Not Reported
C	Calcium & Vitamin D3	N	S	Unknown	Unk	Not Reported
В	Bactrim	N	S	Unknown	Unk	Not Reported
Х	Kantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Z	Zeaxanthin	N	S	Unknown	Unk	Not Reported
٧	/itamiin C	N	S	Unknown	Unk	Not Reported
D	N-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
C	Calcium Carbonate	N	S	Unknown	Unk	Not Reported
А	Acetylsalicylic Acid	N	S	Unknown	Unk (Not Specified)	Not Reported
	Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
	and Atropine Sulf Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
В	Budesonide	N	S	Unknown	Unk	Not Reported
F	- Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Н	lydrochorothiazide	N	S	Endocervical	Unk	Not Reported
Ν	Mesalazine	N	S	Unknown	Unk	Not Reported
Ν	ladolol	N	S	Unknown	Unk	Not Reported
S	Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
S	Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Т	riamcinolone Acetonide	N	S	Intra-articular	Unk (Suspension Intraarticular)	Not Reported
Т	riamcinolone Acetonide	N	S	Unknown	Unk	Not Reported
L	operamide	N	S	Oral	Unk	Not Reported
Ν	/lagnesium Clofibrate	N	S	Unknown	Unk	Not Reported
Ν	flentha Arvensis	N	S	Unknown	Unk	Not Reported
Р	Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Н	łydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
S	Sodium Chloride	N	S	Unknown	Unk (Intra Nasal),	Not Reported
					• "	



							Endosinusial			
	Vitamin	D		N	S	Unknown	Unk			Not Reported
	Ambrox	ol Hydrochloride		Ν	S	Unknown	Unk			Not Reported
	Betamet	hasone		Ν	S	Unknown	Unk			Not Reported
	Calcium	Gluconate		Ν	S	Unknown	Unk			Not Reported
	Cupric C	Oxide		N	S	Unknown	Unk			Not Reported
	Cupric C	Oxide		N	S	Unknown	Unk			Not Reported
	D-Alpha	Tocopherol		Ν	S	Unknown	Unk			Not Reported
	Fructose)		N	S	Unknown	Unk			Not Reported
	Gramici	din		Ν	S	Unknown	Unk			Not Reported
	Loperan	nide Hydrochloride		N	S	Oral	Unk			Not Reported
	Loperan	nide Hydrochloride		N	S	Oral	Unk			Not Reported
	Metronio	dazole Hydrochloride		N	S	Unknown	Unk			Not Reported
	Nicotine			N	S	Unknown	Unk			Not Reported
	Simvast	atin		N	S	Unknown	Unk			Not Reported
	Sodium	Stearate		N	S	Oral	Unk			Not Reported
	Triamcir	nolone		N	S	Intra-articular	Unk (Suspention Intra- Articular)			Not Reported
	Trimetho	pprim		N	S	Unknown	Unk			Not Reported
	Zinc Chl	oride		N	S	Unknown	Unk			Not Reported
	Valsarta	n		N	С	Unknown				Not Reported
	Valsarta	n		N	С	Vaginal	Unk			Not Reported
	Calcium			N	С	Unknown	Unk			Not Reported
FDA Received Date Case #	<u>#</u>	Case Type	Health	Prof	Outcomes	Mfr Contro	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Feb-2023 219966	646	EXPEDITED (15-DAY)	N		ОТ	US-ALLERG 2303880US	AN-		Female	USA
Preferred Term	Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		Mfr
Cataract; Post Procedural	Refresh	Tears		Υ	S	Ophthalmic	Unk			Allergan
Complication	Restasis	3		N	S	Ophthalmic	Unk			Allergan



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FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Feb-2023	21996649	EXPEDITED (15-DAY)	N		НО	US-ALLER 2303891US				Male	USA
Preferred Term	<u>Produ</u>	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Cardiac Disorder; Dry	Eye Refres	sh Relieva		Υ	S	Ophthalmic	Unk			A	Allergan
FDA Received Date	Case #	Case Type	Health	Prof	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Feb-2023	21996650	EXPEDITED (15-DAY)	N		ОТ	US-ALLER 2303997US				Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Eye Ulcer; Macular Degeneration	Refres Patada	sh Tears ay		Y N	S C						Allergan Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Contr	<u>ol #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
15-Feb-2023	21999381	DIRECT			RI				76 YR	Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Conjunctivitis; Product Quality Issue		al Tears Lubricant Eye (Carboxymethylcellulose m)		Y	S	Ophthalmic	Frequ Day;	ency : 4 Times A			Global Pharmaceuticals
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contr	ol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Feb-2023	22004962	DIRECT			DS				72 YR	Female	USA
Preferred Term	Produ	<u>ıct</u>	Comp.	OTC	Role	Route	Dosage	e Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Conjunctivitis		al Tears oxymethylcellulose m)		Y	S	Ophthalmic	Frequ	ency : Twice A Day;		Γ	Oelsam Pharm
	Extens			N	С					N	lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Contr	ol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2023	22020027	DIRECT								Female	USA



Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	Mfr	
Periorbital Swelling; Recalled Product Administered; Suspected	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Υ	S	Ophthalmic	Other Quantity : 2 Drop(S) Frequency : Twice A Day;		Ez	ricare
Product Contamination;	Synthroid		N	С				No	t Reported
Vision Blurred	Phentermine		N	С				No	t Reported
	Multivitamins		N	С					t Reported
	Vitamin D3 Organic Greens With Superfood		N N	C C					t Reported t Reported
	Blend		.,					110	Ктороноа
FDA Received Date Case	# Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2023 22020	0031 DIRECT		0	Т			52 YR	Female	USA
Preferred Term	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Ear Discomfort; Ear Infection; Eye Discharge; Artificial Tears Lubricant Eye Drops (Carboxymethylcellulos			Υ	S	Ophthalmic	Other Quantity: 2 Ounce (S); Frequency: Twice A		Ez	ricare
Eye Swelling; Eyelid	Sodium)					Day;			
Margin Crusting; Pain; Therapy Non-Responder; Tinnitus	Lisinopril		N	С				No	t Reported
FDA Received Date Case	# Case Type	Health	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
17-Feb-2023 22020	0485 DIRECT	N	0	Т			42 YR	Female	USA
Preferred Term	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Product Contamination; Vision Blurred	Ezricare Artificial Tears Lubricant Eye Drops		N	S				No	t Reported
FDA Received Date Case	# Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
18-Feb-2023 2202	1536 DIRECT						42 YR	Female	USA
Preferred Term	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Conjunctivitis; Eye Discharge; Upper Respiratory Tract Infection	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Frequency : Every 8 Hours;		Ez	ricare



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	Effexor Vyvanse Iron Supplements Hydroxychloroquine Eye Drops					C C C C		•	Not Reported Not Reported Not Reported Not Reported Not Reported			
FDA Received Date	Case #	1	Case Type	<u>Health</u>	Prof Ou	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>	
18-Feb-2023	220216	614	DIRECT						78 YR	Prefer not t disclose	o USA	
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	Mfr		
Eyelid Infection		Artificial (Carbox Sodium)	ymethylcellulose		Y	S	Ophthalmic	Other Quantity : 2 Drops; Frequency : Every 8 Hours;		De	lsam Pharm	
FDA Received Date	Case #	1	Case Type	Health	Prof Ou	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country	
19-Feb-2023	220216	316	DIRECT		RI				60 YR	Female	USA	
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>		
Eye Swelling; Instillation Site Erythema; Keratitis Bacterial; Ocular Hyperaemia; Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium) Blood Pressure Meds			Y	s C					ricare t Reported			
Pseudomonas Infection FDA Received Date		!	Case Type	Health	Prof Ou	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	Sex	Country	
19-Feb-2023	220216	648	DIRECT		O	Γ		•	65 YR	Female	USA	
Preferred Term		Produc	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>		
Ear Pain; Eye Pain; Instillation Site Pain; Lung Disorder; Oropharyngeal Pain; Product Contamination; Recalled Product Administered			e Artificial Tears nt Eye Drops		Υ	S	Ophthalmic	Frequency : Twice A Day;		Ez	ricare	
		Erythromycin Inhaler One A Day Vitamin			N N N	C C				No	t Reported t Reported t Reported	



FDA Received Date	Case #	Case Type	Health	Prof O	<u>utcomes</u>	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
20-Feb-2023	219320	01 EXPEDITED (15-DAY)	Υ	H	O, OT	CA-JNJFOC- 20230149335			65 YR	Female	CAN
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	<u>Text</u>	Duration	<u>Mfı</u>	[
Abdominal Pain; Anae Chronic Sinusitis; Coli Colitis Ulcerative;	tic:	Budesonide Cetirizine Hydrochloride		N N	S S	Unknown Unknown					ot Reported ot Reported
Constipation; Drug Ineffective; Dyspepsia Erythema; Female Ge	;	Cetirizine Hydrochloride Cetirizine Hydrochloride		N N	S S	Unknown Unknown				No	ot Reported ot Reported
Tract Fistula; Frequen Bowel Movements; Haematochezia;	t	Cetirizine Hydrochloride Cetirizine Hydrochloride		N N	S S	Unknown Unknown				No	ot Reported ot Reported
Headache; Infusion Related Reaction; Mad Degeneration; Malaise	cular	Nicotine Nicotine		N N	S S	Unknown Unknown				No	ot Reported ot Reported
Nausea; Off Label Use Oral Candidiasis; Pain Paraesthesia Oral;	e;	Nicotine Nicotine		N N	S S	Unknown Unknown				No	ot Reported ot Reported
Procedural Pain; Proc Pyrexia; Radiculopath	titis; y;	Nicoderm Nicoderm		N N	S S	Unknown Unknown				No	ot Reported ot Reported
Rectal Haemorrhage; Therapeutic Product E Incomplete; Vaginal	Effect	Nicoderm Nicoderm		N N	S S	Topical Unknown				No	ot Reported ot Reported
Discharge; Vaginal Flatulence; Weight Decreased		Diphenhydramine Hydrochloride Diphenhydramine Hydrochloride		N N	S S	Unknown Unknown				No	ot Reported ot Reported
		Diphenhydramine Hydrochloride Diphenhydramine Hydrochloride		N N	S S	Unknown Unknown				No	ot Reported ot Reported
		Diphenhydramine Hydrochloride Loperamide Hydrochloride		N N	S S	Oral Unknown				No	ot Reported ot Reported
		Loperamide Hydrochloride Loperamide Hydrochloride		N N	S S	Oral Oral				No	ot Reported ot Reported
		Loperamide Hydrochloride Loperamide Hydrochloride		N N	S S	Oral Oral				No	ot Reported ot Reported
		Loperamide Hydrochloride		N	S	Oral				No	ot Reported



Not Reported Not Reported
Not Doported
Not Reported



			_	
Biaxin XI	N	S	Unknown	Not Reported
Biaxin XI	N	S	Unknown	Not Reported
Bifidobacterium Longum	N	S	Unknown	Not Reported
Bisacodyl	N	S	Unknown	Not Reported
Bisacodyl	N	S	Transplacental	Not Reported
Calcitriol;Calcium Carbonate; Zinc	N	S	Unknown	Not Reported
Calcium & Vitamin D [Calcium; Colecalciferol]	N	S	Unknown	Not Reported
Ciprofloxacin	N	S	Unknown	Not Reported
Ciprofloxacin Hydrochloride	N	S	Unknown	Not Reported
Clarithromycin	N	S	Unknown	Not Reported
Clarithromycin	N	S	Unknown	Not Reported
Clotrimazole	N	S	Unknown	Not Reported
Clotrimazole	N	S	Unknown	Not Reported
Cortenema	N	S	Unknown	Not Reported
Cupric Oxide;Folic Acid; Nicotinamide;Zinc	N	S	Unknown	Not Reported
Desonide	N	S	Unknown	Not Reported
Desonide	N	S	Unknown	Not Reported
Empracet [Paracetamol]	N	S	Unknown	Not Reported
Fentanyl	N	S	Unknown	Not Reported
Fentanyl Citrate	N	S	Unknown	Not Reported
Fluconazole	N	S	Unknown	Not Reported
Fluticasone Propionate	N	S	Unknown	Not Reported
Fructose	N	S	Unknown	Not Reported
Glycerin [Glycerol]	N	S	Unknown	Not Reported
Glycerin [Glycerol]	N	S	Unknown	Not Reported
Glycerin [Glycerol]	N	S	Oral	Not Reported
Glycerol	N	S	Unknown	Not Reported
Glycerol	N	S	Oral	Not Reported



Glyceryl Trinitrate N S Unknown Glyceryl Trinitrate N S Oral Not Reported Gramicidin; Neomycin Sulfate; N S Unknown Polymyxin B Sulfate Habitrol [Nicotine] N S Unknown Humira N S Unknown 6 YR Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate Habitrol [Nicotine] N S Unknown Not Reported Not Reported Not Reported Not Reported Not Reported Not Reported
Polymyxin B Sulfate Habitrol [Nicotine] N S Unknown Not Reported Humira N S Unknown 6 YR Not Reported
Humira N S Unknown 6 YR Not Reported
Cindiewii Cindiewi Cindiewii Cindiewi Cindiewii Cindiewi Cindiewii Cindiewi Cindiewii Cindiewi Cindiewii Cindiewi Cindiewii Ci
No. O. Alex Description
Humira N S Subcutaneous 6 YR Not Reported
Humira N S Subcutaneous 6 YR Not Reported
Hydrochlorothiazide N S _{Unknown} Not Reported
Hydrochlorothiazide N S Subcutaneous Not Reported
Hydrochlorothiazide N S _{Unknown} Not Reported
Hydrochlorothiazide N S Endocervical Not Reported
Hydrochlorothiazide N S Endocervical Not Reported
Hydrochlorothiazide N S Endocervical Not Reported
Hydromorphone Hydrochloride N S Endocervical Not Reported
Hydromorphone Hydrochloride N S Unknown Not Reported
Hydromorphone Hydrochloride N S Unknown Not Reported
Hydromorphone Hydrochloride N S Unknown Not Reported
Hydromorphone Hydrochloride N S Unknown Not Reported
Isoniazid/Pyridoxine N S Unknown Not Reported Hydrochloride/Sulfamethoxazole /Trimethoprim
Macrogol;Potassium Chloride; N S Unknown Not Reported Sodium Bicarbonate;Sodium Chloride
Magnesium N S _{Unknown} Not Reported
Magnesium Carbonate N S Unknown Not Reported
Magnesium Hydroxide N S Unknown Not Reported
Magnesium Oxide N S Unknown Not Reported
Magnesium Sulfate N S Unknown Not Reported
Magnesium Sulfate N S Unknown Not Reported
Magnesium Sulfate N S Unknown Not Reported



Mesalazine	N	S	Unknown	Not Reported
Mesalazine	N	S	Unknown	Not Reported
Methylprednisolone Sodium	N	S	Unknown	Not Reported
Succinate Methylprednisolone Sodium Succinate	N	S	Unknown	Not Reported
Metronidazole	N	S	Unknown	Not Reported
Metronidazole	N	S	Unknown	Not Reported
Metronidazole	N	S	Unknown	Not Reported
Metronidazole	N	S	Unknown	Not Reported
Midazolam	N	S	Unknown	Not Reported
Morphine Sulfate	N	S	Unknown	Not Reported
Morphine Sulfate	N	S	Unknown	Not Reported
Morphine Sulfate	N	S	Unknown	Not Reported
Morphine Sulfate	N	S	Unknown	Not Reported
Morphine Sulfate	N	S	Topical	Not Reported
Mupirocin	N	S	Unknown	Not Reported
Mupirocin	N	S	Topical	Not Reported
Nadolol	N	S	Unknown	Not Reported
Nadolol	N	S	Unknown	Not Reported
Nadolol	N	S	Unknown	Not Reported
Nadolol	N	S	Unknown	Not Reported
Nadolol	N	S	Unknown	Not Reported
Nadolol	N	S	Unknown	Not Reported
Nicotinamide	N	S	Unknown	Not Reported
Oxybutynin Hydrochloride	N	S	Unknown	Not Reported
Oxybutynin Hydrochloride	N	S	Unknown	Not Reported
Pantoprazole	N	S	Unknown	Not Reported
Pantoprazole	N	S	Unknown	Not Reported
Potassium Chloride	N	S	Unknown	Not Reported



			•	
Prednisone	N	S	Unknown	Not Reported
Prednisone	N	S	Unknown	Not Reported
Refresh Tears	N	S	Unknown	Not Reported
Refresh Tears	N	S	Unknown	Not Reported
Salinex [Macrogol;Propylene	N	S	Unknown	Not Reported
Glycol;Sodium Chloride] Sinus Rinse	N	S	Unknown	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Not Reported
Sucralfate	N	S	Unknown	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Not Reported
Ubidecarenone	N	S	Unknown	Not Reported
Vitamin D3	N	S	Unknown	Not Reported
Xantofyl Palmitate	N	S	Unknown	Not Reported
Xantofyl Palmitate	N	S	Oral	Not Reported
Zeaxanthin	N	S	Unknown	Not Reported
Zeaxanthin	N	S	Oral	Not Reported
Zopiclone	N	S	Unknown	Not Reported
Alprazolam	N	S	Unknown	Not Reported
Alprazolam	N	S	Unknown	Not Reported
Alprazolam	N	S	Unknown	Not Reported
Amoxicillin	N	S	Unknown	Not Reported
Budesonide	N	S	Unknown	Not Reported
Budesonide	N	S	Unknown	Not Reported



	Budeso	onide		N	S	Oral			1	Not Reported
	Entyvio)		N	S	Unknown			1	Not Reported
		nem Sodium nem Sodium		N N	S S	Intramuscular				Not Reported Not Reported
	Ertaper	nem Sodium		Ν	S	Unknown			1	Not Reported
	Flovent	t		N	S	Unknown			1	Not Reported
	Flovent	İ		N	S	Unknown			1	Not Reported
		sone Propionate; erol Xinafoate		N	S	Unknown			1	Not Reported
	Pregab	alin		Ν	S	Unknown			1	Not Reported
	Pregab	alin		Ν	S	Unknown			1	Not Reported
	Pregab	alin		Ν	S	Unknown			1	Not Reported
	Simvas	statin		Ν	S	Unknown			1	Not Reported
	Simvas	statin		Ν	S	Unknown			1	Not Reported
	Zinc Ox	kide		N	S	Unknown			1	Not Reported
	Teva A	lprazolam		N	S	Unknown			1	Not Reported
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facilit	y <u>Age</u>	<u>Sex</u>	Country
21-Feb-2023	22018055	EXPEDITED (15-DAY)	N		ОТ	US-ALLERGA 2304462US	AN-		Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Corneal Transplant; Surgery	Refresi	n Plus		Y	S				1	Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Control	1# 503B Facilit	<u>y Age</u>	<u>Sex</u>	Country
21-Feb-2023	22018067	EXPEDITED (15-DAY)	N		ОТ	US-ALLERGA 2304581US	AN-		Female	USA
Preferred Term	Produc	<u>ct</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Cataract; Eye Disorde	r Refresi	n Tears		Υ	S	Ophthalmic	Unk		,	Allergan



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FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2023	220288	37 DIRECT			DS, RI			77 YR	Female	USA
Preferred Term		<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Eye Infection; Eye Pruritus; Ulcerative Keratitis		Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Other Quantity : 1 Dr Frequency : As Need			zricare
		Vit B Biotin Probiotic Turmeric Fish Oil Magnesium Iron And Vit C Milk Thistle Baby Aspirin		X	00000000					lot Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
21-Feb-2023	220288	72 DIRECT			DS, HO, LT OT	, RI,		63 YR	Female	USA
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Blindness Unilateral; Corneal Transplant; E Infection Bacterial; Instillation Site Infection Pseudomonas Infection	ye on;	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S				E	zricare
FDA Received Date	Case #	Case Type	Health	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>/ Age</u>	<u>Sex</u>	Country
22-Feb-2023	212111	23 EXPEDITED (15-DAY)	Y		HO, OT	CA-MYLANLA 2022M108589		71 YR	Female	CAN
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Chronic Sinusitis; Drug Ineffective; Dyspepsia Infusion Related Read	; ction;	Biaxin XI Acetaminophen		N N	S S	Unknown Unknown	Unk Unk		٨	Mylan Not Reported
Macular Degeneration Malaise; Nausea; Off	1;	Calcium Carbonate		N	S	Unknown	Unk		٨	lot Reported



Label Use; Pain; Paraesthesia Oral; Procedural Pain; Pyrexia; Therapeutic Product Effect Incomplete; Weight Decreased

			Detailed Ne	port
Clarithromycin	N	S	Unknown	Unk
Tocopherol	N	S	Unknown	Unk
Magnesium Oxide	N	S	Unknown	Unk
Mesalazine	N	S	Unknown	Unk
Sodium Chloride	N	S	Unknown	Unk
Zinc Oxide	N	S	Unknown	Unk
Amoxicillin Trihydrate	N	S	Unknown	Unk
Atorvastatin Calcium	N	S	Unknown	Unk
Avamys	N	S	Unknown	Unk
Bactrim	N	S	Unknown	Unk
Benadryl	N	S	Oral	50 Milligram
Bisacodyl	N	S	Unknown	Unk
Cetirizine Hydrochloride	N	S	Unknown	Unk
Cholecalciferol	N	S	Unknown	Unk
Clotrimazole	N	S	Unknown	Unk
Cupric Oxide	N	S	Unknown	Unk
Desonide	N	S	Unknown	Unk
Dilaudid	N	S	Unknown	Unk
Diphenhydramine Hydrochloride	N	S	Unknown	Unk
Entocort	N	S	Oral	Unk
Ertapenem Sodium	N	S	Unknown	Unk
Flovent	N	S	Unknown	Unk
Glycerol	N	S	Oral	Unk
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown	Unk
Humira	N	S	Subcutaneous	Unk
Hydromorphone Hydrochloride	N	S	Endocervical	Unk
Infliximab	N	S	Intravenous (not otherwise specified)	Unk
		_		

Ν

Not	Reported
Not	Reported
	Reported
	Reported
	-
Not	Reported

Isoniazid;Pyridoxine

Hydrochloride;

Unknown

Unk

S



FDA Adverse Event Reporting System Freedom of Information Act (FOIA) **Detailed Report**

Preferred Term	Proc	duct	Comp.	OTC	Role	<u>Route</u>	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
22-Feb-2023	21850397	EXPEDITED (15-DAY)	N			US-ALLERG 2242708US	AN-		Unknown	USA
FDA Received Date		Case Type		Prof	<u>Outcomes</u>	Mfr Contro	•	<u>Age</u>	<u>Sex</u>	Country
	Ergo	calciferol		N	С	Unknown	Unk		No	t Reported
	Vals	artan		N	С	Unknown	Unk		No	t Reported
	Vals	artan		N	С	Oral	4 Dosage Form, Qd		No	t Reported
	Lope	eramide		N	С	Oral	4 Dosage Form, Qd		No	t Reported
	Meto	oclopramide Hydrochloride		N	С	Oral	Unk		No	t Reported
	Calc	ium Carbonate		N	С	Unknown	Unk		No	t Reported
	Zeax	kanthin		N	S	Unknown	Unk		No	t Reported
	Xant	ofyl Palmitate		Ν	S	Unknown	Unk		No	t Reported
	Triar	ncinolone Acetonide		Ν	S	Unknown	Unk		No	t Reported
	Refre	esh Tears		Ν	S	Ophthalmic	Unk		No	t Reported
	Pulm	nicort		Ν	S	Unknown	Unk		No	t Reported
	Preg	abalin		Ν	S	Unknown	Unk		No	t Reported
	Pred	Inisone		N	S	Unknown	Unk		No	t Reported
	Azith	nromycin		N	S	Unknown	Unk		No	t Reported
	Pant	oprazol		N	S	Unknown	Unk		No	t Reported
	Nico	tine		N	S	Unknown	Unk			t Reported
	Nico	derm		N	S	Unknown	Unk			t Reported
	Nado			N	S	Unknown	Unk			t Reported
	•	irocin		N	S	Topical	Unk			t Reported
		onidazole irocin		N N	S S	Unknown Unknown	Unk Unk			t Reported t Reported
	Sodi	rogol;Potassium Chloride; um Bicarbonate		N	S	Unknown	Unk			t Reported
	Sulfa Lom	amethoxazole;Trimethoprim otil		N	S	Oral	Unk		No	t Reported



202200579945

Accidental Exposure To

Refresh Optive Advanced

Product

Ophthalmic

Allergan

Not Reported

Not Reported

Product Packaging; Foreign Body In Eye; Product Primary Packaging Issue

Preferred Term

Mfr Control # FDA Received Date Case # **Case Type Health Prof Outcomes** 503B Facility Sex Country <u>Age</u> 22-Feb-2023 22013128 **EXPEDITED (15-DAY)** Ν OT US-ALLERGAN-Male USA

Role

S

Υ

OTC

Comp.

2304530US

Route Dosage Text Duration Mfr

Cataract; Condition
Aggravated; Eye
Discharge; Eye Disorder;
Eye Pain; Eye Pruritus;
Eye Swelling;

Refresh Plus Y S Ophthalmic Unk 3 DAY
Refresh Plus Y S Ophthalmic Unk

Hypersensitivity; Lacrimation Increased; Ocular Hyperaemia; Vision

Date - Time: 11-Apr-2023 10:56:54 AM EST

Blurred

Health Prof Outcomes FDA Received Date Case # Mfr Control # **503B Facility** Case Type <u>Age</u> Sex Country CA-PFIZER INC-22-Feb-2023 22022359 EXPEDITED (15-DAY) Ν HO, OT 71 YR Female CAN

Preferred Term	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>
Chronic Sinusitis; Drug	Alprazolam Mylan		N	S	Unknown	0.25 Milligram		Mylan
Ineffective; Dyspepsia; Infusion Related Reaction;	Atorvastatin Calcium		N	S	Unknown	Unk		Mylan
Macular Degeneration;	Pregabalin Mylan		N	S	Unknown	150 Milligram		Mylan
Malaise; Nausea; Off Label Use; Pain;	Biaxin XI		N	S	Unknown	Unk		Mylan
Paraesthesia Oral;	Pantoprazole		N	S	Unknown	Unk		Not Reported
Procedural Pain; Pyrexia;	Metronidazole		N	S	Unknown	Unk		Not Reported
Therapeutic Product Effect Incomplete; Weight	Adalimumab		N	S	Subcutaneous	Unk		Not Reported
Decreased	Azithromycin		N	S	Unknown	Unk		Not Reported
	Hydromorphone Hydrochloride		N	S	Endocervical	Unk		Not Reported
	Hydromorphone Hydrochloride		N	S	Unknown	Unk		Not Reported



Infliximab Bs Pfizer	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Potassium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Respiratory (inhalation)	Unk	Not Reported
Caltrate + D	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Amoxicillin	N	S	Unknown	Unk	Not Reported
Acetaminophen	N	S	Unknown	Unk	Not Reported
Diphenoxylate/Atropine	N	S	Oral	Unk Dosage Form	Not Reported
Diphenoxylate/Atropine	N	S	Oral	1 Df	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Fluticasone Propionate	N	S	Unknown	Unk	Not Reported
Glycerine Monolaurate	N	S	Unknown	Unk	Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported



Mupirocin	N	S	Topical	Unk	Not Reported
Nadolol	N	S	Unknown	40 Milligram	Not Reported
Nicoderm	N	S	Unknown	Unk, Dosage Form: Patch	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	200 Milligram	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Oral	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk, Suspension For Infusion	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	0.122 Gram	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
Glycerol	N	S	Oral	Unk	Not Reported
Macrogol	N	S	Unknown	Unk	Not Reported
Avamys	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Unknown	Unk	Not Reported
Bactrim	N	S	Unknown	Unk	Not Reported
Cholecalciferol	N	S	Unknown	Unk	Not Reported
Dilaudid	N	S	Unknown	Unk	Not Reported
Entocort	N	S	Unknown	Unk	Not Reported
Flovent	N	S	Unknown	Unk	Not Reported
Neomycin And Polymyxin B Sulfates And Gramici	N	S	Unknown		Not Reported
Humira	N	S	Unknown	Unk	Not Reported
Isoniazid;Pyridoxine Hydrochloride;	N	S	Unknown	Unk	Not Reported



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		Sulfame Lomotil	thoxazole;Trimethoprim		N	S	Unknown	Unk			Not Reported
		Macrogo	ol;Potassium Chloride;		N	S	Unknown	Unk			Not Reported
		Sodium Pentasa	Bicarbonate		N	S	Unknown	Unk			Not Reported
		Pulmico	rt		N	S	Unknown	Unk			Not Reported
		Benadry	l Allergy		N	С	Unknown	Unk			Not Reported
		Calcium	And Ergocalciferol		N	С	Unknown	Unk			Not Reported
		Sodium	Bicarbonate		N	S	Unknown	Unk			Not Reported
		Tocophe	erols Mixed		N	S	Unknown	Unk			Not Reported
		Calcium	Gluconate Cox		N	С	Unknown	Unk			Not Reported
		Metoclo	pramide Hydrochloride		N	С	Unknown	Unk			Not Reported
		Valsarta	ın		N	С	Unknown	Unk			Not Reported
		Valsarta	ın		N	С	Unknown	4 Dosage Form, Qd			Not Reported
		Loperan	nide Chlorhydrate		N	С	Unknown	Unk			Not Reported
FDA Received Date	Case #	<u>ŧ</u>	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Feb-2023	220224	109	EXPEDITED (15-DAY)	N	0	Т	US-ALLERGA 2304817US	N-		Female	USA
referred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>N</u>	<u>Mfr</u>
Cataract; Product Use Complaint		Refresh	Tears		Υ	S		Unk			Not Reported
FDA Received Date	Case #	<u>ŧ</u>	Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Feb-2023	220278	370	DIRECT		R	I			60 YR	Female	USA
Preferred Term		Produc	<u>t</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>Mfr</u>
Ory Eye; Eye Infection Eye Inflammation; Eye Pritation; Eye Pain;			Tears Lubricant Eye Carboxymethylcellulose		Y	S	Intraocular	Frequency : As Needed;	1 WEEK		Ezricare
Foreign Body Sensatic Eyes; Hypersensitivity; Ocular Hyperaemia;		Vitamin Zinc Elderbe	D		N N N	C C C					Not Reported Not Reported Not Reported



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Preferred Term]	<u>Product</u>		Comp.	OTC	Role		Dosage Text	<u>Duration</u>	ļ	<u>Mfr</u>
24-Feb-2023	2185550	08	EXPEDITED (15-DAY)	Υ		ОТ	CA-BAXTER- 2023BAX00999	2		Female	CAN
FDA Received Date	Case #		Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
	-	Trazodoi Cetrizine Multivitai	ne e Hcl		N N N	C C C					Not Reported Not Reported Not Reported
	ı	Meloxica Hydroxy Valsarta	chloroquine		N N N	C					Not Reported Not Reported Not Reported
	I	Cymbalta Prednisc	one		N N	C C C					Not Reported Not Reported
Eye Pain; Lacrimation Increased; Recalled Product Administered	!	Drops (C Sodium)	Tears Lubricant Eye Carboxymethylcellulose		Y	S	Ophthalmic	Other Quantity: 50 Drop (S); Other Frequency: As Needed;			Ezricare
Preferred Term	1	<u>Product</u>		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u>Mfr</u>
23-Feb-2023	2203277	72	DIRECT			DS			68 YR	Female	USA
FDA Received Date	Case #		Case Type	Health	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Hyperaemia; Periorbita Swelling; Photosensiti Reaction	vity (Sodium) Crestor Tylenol			N N	C C					Not Reported Not Reported
Erythema Of Eyelid; E Irritation; Eye Pain; Od	cular I	Drops (C	Tears Lubricant Eye Carboxymethylcellulose		Υ	S	Ophthalmic	Frequency : Twice A Day;	2 DAY		Global Pharmaceuticals
Preferred Term		<u>Product</u>		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	ļ	<u>Mfr</u>
23-Feb-2023	2203276	69	DIRECT						62 YR	Female	USA
FDA Received Date	Case #		Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
Product Contamination Microbial	 	Tumeric Flaxseed Collagen Coq10 Garlic Ex	For Joint Health		N N N N	C C C C					Not Reported Not Reported Not Reported Not Reported Not Reported



Drug Ineffective; Macular Degeneration

				1	
Sodium Chloride	N	S	Endosinusial	Dosage Form: Not Specified	Baxter
Metronidazole	N	S	Unknown	Dosage Form: Not Specified	Baxter
Magnesium Sulfate	N	S	Unknown	(Dosage Form: Not Specified)	Baxter
Potassium Chloride	N	S	Unknown	Dosage Form: Not Specified	Baxter
Sodium Hydrogen Carbonate Haemodialysis	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Calcium Gluconate	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
Acetylsalicylic Acid	N	S	Oral	Dosage Form: Not Specified	Not Reported
Adalimumab	N	S	Subcutaneous	(Dosage Form: Solution Subcutaneous)	Not Reported
Alprazolam	N	S	Unknown		Not Reported
Ambroxol Hydrochloride	N	S	Unknown		Not Reported
Amoxicillin	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown		Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
Atropine Sulfate	N	S	Oral	Dosage Form: Not Specified	Not Reported
Avamys	N	S	Unknown	(Dosage Form: Spray, Metered Dose)	Not Reported
Azithromycin	N	S	Oral	(Dosage Form: Not Specified)	Not Reported
Bactrim	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Betamethasone	N	S	Unknown		Not Reported



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Betamethasone Dipropionate	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Betamethasone Valerate	N	S	Unknown		Not Reported
Bisacodyl	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
Budesonide	N	S		(Dosage Form: Not Specified)	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
Calcium Carbonate/Vitamin D3	N	S	Unknown		Not Reported
Cetirizine	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
Clarithromycin	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
Clotrimazole	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
Cupric Oxide	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
Desonide	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Dilaudid	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Diphenoxylate Hydrochloride	N	S	Oral		Not Reported
Entocort	N	S	Unknown	(Dosage Form: Capsule, Sustained Release)	Not Reported
Ergocalciferol	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Ertapenem Sodium	N	S	Unknown		Not Reported
Flovent	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
Fluticasone Furoate	N	S	Unknown		Not Reported

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Glycerine	N	S	Oral	Dosage Form: Liquid Oral	Not Reported
Glycerol	N	S	Oral		Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Humira	N	S	Subcutaneous	(Dosage Form: Solution Subcutaneous)	Not Reported
Hydrochlorothiazide	N	S	Unknown		Not Reported
Hydromorphone	N	S	Unknown	Dosage Form: Not Specified, 1 Every 1 Week	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown		Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Every 1 Week	Not Reported
Macrogol	N	S	Unknown		Not Reported
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate; Sodium Chloride;So	N	S	Unknown		Not Reported
Mesalazine	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
Morphine Sulfate	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Ms Ir	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
Mupirocin	N	S	Topical	Dosage Form: Ointment Topical	Not Reported
Mupirocin Calcium Hydrate	N	S	Unknown		Not Reported
Mupirocin Calcium Hydrate	N	S	Topical	Unk	Not Reported
Nadolol	N	S	Unknown		Not Reported
Neomycin Sulfate	N	S	Unknown		Not Reported
Nicoderm	N	S	Unknown		Not Reported
Nicotinamide	N	S	Unknown		Not Reported
Nicotine	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Nicotine Polacrilex	N	S	Unknown		Not Reported
Pantoprazole	N	S	Unknown	(Dosage Form: Not	Not Reported

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Polymyxin B Sulfate N Specified) Prednisone N S Unknown Dosage Form: Not Specified Pregabalin Pregabalin N S Unknown N S Unknown N Specified) N S Unknown N Specified) N S Unknown N Specified) N S Specified N Specified)	Not Reported
Polymyxin B Sulfate N Specified) Prednisone N S Unknown Dosage Form: Not Specified Pregabalin Pregabalin N S Unknown N S Unknown N Specified) N S Unknown N Specified) N S Unknown N Specified) N S Specified N Specified)	Not Reported Not Reported Not Reported Not Reported Not Reported
Prednisone N S Unknown (Dosage Form: Not Specified) Pregabalin N S Unknown N S Unknown (Dosage Form: Not Specified) Pulmicort N S Unknown (Dosage Form: Not Specified)	Not Reported Not Reported Not Reported Not Reported
Pregabalin N S Unknown Specified) Pulmicort N S Unknown (Dosage Form: Not N Specified)	Not Reported Not Reported
Pulmicort N S Unknown (Dosage Form: Not N Specified)	Not Reported
Specified)	Not Reported
0: 0:	·
Sinus Rinse N S Endosinusial Dosage Form: Solution N Nasal	Not Reported
Sodium Carboxymethylcellulose N S Ophthalmic N	
Sodium Stearate N S Oral N	Not Reported
Sulfamethoxazole;Trimethoprim N S Unknown Dosage Form: Not N Specified	Not Reported
Triamcinolone N S Intra-articular N	Not Reported
Trimethoprim N S Unknown N	Not Reported
Vitamin D3 N S Unknown N	Not Reported
Xantofyl Palmitate N S Unknown N	Not Reported
Zeaxanthin N S Unknown N	Not Reported
Zinc Chloride N S Unknown N	Not Reported
Zinc Oxide N S Unknown Dosage Form: Not N Specified	Not Reported
Acetaminophene N S Unknown N	Not Reported
Amoxicillin Trihydrate N S Unknown N	Not Reported
Atropine N S Oral (Dosage Form: Not N Specified)	Not Reported
Azithromycin Dihydrate N S Oral Unk N	Not Reported
Biaxin XI N S Unknown (Dosage Form: Tablet N (Extended Release))	Not Reported
Calcium Gluconate N S Unknown N	Not Reported



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Cupric Oxide;Folic Acid;Nicotinic Acid;Zinc Oxide	N	S	Unknown		Not Reported
DI-Alpha Tocopherol	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
DI-Alpha Tocopheryl Acetate	N	S	Unknown		Not Reported
Fructose;Glycerol;Sodium Chloride	N	S	Unknown		Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
Kenalog	N	S	Intra-articular	(Dosage Form: Suspension Intra-Articular)	Not Reported
Loperamide Hydrochloride; Simeticone	N	S	Oral	·	Not Reported
Metronidazole Hydrochloride	N	S	Unknown		Not Reported
Mupirocin Calcium Hydrate	N	S	Unknown		Not Reported
Mupirocin Calcium Hydrate	N	S	Topical	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	(Dose Description: Drops Ophthalmic)	Not Reported
Sodium Chloride	N	S	Endosinusial	(Dosage Form: Solution Nasal)	Not Reported
Simvastatin	N	S	Unknown	·	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	(Dosage Form: Suspension Intra-Articular)	Not Reported
Valsartan	N	S	Intracardiac	Dosage Form: Not Specified	Not Reported
Vitamin C	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
Diphenoxylate Hcl And Atropine Sulfate	N	S	Oral		Not Reported
Pms Azithromycin	N	S	Oral	Dosage Form: Not Specified	Not Reported
Valsartan	N	С	Intracardiac	Dosage Form: Not Specified	Not Reported
Calcium	N	С	Unknown	(Dosage Form: Not Specified)	Not Reported



FDA Received Date	Case #	Case Type	<u>Health</u>	Prof (<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Feb-2023	219210	73 EXPEDITED (15-DAY)	Υ	ŀ	HO, OT	CA-JNJFOC- 20230146070		71 YR	Female	CAN
Preferred Term		Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>	
Chronic Sinusitis; Drug		Remicade		N	S	Intravenous drip			No	t Reported
Ineffective; Dyspepsia Infusion Related Reac		Cetirizine Hydrochloride		N	S	Unknown			No	t Reported
Macular Degeneration		Acetaminophen		N	S	Unknown			No	t Reported
Malaise; Nausea; Off Label Use; Pain;		Adalimumab		N	S	Subcutaneous			No	t Reported
Paraesthesia Oral;		Alprazolam		N	S	Unknown			No	t Reported
Procedural Pain; Pyre		Alprazolam		N	S	Unknown			No	t Reported
Therapeutic Product E Incomplete; Weight	illect	Azithromycin		N	S	Unknown			No	t Reported
Decreased		Betamethasone Valerate		N	S	Unknown			No	t Reported
		Budesonide		N	S	Unknown			No	t Reported
		Budesonide		N	S	Unknown			No	t Reported
		Budesonide		N	S	Unknown			No	t Reported
		Calcium Carbonate		Ν	S	Unknown			No	t Reported
		Diphenhydramine Hydrochloride		N	S	Unknown			No	t Reported
		Loperamide		N	S	Unknown			No	t Reported
		Nicotine Polacrilex		N	S	Unknown			No	t Reported
		Nicotine Polacrilex		N	S	Unknown			No	t Reported
		Zinc Oxide		N	S	Unknown			No	t Reported
		Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate		N	S	Unknown			No	t Reported
		Sodium Chloride		N	S					t Reported
		Amoxicillin Trihydrate		N	S	Unknown				t Reported
		Atropine Sulfate; Diphenoxylate Hydrochloride		N	S	Oral			NO.	t Reported
		Atorvastatin Calcium		N	S	Unknown			No	t Reported
		Betamethasone Valerate		N	S	Unknown			No	t Reported
		Calcium Carbonate/Vitamin D3		N	S	Unknown			No	t Reported



Clarithromycin	N	S	Unknown	Not Reported
Clotrimazole	N	S	Unknown	Not Reported
Cupric Oxide	N	S	Unknown	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Not Reported
Ertapenem Sodium	N	S	Unknown	Not Reported
Fluticasone Furoate	N	S	Unknown	Not Reported
Fluticasone Propionate	N	S	Unknown	Not Reported
Glycerin [Glycerol]	N	S	Unknown	Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Not Reported
Magnesium Sulfate	Ν	S	Unknown	Not Reported
Mesalazine	Ν	S	Unknown	Not Reported
Metronidazole	Ν	S	Unknown	Not Reported
Morphine Sulfate	Ν	S	Unknown	Not Reported
Mupirocin	N	S	Topical	Not Reported
Nadolol	Ν	S	Unknown	Not Reported
Pantoprazole	Ν	S	Unknown	Not Reported
Potassium Chloride	Ν	S	Unknown	Not Reported
Prednisone	Ν	S	Unknown	Not Reported
Pregabalin	Ν	S	Unknown	Not Reported
Sodium Carboxymethylcellulose	Ν	S	Unknown	Not Reported
Sulfamethoxazole;Trimethoprim	Ν	S	Unknown	Not Reported
Triamcinolone Acetonide	Ν	S	Intra-articular	Not Reported
Vitamin D3	Ν	S	Unknown	Not Reported
Xantofyl Palmitate	Ν	S	Unknown	Not Reported
Zeaxanthin	Ν	S	Unknown	Not Reported
Betamethasone Dipropionate	Ν	S	Unknown	Not Reported
Nicoderm	Ν	S	Unknown	Not Reported
Lomotil [Atropine Sulfate; Diphenoxylate Hydrochloride]	N	С	Unknown	Not Reported



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		Valsartan			N	С	Unknown				Not Reported
		Metoclopra	amide Hydrochloride		Ν	С	Unknown				Not Reported
			actate;Calcium ;Ergocalciferol		N	С	Unknown				Not Reported
			Diphenhydramine		N	С					Not Reported
FDA Received Date	Case #	<u>C</u>	ase Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
24-Feb-2023	220399)37 D	DIRECT			ОТ			65 YR	Female	USA
Preferred Term		Product		Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Eye Swelling; Hordeoli Instillation Site Pruritus Swelling Of Eyelid		Refresh Op	otive Drops		Y	S	Ophthalmic	Other Quantity: .33 Ounc (S); Frequency: Twice A Day;	е		Allergan
FDA Received Date	Casa #	Gabapentii Baclofen Buspirone Cetrizine Naproxen Scopolamii Amitriptyln Ventolin Gentamyci Magnesiun B-12 Vitamin D3	ne n n	Haalth	Prof	C C C C C C C C C C C C C C C C C C C	Mfr Control #	503B Facility	Ago	Sav	Not Reported
	Case #							-	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2023	220132	286 E	XPEDITED (15-DAY)	N		НО	US-ALLERGAN 2304587US	 -		Female	USA
Preferred Term		Product		Comp.	OTC	Role	Route	<u>Dosage Text</u>	Duration		<u>Mfr</u>
Blood Magnesium		Refresh Te	ears		Υ	S	Ophthalmic	2 Gtt, Qd			Allergan
Decreased; Burning Sensation; Condition		Refresh Te	ears		Υ	S		Unk			Allergan
Aggravated; Headache		Losartan			N	С		Unk			Not Reported
Hypoaesthesia; Illness Ocular Hyperaemia;	s;	Atorvastati	n		N	С		Unk			Not Reported



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FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

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FDA Received Date Case	# Case Type	<u>Health</u>	Prof O	utcomes	Mfr Control	#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Feb-2023 20484	EXPEDITED (15-DAY)	Υ	Н	O, OT	CA-drreddys- SPO/CAN/22/	/0146792		71 YR	Female	CAN
Preferred Term	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	<u>Mf</u> ı	1
Chronic Sinusitis; Drug	Reddy-Atorvastatin		N	S	Unknown				No	ot Reported
Ineffective; Dyspepsia; Infusion Related Reaction;	Reddy-Atorvastatin		N	S	Unknown				No	ot Reported
Macular Degeneration;	Ertapenem For Injection, 1		N	S					No	ot Reported
Malaise; Nausea; Off Label Use; Pain;	G/Vial Acetaminophen		N	S					No	ot Reported
Paraesthesia Oral;	Acetaminophen		N	S						ot Reported
Procedural Pain; Pyrexia;	Amoxicillin Trihydrate		N	S						ot Reported
Therapeutic Product Effect	Avamys		N	S						ot Reported
Incomplete; Weight	Bactrim		N	S						ot Reported
Decreased	Benadryl		N	S	Oral				No	ot Reported
	Biaxin XI		N	S						ot Reported
	Bisacodyl		N	S					No	ot Reported
	Calcium Carbonate		N	S						ot Reported
	Cetirizine Hydrochloride		N	S						ot Reported
	Cholecalciferol		N	S						ot Reported
	Clarithromycin		N	S						ot Reported
	Clotrimazole		N	S						ot Reported
	Cupric Oxide		N	S						ot Reported
	D-Alpha Tocopherol		N	S						ot Reported
	Desonide		N	S						ot Reported
	Dilaudid		N	S						ot Reported
	Diphenhydramine Hydrochloride		N	S						ot Reported
	Entocort		N	S	Oral				No	ot Reported
	Flovent		N	S					No	ot Reported
	Glycerol		N	S	Oral				No	ot Reported
	Gramicidin/Neomycin Sulfate/Polymyxin B Sulfate		N	S	Unknown				No	ot Reported
	Humira		N	S	Subcutaneous			12 YR	No	ot Reported
	Humira		N	S	Unknown			12 YR	No	ot Reported
	Humira		N	S				12 YR	No	ot Reported



Hydromorphone Hydrochloride	N	S	Endocervical	Not Reported
Infliximab	N	S	Intravenous (not otherwise specified)	Not Reported
Isoniazid/Pyridoxine Hydrochloride/Sulfa Methoxazole/Trimeth Oprim	N	S		Not Reported
Lomotil	N	S	Oral	Not Reported
Macrogol/Potassium/ Sodium Bicarbonate	N	S		Not Reported
Magnesium Sulfate	N	S		Not Reported
Metronidazole Municacia	N N	S S		Not Reported
Mupirocin			Topical	Not Reported
Mupirocin	N	S	Topical	Not Reported
Nadolol	N	S		Not Reported
Nicoderm Nicotine	N N	S S		Not Reported Not Reported
Pantoprazole	N	S	Unknown	Not Reported
Pentasa	N	S	GIRHOWH	Not Reported
Pms-Azithromycin	N	S	Unknown	Not Reported
Prednisone	N	S	C	Not Reported
Pregabalin	N	S		Not Reported
Pulmicort	N	S	Respiratory (inhalation)	Not Reported
Refresh Tears	Ν	S	Ophthalmic	Not Reported
Sodium Chloride	N	S		Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Not Reported
Xantofyl Palmitate	N	S		Not Reported
Zeaxanthin	N	S		Not Reported
Zinc Oxide Adalimumab	N N	S S		Not Reported Not Reported
			Subcutaneous	·
Alprazolam Alprazolam	N N	S S	Halmanna	Not Reported Not Reported
Macrogol	N	S	Unknown	Not Reported
· ·			Unknown	•
Sodium Bicarbonate	N	S	Unknown	Not Reported
Acetaminophen/Dextropropoxyp hene	N	S		Not Reported



			-	
Ambroxol/Cetirizine	N	S		Not Reported
Hydrochloride	NI			Not Deported
Atropine Sulfate/Diphenoxylate Hydrochloride	N	S	Oral	Not Reported
Atropine Sulfate/Diphenoxylate	N	S	Oral	Not Reported
Hydrochloride		Ü	Orai	Not Reported
Atropine Sulfate/Diphenoxylate	N	S	Oral	Not Reported
Hydrochloride		_		
Betamethasone	N	S	Unknown	Not Reported
Betamethasone	N	S	Unknown	Not Reported
Calcium Carbonate/Ergocaci	N	S	Unknown	Not Reported
Ferol				·
Glycerine	N	S		Not Reported
Glycerine	N	S	Oral	Not Reported
Glycerol/Sodium Stearate	N	S		Not Reported
Hydrochlorothiazide	N	S	Unknown	Not Reported
Hydrochlorothiazide	N	S	Unknown	Not Reported
Morphine Sulfate	N	S		Not Reported
Nicotinamide	N	S	Unknown	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Not Reported
Sinus Rinse	N	S		Not Reported
Sodium Carboxymethyl	N	S	Ophthalmic	Not Reported
Cellulose			- F	
Sulfamethoxazole/Trimethoprim	N	S		Not Reported
Vitamin D3	N	S C		Not Reported
Calcium Carbonate With Vitamin D	N	C		Not Reported
Loperamide	N	С	Oral	Not Reported
Metoclopramide Hydrochloride	N	С	Oral	Not Reported
Valsartan	N	С	Oral	Not Reported
Diphenoxylate Hydrochloride	N	С	Oldi	Not Reported
Lomotil	N	C	Linknown	Not Reported
			Unknown	·
Benadryl Allergy	N	С	Oral	Not Reported

FDA Received Date	Case #	Case Type	Health Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Mar-2023	21852526	EXPEDITED (15-DAY)	Υ	HO, OT	CA-BAXTER- 2023BAX009995		71 YR	Female	CAN



Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>
Chronic Sinusitis; Drug Ineffective; Dyspepsia;	Magnesium Sulfate		N	S	Intramuscular	Dosage Form: Not Specified		Baxter
Infusion Related Reaction; Macular Degeneration; Malaise; Nausea; Off	Potassium Chloride		N	S	Unknown	Dosage Form : Not Specified		Baxter
Label Use; Pain; Paraesthesia Oral;	Sodium Bicarbonate Concentrate		N	S	Unknown	Dosage Form: Not Specified		Baxter
Procedural Pain; Pyrexia; Therapeutic Product Effect Incomplete; Weight	Sodium Chloride		N	S		Dosage Form: Not Specified		Baxter
Decreased	Metronidazole		N	S	Unknown	Dosage Form: Not Specified		Baxter
	Acetaminophen		N	S	Unknown	Dosage Form: Not Specified		Not Reported
	Adalimumab		N	S	Subcutaneous	Dosage Form: Solution Subcutaneous		Not Reported
	Alprazolam		N	S	Unknown	0.25 Mg		Not Reported
	Amoxicillin Trihydrate		N	S	Unknown	Unk		Not Reported
	Atorvastatin		N	S	Unknown	Unk		Not Reported
	Atropine Sulfate;Diphenoxylate Hydrochloride		N	S	Oral	Dosage Form: Not Specified		Not Reported
	Atropine Sulfate;Diphenoxylate Hydrochloride		N	S	Oral	1 Dosage Form		Not Reported
	Atropine Sulfate		N	S	Oral	1 Dosage Form		Not Reported
	Atropine Sulfate		N	S	Oral	4 Dosage Forms		Not Reported
	Atropine Sulfate		N	S	Unknown	Unk		Not Reported
	Amoxicillin		N	S	Unknown	Dosage Form: Not Specified		Not Reported
	Azithromycin Dihydrate		N	S	Unknown	Unk		Not Reported
	Atorvastatin Calcium		N	S	Unknown	Dosage Form : Not Specified		Not Reported
	Azithromycin		N	S	Unknown	Dosage Form: Not Specified		Not Reported
	Benzydamine Hydrochloride		N	S	Unknown	Unk		Not Reported



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Betamethasone	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Betamethasone Valerate	N	S	Unknown	0.122 Gm	Not Reported
Biaxin XI	N	S	Unknown	Dosage Form: Tablet (Extended Release)	Not Reported
Bisacodyl	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Budesonide	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Calcitriol	N	S	Intra-articular	Dosage Form: Not Specified	Not Reported
Calcium Carbonate	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Clotrimazole	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Cupric Oxide	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Cupric Oxide;Folic Acid;Nicotinic Acid;Zinc	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Diphenhydramine	N	S	Unknown	Unk	Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown	Unk	Not Reported
Entocort	N	S	Unknown	Dosage Form: Capsule, Sustained Release	Not Reported
Ergocalciferol	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported



				<u> </u>	
Flovent	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Fluticasone Propionate	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Unknown	Dosage Form: Liquid Oral	Not Reported
Glycerol	N	S	Oral	Unk	Not Reported
Glycerol	N	S	Unknown	Unk	Not Reported
Glycerol;Sodium Stearate	N	S	Unknown	Unk	Not Reported
Glyceryl Trinitrate	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Gramicidin;Polymyxin B	N	S	Unknown	Unk	Not Reported
Humira	N	S	Subcutaneous	Solution Subcutaneous, 6 Years	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Unk	Not Reported
Imodium	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Gramicidin\Neomycin\Polymyxin B Sulfate	N	S	Unknown	Dosage Form: Ointment Dental	Not Reported
Infliximab	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Infliximab	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Isoniazid/Pyridoxine Hydrochloride/Sulfamethoxazole /Trimethoprim	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk	Not Reported



Macrogol	N	S	Unknown	Unk	Not Reported
Magnesium Oxide	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Mentha Arvensis	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Morphine Sulfate	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Mupirocin	N	S	Topical	Dosage Form: Ointment Topical	Not Reported
Mupirocin	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	40 Mg	Not Reported
Nicoderm	N	S	Transdermal	Unk	Not Reported
Nicomorphine	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Pantoprazole Sodium	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium Anhydrous	N	S	Unknown	Unk	Not Reported
Amoxicillin	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Pregabalin	N	S	Unknown	150 Mg	Not Reported
Sodium Chloride	N	S	Nasal	Dosage Form: Solution Nasal, Intra-Nasal	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported

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Sinus Rinse	N	S	Nasal	Dosage Form: Solution Nasal, Intra-Nasal	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Sulfamethoxazole	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	200 Mg, Dosage Form: Not Specified	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Dosage Form: Suspension Intra-Articular	Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Oral	Unk	Not Reported
Zinc Chloride	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Benadryl	N	С	Unknown	Dosage Form: Not Specified	Not Reported
Benadryl Allergy	N	С	Oral		Not Reported
Calcium Carbonate And Vitamin D3	N	С	Unknown	Unk	Not Reported
Neomycin Sulfate	N	С	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	С	Unknown	Unk	Not Reported
Sodium Stearate	N	С	Unknown	Unk	Not Reported
Valsartan	N	С	Unknown	Not Specified	Not Reported
Mupirocin Calcium Hydrate	N	С	Unknown	Unk	Not Reported
Lomotil	N	С	Unknown		Not Reported
Metoclopramide Hydrochloride	N	С	Unknown		Not Reported
Calcium Lactate	N	С	Unknown		Not Reported
Calcium Gluconate	N	С	Unknown	Not Specified	Not Reported



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FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Mar-2023	170154	51 EXPEDITED (15-DAY) N		HO, OT	CA-009507513- 1911CAN00174		71 YR	Female	CAN
Preferred Term		Product	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Abdominal Pain; Anaen Chronic Sinusitis; Coliti	ie ·	Invanz Invanz		N N	s s	Unknown	Unk			Merck Merck
Colitis Ulcerative; Constipation; Drug		Invanz		N	S	Unknown	Unk			Merck
Ineffective; Dyspepsia;		Invanz		N	S	Unknown	Unk			Merck
Erythema; Female Gen	nital	Invanz		N	S	Unknown	Unk			Merck
Tract Fistula; Frequent Bowel Movements;		Remicade			S	Nasal	Unk			Not Reported
Haematochezia; Headache; Infusion		Remidade		N		Intravenous (not otherwise specified)	Unk		!	лог керопеа
Related Reaction; Mac Degeneration; Malaise;	ulai	Remicade		N	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		I	Not Reported
Nausea; Off Label Use; Oral Candidiasis; Pain;	;	Remicade		N	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		I	Not Reported
Paraesthesia Oral; Procedural Pain; Procti Pyrexia; Radiculopathy	itis;	Remicade		N	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		I	Not Reported
Rectal Haemorrhage; Therapeutic Product Ef		Remicade		N	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		I	Not Reported
Incomplete; Vaginal Discharge; Vaginal Flatulence; Weight		Remicade		N	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		1	Not Reported
Decreased		Remicade		N	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		1	Not Reported
		Remicade		N	S	Intravenous (not otherwise specified)	10 Milligram/Kilogram		1	Not Reported
		Remicade		N	S	Intravenous (not otherwise specified)	10 Milligram/Kilogram		1	Not Reported
		Zocor		N	S	Unknown	Unk		I	Merck
		Zocor		Ν	S	Unknown			I	Merck
		Betamethasone Dipropionate		Ν	S	Unknown	Unk		ı	Merck
		Betamethasone Dipropionate		N	S	Unknown	Unk		l	Merck



Betamethasone Dipropionate	N	S	Unknown	Unk		Merck
Betamethasone Dipropionate	N	S	Unknown	Unk		Merck
Acetaminophen	N	S	Unknown	Unk		Not Reported
Acetaminophen	N	S	Unknown	Unk		Not Reported
Acetaminophen	N	S	Unknown	Unk		Not Reported
Humira	N	S	Subcutaneous	Unk, Dosage Form: Solution Subcutaneous	6 YR	Not Reported
Humira	N	S	Subcutaneous	Unk, Dosage Form: Solution Subcutaneous	6 YR	Not Reported
Humira	N	S	Subcutaneous	Unk, Dosage Form: Solution Subcutaneous	2190 DAY	Not Reported
Humira	N	S	Subcutaneous	Unk, Dosage Form: Solution Subcutaneous	6 YR	Not Reported
Humira	N	S	Subcutaneous	Unk, Dosage Form: 5 YR Solution Subcutaneous		Not Reported
Humira	N	S	Unknown	Unk		Not Reported
Humira	N	S	Subcutaneous	Unk, Dosage Form: Solution Subcutaneous	2190 DAY	Not Reported
Amoxicillin	N	S	Unknown	Unk		Not Reported
Amoxicillin	N	S	Unknown	Unk		Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk		Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk		Not Reported
Alprazolam	N	S	Unknown	Unk		Not Reported
Alprazolam	N	S	Unknown	Unk		Not Reported
Alprazolam	N	S	Unknown	0.25 Milligram		Not Reported
Alprazolam	N	S	Unknown	Unk		Not Reported
Alprazolam	N	S	Unknown	Unk		Not Reported
Alprazolam	N	S	Oral	Unk		Not Reported
Alprazolam	N	S	Oral	Unk		Not Reported
Alprazolam	N	S		Unk		Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk		Not Reported

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Atorvastatin Calcium N S Unknown Dosage Form: Film- Coated Tablet Atorvastatin Calcium N S Unknown Dosage Form: Tablet Not	Reported Reported Reported Reported Reported Reported
Atorvastatin Calcium N S Unknown Dosage Form: Tablet Not Atorvastatin Calcium N S Unknown Dosage Form: Film-	Reported
Atorvastatin Calcium N S Unknown Dosage Form: Film- Not	Reported
Official Policy Control of the Contr	•
	Reported
Atorvastatin Calcium N S Unknown Dosage Form: Film- Not Coated Tablet	
Avamys N S Unknown Unk, Dosage Form: Spray, Not Metered Dose	Reported
Avamys N S Unknown Unk, Dosage Form: Spray, Not Metered Dose	Reported
Avamys N S Ophthalmic Unk Not	Reported
Avamys N S _{Unknown} Unk Not	Reported
Azithromycin N S _{Unknown} Not	Reported
Azithromycin N S _{Unknown} Unk Not	Reported
Azithromycin N S Oral Unk Not	Reported
Betaderm Ointment N S Unknown Unk, Dosage Form: Not Not Specified	Reported
Betaderm Ointment N S Unknown Unk, Dosage Form: Not Not Specified	Reported
Betaderm Ointment N S Unknown Dosage Form: Ointment Not	Reported
Betaderm Ointment N S Unknown Dosage Form: Ointment Not 0.122 Gram	Reported
Betaderm Ointment N S Topical Dosage Form: Ointment Not	Reported
Bisacodyl N S Unknown Unk, Dosage Form: Not Not Specified	Reported
Bisacodyl N S Unknown Unk Not	Reported
Bisacodyl N S _{Unknown} Unk Not	Reported
Bisacodyl N S Transplacental Unk Not	Reported
Entocort N S Unknown Unk Not	Reported
Entocort N S Unknown Unk Not	Reported



				-	
Entocort	N	S	Oral	Unk	Not Reported
Pulmicort	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Pulmicort	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Pulmicort	N	S	Oral	Unk	Not Reported
Pulmicort	N	S		Unk	Not Reported
Pulmicort	N	S	Other	Unk	Not Reported
Calcium Carbonate	N	S	Unknown		Not Reported
Calcium Carbonate	N	S	Unknown		Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Dosage Form: Film- Coated Tablet	Not Reported
Biaxin XI	N	S	Oral	Dosage Form: Film- Coated Tablet	Not Reported
Biaxin XI	N	S	Oral	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Desonide	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Oral	Unk	Not Reported
Ergocalciferol	N	S	Unknown		Not Reported
Ergocalciferol	N	S	Unknown		Not Reported



Flovent N S Unknown Unk Dosage Form: Not Specified Not Reported Unk Dosage Form: Not Specified Not Reported Unk Dosage Form: Not Specified Not Reported Unk Not Reported Metalazine N S Unknown Unk Not Reported Metalazine N S Unknown Unk Not Reported Metoclopramide Hydrochloride N S Unknown Unk Not Reported Metoclopramide Hydrochloride N S Unknown Unk Not Reported Metronidazole N S Unknown Unk Not Reported Metronidazole N S Unknown Unk Not Reported Mupirocin N S Unknown Unk Not Reported Mupirocin N S Unknown Unk Not Reported Not Reported Mupirocin N S Unknown Unk Not Reported Not Reported Not Dik Not Reported Not Dik Unknown Unk Not Reported Not Dik Unknown Unk Not Reported Not Dik Unknown Unk Not Reported Not Dik Unknown						
Adalimumab N S Unknown Unk Not Reported Benadryl E N C Unknown Unk Not Reported Budesonide N S Unknown Unk Not Reported Calcium Carbonate/Vitamin D3 N S Unknown Unk Not Reported Calcium Lactate; Calcium N C Unknown Unk Not Reported Calcium Lactate; Calcium N C Unknown Unk Not Reported Calcium Lactate; Calcium N S Unknown Unk Not Reported Calcium Lactate; Calcium N S Unknown Unk Not Reported Calcium Lactate; Calcium N S Unknown Unk Not Reported Calcium Lactate; Calcium N S Unknown Unk Not Reported Calcium Lactate; Calcium N S Unknown Unk Not Reported Calcium Lactate; Calcium N S Unknown Unk Not Reported Calcium Lactate; Calcium N S Unknown Unk Not Reported Calcium Lactate; Calcium N S Unknown Unk Not Reported Calcium Lactate; Calcium N S Unknown Unk Not Reported Calcium Lactate; Calcium N S Unknown Unk Not Reported Unknown Unk Not Reported D-Alpha Tocopherol N S Unknown Unk Not Reported Glycerin [Glycerol] N S Unknown Unk Not Reported Glycerin [Glycerol] N S Unknown Unk Not Reported Gramicidin; Neomycin Sulfate; N S Unknown Unk Not Reported Polymyxin B Sulfate Hydromorphone Hydrochloride N S Unknown Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Loperamide N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Not Reported Mesalazine N S Unknown Unk Not Reported Mesalazine N S Unknown Unk Not Reported Metoclopramide Hydrochloride N S Unknown Unk Not Reported Metoclopramide Hydrochloride N S Unknown Unk Not Reported Motronidazole N S Unknown Unk Not Reported Mupirocin N S Unknown Unk Not Reported Mupirocin N S Unknown Unk Not Reported Not Reported Mupirocin N S Unknown Unk Not Reported Not Reported Not Information Unk Not Reported Not Reported Not Information Unk Not Reported Not Reported Not Information Unk Not Reporte	Flovent	N	S	Unknown		Not Reported
Benadryl E N C Unknown Unk Not Reported Budesonide N S Unknown Unk Not Reported Calcium Carbonate/Vitamin D3 N S Unknown Unk Not Reported Calcium Lactate; Calcium N C Unknown Unk Not Reported Calcium Lactate; Calcium N S Unknown Unk Not Reported Phosphate; Ergocalciferol Cetirizine Hydrochloride N S Unknown Unk Not Reported Clarithromycin N S Unknown Unk Not Reported Curic Oxide N S Unknown Unk Not Reported Curic Oxide N S Unknown Unk Not Reported Clarithromycin N S Unknown Unk Not Reported Clarithromycin N S Unknown Unk Not Reported Curic Oxide N S Unknown Unk Not Reported Glycerin [Glycerol] N S Unknown Unk Not Reported Glycerin [Glycerol] N S Unknown Unk Not Reported Glycerin [Glycerol] N S Unknown Unk Not Reported Hydromycin B Sulfate Hydromorphone Hydrochloride N S Endocervical Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Not Reported Mesalazine N S Unknown Unk Not Reported Mesalazine N S Unknown Unk Not Reported Metoclopramide Hydrochloride N S Unknown Unk Not Reported Metoclopramide N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Mupirocin N S Unknown Unk Not Reported Not Reported Mupirocin N S Unknown Unk Not Reported Not Reported Mupirocin N S Unknown Unk Not Reported Not Reported Mupirocin N S Unknown Unk Not Reported Not Reported Mupirocin N S Unknown Unk Not Reported Not Reported Mupirocin N S Unknown Unk Not Reported Not Repor	Flovent	N	S	Unknown		Not Reported
Budesonide N S Unknown Unk Not Reported Calcium Carbonate/Vitamin D3 N S Unknown Unk Not Reported Calcium Lactate; Calcium N C Unknown Unk Not Reported Phosphate; Ergocalciferrol Cettirzine Hydrochloride N S Unknown Unk Not Reported Clarithromycin N S Unknown Unk Not Reported Clarithromycin N S Unknown Unk Not Reported Cupric Oxide N S Unknown Unk Not Reported Cupric Oxide N S Unknown Unk Not Reported Fluticasone Furcate N S Unknown Unk Not Reported Glycerin [Glycerol] N S Unknown Unk Not Reported Gramicidin; Neomycin Sulfate; N S Unknown Unk Not Reported Gramicidin; Neomycin Sulfate; N S Unknown Unk Not Reported Hydromorphone Hydrochloride N S Endocervical Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Loperamide N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Not Reported Mesalazine N S Unknown Unk Not Reported Mesalazine N S Unknown Unk Not Reported Metronidazole N S Unknown Unk Not Reported Metronidazole N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Motochopramide Hydrochloride N S Unknown Unk Not Reported Metronidazole N S Unknown Unk Not Reported Motochopramide Hydrochloride N S Unknown Unk Not	Adalimumab	N	S	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D3 N S Unknown Unk Not Reported Calcium Lactate; Calcium N C Unknown Unk Not Reported Phosphate; Ergocalciferol Cetirizine Hydrochloride N S Unknown Unk Not Reported Clarithromycin N S Unknown Unk Not Reported Clarithromycin N S Unknown Unk Not Reported Cupric Oxide N S Unknown Unk Not Reported D-Alpha Tocopherol N S Unknown Unk Not Reported Fluticasone Furoate N S Unknown Unk Not Reported Glycerin [Glycerol] N S Unknown Unk Not Reported Glycerol] N S Unknown Unk Not Reported Glycerol] N S Unknown Unk Not Reported Gramicidin; Neomycin Sulfate; N S Unknown Unk Not Reported Gramicidin; Neomycin Sulfate N S Unknown Unk Not Reported Hydromorphone Hydrochloride N S Endocervical Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Not Reported Metoclopramide Hydrochloride N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Not Reported Morphine Sulfate N S Unknown Unk Not Reported Not Reported Morphine Sulfate N S Unknown Unk Not Reported Not Reported Morphine Sulfate N S Unknown Unk Not Reported No	Benadryl E	N	С	Unknown	Unk	Not Reported
Calcium Lactate; Calcium Phosphate; Ergocalciferol Phosphate; Ergocalciferol Cetirizine Hydrochloride N S Unknown Unk Not Reported Clarithromycin N S Unknown Unk Not Reported Cupric Oxide N S Unknown Unk Not Reported Cupric Oxide N S Unknown Unk Not Reported Fluticasone Furoate N S Unknown Unk Not Reported Fluticasone Furoate N S Unknown Unk Not Reported Glycerin [Glycerol] N S Unknown Unk Not Reported Glycerin [Glycerol] N S Unknown Unk Not Reported Glycerin [Glycerol] N S Unknown Unk Not Reported Hydromorphone Hydrochloride N S Endocervical Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Not Reported Metoclopramide Hydrochloride N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Not Repo	Budesonide	N	S	Unknown	Unk	Not Reported
Phosphate; Ergocalciferol Cetirizine Hydrochloride N S Unknown Unk Not Reported Clarithromycin N S Unknown Unk Not Reported Cupric Oxide N S Unknown Unk Not Reported D-Alpha Tocopherol N S Unknown Unk Not Reported Fluticasone Furoate N S Unknown Unk Not Reported Glycerin [Glycerol] N S Unknown Unk Not Reported Glycerin [Glycerol] N S Unknown Unk Not Reported Gramicidin; Neomycin Sulfate; N S Unknown Unk Not Reported Hydromorphone Hydrochloride N S Endocervical Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Loperamide N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Not Reported Mesalazine N S Unknown Unk Not Reported Mesalazine N S Unknown Unk Not Reported Metronidazole N S Unknown Unk Not Reported Metronidazole N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Metronidazole N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Morphine Sulfat	Calcium Carbonate/Vitamin D3	N	S	Unknown	Unk	Not Reported
Clarithromycin N S Unknown Unk Not Reported Cupric Oxide N S Unknown Unk Not Reported D-Alpha Tocopherol N S Unknown Unk Not Reported Fluticasone Furoate N S Unknown Unk Not Reported Glycerin [Glycerol] N S Unknown Unk Not Reported Glycerin [Glycerol] N S Unknown Unk Not Reported Gramicidin;Neomycin Sulfate; N S Unknown Unk Not Reported Polymyxin B Sulfate Hydromorphone Hydrochloride N S Endocervical Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Loperamide N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Not Reported Mesalazine N S Unknown Unk Not Reported Metoclopramide Hydrochloride N C Unknown Unk Not Reported Metoclopramide Hydrochloride N S Unknown Unk Not Reported Metoclopramide Hydrochloride N S Unknown Unk Not Reported Metoclopramide Hydrochloride N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Mupirocin N S Unknown Unk Not Reported Mupirocin N S Unknown Unk Not Reported Nadolol N S Unknown Unk	Phosphate; Ergocal ciferol	N		Unknown	Unk	•
Cupric OxideNSUnknownUnkNot ReportedD-Alpha TocopherolNSUnknownUnkNot ReportedFluticasone FuroateNSUnknownUnkNot ReportedGlycerin [Glycerol]NSUnknownUnkNot ReportedGramicidin; Neomycin Sulfate; Polymyxin B Sulfate Hydromorphone HydrochlorideNSUnknownUnkNot ReportedHydromorphone HydrochlorideNSEndocervicalUnkNot ReportedHydromorphone HydrochlorideNSUnknownUnkNot ReportedLoperamideNSUnknownUnkNot ReportedMagnesium SulfateNSUnknownUnkNot ReportedMesalazineNSUnknownUnkNot ReportedMetoclopramide HydrochlorideNCUnknownUnkNot ReportedMetronidazoleNSUnknownUnkNot ReportedMorphine SulfateNSUnknownUnkNot ReportedMupirocinNSUnknownUnkNot ReportedNadololNSUnknownUnkNot ReportedNicodermNSUnknownUnkNot ReportedNicodermNSUnknownUnkNot Reported	Cetirizine Hydrochloride	N	S	Unknown	Unk	
D-Alpha Tocopherol N S Unknown Unk Not Reported Fluticasone Furoate N S Unknown Unk Not Reported Glycerin [Glycerol] N S Unknown Unk Not Reported Glycerin [Glycerol] N S Unknown Unk Not Reported Gramicidin; Neomycin Sulfate; N S Unknown Unk Not Reported Hydromorphone Hydrochloride N S Endocervical Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Loperamide N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Not Reported Mesalazine N S Unknown Unk Not Reported Metoclopramide Hydrochloride N S Unknown Unk Not Reported Metoclopramide Hydrochloride N C Unknown Unk Not Reported Metoclopramide Hydrochloride N S Unknown Unk Not Reported Metoclopramide Hydrochloride N S Unknown Unk Not Reported Metoclopramide Hydrochloride N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Mupirocin N S Unknown Unk Not Reported Mupirocin N S Unknown Unk Not Reported Nadolol N S Unknown Unk Not Reported Nadolol N S Unknown Unk Not Reported Nadolol N S Unknown Unk Not Reported Nicoderm N S Unknown Unk Not Reported Not Reported Nicoderm N S Unknown Unk Not Reported Not Reported Nicoderm N S Unknown Unk Not Reported Not Reported Nicoderm N S Unknown Unk Not Reported Not Reported Nicoderm N S Unknown Unk Not Reported Not Reported Nicoderm N S Unknown Unk Not Reported Not Reported Nicoderm N S Unknown Unk Not Reported N	Clarithromycin	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate N S Unknown Unk Not Reported Glycerin [Glycerol] N S Unknown Unk Not Reported Glycerin [Glycerol] N S Unknown Unk Not Reported Gramicidin; Neomycin Sulfate; N S Unknown Unk Not Reported Polymyxin B Sulfate Hydromorphone Hydrochloride N S Endocervical Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Loperamide N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Not Reported Mesalazine N S Unknown Unk Not Reported Mesalazine N S Unknown Unk Not Reported Metoclopramide Hydrochloride N C Unknown Unk Not Reported Metronidazole N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Mupirocin N S Unknown Unk Not Reported Mupirocin N S Unknown Unk Not Reported Nadolol N S Unknown 40 Milligram Not Reported Not Reported Nadolol N S Unknown Unk Not Reported Not Reported Not Reported Nadolol N S Unknown Unk Not Reported Not Reported Nadolol N S Unknown Unk Not Reported Nadolol N S Unknown Unk Not Reported Not Reported Nadolol N S Unknown Unk Not Reported Not Reported Nadolol N S Unknown Unk Not Reported Not Reported Nadolol N S Unknown Unk Not Reported Not Repor	Cupric Oxide	N	S	Unknown	Unk	Not Reported
Glycerin [Glycerol] N S Unknown Unk Not Reported Gramicidin; Neomycin Sulfate; N S Unknown Unk Not Reported Polymyxin B Sulfate Hydromorphone Hydrochloride N S Endocervical Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Loperamide N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Not Reported Mesalazine N S Unknown Unk Not Reported Metoclopramide Hydrochloride N C Unknown Unk Not Reported Metoclopramide Hydrochloride N C Unknown Unk Not Reported Metronidazole N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Mupirocin N S Unknown Unk Not Reported Mupirocin N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Mupirocin N S Unknown Unk Not Reported Not Reported Nadolol N S Unknown Unk Not Reported Not Reported Nadolol N S Unknown Unk Not Reported Not Rep	D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Gramicidin; Neomycin Sulfate; Polymyxin B Sulfate Hydromorphone Hydrochloride N S Endocervical Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Loperamide N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Not Reported Mesalazine N S Unknown Unk Not Reported Metoclopramide Hydrochloride N C Unknown Unk Not Reported Metronidazole N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported	Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate Hydromorphone Hydrochloride N S Endocervical Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Loperamide N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Not Reported Mesalazine N S Unknown Unk Not Reported Metoclopramide Hydrochloride N C Unknown Unk Not Reported Metoclopramide Hydrochloride N C Unknown Unk Not Reported Metronidazole N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported	Glycerin [Glycerol]	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride N S Unknown Unk Not Reported Unk Not Reported Unk Magnesium Sulfate N S Unknown Unk Not Reported Unk Mesalazine N S Unknown Unk Not Reported Unk Metoclopramide Hydrochloride N C Unknown Unk Not Reported Unk Metronidazole N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Not Reported Unk Not Reported	Polymyxin B Sulfate			Unknown	Unk	·
LoperamideNSUnknownUnkNot ReportedMagnesium SulfateNSUnknownUnkNot ReportedMesalazineNSUnknownUnkNot ReportedMetoclopramide HydrochlorideNCUnknownUnkNot ReportedMetronidazoleNSUnknownUnkNot ReportedMorphine SulfateNSUnknownUnkNot ReportedMupirocinNSTopicalUnkNot ReportedNadololNSUnknown40 MilligramNot ReportedNicodermNSUnknownUnkNot Reported		N	S	Endocervical	Unk	•
Magnesium SulfateNSUnknownUnkNot ReportedMesalazineNSUnknownUnkNot ReportedMetoclopramide HydrochlorideNCUnknownUnkNot ReportedMetronidazoleNSUnknownUnkNot ReportedMorphine SulfateNSUnknownUnkNot ReportedMupirocinNSTopicalUnkNot ReportedNadololNSUnknown40 MilligramNot ReportedNicodermNSUnknownUnkNot Reported	Hydromorphone Hydrochloride	N		Unknown	Unk	
MesalazineNSUnknownUnkNot ReportedMetoclopramide HydrochlorideNCUnknownUnkNot ReportedMetronidazoleNSUnknownUnkNot ReportedMorphine SulfateNSUnknownUnkNot ReportedMupirocinNSTopicalUnkNot ReportedNadololNSUnknown40 MilligramNot ReportedNicodermNSUnknownUnkNot Reported	Loperamide	N	S	Unknown	Unk	
Metoclopramide HydrochlorideNCUnknownUnkNot ReportedMetronidazoleNSUnknownUnkNot ReportedMorphine SulfateNSUnknownUnkNot ReportedMupirocinNSTopicalUnkNot ReportedNadololNSUnknown40 MilligramNot ReportedNicodermNSUnknownUnkNot Reported	Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
MetronidazoleNSUnknownUnkNot ReportedMorphine SulfateNSUnknownUnkNot ReportedMupirocinNSTopicalUnkNot ReportedNadololNSUnknown40 MilligramNot ReportedNicodermNSUnknownUnkNot Reported	Mesalazine	N	S	Unknown	Unk	Not Reported
Morphine Sulfate N S Unknown Unk Not Reported Mupirocin N S Topical Unk Not Reported Nadolol N S Unknown 40 Milligram Not Reported Nicoderm N S Unknown Unk Not Reported	Metoclopramide Hydrochloride	N	С	Unknown	Unk	Not Reported
MupirocinNSTopicalUnkNot ReportedNadololNSUnknown40 MilligramNot ReportedNicodermNSUnknownUnkNot Reported	Metronidazole	N	S	Unknown	Unk	Not Reported
Nadolol N S Unknown 40 Milligram Not Reported Nicoderm N S Unknown Unk Not Reported	Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Nicoderm N S Unknown Unk Not Reported	Mupirocin	N	S	Topical	Unk	Not Reported
	Nadolol	N	S	Unknown	40 Milligram	Not Reported
	Nicoderm	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex N S Unknown Unk Not Reported	Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Pantoprazole N S Unknown Unk Not Reported	Pantoprazole	N	S	Unknown	Unk	Not Reported



	Potassium Chloride		N	S	Unknown	Unk			Not Reported
	Prednisone		N	S	Unknown	Unk			Not Reported
	Pregabalin		N	S	Unknown	150 Milligram			Not Reported
	Carboxymethylcellulose Sodium		N	S	Unknown	Unk			Not Reported
	Sodium Chloride		N	S	Unknown	Unk			Not Reported
	Trimethoprim Sulfamethoxazole		N	S	Unknown	200 Milligram			Not Reported
	Triamcinolone Acetonide		N	S	Intra-articular	Unk			Not Reported
	Valsartan		N	С	Unknown	Unk			Not Reported
	Vitamin D3		N	S	Unknown	Unk			Not Reported
	Xantofyl Palmitate		N	S	Unknown	Unk			Not Reported
	Zeaxanthin		N	S	Unknown	Unk			Not Reported
	Zinc Oxide		N	S	Unknown	Unk			Not Reported
	Lomotil [Loperamide Hydrochloride]		N	С	Unknown	Unk			Not Reported
FDA Received Date Case :	<u>Case Type</u>	<u>Health</u>	Prof C	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
03-Mar-2023 21168	433 EXPEDITED (15-DAY)	Υ	H	lO, OT	CA-BAUSCH- 018901	BL-2022-	71 YR	Female	CAN
Preferred Term	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>	1	<u>Mfr</u>
Chronic Sinusitis; Drug	Metronidazole		N	S	Unknown				Not Reported
Ineffective; Dyspepsia; Infusion Related Reaction;	Budesonide		N	S	Unknown				Santarus
Macular Degeneration;	Mesalazine		N	S	Unknown				Valeant
Malaise; Nausea; Off Label Use; Pain;	Glyceryl Trinitrate		N	S	Unknown				Not Reported
Paraesthesia Oral;	A			_					Not Donostod
Dropodural Dainy Dyrovia	Amoxicillin		N	S	Unknown				Not Reported
Procedural Pain; Pyrexia;	Amoxicillin Atorvastatin Calcium		N N	S	Unknown Unknown				Not Reported
Therapeutic Product Effect Incomplete; Weight									•
Therapeutic Product Effect	Atorvastatin Calcium		N	S	Unknown				Not Reported
Therapeutic Product Effect Incomplete; Weight	Atorvastatin Calcium Azithromycin Dihydrate		N N	s s	Unknown Oral				Not Reported Not Reported
Therapeutic Product Effect Incomplete; Weight	Atorvastatin Calcium Azithromycin Dihydrate Bisacodyl		N N N	\$ \$ \$	Unknown Oral Unknown				Not Reported Not Reported Not Reported



				•	
Desonide	N	S	Unknown		Not Reported
Diphenhydramine Hydrochloride; Zinc Oxide	N	S	Unknown		Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical		Not Reported
Hydromorphone Hydrochloride	N	S	Unknown		Not Reported
Magnesium Sulfate	N	S	Intramuscular		Not Reported
Metoclopramide Hydrochloride	N	S	Oral		Not Reported
Nadolol	N	S	Unknown		Not Reported
Nicoderm	N	S	Transdermal		Not Reported
Nicoderm	N	S	Unknown	Patch	Not Reported
Pantoprazole Sodium Anhydrous	N	S	Unknown		Not Reported
Prednisone	N	S	Unknown		Not Reported
Pregabalin	N	S	Unknown		Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Suspension Intra- Articular	Not Reported
Zinc Oxide	N	S	Unknown	·	Not Reported
Ergocalciferol	N	S	Unknown		Not Reported
Alprazolam	N	S	Unknown		Not Reported
Atropine Sulfate	N	S	Oral		Not Reported
Avamys	N	S	Unknown	Spray, Metered Dose	Not Reported
Betamethasone Dipropionate	N	S	Unknown		Not Reported
Betamethasone Valerate	N	S	Unknown		Not Reported
Glycerine	N	S	Oral	Liquid Oral	Not Reported
Apo-Hydrochlorothiazide	N	S	Endocervical	·	Not Reported
Morphine Sulfate	N	S	Unknown		Not Reported
Mupirocin	N	S	Topical		Not Reported
Mupirocin	N	S	Unknown		Not Reported
Carmellose Sodium	N	S	Ophthalmic		Not Reported
Simvastatin	N	S	Unknown		Not Reported
Sulfamethoxazole	N	S	Unknown		Not Reported
Amoxicillin Trihydrate	N	S	Unknown		Not Reported



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Pentasa	N	S	Unknown	Not Reported
Magnesium Oxide	N	S	Unknown	Not Reported
Lomotil [Loperamide Hydrochloride]	N	S	Oral	Not Reported
Lomotil [Loperamide Hydrochloride]	N	S	Unknown	Not Reported
Macrogol	N	S	Unknown	Not Reported
Trimethoprim	N	S	Unknown	Not Reported
Bactrim	N	S	Oral ! Df	Not Reported
Acetaminophen	N	S	Unknown	Not Reported
Calcitriol	N	S	Intra-articular	Not Reported
Gramicidin	N	S	Unknown	Not Reported
Ertapenem Sodium	N	S	Respiratory (inhalation)	Not Reported
Vitamin D3	N	S	Unknown	Not Reported
Zeaxanthin	N	S	Oral	Not Reported
Zinc Chloride	N	S	Unknown	Not Reported
Salinex [Sodium Chloride]	N	S	Nasal	Not Reported
Salinex [Sodium Chloride]	N	S	Respiratory (inhalation)	Not Reported
Xantofyl Palmitate	N	S	Unknown	Not Reported
Biaxin XI	N	S	Unknown	Not Reported
Mentha Arvensis	N	S	Unknown	Not Reported
Nicomorphine	N	S	Unknown	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Not Reported
Imodium	N	S	Unknown	Not Reported
Habitrol [Nicotine Polacrilex]	N	S	Unknown	Not Reported
Infliximab	N	S	Intravenous (not otherwise specified)	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Not Reported



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Cupric Oxide	N	S	Unknown			Not Reported
Entocort	N	S	Oral			Not Reported
Entocort	N	S	Unknown	Capsule, Sustained Release		Not Reported
Humira	N	S	Subcutaneous	6	3 YR	Not Reported
Flovent	N	S	Unknown			Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown			Not Reported
Cupric Oxide;Folic Acid;Nicotinic Acid;Zinc	N	S	Unknown			Not Reported
Glycerol;Sodium Stearate	N	S	Unknown			Not Reported
Gramicidin;Polymyxin B	N	S	Unknown			Not Reported
Isoniazid;Pyridoxine Hydrochloride;	N	S	Unknown			Not Reported
Sulfamethoxazole;Trimethoprim Pantoprazole Sodium [Pantoprazole Sodium Sesquihydrate]	N	S	Unknown			Not Reported
Sinus Rinse	N	S	Nasal			Not Reported
Benzydamine Hydrochloride	N	S	Unknown			Not Reported
Acetylsalicylic Acid	N	S	Unknown			Not Reported
Calcium Citrate	N	S	Unknown			Not Reported
Vitamin E Natural [Tocopheryl Acetate]	N	S	Unknown			Not Reported
Potassium Chloride	N	S	Unknown			Not Reported
Pulmicort	N	S	Unknown			Not Reported
Sodium Bicarbonate	N	S	Unknown			Not Reported
Vitamin E Nos	N	S	Unknown			Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown			Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral			Not Reported
Calcium Lactate/Calcium Phosphate/Ergocalciferol	N	S	Unknown			Not Reported
Benadryl [Diphenhydramine Hydrochloride]	N	S	Unknown			Not Reported



Date - Time: 11-Apr-2023 10:56:54 AM EST

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) **Detailed Report**

					zotanoa report				
	Calciu	m Gluconate	N	S	Unknown			Not	Reported
	Neomycin Sulfate		N	S	Unknown			Not	Reported
	Valsartan		N	S	Intracardiac			Not	Reported
	Ambroxol Hydrochloride		N	S	Unknown			Not	Reported
	Betamethasone		N	S	Unknown			Not	Reported
	Calcium Carbonate/Vitamin D3		N	S	Unknown			Not	Reported
	Dilaudid		N	S	Unknown			Not	Reported
	Ms Ir		N	S	Unknown			Not	Reported
	Nicotir	namide	N	S	Unknown			Not	Reported
	Polym	yxin B Sulfate	N	S	Unknown			Not	Reported
	Valsartan		N	С	Intracardiac			Not	Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Mar-2023	19920558	EXPEDITED (15-DAY)	Υ	HO, OT	CA-VALIDUS PHARMACEUTICALS			Unknown	CAN

FDA Received Date	Case #	Case Type	Health Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Mar-2023	19920558	EXPEDITED (15-DAY)	Υ	HO, OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-VDP-2021- 002865			Unknown	CAN

Preferred Term	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	<u>Mfr</u>
Chronic Sinusitis; Drug	Calcitriol		N	S	Intra-articular	Unk		Validus
Ineffective; Dyspepsia; Infusion Related Reaction;	Ergocalciferol		N	S	Unknown	Unk		Validus
Macular Degeneration;	Acetaminophen		N	S	Unknown	Unk		Not Reported
Malaise; Nausea; Off Label Use; Pain;	Acetaminophen		N	S	Unknown	Unk		Not Reported
Paraesthesia Oral;	Adalimumab		N	S	Subcutaneous	Unk		Not Reported
Procedural Pain; Pyrexia; Therapeutic Product Effect	Adalimumab Alprazolam		N N	S S	Unknown	0.25 Mg		Not Reported Not Reported
Incomplete; Weight Decreased	Alprazolam		N	S	Unknown	Unk		Not Reported
	Alprazolam		N	S	Unknown Unk		Not Reported	
	Atorvastatin Calcium		N	S	Unknown	Unk		Not Reported
	Atropine Sulfate		N	S	Oral	Unk		Not Reported
	Atropine Sulfate		N	S	Oral	4 Dosage Form		Not Reported
	Atropine Sulfate		N	S	Oral	1 Dosage Form		Not Reported



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Atropine Sulfate	N	S	Unknown	Unk	Not Reported
Avamys	N	S	Unknown	Unk	Not Reported
Azithromycin Dihydrate	N	S	Unknown	Unk	Not Reported
Azithromycin Dihydrate	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Oral	Unk	Not Reported
Budesonide	N	S		Unk, Inhalation	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Diphenhydramine	N	S	Oral	50 Mg	Not Reported
Diphenhydramine	N	S	Unknown	Unk	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Ertapenem Sodium	N	S	Other	Unk, Inhalation	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Mupirocin	N	S	Unknown	Unk	Not Reported



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Mupirocin	N	S	Topical	Unk	Not Reported
Nadolol	N	S	Unknown	40 Mg	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Transdermal	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Unknown	150 Mg	Not Reported
Pregabalin	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk, Drops Ophthalmic	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Oral	Unk	Not Reported
Zinc Chloride	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Sinus Rinse	N	S	Nasal	Unk, Intra-Nasal	Not Reported
Salinex [Sodium Chloride]	N	S	Nasal	Unk, Intra-Nasal	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported



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Nicomorphine	N	S	Unknown	Unk		Not Reported
Mentha Arvensis	N	S	Unknown	Unk		Not Reported
Magnesium Sulfate	N	S	Intramuscular	Unk		Not Reported
Magnesium Sulfate	N	S	Unknown	Unk		Not Reported
Magnesium Oxide	N	S	Unknown	Unk		Not Reported
Benzydamine Hydrochloride	N	S	Unknown	Unk		Not Reported
Biaxin XI	N	S	Unknown	Unk		Not Reported
Macrogol	N	S	Unknown	Unk		Not Reported
Macrogol	N	S	Unknown	Unk		Not Reported
Macrogol	N	S	Unknown	Unk		Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk		Not Reported
Loperamide Hydrochloride	N	S	Unknown	Unk		Not Reported
Loperamide Hydrochloride	N	S	Unknown	Unk		Not Reported
Loperamide Hydrochloride	N	S	Unknown	Unk		Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk		Not Reported
Imodium	N	S	Unknown	Unk		Not Reported
Habitrol [Nicotine Polacrilex]	N	S	Unknown	Unk		Not Reported
Humira	N	S	Unknown	Unk		Not Reported
Humira	N	S	Subcutaneous	Unk	6 YR	Not Reported
Humira	N	S	Subcutaneous	Unk	6 YR	Not Reported
Glyceryl Trinitrate	N	S	Unknown	Unk		Not Reported
Flovent	N	S	Unknown	Unk		Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown	Unk		Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk (Mixed Tocopherol)		Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk		Not Reported
Cupric Oxide	N	S	Unknown	Unk		Not Reported
Entocort	N	S	Oral	Unk		Not Reported
Fluticasone Furoate	N	S	Unknown	Unk (Metered Dose)		Not Reported
Fluticasone Propionate	N	S	Unknown	Unk		Not Reported

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Glycerol	N	S	Oral	Unk	Not Reported
Infliximab	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Cupric Oxide;Folic Acid;Nicotinic Acid;Zinc	N	S	Unknown	Unk	Not Reported
Glycerol;Sodium Stearate	N	S	Unknown	Unk	Not Reported
Infa-3 [Gramicidin;Neomycin Sulfate;Polymyxin B]	N	S	Unknown	Unk	Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Gramicidin;Polymyxin B	N	S	Unknown	Unk	Not Reported
Isoniazid/Pyridoxine Hydrochloride/Sulfamethoxazole /Trimethoprim	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium Anhydrous	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Oral	1 Dosage Form	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	200 Mg	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	200 Mg	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	Unk	Not Reported
Valsartan	N	S	Oral	4 Df, Qd	Not Reported
Valsartan	N	S	Oral	40 Mg, Qd	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Unk	Not Reported
Calcium Citrate	N	S	Unknown	Unk	Not Reported
Diphenhydramine	N	S	Unknown		Not Reported
Lomotil [Loperamide Hydrochloride]	N	S	Oral	Unk	Not Reported



	Na	atural Vitamin E [Tocopherol]		N	S	Unknown	Unk			Not Reported
	Po	otassium Chloride		N	S	Unknown	Unk			Not Reported
	Po	otassium Chloride		N	S	Unknown				Not Reported
	Pt	ulmicort		N	S	Other	Unk, Inhalation			Not Reported
	Sc	odium Bicarbonate		N	S	Unknown	Unk			Not Reported
	Vi	tamin E Nos		N	S	Unknown	Unk			Not Reported
	To	ocopherols Mixed		N	S	Unknown	Unk			Not Reported
	Ar	moxicillin Trihydrate		N	С	Unknown	Unk			Not Reported
	Ar	moxicillin		N	С	Unknown	Unk			Not Reported
	Ne	eomycin Sulfate		N	С	Unknown	Unk			Not Reported
	So	odium Stearate		N	С	Unknown	Unk			Not Reported
		alcium Carbonate And Vitamin		N	С	Unknown	Unk			Not Reported
	D: Di	3 iphenhydramine Hydrochloride		N	С	Unknown	Unk			Not Reported
	М	upirocin Calcium		N	С	Unknown	Unk			Not Reported
	Ca	alcium		N	С	Unknown	Unk			Not Reported
	Ca	alcium And Ergocalciferol		N	С	Unknown	Unk			Not Reported
	Lo	operamide		N	С	Oral	4 Df, Qd			Not Reported
	M	etoclopramide Hydrochloride		N	С	Oral	Unk			Not Reported
	Va	alsartan		N	С	Unknown	Unk			Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Mar-2023	21996600	EXPEDITED (15-DAY)	N	1	ОТ	US-ALLERGAN 2303874US	-		Male	USA
Preferred Term	<u>P</u>	roduct	Comp.	<u>OTC</u>	Role	<u>Route</u>	Dosage Text	<u>Duration</u>		Mfr
Cataract; Visual	Re	efresh Plus		Υ	S	Ophthalmic	Unk			Allergan
Impairment	Re	efresh Plus		Υ	S	Ophthalmic	2 Gtt, Qd			Allergan
	Da	apsone		N	С		Unk			Not Reported
	O:	zempic		N	С		Unk			Not Reported



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FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date Case	# Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Control	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Mar-2023 20723	601 EXPEDITED (15-DAY)	Υ	НО	, OT	CA-ICU MED ICU2022CA0		-		Unknown	CAN
Preferred Term	<u>Product</u>	Comp.	<u>OTC</u>	Role	Route	<u>Dosage</u>	e Text	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Anaemia; Chronic Sinusitis; Colitis; Colitis Ulcerative; Constipation; Drug Ineffective; Dyspepsia; Erythema; Female Genital Tract Fistula; Frequent Bowel Movements; Haematochezia; Headache; Infusion Related Reaction; Macular Degeneration; Malaise; Nausea; Off Label Use; Oral Candidiasis; Pain; Paraesthesia Oral; Procedural Pain; Proctitis; Pyrexia; Radiculopathy; Rectal Haemorrhage; Therapeutic Product Effect Incomplete; Vaginal Discharge; Vaginal Flatulence; Weight Decreased	Sodium Chloride Injection Acetaminophen Acetylsalicylic Acid Alprazolam Amoxicillin Trihydrate Atorvastatin Calcium Atropine Sulfate W/Diphenoxylate Hydrochlor. Avamys Azithromycin Bactrim Betamethasone Betamethasone Valerate Biaxin XI Bisacodyl Calcium Carbonate Calcium Carbonate W/Colecalciferol Calcium Carbonate/Vitamin D3 Calcium Carbonate\Ergocalciferol Cetirizine Hydrochloride Cetirizine Hydrochloride Cholecalciferol Clarithromycin Clotrimazole Cupric Oxide D-Alpha Tocopherol Desonide Difenoxin Hydrochloride Dilaudid Diphenhydramine Hydrochloride Entocort Ertapenem Sodium Flovent				Unknown				Icu Noi	Medical t Reported



			<u>. </u>
Fluticasone Propionate	N	S	Not Reported
Glycerine	N	S	Not Reported
Glycerinum	N	S S	Not Reported
Glycerol	N	S	Not Reported
Gramicidin;Naphazoline;	N	S	Not Reported
Neomycin;Phenylephrine			
Humira	N	S	Not Reported
Hydromorphone Hydrochloride	N	S	Not Reported
Infliximab	N	S	Not Reported
Isoniazid W/Pyridoxine	N	S	Not Reported
Hydrochloride		-	
Loperamide	N	S	Not Reported
Polyethylene Glycol	N	S	Not Reported
3350\Potassium\Sodium			
Chloride\Sodium Sulfate		_	
Macrogol;Potassium;Sodium	N	S	Not Reported
Bicarbonate		_	
Magnesium Sulfate	N	S	Not Reported
Metronidazole	N	S	Not Reported
Morphine Sulfate	N	S	Not Reported
Ms Ir	N	S	Not Reported
Mupirocin	N	S S	Not Reported
Nadolol	N	S	Not Reported
Nicoderm	N	S	Not Reported
Nicotine	N	S	Not Reported
Nicotine Polacrilex	N	S S S	Not Reported
Nitroglycerin	N	S	Not Reported
Pantoprazole	N	S	Not Reported
Pentasa	N	S S	Not Reported
Prednisone	N	5	Not Reported
Pregabalin	N	S	Not Reported
Pulmicort	N	S	Not Reported
Refresh Tears	N	S S	Not Reported
Sinus Rinse	N	S	Not Reported
Sodium Chloride	N	S S	Not Reported
Sulfamethoxazole And	N	5	Not Reported
Trimethoprim Triamcinolone Acetonide	NI	9	Not Reported
Valsartan	N N	S S	
Valsartan Vitamin-E /00110506/	N N	S	Not Reported
			Not Reported
Xantofyl Palmitate	N N	S S	Not Reported
Zeaxanthin	IN	ა	Not Reported



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FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

	Zin	c Oxide	N	S				No	ot Reported
	Ada	alimumab	N	S				No	ot Reported
Betaderm /00008501/			N	S				No	ot Reported
	Betamethasone Dipropionate			S				No	ot Reported
	Am	broxol Hydrochloride	N	S				No	ot Reported
		cium Amino Acid Chelate	N	S				No	ot Reported
	Difl	ucan	N	S				No	ot Reported
	Infa	-3 /06152501/	N	S				No	ot Reported
	Ker	nalog /00031902/	N	S				No	ot Reported
	Lon	notil	N	S				No	ot Reported
	Met	hylprednisolone Sodium	N	S				No	ot Reported
	Suc	ccinate							
	Mid	azolam	N	S				No	ot Reported
	Pm	s Azithromycin	N	S				No	ot Reported
	Pot	assium Chloride	N	S				No	ot Reported
	Soc	lium Bicarbonate	N	S				No	ot Reported
	Sol	u-Medrol	N	S				No	ot Reported
	Vita	nmin D3	N	S				No	ot Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Mar-2023	21917217	EXPEDITED (15-DAY)	Υ	HO, OT	CA-ORGANON- O2301CAN001959		65 YR	Female	CAN

					020010/1110	301000		
Preferred Term	Product	Comp.	<u>OTC</u>	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaemia;	Zocor		N	S	Unknown	Unk		Organon
Chronic Sinusitis; Colitis; Colitis Ulcerative;	Invanz		N	S	Nasal	Unk		Not Reported
Constipation; Drug	Invanz		N	S	Intramuscular	Unk		Not Reported
Ineffective; Dyspepsia; Erythema; Female Genital	Acetaminophen		N	S	Unknown	Unk		Not Reported
Tract Fistula; Frequent	Dextropropoxyphene Hcl; Paracetamol		N	S	Unknown	Unk		Not Reported
Bowel Movements; Haematochezia; Headache: Infusion	Acetaminophen; Pseudoephedrine		N	S	Unknown	Unk		Not Reported
Related Reaction; Macular	Acetylsalicylic Acid		N	S	Unknown	Unk		Not Reported
Degeneration; Malaise; Nausea; Off Label Use;	Triamcinolone [Triamcinolone Diacetate]		N	S	Unknown	Unk		Not Reported
Oral Candidiasis; Pain; Paraesthesia Oral; Procedural Pain; Proctitis;	Aspirin Cupal [Acetylsalicylic Acid;Calcium Carbonate;Citric		N	S	Unknown	Unk		Not Reported
Pyrexia; Radiculopathy;	Acid] Alprazolam		N	S	Unknown	Unk		Not Reported



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FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Rectal Haemorrhage; Therapeutic Product Effect Incomplete; Vaginal Discharge; Vaginal Flatulence; Weight Decreased

			Detailed it	eport	
Alprazolam	N	S	Unknown	0.25 Milligram	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Amoxicilina [Amoxicillin]	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Atropine Sulfate; Diphenoxylate Hydrochloride	N	S	Oral	4 Every 1 Day	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	4 Every 1 Day	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	1 Dosage Form	Not Reported
Azithromycin	N	S	Oral	Unk	Not Reported
Azithromycin	N	S	Unknown	Unk	Not Reported
Benzydamine	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Bifidobacterium Longum	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Transplacental	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Oral	Unk	Not Reported
Calcitriol;Calcium Carbonate; Zinc	N	S	Unknown	Unk	Not Reported
Calcium & Vitamin D [Calcium; Colecalciferol]	N	S	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D3	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Ciprofloxacin Hydrochloride	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Cupric Oxide;Folic Acid; Nicotinamide;Zinc	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported



Describle	h 1			-	Nat Dan 1 1
Desonide	N	S	Unknown	Unk	Not Reported
Vitamins	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Oral	50 Milligram	Not Reported
Entyvio	N	S	Unknown	Unk	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Fentanyl Citrate	N	S	Unknown	Unk	Not Reported
Flovent	N	S	Unknown	Unk	Not Reported
Fluconazole	N	S	Unknown	Unk	Not Reported
Fluticasone Propionate	N	S	Unknown	Unk	Not Reported
Fluticasone Propionate;	N	S	Unknown	Unk	Not Reported
Salmeterol Xinafoate Glycerine	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Glycerine	N	S	Unknown	Unk	Not Reported
Glyceryl Trinitrate	N	S	Oral	Unk	Not Reported
Glyceryl Trinitrate	N	S	Unknown	Unk	Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Habitrol [Nicotine]	N	S	Unknown	Unk	Not Reported
Humira	N	S	Subcutaneous	2190.0 Days	Not Reported
Humira	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Subcutaneous	Unk	Not Reported
Hydrochlorothiazide	N	S	Endocervical	100 Milligram	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Isoniazid/Pyridoxine	N	S	Unknown	Unk	Not Reported
Hydrochloride/Sulfamethoxazole /Trimethoprim					
Loperamide Hydrochloride	N	S	Oral	4 Every 1 Days	Not Reported



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Loperamide Hydrochloride	N	S	Oral	1 Every 1 Days	Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Every 1 Days	Not Reported
Macrogol 3350;Potassium; Sodium Bicarbonate;Sodium Chloride	N	S	Unknown	Unk	Not Reported
Magnesium	N	S	Unknown	Unk	Not Reported
Magnesium Carbonate	N	S	Unknown	Unk	Not Reported
Magnesium Hydroxide	N	S	Unknown	Unk	Not Reported
Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Methylprednisolone Sodium Succinate	Ν	S	Unknown	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Midazolam	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Topical	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Nadolol	N	S	Unknown	40 Milligram	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Topical	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Oxybutynin Hydrochloride	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Potassium Chloride	N	S	Unknown	Unk	Not Reported
Apo Pregabalin	N	S	Unknown	150 Milligram	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Salinex [Sodium Chloride]	N	S	Nasal	Unk	Not Reported
Sinus Rinse	N	S	Nasal	Unk	Not Reported



Constipation; Drug Ineffective; Dyspepsia; Mezavant			N	S	Unknown	Unk				Takeda			
Colitis Ulcerative; Pentasa				N	S	Unknown	Unk				Takeda		
Abdominal Pain; Anaemia; Chronic Sinusitis; Colitis;		Mesalazine/Mesalamine (Pentasa)			N	S	Unknown	Unk				Takeda	
Preferred Term		Product	<u> </u>	Comp.	OTO	Role	Route	Dosage	<u>e Text</u>	<u>Duration</u>	<u> </u>	<u>Mfr</u>	
13-Mar-2023	191117	'04	EXPEDITED (15-DAY)	Υ		HO, OT		TAKEDA- ITUS063868		65 YR	Female	CAN	
FDA Received Date	Case #		Case Type	Health	Prof	Outcomes	Mfr	Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
		Diphenh	ydramine		N	S	Unknown	Unk				Not Reported	
Cortenema			N	S	Unknown	Unk				Not Reported			
		Emprace	et [Paracetamol]		N	S	Unknown	Unk				Not Reported	
		Fentany			N N	S	Unknown	Unk				Not Reported	
		Fructose	•			S	Unknown Unk				Not Reported		
		Acetaminophen; Dextropropoxyphene Acetic Acid;Triamcinolone Acetonide Align Amoxicillin Trihydrate			N	S	Unknown	Unk		Not Reported			
					N	S	Unknown	Unk				Not Reported	
					N	S	Unknown	Unk Unk				Not Reported	
		•			N	S	Unknown	Unk			Not Reported		
		Zopiclon			N	S	Unknown	Unk				Not Reported	
		Zeaxant Zinc Oxi			N N	S	Oral	Unk				Not Reported Not Reported	
		-	Palmitate		N	S S	Oral	Unk				Not Reported	
		Vitamin			N	S	Unknown	Unk				Not Reported	
		Ubideca			N	S	Unknown	Unk				Not Reported	
			olone Acetonide		N	S	Intra-articu		Unk			Not Reported	
	Triamcinolone Acetonide			N	S	Intra-articu	lar Unk				Not Reported		
Sucralfate Sulfamethoxazole;Trimethoprim			N	S	Unknown	200 M	illigram			Not Reported			
			Ν	S	Unknown	Unk				Not Reported			
Sodium Carboxymethylcellulose			Ν	S	Unknown	Unk				Not Reported			



Erythema; Female Genital Tract Fistula; Frequent Bowel Movements; Haematochezia; Headache; Infusion Related Reaction; Macular Degeneration; Malaise; Nausea: Off Label Use: Oral Candidiasis; Pain; Paraesthesia Oral: Procedural Pain; Proctitis; Pyrexia; Radiculopathy; Rectal Haemorrhage; Therapeutic Product Effect Incomplete; Vaginal Discharge; Vaginal Flatulence; Weight Decreased

Pantoprazole	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Calcium Carbonate, Cholecalciferol	N	S	Unknown	Unk	Not Reported
Amoxicillin	N	S	Unknown	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Unk	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
Macrogol	N	S	Urethral	Unk	Not Reported
Entyvio	N	S	Unknown	Unk	Takeda
Acetaminophene	N	S	Unknown	Unk	Not Reported
Adalimumab	N	S	Subcutaneous	Unk	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Atorvastatin	N	S	Oral	Unk	Not Reported
Atorvastatin	N	S	Unknown	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	4 Dosage Form, Qd	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Unknown	Unk	Not Reported
Azithromycin	N	S	Unknown	Unk	Not Reported
Ascorbic Acid W/Copper/Tocopherol/Xantofyl/Z e	N	S	Unknown	Unk	Not Reported
Atropine	N	S	Oral	Unk	Not Reported
Avamys	N	S	Unknown	Unk	Not Reported
Alka Seltzer Heartburn Reliefchews	N	S	Unknown	Unk	Not Reported
Apo Hydro	Ν	S	Endocervical	Unk	Not Reported
Acetaminophen; Dextropropoxyphene	N	S	Oral	Unk	Not Reported
D	N.I.	0			Mat Danadad

Date - Time: 11-Apr-2023 10:56:54 AM EST Note: If the field is blank, there is no data.

Ν

Ν

S

S

Unknown

Unknown

Unk

Unk

Betamethasone

Betamethasone Valerate

Not Reported

Not Reported



				•	
Bisacodyl	N	S	Transplacental	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Oral	Unk	Not Reported
Budesonide	N	S	Cutaneous	Unk	Not Reported
Budesonide	N	S	Other	Unk	Not Reported
Budesonide	N	S	Subcutaneous	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Bactroban	N	S	Unknown	Unk	Not Reported
Bactrim	N	S	Unknown	Unk	Not Reported
Cetirizine	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
Dexpanthenol	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Diphenhydramine	N	S	Unknown	Unk	Not Reported
Dilaudid	N	S	Unknown	Unk	Not Reported
DI-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
Dimethyl Sulfoxide	N	S	Unknown	Unk	Not Reported
Diphenoxylate Hydrochloride And Atropine Sulfate	N	S	Oral	Unk	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Entocort	N	S	Oral	Unk	Not Reported
Fluticasone	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Flovent	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Glycerol	N	S	Oral	Unk	Not Reported



				1		
Gramicidin;Neomycin Sulfate;	N	S	Unknown	Unk		Not Reported
Polymyxin B Sulfate Humira	N	S	Subcutaneous	Unk	2190 DAY	Not Reported
Humira	N	S	Unknown	Unk		Not Reported
Hydrochlorothiazide	N	S	Endocervical	100 Milligram		Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk		Not Reported
Hydrochlorothiazide	N	S	Subcutaneous	Unk		Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk		Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk		Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Unk		Not Reported
Habitrol	N	S	Other	Unk		Not Reported
Habitrol	N	S	Unknown	Unk		Not Reported
Kenalog	N	S	Intra-articular	Unk		Not Reported
Loperamide	N	S	Oral	4 Dosage Form, Qd		Not Reported
Loperamide	N	S	Unknown	Unk		Not Reported
Lomotil	N	S	Oral	Unk, Qid		Not Reported
Macrogol; Potassium Chloride;	N	S	Unknown	Unk		Not Reported
Sodium Bicarbonate Magnesium Sulfate	N	S	Unknown	Unk		Not Reported
Magnesium Sulfate	N	S	Intramuscular	Unk		Not Reported
Magnesium	N	S	Unknown	Unk		Not Reported
Morphine Sulfate	N	S	Unknown	Unk		Not Reported
Mupirocin	N	S	Topical	Unk		Not Reported
Mupirocin	N	S	Unknown	Unk		Not Reported
Mupirocin Calcium	N	S	Topical	Unk		Not Reported
Nadolol	N	S	Unknown	40 Milligram		Not Reported
Nadolol	N	S	Unknown	Unk		Not Reported
Neomycin Sulphate	N	S	Unknown	Unk		Not Reported
Nicoderm	N	S	Transdermal	Unk		Not Reported
Nicoderm	N	S	Unknown	Unk		Not Reported



Nicotine	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Potassium Chloride	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Intraocular	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Nasal	Unk	Not Reported
Sodium Chloride	N	S	Other	Unk	Not Reported
Sodium Chloride	N	S	Endosinusial	Unk	Not Reported
Sulfamethoxazole And	N	S	Unknown	Unk	Not Reported
Trimethoprim Sulfamethoxazole And Trimethoprim	N	S	Unknown	200 Milligram	Not Reported
Sinus Rinse	N	S	Nasal	Unk	Not Reported
Sinus Rinse	N	S	Other	Unk	Not Reported
Sinus Rinse	N	S	Endosinusial	Unk	Not Reported
Statex	N	S	Unknown	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Nasal	Unk	Not Reported
Sodium Chloride	N	S	Endosinusial	Unk	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intraocular	Unk	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk	Not Reported
Vitamin E	N	S	Unknown	Unk	Not Reported
Vitamin D	N	S	Unknown	Unk	Not Reported



	Xantofyl Palmitate		N	S	Unknown	Unk		N	ot Reported
	Zeaxanthin		N	S	Unknown	Unk		N	ot Reported
	Zinc Oxide		Ν	S	Unknown	Unk		N	ot Reported
	Cetirizine Hydrochloride		Ν	S	Unknown	Unk		N	ot Reported
	Diphenhydramine Hydrochloride		N	S	Unknown	Unk		N	ot Reported
	Gramicidin		Ν	S	Unknown	Unk		N	ot Reported
	Vitamin D3		Ν	S	Unknown	Unk		N	ot Reported
	Calcium Carbonate;Calcium Citrate;Calcium Phosphate; Colecalciferol;Mag		N	S	Unknown	Unk		N	ot Reported
	Betaderm		N	S	Unknown	Unk		N	ot Reported
	Acetylsalicylic Acid;Citric Acid; Sodium Bicarbonate		N	S	Unknown	Unk		N	ot Reported
	Apo-Hydrochlorothiazide		Ν	S	Endocervical	Unk		N	ot Reported
	Difenoxin Hydrochloride		Ν	S	Unknown	Unk		N	ot Reported
	Loperamide Hydrochloride		Ν	S	Oral	1 Dosage Form, Q6hr		N	ot Reported
	Loperamide Hydrochloride		Ν	S	Oral	1 Dosage Form		N	ot Reported
	Valsartan		N	S	Unknown	Unk		N	ot Reported
	Atorvastatin Calcium		N	S	Unknown	Unk		N	ot Reported
	Azithromycin Dihydrate		N	S	Unknown	Unk		N	ot Reported
FDA Received Date Case	# Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
16-Mar-2023 20578	742 EXPEDITED (15-DAY)	N		ОТ	BR-ALLERGAN 2206173US	-		Female	BRA
Preferred Term	<u>Product</u>	Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	<u>Mf</u>	<u>r</u>
Abdominal Pain; Abdominal Pain Upper; Abnormal Sensation In Eye; Asthenopia; Blindness Transient; Cerebrovascular Accident; Dry Eye; Dry Throat; Dysgeusia; Dysphagia; Eye Discharge; Eye	Optive Fusion		N	S		2 Drops On Sunday And 1 Drop On Tuesday	I	N	ot Reported



Irritation; Eye Pain; Headache; Hepatic Pain; Joint Effusion; Ocular Hyperaemia; Product Colour Issue; Product Odour Abnormal; Product Packaging Issue; Product Quality Issue; Retching; Taste Disorder; Vision

Blurred

FDA Received Date	Case #	Case Type	Health Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Mar-2023	20117899	EXPEDITED (15-DAY)	N	OT	CA-Accord-245819			Female	CAN

Preferred Term	<u>Product</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	Duration	<u>Mfr</u>
Drug Ineffective; Macular	Atorvastatin		N	S	Unknown			Not Reported
Degeneration	Atropine Sulfate		N	S	Oral			Not Reported
	Hydrochlorothiazide		N	S	Endocervical			Not Reported
	Simvastatin Pantoprazole		N N	S S	Unknown			Not Reported Not Reported
	Pregabalin		N	S	Unknown			Not Reported
	Acetaminophen		N	S	Unknown			Not Reported
	Alprazolam		N	S	Unknown			Not Reported
	Amoxicillin		N	S	Unknown			Not Reported
	Apo Hydro		N	S	Endocervical			Not Reported
	Avamys		N	S	Unknown	Spray, Metered Dose		Not Reported
	Azithromycin		N	S	Oral			Not Reported
	Bactroban		N	S	Unknown			Not Reported
	Betaderm		N	S	Unknown			Not Reported
	Betamethasone Dipropionate		N	S	Unknown			Not Reported
	Biaxin XI		N	S	Unknown	Extended Release		Not Reported
	Bisacodyl		N	S	Unknown			Not Reported
	Budesonide		N	S	Oral	Also Subcutaneous Also	1	Not Reported



				Modified-Release Capsule, Hard		
Calcium Carbonate	N	S	Unknown	Capsaio, Hara		Not Reported
Calcium Carbonate W/Cholecalciferol	N	S	Unknown			Not Reported
Cetirizine	N	S	Unknown			Not Reported
Clarithromycin	N	S	Unknown			Not Reported
Clotrimazole	N	S	Unknown			Not Reported
Desonide	N	S	Unknown			Not Reported
Dilaudid	N	S	Unknown			Not Reported
Diphenhydramine	N	S	Unknown			Not Reported
Ertapenem Sodium	N	S	Intramuscular			Not Reported
Flovent	N	S	Unknown			Not Reported
Glycerin	N	S	Oral			Not Reported
Gramicidin W/Polymyxin B Sulfate	N	S	Unknown	Ophthalmic		Not Reported
Habitrol	N	S	Transdermal			Not Reported
Humira	N	S	Subcutaneous		2190 DAY	Not Reported
Kenalog	N	S	Intra-articular			Not Reported
Lomotil	N	S	Oral	4 Every 1 Days		Not Reported
Metronidazole	N	S	Unknown			Not Reported
Morphine Sulfate	N	S	Unknown			Not Reported
Multivitamin	N	S	Unknown			Not Reported
Mupirocin	N	S	Topical	Ointment Topical		Not Reported
Nadolol	N	S	Unknown			Not Reported
Nicoderm	N	S	Transdermal			Not Reported
Niquitin	N	S	Unknown	4 Mg, Mint		Not Reported
Pentasa	N	S	Unknown			Not Reported
Polyethylene Glycol	N	S	Urethral	Potassium Chloride, Sodium Bicarbonate		Not Reported
Prednisone	N	S	Unknown			Not Reported

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Note: If the field is blank, there is no data.



			= = = = = = = = = = = = = = = = = = = =	1	
Pulmicort	N	S	Respiratory (inhalation)		Not Reported
Refresh Tears	N	S		Ophthalmic	Not Reported
Salinex Drops	N	S	Unknown	Route: Intra-Nasal	Not Reported
Statex	N	S	Unknown		Not Reported
Sulfamethoxazole W/Trimethoprim	N	S	Unknown		Not Reported
Triamcinolone Acetonide	N	S	Intra-articular		Not Reported
Vitamin D3	N	S	Unknown	1000 lu,	Not Reported
Cupric Oxide	N	S	Unknown		Not Reported
Ergocalciferol	N	S	Unknown		Not Reported
Mezavant	N	S		Delayed And Extended Release	Not Reported
Nicotine	N	S	Transdermal		Not Reported
Entocort	N	S	Oral	Sustained-Release	Not Reported
Acetylsalicylic Acid	N	S	Oral		Not Reported
Atropine Sulfate W/Diphenoxylate Hy	N	S	Oral		Not Reported
Bactrim DI-Alpha Tocopheryl Acetate Dulcolax Gramicidin Loperamide Hydrochloride	N N N N N	\$ \$ \$ \$	Oral	1 Every 6 Hours	Not Reported Not Reported Not Reported Not Reported Not Reported
Magnesium Sulfate Neomycin Sulfate Paracetamol W/Pseudoephedrine Hcl	N N N	S S S		. 210., 0.100.0	Not Reported Not Reported Not Reported
Potassium Chloride	N	S	Endocervical		Not Reported
Vitamin E	N	S	Intracardiac	400unit	Not Reported
Xantofyl Palmitate	N	S	Oral		Not Reported
Zeaxanthin	N	S	Oral		Not Reported
Zinc Oxide	N	S	Oral		Not Reported
Gramicidin W/Neomycin/Polymyxin B	N	S		Ointment Dental	Not Reported



			201000		
Ms Ir Adalimumab	N N	S S	Subcutaneous		Not Reported Not Reported
Hydromorphone Hydrochloride	N	S		1 Every 1 Weeks	Not Reported
Mesalazine Carboxymethylcellulose Sodium	N N	S S		Route- Ophthalmic	Not Reported Not Reported
Glycerol	N	S	Oral		Not Reported
Sodium Hydrogen Carbonate, Potassium Chloride, Mac	N	S			Not Reported
Macrogol Polymyxin B Sulfate Sodium Bicarbonate Dextropropoxyphene W/Acetaminophen	N N N N	S S S	Unknown		Not Reported Not Reported Not Reported Not Reported
Betamethasone Valerate Nicotine Polacrilex Acetylsalicylic Acid, Sodium Bicarbonate, Anhydrous Citric Acid	N N N	S S S			Not Reported Not Reported Not Reported
Azithromycin	N	S	Oral		Not Reported
Vitamin B Complex Nos	N	S	Unknown		Not Reported
Isoniazid W/Pyridoxine	N	S	Unknown		Not Reported
Sulfatrim	N	S	Unknown		Not Reported
Sodium Chloride	N	S		Route Of Administration- Intra-Nasal	Not Reported
Ambroxol Hydrochloride Nicotinamide Trimethoprim Calcium Carbonate	N N N	S S S			Not Reported Not Reported Not Reported Not Reported
W/Ergocalciferol Nystatine Imodium Mentha Arvensis Valsartan	N N N	S S S	Intracardiac		Not Reported Not Reported Not Reported Not Reported
Calcitriol, Calcium Carbonate, Zinc	N	S	Intra-articular		Not Reported
Sulfamethoxazole Fructose W/Glycerin/Sodium Chloride	N N	S S	Oral		Not Reported Not Reported



				<u> </u>	
Calcium Gluconate	N	S			Not Reported
Ambroxol,Cetirizine Hydrochloride	N	S			Not Reported
Zinc Chloride	N	S			Not Reported
Atropine Sulfate	N	S	Oral		Not Reported
Minerals	N	S			Not Reported
Magnesium Oxide	N	S			Not Reported
Pseudoephedrine	N	S			Not Reported
Vitamin C Potassium Phosphate	N N	S S			Not Reported Not Reported
Monobasic	IN	5			Not Reported
Niacinamide\Pyridoxine	N	S			Not Reported
Hydrochloride\Riboflavin\Thiami ne Hydrochloride					
Fluticasone	N	S			Not Reported
Hydrochlorothiazide	N	S C			Not Reported
Valsartan	Ν	C	Vaginal		Not Reported
Calcium Carbonate W/Vitamin D	N	С	-		Not Reported
Betamethasone Dipropionate	N	S	Unknown	Betamethasone Valerate	Not Reported
Vitamin D3	N	S	Unknown		Not Reported
Clarithromycin	N	S	Unknown		Not Reported
Atropine Sulfate	N	S	Oral	4 Every 1 Days	Not Reported
W/Diphenoxylate Hy Flovent	N	c			Not Papartad
		S	Unknown		Not Reported
Budesonide	N	S	Unknown	Inhalation	Not Reported
Budesonide	N	S	Cutaneous		Not Reported
Apo Hydro	N	S	Unknown		Not Reported
Pregabalin	N	S	Unknown		Not Reported
Valsartan	N	С	Intracardiac		Not Reported
Atropine Sulfate	N	S	Oral		Not Reported
Atropine Sulfate	N	S			Not Reported
Calcium Carbonate	N	S	Unknown		Not Reported
Hydrochlorothiazide	N	S	Unknown		Not Reported
Kenalog	N	S	Unknown	Suspension Intra- Articular	Not Reported



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FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #		Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control	# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
22-Mar-2023	204307	'04	EXPEDITED (15-DAY)	Υ		HO, OT	CA-JNJFOC- 20220162776		71 YR	Female	CAN
Preferred Term		Product		Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>	Mf	<u>.</u>
Abdominal Pain; Anaemia; Chronic Sinusitis; Colitis; Colitis Ulcerative;		Remicad	le		N	S	Intravenous drip			No	ot Reported
		Remicad	le		N	S	Intravenous drip			No	ot Reported
Constipation; Drug		Imodium			N	S	Unknown			No	ot Reported
Ineffective; Dyspepsia; Dyspepsia; Erythema;	Imodium			N	S	Unknown			No	ot Reported	
Female Genital Tract		Cetirizine	e Hydrochloride		N	S	Endocervical			No	ot Reported
Fistula; Frequent Bowe	el	Cetirizine	e Hydrochloride		N	S	Unknown			No	ot Reported
Movements; Haematochezia;		Cetirizine	e Hydrochloride		N	S	Unknown			No	ot Reported
Headache;		Benadryl			N	S	Oral			No	ot Reported
Hypersensitivity; Infusion Related Reaction; Mac		Nicodern	n		N	S	Unknown			No	ot Reported
Degeneration; Malaise	;	Nicodern	n		N	S	Transdermal			No	ot Reported
Malaise; Nausea; Naus Off Label Use; Off Labe		Nicodern	n		Ν	S	Unknown			No	ot Reported
Use; Oral Candidiasis;		Nicotine			Ν	S	Unknown			No	ot Reported
Pain; Pain; Paraesthes Oral; Paraesthesia Ora		Paraceta	ımol		Ν	S	Unknown			No	ot Reported
Procedural Pain;	а,	Invanz			Ν	S	Unknown			No	ot Reported
Procedural Pain; Proct Pyrexia; Pyrexia;	itis;	Alka Selt Reliefche	zer Heartburn ews		N	S	Unknown			No	ot Reported
Radiculopathy; Rectal		Amoxicill	lin		N	S	Unknown			No	ot Reported
Haemorrhage; Therapeutic Product E	ffect	Amoxicill	lin		N	S	Unknown			No	ot Reported
Incomplete; Vaginal			ina [Amoxicillin		N	S	Unknown			No	ot Reported
Discharge; Vaginal Flatulence; Weight		Trihydrat Apo-Hyd			N	S	Endocervical			No	ot Reported
Decreased		Avamys			N	S	Unknown			No	ot Reported
		Bactrim			N	S	Unknown			No	ot Reported
		Bactrim			N	S	Unknown			No	ot Reported
		Bactrim			N	S	Nasal			No	ot Reported
		Betametl	hasone		N	S	Unknown			No	ot Reported

Note: If the field is blank, there is no data.



				<u> </u>	
Biaxin XI	N	S	Unknown		Not Reported
Biaxin XI	N	S	Unknown		Not Reported
Colecalciferol	N	S	Unknown		Not Reported
Colecalciferol	N	S	Unknown		Not Reported
Colecalciferol	N	S	Cutaneous		Not Reported
Clarithromycin	N	S	Unknown		Not Reported
Clarithromycin	N	S	Unknown		Not Reported
Clarithromycin	N	S	Unknown		Not Reported
Clarithromycin	N	S	Unknown		Not Reported
Cupric Oxide	N	S	Unknown		Not Reported
D-Alpha Tocopherol	N	S	Unknown		Not Reported
Desonide	N	S	Unknown		Not Reported
Entocort	N	S	Unknown		Not Reported
Entocort	N	S	Vaginal		Not Reported
Entocort	N	S	Oral		Not Reported
Flovent	N	S	Unknown		Not Reported
Flovent	N	S	Oral		Not Reported
Flovent	N	S	Unknown		Not Reported
Flovent	N	S	Unknown		Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown		Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Endocervical		Not Reported
Magnesium Sulfate	N	S	Unknown		Not Reported
Magnesium Sulfate	N	S	Intramuscular		Not Reported
Magnesium Sulfate	N	S	Intramuscular	Inj 50%, Liquid Intramuscular	Not Reported
Nadolol	N	S	Unknown		Not Reported
Nadolol	N	S	Intra-articular		Not Reported
Nadolol	N	S	Oral		Not Reported
Refresh Tears	N	S	Ophthalmic		Not Reported



Refresh Tears	N	S	Intraocular	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Not Reported
Triamcinolone Acetonide	N	S	Intraocular	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Not Reported
Tocopherol	N	S	Unknown	Not Reported
E Vitamin	N	S	Unknown	Not Reported
Xantofyl Palmitate	N	S	Unknown	Not Reported
Zeaxanthin	N	S	Unknown	Not Reported
Zeaxanthin	N	S	Unknown	Not Reported
Alprazolam	N	S	Unknown	Not Reported
Alprazolam	N	S	Unknown	Not Reported
Alprazolam	N	S	Unknown	Not Reported
Atorvastatin	N	S	Endocervical	Not Reported
Atorvastatin	N	S	Unknown	Not Reported
Atorvastatin	N	S	Unknown	Not Reported
Atorvastatin Calcium	N	S	Unknown	Not Reported
Atorvastatin Calcium	N	S	Unknown	Not Reported
Atorvastatin Calcium	N	S	Unknown	Not Reported
Atorvastatin Calcium	N	S	Unknown	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Unknown	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Not Reported
Azithromycin	N	S	Unknown	Not Reported



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Azithromycin	N	S	Oral		Not Reported
Azithromycin	N	S	Unknown		Not Reported
Betamethasone Valerate	Ν	S	Unknown		Not Reported
Betamethasone Valerate	Ν	S	Unknown		Not Reported
Betamethasone Valerate	Ν	S	Unknown		Not Reported
Betamethasone Valerate	Ν	S	Unknown		Not Reported
Bisacodyl	Ν	S	Transplacental		Not Reported
Bisacodyl	N	S	Unknown		Not Reported
Calcium Carbonate	N	S	Unknown		Not Reported
Calcium Carbonate	N	S	Unknown		Not Reported
Calcium Carbonate;Vitamin D Nos	N	S	Unknown		Not Reported
Calcium Carbonate;Vitamin D Nos	N	S	Unknown		Not Reported
Clotrimazole	N	S	Unknown		Not Reported
Dilaudid	N	S	Unknown	1 Dosage Form, Bid	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	<u> </u>	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown		Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown		Not Reported
Glycerol	N	S	Oral		Not Reported
Glycerol	N	S	Unknown		Not Reported
Glycerol	N	S	Oral		Not Reported
Glycerol	N	S	Oral		Not Reported
Humira	N	S	Subcutaneous		Not Reported
Humira	N	S	Subcutaneous		Not Reported
Humira	N	S	Subcutaneous		Not Reported
Humira	N	S	Subcutaneous	Unknown Solution (Except Syrup)	Not Reported
Humira	N	S	Unknown	Unknown Solution (Except Syrup)	Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	• 17	Not Reported



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Hydromorphone Hydrochloride	N	S	Endocervical		Not Reported
Hydromorphone Hydrochloride	N	S	Unknown		Not Reported
Loperamide	N	S	Unknown		Not Reported
Loperamide	N	S	Unknown		Not Reported
Loperamide	N	S	Oral	4 Dosage Form, Qd	Not Reported
Loperamide	N	S	Oral	1 Dosage Form, Q6hr	Not Reported
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate; Sodium Chloride	N	S	Unknown		Not Reported
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate; Sodium Chloride	N	S	Urethral		Not Reported
Macrogol;Potassium Chloride; Sodium Bicarbonate	N	S	Unknown		Not Reported
Metronidazole	N	S	Unknown		Not Reported
Metronidazole	N	S	Unknown		Not Reported
Metronidazole	Ν	S	Unknown		Not Reported
Morphine Sulfate	N	S	Unknown		Not Reported
Morphine Sulfate	N	S	Topical		Not Reported
Mupirocin	N	S	Topical		Not Reported
Mupirocin	N	S	Unknown		Not Reported
Mupirocin	N	S	Unknown		Not Reported
Mupirocin	N	S	Unknown		Not Reported
Nicotine Polacrilex	N	S	Unknown		Not Reported
Nicotine Polacrilex	N	S	Unknown		Not Reported
Pantoprazole	N	S	Unknown		Not Reported
Pentasa	N	S	Unknown		Not Reported
Prednisone	N	S	Unknown		Not Reported
Prednisone	N	S	Unknown		Not Reported
Pregabalin	N	S	Unknown		Not Reported
Pregabalin	N	S	Unknown		Not Reported
Pregabalin	N	S	Unknown		Not Reported



Pregabalin	N	S	Unknown	Not Reported
Pregabalin	Ν	S	Topical	Not Reported
Pulmicort	Ν	S	Unknown	Not Reported
Pulmicort	N	S	Oral	Not Reported
Sodium Chloride Sodium Chloride	N N	S S	Unknown	Not Reported Not Reported
Sodium Chloride	N	S	Nasal	Not Reported
Sodium Chloride	N	S	Unknown	Not Reported
Sodium Chloride	N	S	Nasal	Not Reported
Sodium Chloride	N	S	Respiratory (inhalation)	Not Reported
Sodium Chloride	N	S	Other	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Not Reported
Zinc Oxide	Ν	S	Unknown	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Not Reported
Betamethasone Dipropionate	Ν	S	Unknown	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Not Reported
Zocor	N	S	Unknown	Not Reported
Zocor	N	S	Unknown	Not Reported
Adalimumab	N	S	Subcutaneous	Not Reported
Adalimumab	N	S	Subcutaneous	Not Reported
Adalimumab	N	S	Subcutaneous	Not Reported
Adalimumab	N	S	Subcutaneous	Not Reported
Adalimumab	N	S	Unknown	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Not Reported
Apo-Hydro	N	S	Unknown	Not Reported



Budesonide	N	S	Unknown	Not Reported
Budesonide	N	S	Unknown	Not Reported
Budesonide	N	S	Oral	Not Reported
Budesonide	N	S	Cutaneous	Not Reported
Budesonide	N	S	Other	Not Reported
Budesonide	N	S	Subcutaneous	Not Reported
Budesonide	N	S	Oral	Not Reported
Ergocalciferol	N	S	Unknown	Not Reported
Mesala	N	S	Unknown	Not Reported
Fluticasone Furoate	N	S	Unknown	Not Reported
Fluticasone Furoate	N	S	Unknown	Not Reported
Mesalamine	N	S	Unknown	Not Reported
Mesalamine	N	S	Unknown	Not Reported
Bactroban [Mupirocin]	N	S	Unknown	Not Reported
Bactroban [Mupirocin]	N	S	Topical	Not Reported
Bactroban [Mupirocin]	N	S	Unknown	Not Reported
Betaderm Ointment	N	S	Unknown	Not Reported
Calcium, Magnesium & Vitamin D3	N	S	Unknown	Not Reported
Statex [Morphine Sulfate]	N	S	Unknown	Not Reported
Alka-Seltzer	N	S	Unknown	Not Reported
Sinus Rinse	N	S	Unknown	Not Reported
Sinus Rinse	N	S	Nasal	Not Reported
Sinus Rinse	N	S		Not Reported
Sinus Rinse	N	S	Nasal	Not Reported
Sinus Rinse	N	S	Unknown	Not Reported
Sinus Rinse	N	S	Nasal	Not Reported
Sinus Rinse	N	S	Other	Not Reported
Benzydamine Hydrochloride	N	S	Unknown	Not Reported
Vitamin D3	N	S	Unknown	Not Reported



Vitamin D3	N	S	Unknown	Not Reported
Vitamin D3	N	S	Unknown	Not Reported
Vitamin E [Tocopherol]	N	S	Unknown	Not Reported
Dulcolax [Sodium Picosulfate]	N	S	Unknown	Not Reported
Pantoprazole Sodium Anhydrous	N	S	Unknown	Not Reported
Azithromycin Dihydrate	N	S	Unknown	Not Reported
DI-Alpha Tocopheryl Acetate	N	S	Unknown	Not Reported
Ascorbic Acid	N	S	Unknown	Not Reported
Povidone-Iodine	N	S	Unknown	Not Reported
Calcium Citrate	N	S	Unknown	Not Reported
Calcium Phosphate	N	S	Unknown	Not Reported
Calcium	N	S	Unknown	Not Reported
Magnesium	N	S	Unknown	Not Reported
Macrogol Hexal	N	S	Unknown	Not Reported
Mupirocin Calcium	N	S	Unknown	Not Reported
Clobetasone Butyrate;	N	S	Unknown	Not Reported
Miconazole Nitrate Pantoprazole Sodium Sesquihydrate	N	S	Unknown	Not Reported
Sinus Inhalaciones	N	S	Unknown	Not Reported
Ertapenem	N	S	Unknown	Not Reported
Ertapenem	N	S	Unknown	Not Reported
Isoniazid/Pyridoxine Hydrochloride/Sulfamethoxazole /Trimethoprim	N	S	Unknown	Not Reported
Fluticasone Propionate	N	S	Unknown	Not Reported
Fluticasone Propionate	N	S	Ophthalmic	Not Reported
Nicotinamide	N	S	Unknown	Not Reported
Nicotinamide	N	S	Unknown	Not Reported
Carmellose Sodium	N	S	Unknown	Not Reported
Carmellose Sodium	N	S	Intra-articular	Not Reported



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Potassium Chloride	N	S	Unknown		Not Reported
Minerals\Vitamins	N	S	Unknown		Not Reported
Polymyxin B Sulfate	N	S	Unknown		Not Reported
Macrogol 4000	N	S	Unknown		Not Reported
Macrogol 4000	N	S	Urethral		Not Reported
Macrogol 4000	N	S	Endocervical		Not Reported
Apo Hydroxychloroquine	N	S	Unknown		Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown		Not Reported
Apo-Hydrochlorothiazide	N	S	Endocervical		Not Reported
Apo-Hydrochlorothiazide	N	S	Endocervical		Not Reported
Ertapenem Sodium	N	S	Unknown		Not Reported
Habitrol [Nicotine]	N	S	Unknown		Not Reported
Kenalog [Triamcinolone Acetonide]	N	S	Intra-arterial		Not Reported
Kenalog [Triamcinolone Acetonide]	N	S	Intra-articular		Not Reported
Lomotil [Atropine Sulfate; Diphenoxylate Hydrochloride]	N	S	Oral	Unk, 4x/Day, Qid	Not Reported
Lomotil [Atropine Sulfate; Diphenoxylate Hydrochloride]	N	S	Oral	4 Df, 1x/Day, Qd	Not Reported
Lomotil [Atropine Sulfate; Diphenoxylate Hydrochloride]	N	S	Oral		Not Reported
Msir	N	S	Unknown		Not Reported
Salinex [Sodium Chloride]	N	S	Nasal		Not Reported
Salinex [Sodium Chloride] Salinex [Sodium Chloride]	N N	S S	Nasal		Not Reported Not Reported
Triamcinolone	N	S	Unknown		Not Reported
Glycerine	N	S	Oral		Not Reported
Glycerine	N	S	Unknown		Not Reported
Calcium Phosphate	N	S	Unknown		Not Reported
Vitamine D	N	S	Unknown		Not Reported
Lomotil [Loperamide Hydrochloride]	N	S	Oral		Not Reported



Lomotil [Loperamide	N	S	Oral	Not Reported
Hydrochloride] Lomotil [Loperamide	N	S	Oral	Not Reported
Hydrochloride] Lomotil [Loperamide	N	S	Oral	Not Reported
Hydrochloride] Alrex [Alprazolam]	N	S	Unknown	Not Reported
Pantoprazole Sodium	N	S	Unknown	Not Reported
Sesquihydrate Cupric Oxide;Folic Acid; Nicotinamide;Zinc	N	S	Unknown	Not Reported
Gramicidin;Polymyxin B	N	S	Unknown	Not Reported
Niquitin Mint	N	S	Unknown	Not Reported
Ascorbic Acid;Copper;DI-Alpha Tocopherol;Xantofyl;Zeaxanthin;	N	S	Unknown	Not Reported
Zinc Neomycin Sulfate	N	S	Unknown	Not Reported
Sodium Sulfate	N	S	Unknown	Not Reported
Calcium Carbonate;Calcium	N	S	Unknown	Not Reported
Gluconate; Vitamin D Nos Isoniazid/Pyridoxine Hydrochloride/Sulfamethoxazole /Trimethoprim	N	S	Unknown	Not Reported
Carmellose Sodium	N	S	Unknown	Not Reported
Carmellose Sodium	N	S	Unknown	Not Reported
Carmellose Sodium	N	S	Ophthalmic	Not Reported
Acetylsalicylic Acid;Citric Acid; Sodium Bicarbonate	N	S	Unknown	Not Reported
Calcium Carbonate;Vitamins Nos	N	S	Unknown	Not Reported
Benzydamine Hydrochloride	N	S	Unknown	Not Reported
1,3-Butandiol;Dexpanthenol; Dimethyl Sulfoxide;Glycerol	N	S	Oral	Not Reported
Gramicidin	N	S	Unknown	Not Reported
Betamethasone;Sodium	N	S	Unknown	Not Reported
Phosphate Infa-3 [Gramicidin;Neomycin Sulfate;Polymyxin B]	N	S	Unknown	Not Reported



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Macrogol 4000	N	S	Unknown	Not Reported
Calcium And Vitamin D	N	S	Unknown	Not Reported
Cholecalciferol	N	S	Unknown	Not Reported
Difenoxin Hydrochloride	N	S	Unknown	Not Reported
Glicerin	N	S	Oral	Not Reported
Gramicidin\Neomycin\Polymyxin B Sulfate	N	S	Unknown	Not Reported
Macrogol;Potassium Chloride; Sodium Bicarbonate	N	S	Unknown	Not Reported
Nitroglycerin	N	S	Oral	Not Reported
E-Vitamin	N	S	Unknown	Not Reported
Ambroxol Hydrochloride	N	S	Unknown	Not Reported
Atropine Sulfate	N	S	Oral	Not Reported
Atropine Sulfate	N	S	Oral	Not Reported
Acetaminophen; Pseudoephedrine	N	S	Unknown	Not Reported
Betamethasone;Mupirocin	N	S	Topical	Not Reported
Bromhexine;Sulfamethoxazole; Trimethoprim	N	S	Unknown	Not Reported
Calcitriol;Calcium Carbonate; Zinc	N	S	Unknown	Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown	Not Reported
Fructose;Glycerin;Sodium Chloride	N	S	Oral	Not Reported
Mentha Arvensis	N	S	Unknown	Not Reported
Calcium Phosphate	N	S	Unknown	Not Reported
Calcium Carbonate; Colecalciferol;Magnesium Carbonate	N	S	Unknown	Not Reported
Carmellose Sodium	N	S	Unknown	Not Reported
Minerals\Vitamins	N	S	Unknown	Not Reported
Calcium Amino Acid Chelate;	N	S	Unknown	Not Reported
Calcium Carbonate; Colecalciferol;Magnesium				
Minerals\Vitamins	N	S	Unknown	Not Reported



N	S	Unknown		Not Reported
N	S	Oral		Not Reported
N	S	Topical		Not Reported
N	S	Unknown		Not Reported
N	S	Unknown		Not Reported
N	S	Unknown		Not Reported
N	S	Unknown		Not Reported
N	S	Unknown		Not Reported
N	S	Unknown		Not Reported
N	S	Unknown		Not Reported
N	S	Unknown		Not Reported
N	S	Unknown		Not Reported
N	S	Unknown		Not Reported
N	S	Unknown		Not Reported
N	S	Unknown		Not Reported
N	S	Ophthalmic		Not Reported
N	S	Ophthalmic		Not Reported
N	S	Unknown		Not Reported
N	S	Intravenous (not otherwise specified)	263 DAY	Not Reported
N	S	Intravenous (not otherwise specified)	263 DAY	Not Reported
N	S	Intravenous (not otherwise specified)	263 DAY	Not Reported
N	S	Intravenous (not otherwise specified)	263 DAY	Not Reported
N	S	Intravenous (not otherwise specified)	263 DAY	Not Reported
N	S	Intravenous (not otherwise specified)	263 DAY	Not Reported
	X X X X X X X X X X X X X X X X X X X		N S Oral N S Topical N S Unknown N S Intravenous (not otherwise specified)	N S Oral N S Topical N S Unknown N S Intravenous (not otherwise specified)



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Inflectra [Infliximab]	N	S	Intravenous (not otherwise specified)		263 DAY	Not Reported
Inflectra [Infliximab]	N	S	Intravenous (not otherwise specified)		263 DAY	Not Reported
Inflectra [Infliximab]	N	S	Intravenous (not otherwise specified)		263 DAY	Not Reported
Inflectra [Infliximab]	N	S	Intravenous (not otherwise specified)		263 DAY	Not Reported
Diflucan	N	S	Unknown			Not Reported
Solu-Medrol	N	S	Intravenous (not otherwise specified)			Not Reported
Apo Hydromorphone	N	S	Endocervical			Not Reported
Pronutrients Calcium + D	Ν	S	Unknown			Not Reported
Salix [Salix Alba Extract]	Ν	S	Intramuscular	Solution (Except Syrup)		Not Reported
Dimethyl Sulfoxide	Ν	S	Unknown			Not Reported
Cortenema	Ν	S	Unknown			Not Reported
Empracet [Paracetamol]	Ν	S	Unknown			Not Reported
Flagyl [Metronidazole Benzoate]	Ν	S	Unknown			Not Reported
Imovan	Ν	S	Unknown			Not Reported
Sulcrate	Ν	S	Unknown			Not Reported
Versed	Ν	S	Unknown			Not Reported
Ambroxol;Cetirizine Hydrochloride	N	S	Unknown			Not Reported
Calcium Carbonate; Ergocalciferol	N	S	Unknown			Not Reported
Glycerol;Sodium Stearate	N	S	Unknown			Not Reported
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate; Sodium Chloride;So	N	S	Unknown			Not Reported
Xantofyl Palmitate	N	S	Unknown			Not Reported
Align	N	S	Unknown			Not Reported
Ciprofloxacin Hydrochloride	N	S	Intravenous (not otherwise specified)			Not Reported



Ciprofloxacin Hydrochloride Diflucan	N N	S S	Unknown	Not Reported Not Reported
Diflucan Entyvio	N N	S S	Unknown	Not Reported Not Reported
Entyvio	N	S	Intravenous (not otherwise specified)	Not Reported
Entyvio	N	S	Intravenous (not otherwise specified)	Not Reported
Ergocalciferol	N	S	Unknown	Not Reported
Hydrocortisone Butyrate	N	S	Unknown	Not Reported
Midazolam Hydrochloride	N	S	Unknown	Not Reported
Vitamin D [Ergocalciferol]	N	S	Unknown	Not Reported
Diphenhydramine Hydrochloride; Zinc Oxide	N	S	Unknown	Not Reported
Metoclopramide Hydrochloride	N	S	Unknown	Not Reported
Zinc Chloride	Ν	S	Unknown	Not Reported
Glycerinum	N	S	Oral	Not Reported
Calcium Carbonate; Colecalciferol;Zinc	N	S	Intra-articular	Not Reported
Sulfamethoxazole	Ν	S	Unknown	Not Reported
Lutein\Zeaxanthin	Ν	S	Unknown	Not Reported
Lutein\Zeaxanthin	N	S	Oral	Not Reported
Ascorbic Acid;Macrogol; Potassium Chloride;Sodium Ascorbate;Sodium Chlo	N	S	Unknown	Not Reported
Ascorbic Acid;Macrogol; Potassium Chloride;Sodium	N	S	Urethral	Not Reported
Ascorbate;Sodium Chlo Sulfamethoxazole, Trimethoprim, Bromhexine Hydrochloride And Clorprena	N	S	Unknown	Not Reported
Sodium Carboxymethylcellulose	N	s	Ophthalmic	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Not Reported



Dexpanthenol	N	S	Unknown	Not Reported
Sulfatrim [Sulfadiazine;	Ν	S	Unknown	Not Reported
Trimethoprim] Caltrate + D [Calcium Carbonate;Colecalciferol]	N	S	Unknown	Not Reported
Acetaminophen;Codeine Phosphate	N	S	Unknown	Not Reported
Calcitriol	Ν	S	Intra-articular	Not Reported
Sodium Bicarbonate	N	S	Unknown	Not Reported
Acetaminophen	N	S	Auricular (otic)	Not Reported
Acetaminophen	Ν	S	Subcutaneous	Not Reported
Acetaminophen	Ν	S	Unknown	Not Reported
Acetaminophen	Ν	S	Unknown	Not Reported
Glyceryl Trinitrate	Ν	S	Unknown	Not Reported
Acetylsalicylic Acid	Ν	S	Unknown	Not Reported
Macrogol	Ν	S	Unknown	Not Reported
Hydrochlorothiazide	N	S	Unknown	Not Reported
Hydrochlorothiazide	Ν	S	Unknown	Not Reported
Simvastatin	Ν	S	Unknown	Not Reported
Simvastatin	Ν	S	Unknown	Not Reported
Methotrexate	N	S	Unknown	Not Reported
Diphenhydramine	N	S	Unknown	Not Reported
Pseudoephedrine	N	S	Unknown	Not Reported
Magnesium Oxide	N	S	Unknown	Not Reported
Nystatin	Ν	S	Unknown	Not Reported
Methylprednisolone Sodium Succinate	N	S	Unknown	Not Reported
Midazolam	N	S	Unknown	Not Reported
Oxybutynin Hydrochloride	N	S	Unknown	Not Reported
Ditropan	N	S	Unknown	Not Reported
Morphine	N	S	Unknown	Not Reported
Zopiclone	N	S	Unknown	Not Reported



Zopiclone				<u>-</u>	
Mesalazine N S Unknown Not Reported Fentanyl N S Unknown Not Reported Isoniazid N S Unknown Not Reported Acetic Acid; Triamcinolone N S Unknown Not Reported Calcium Card; Triamcinolone N S Unknown Not Reported Gluconate; Calcium N S Unknown Not Reported Gluconate; Calcium N S Unknown Not Reported Fentanyl Citrate N S Unknown Not Reported Fentanyl Citrate N S <td< td=""><td>Zopiclone</td><td>N</td><td>S</td><td>Unknown</td><td>Not Reported</td></td<>	Zopiclone	N	S	Unknown	Not Reported
Fentanyl	Mesalazine	N	S	Unknown	Not Reported
Isoniazid N S Unknown Not Reported Macrogol 3350 N S Unknown Not Reported Acetic Acid; Triamcinolone Acetonide Bifidobacterium Infantis N S Unknown Not Reported Acetonide Bifidobacterium Infantis N S Unknown Not Reported Calcium Carbonate; Calcium Not Reported Gluconate; Calcium Acetonide N S Unknown Not Reported Gluconate; Calcium Lactate Ciprofloxacin N S Unknown Not Reported Fentanyl Citrate N S Unknown Not Reported Filuconazole N S Unknown Not Reported Filuconazole N S Unknown Not Reported Framycetin Sulfate N S Unknown Not Reported Fructose N S Unknown Not Reported Fructose N S Unknown Not Reported Hydrocortisone N S Unknown Not Reported Magnesium Carbonate N S Unknown Not Reported Sodium Stearate N S Unknown Not Reported Sodium Stearate N S Unknown Not Reported Sucralfate N S Unknown Not Reported Sucralfate N S Unknown Not Reported Fluccinolone Acetonide; N S Unknown Not Reported Sucralfate N S Unknown Not Reported Fluccinolone Acetonide; N S Unknown Not Reported Pluccinolone Acetonide; N S Unknown Not Reported Fluccinolone Acetonide; N S Unknown Not Reported Pluccinolone Acetonide; N S Unknown Not Reported Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Endocervical Not Reported Polyethylene Glycol 4000 N S Endocervical Not Reported Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S S Unknown Not Reported Polyethylene Glycol 4000 N S S Unknown	Mesalazine	N	S	Unknown	Not Reported
Macrogol 3350 N S Unknown Not Reported Acetic Acid; Triamcinolone Acid; Not Reported Polyethylene Glycol 4000 Not Senoted Polyethylene Glycol 4000 Not	Fentanyl	N	S	Unknown	Not Reported
Acetic Acid; Triamcinolone Acetonide Biffdobacterium Infantis N S Unknown Calcium Carbonate; Calcium Gluconate; Calcium Lactate Ciprofloxacin N S Unknown Not Reported Not Reported Filuconazole Framycetin Sulfate N S Unknown Not Reported N S Unknown Not Reported Fructose N S Unknown Not Reported Hydrocortisone N S Unknown Not Reported Magnesium Carbonate N S Unknown Not Reported Ubidecarenone N S Unknown Not Reported	Isoniazid	N	S	Unknown	Not Reported
Acetonide Bifidobacterium Infantis N S Unknown Not Reported Gluconate;Calcium Lactate Ciprofloxacin N S Unknown Not Reported Gluconate;Calcium Lactate Ciprofloxacin N S Unknown Not Reported Fentanyl Citrate Filuconazole N S Unknown Not Reported Framycetin Sulfate N S Unknown Not Reported Fructose N S Unknown Not Reported Fructose N S Unknown Not Reported Hydrocortisone N S Unknown Not Reported Magnesium Carbonate N S Unknown Not Reported Sodium Stearate N S Unknown Not Reported Ubidecarenone N S Unknown Not Reported Flucoinolone Acetonide; N S Unknown Not Reported Not Reported Not Reported Flucinolone Acetonide; N S Unknown Not Reported Not Reported Not Reported Polyethylene Glycol 4000 N S Endocervical Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Unknown Not Reported	Macrogol 3350	N	S	Unknown	Not Reported
Calcium Carbonate; Calcium Gluconate; Calcium Lactate N S Unknown Not Reported Ciprofloxacin N S Unknown Not Reported Fentanyl Citrate N S Unknown Not Reported Fluconazole N S Unknown Not Reported Framycetin Sulfate N S Unknown Not Reported Framycetin Sulfate N S Unknown Not Reported Fructose N S Unknown Not Reported Hydrocortisone N S Unknown Not Reported Magnesium Carbonate N S Unknown Not Reported Pyridoxine N S Unknown Not Reported Sodium Stearate N S Unknown Not Reported Sucralfate N S Unknown Not Reported Ubidecarenone N S Unknown Not Reported Fluctioniolone Acetonide; Neomycin Sulfate; Polymyxin B Sulfate N S		N	S	Unknown	Not Reported
Gluconate; Calcium Lactate		N	S	Unknown	Not Reported
Fentanyl Citrate N S Unknown Not Reported Fluconazole N S Unknown Not Reported Fluconazole N S Unknown Not Reported Framycetin Sulfate N S Unknown Not Reported Fructose N S Unknown Not Reported Hydrocortisone N S Unknown Not Reported Magnesium Carbonate N S Unknown Not Reported Pyridoxine N S Unknown Not Reported Sodium Stearate N S Unknown Not Reported Sodium Stearate N S Unknown Not Reported Ubidecarenone N S Unknown Not Reported Ubidecarenone N S Unknown Not Reported Fluocinolone Acetonide; N S Unknown Not Reported Fluocinolone Acetonide; N S Unknown Not Reported Neomycin Sulfate; Polymyxin B Sulfate Fluticasone Propionate; N S Unknown Not Reported Salmeterol Xinafoate Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Endocervical Not Reported Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Oral Not Reported	·	N	S	Unknown	Not Reported
Fluconazole N S Unknown Not Reported Framycetin Sulfate N S Unknown Not Reported Fractose N S Unknown Not Reported Hydrocortisone N S Unknown Not Reported Hydrocortisone N S Unknown Not Reported Magnesium Carbonate N S Unknown Not Reported Pyridoxine N S Unknown Not Reported Sodium Stearate N S Unknown Not Reported Sucralfate N S Unknown Not Reported Ubidecarenone N S Unknown Not Reported Ubidecarenone N S Unknown Not Reported Fluocinolone Acetonide; N S Unknown Not Reported Neomycin Sulfate; Polymyxin B Sulfate Fluticasone Propionate; N S Unknown Not Reported Salmeterol Xinafoate Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Endocervical Not Reported Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Oral		N	S	Unknown	Not Reported
Framycetin Sulfate N S Unknown Not Reported Fructose N S Unknown Not Reported Hydrocortisone N S Unknown Not Reported Magnesium Carbonate N S Unknown Not Reported Pyridoxine N S Unknown Not Reported Sodium Stearate N S Unknown Not Reported Sucralfate N S Unknown Not Reported Ubidecarenone N S Unknown Not Reported Ubidecarenone N S Unknown Not Reported Flucionolone Acetonide; N S Unknown Not Reported Neomycin Sulfate; Polymyxin B Sulfate Fluticasone Propionate; N S Unknown Not Reported Salmeterol Xinafoate Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Endocervical Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Oral	Fentanyl Citrate	N	S	Unknown	Not Reported
Fructose N S Unknown Not Reported Hydrocortisone N S Unknown Not Reported Magnesium Carbonate N S Unknown Not Reported Pyridoxine N S Unknown Not Reported Sodium Stearate N S Unknown Not Reported Sucralfate N S Unknown Not Reported Ubidecarenone N S Unknown Not Reported Ubidecarenone N S Unknown Not Reported Flucinolone Acetonide; N S Unknown Not Reported Neomycin Sulfate; Polymyxin B Sulfate Fluticasone Propionate; N S Unknown Not Reported Salmeterol Xinafoate Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Endocervical Not Reported Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Oral Not Reported	Fluconazole	N	S	Unknown	Not Reported
Hydrocortisone N S Unknown Not Reported Magnesium Carbonate N S Unknown Not Reported Pyridoxine N S Unknown Not Reported Sodium Stearate N S Unknown Not Reported Sucralfate N S Unknown Not Reported Ubidecarenone N S Unknown Not Reported Fluocinolone Acetonide; N S Unknown Not Reported Fluocinolone Acetonide; N S Unknown Not Reported Neomycin Sulfate; Polymyxin B Sulfate Fluticasone Propionate; N S Unknown Not Reported Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Endocervical Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Oral Not Reported	Framycetin Sulfate	N	S	Unknown	Not Reported
Magnesium CarbonateNSUnknownNot ReportedPyridoxineNSUnknownNot ReportedSodium StearateNSUnknownNot ReportedSucralfateNSUnknownNot ReportedUbidecarenoneNSUnknownNot ReportedFluocinolone Acetonide; Neomycin Sulfate;Polymyxin B SulfateNSUnknownNot ReportedFluticasone Propionate; Salmeterol Xinafoate Polyethylene Glycol 4000NSUnknownNot ReportedPolyethylene Glycol 4000NSUnknownNot ReportedPolyethylene Glycol 4000NSEndocervicalNot ReportedPolyethylene Glycol 4000NSUnknownNot ReportedPolyethylene Glycol 4000NSUnknownNot ReportedPolyethylene Glycol 4000NSUnknownNot ReportedPolyethylene Glycol 4000NSOralNot Reported	Fructose	N	S	Unknown	Not Reported
Pyridoxine N S Unknown Not Reported Sodium Stearate N S Unknown Not Reported Sucralfate N S Unknown Not Reported Ubidecarenone N S Unknown Not Reported Ubidecarenone N S Unknown Not Reported Fluocinolone Acetonide; N S Unknown Not Reported Neomycin Sulfate; Polymyxin B Sulfate Fluticasone Propionate; Salmeterol Xinafoate Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Endocervical Not Reported Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Oral Not Reported	Hydrocortisone	N	S	Unknown	Not Reported
Sodium Stearate N S Unknown Not Reported Sucralfate N S Unknown Not Reported Ubidecarenone N S Unknown Not Reported Ubidecarenone N S Unknown Not Reported Fluocinolone Acetonide; N S Unknown Not Reported Neomycin Sulfate; Polymyxin B Sulfate Fluticasone Propionate; N S Unknown Not Reported Salmeterol Xinafoate Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Endocervical Not Reported Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Oral Not Reported	Magnesium Carbonate	N	S	Unknown	Not Reported
Sucralfate N S Unknown Not Reported Ubidecarenone N S Unknown Not Reported Fluocinolone Acetonide; N S Unknown Not Reported Neomycin Sulfate; Polymyxin B Sulfate Fluticasone Propionate; N S Unknown Not Reported Salmeterol Xinafoate Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Endocervical Not Reported Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Oral Not Reported	Pyridoxine	N	S	Unknown	Not Reported
Ubidecarenone N S Unknown Not Reported Fluocinolone Acetonide; N S Unknown Not Reported Neomycin Sulfate; Polymyxin B Sulfate Fluticasone Propionate; N S Unknown Not Reported Salmeterol Xinafoate Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Endocervical Not Reported Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Oral Not Reported	Sodium Stearate	N	S	Unknown	Not Reported
Fluocinolone Acetonide; Neomycin Sulfate;Polymyxin B Sulfate Fluticasone Propionate; Salmeterol Xinafoate Polyethylene Glycol 4000 N S Unknown Not Reported Not Reported Not Reported Not Reported Not Reported Polyethylene Glycol 4000 N S Endocervical Polyethylene Glycol 4000 N S Unknown Not Reported Not Reported Not Reported Not Reported Polyethylene Glycol 4000 N S Oral Not Reported	Sucralfate	N	S	Unknown	Not Reported
Neomycin Sulfate; Polymyxin B Sulfate Fluticasone Propionate; Salmeterol Xinafoate Polyethylene Glycol 4000 N S Endocervical Polyethylene Glycol 4000 N S Unknown Not Reported Not Reported Not Reported Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Oral Not Reported Not Reported	Ubidecarenone	N	S	Unknown	Not Reported
Fluticasone Propionate; N S Unknown Not Reported Salmeterol Xinafoate Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Endocervical Not Reported Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Oral Not Reported	Neomycin Sulfate;Polymyxin B	N	S	Unknown	Not Reported
Polyethylene Glycol 4000 N S Endocervical Not Reported Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Oral Not Reported	Fluticasone Propionate; Salmeterol Xinafoate			Unknown	·
Polyethylene Glycol 4000 N S Unknown Not Reported Polyethylene Glycol 4000 N S Oral Not Reported	• • •	N	S	Unknown	•
Polyethylene Glycol 4000 N S Oral Not Reported	Polyethylene Glycol 4000	N	S	Endocervical	Not Reported
	Polyethylene Glycol 4000	N	S	Unknown	Not Reported
Mupirocin Calcium N C Topical Not Reported	Polyethylene Glycol 4000	N	S	Oral	Not Reported
	Mupirocin Calcium	N	С	Topical	Not Reported



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Valsartan

Benadryl A

Metoclopramide Hydrochloride

Metoclopramide Hydrochloride

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Not Reported

Not Reported

Not Reported

Not Reported

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		•	•				Officiowii				•
		Calcium Carbor Cholecalciferol;			Ν	С					Not Reported
		Hydrochlorothia			N	С					Not Reported
		Amoxicillin	2100		N	Č					Not Reported
		Calcium Ergoca	lciferol		N	Č					Not Reported
		Lomotil [Atropin			N	Č	Unknown				Not Reported
		Diphenoxylate H					OTIKITOWIT				
		Maxeran	.,,		Ν	С	Oral				Not Reported
		Calcium Carbor	ate/Vitamin D3		Ν	С					Not Reported
		Diphenoxylate H	Hydrochloride		Ν	С					Not Reported
		Neomycin Sulfa			N	С					Not Reported
		Sodium Stearat	е		N	С					Not Reported
		Calcium Glucon	ate		Ν	С					Not Reported
		Ammonium Chl	oride		Ν	С					Not Reported
		Calcium Lactate			Ν	С					Not Reported
		Phosphate;Ergo									·
			le\Trimethoprim			S					Not Reported
		Naphazoline	•			S					Not Reported
		Promethazine H	lydrochloride			S					Not Reported
FDA Received Date	Case:	<u>Case</u>	<u>Гуре</u>	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Mar-2023	19454	468 EXPE	DITED (15-DAY)	Y		HO, OT	CA-PFIZER INC 2019070530	C-	71 YR	Female	CAN
Preferred Term		Product		Comp.	OTO	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Abdominal Pain; Anae		Pantoprazole			Ν	S	Unknown	Unk			Unknown
Chronic Sinusitis; Coli Colitis Ulcerative; Constipation; Drug	tis;	Inflectra			N	S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks			Pfizer
Ineffective; Dyspepsia Erythema; Female Ge	enital	Inflectra			N	S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks			Pfizer
Tract Fistula; Frequen Bowel Movements; Haematochezia;	it	Inflectra			N	S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks			Pfizer
Headache; Infusion Related Reaction; Ma	cular	Inflectra			N	S	Intravenous (not	5 Mg/Kg, Every 6 Weeks			Pfizer

Note: If the field is blank, there is no data.

С

С

С

С

Oral

Oral

Unknown

Ν

Ν

Ν

Ν



Degeneration; Malaise;
Nausea; Off Label Use;
Oral Candidiasis; Pain;
Paraesthesia Oral;
Procedural Pain; Proctitis;
Pyrexia; Radiculopathy;
Rectal Haemorrhage;
Therapeutic Product Effect
Incomplete; Vaginal
Discharge; Vaginal
Flatulence; Weight
Decreased

			otherwise specified)		
Inflectra	N	S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks	Pfizer
Inflectra	N	S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks	Pfizer
Inflectra	N	S	Intravenous (not otherwise specified)	10 Mg/Kg, Every 6 Weeks	Pfizer
Inflectra	N	S	Intravenous (not otherwise specified)	10 Mg/Kg, Every 6 Weeks 132 DAY	Pfizer
Atorvastatin Calcium	N	S	Unknown	Unk	Pfizer
Atorvastatin Calcium	N	S	Oral	Unk	Pfizer
Alprazolam	N	S	Unknown	0.25 Mg	Pfizer
Alprazolam	N	S	Unknown	Unk	Pfizer
Diflucan	N	S		Unk	Pfizer
Solu-Medrol	N	S	Intravenous (not otherwise specified)	Unk	Pfizer
Methylprednisolone Sodium Succinate	N	S	Intravenous (not otherwise specified)	Unk	Pfizer
Midazolam	N	S		2 Df	Pfizer
Midazolam	N	S		2 Df (Pre-Filled Syringe)	Pfizer
Pregabalin	N	S	Unknown	Unk	Pfizer
Pregabalin	N	S	Unknown	150 Mg	Pfizer
Azithromycin	N	S	Unknown	Unk	Pfizer
Lomotil	N	S	Oral	Unk Unk, Qid	Pfizer
Lomotil	N	S	Oral	4 Df, 1x/Day, Qd	Pfizer
Lomotil	N	S	Unknown	Unk	Pfizer
Nitroglycerin	N	S	Oral	Unk	Pfizer
Pronutrients Calcium + D	N	S	Unknown	Unk	Pfizer
Sodium Chloride Bacteriostatic	N	S	Unknown	Unk	Pfizer
Hydromorphone Hydrochloride	N	S	Unknown	Unk	Pfizer
Hydromorphone Hydrochloride	N	S	Endocervical	Unk	Pfizer



			Dotaliou I	oport	
Adalimumab	N	S	Subcutaneous	Unk Solution (Except Syrup)	Pfizer
Potassium Chloride	N	S	Unknown	Unk	Pfizer
Potassium Chloride	N	S		Unk	Pfizer
Sodium Bicarbonate	N	S	Unknown	Unk	Pfizer
Neomycin Sulfate	N	S	Unknown	Unk	Pfizer
Fluconazole	N	S	Unknown		Pfizer
Hydrocortisone	N	S	Unknown		Pfizer
Sertraline Hcl	N	S	Unknown	25 Milligram, Qd	Pfizer
Acetaminophen W/Codeine Phosphate	N	S		Unk	Not Reported
Sodium Chloride	N	S	Nasal	Formulation:Pellet	Not Reported
Sodium Chloride	N	S	Nasal	Unk	Not Reported
Sodium Chloride	N	S	Respiratory (inhalation)	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Other	Unk	Not Reported
Bactrim	N	S	Unknown	Unk	Not Reported
Bactrim	N	S	Nasal	Unk	Not Reported
Apo Hydromorphone	N	S	Endocervical	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk	Takeda
Pentasa	N	S	Unknown	Unk	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Acetaminophen; Dextropropoxyphene	N	S	Oral	Unk	Not Reported
Avamys	N	S	Unknown	Unk (Spray, Metered)	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	0.122 Gram	Not Reported
Biaxin XI	N	S	Unknown	Unk (Tablet, Extended	Not Reported



				Release)		
Clarithromycin	N	S	Unknown	Unk		Not Reported
Clotrimazole	N	S	Unknown	Unk		Not Reported
Cupric Oxide	N	S	Unknown	Unk		Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk		Not Reported
Desonide	N	S	Unknown	Unk		Not Reported
Dilaudid	N	S	Unknown	Unk		Not Reported
Dilaudid	N	S	Unknown	1 Dosage Form, Bid		Not Reported
Diphenhydramine [Diphenhydramine Hydrochloride]	N	S	Unknown	Unk		Not Reported
Entocort	N	S	Unknown	Unk, Extended		Not Reported
Entocort	N	S	Oral	Unk		Not Reported
Ertapenem Sodium	N	S	Unknown	Unk		Not Reported
Nadolol	N	S	Unknown	Unk		Not Reported
Nadolol	N	S	Unknown	40 Milligram		Not Reported
Flovent	N	S	Unknown	Unk		Not Reported
Humira	N	S	Subcutaneous	Unk Solution (Except Syrup)	2190 DAY	Not Reported
Humira	N	S	Unknown	Unk Solution (Except Syrup)		Not Reported
Macrogol/Potassium Chloride/Sodium Bicarbonate	N	S	Unknown	Unk		Not Reported
Magnesium Sulfate	N	S	Unknown	Unk		Not Reported
Magnesium Sulfate	N	S	Intramuscular	Unk		Not Reported
Nicoderm	N	S	Transdermal	Unk		Not Reported
Nicoderm	N	S	Unknown	Unk		Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk		Not Reported
Prednisone	N	S	Unknown	Unk		Not Reported
Pulmicort	N	S	Unknown	Unk		Not Reported
Pulmicort	N	S	Oral	Unk		Not Reported



Pulmicort	N	S	Respiratory (inhalation)	Unk	Not Reported
Refresh Tears	N	S	Intraocular	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Refresh Tears	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Vitamin E Nos	N	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Unk	Not Reported
Glycerinum	N	S	Oral	Unk	Not Reported
Macrogol 3350/Potassium Chloride/Sodium Bicarbonate/Sodium	N	S	Urethral	Unk	Not Reported
Chloride/Sodium Sulfate Difenoxin Hydrochloride	N	S	Unknown	Unk	Not Reported
Isoniazid/Pyridoxine Hydrochloride/Sulfamethoxazole /Trimethoprim	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Glycerine	N	S	Unknown	Unk	Not Reported
Infa-3 [Gramicidin;Neomycin Sulfate;Polymyxin B]	N	S	Unknown	Unk	Not Reported
Ms Ir	N	S	Unknown	Unknown	Not Reported
Sinus Rinse	N	S	Unknown	Unk	Not Reported
Sinus Rinse	N	S	Nasal	Unk	Not Reported
Sinus Rinse	N	S	Other	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Mupirocin	N	S	Unknown	Unk	Not Reported
Betamethasone [Betamethasone Dipropionate]	N	S	Unknown	Unk	Not Reported
Habitrol	N	S	Other	Unk	Not Reported



				<u> </u>	
Kenalog	N	S	Intra-articular	Unk	Not Reported
Statex	N	S	Unknown	Unk	Not Reported
Betaderm	N	S	Unknown	Unk	Not Reported
Calcium Amino Acid Chelate/Calcium Carbonate/Colecalciferol/Magne sium Amino Acid Chelate/Magnesium Oxide Heavy	N	S	Unknown	Unk	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Acetaminophene	N	S	Unknown	Unk	Not Reported
Calcium Carbonate/Colecalciferol/Zinc	N	S	Intra-articular	Unknown	Not Reported
Sulfamethoxazole	N	S	Unknown	Unknown	Not Reported
Lutein\Zeaxanthin	N	S	Unknown	Unk	Not Reported
Lutein\Zeaxanthin	N	S	Oral	Unk	Not Reported
Atorvastatin	N	S	Unknown	Unknown	Not Reported
Cetirizine [Cetirizine Hydrochloride]	N	S	Unknown	Unk	Not Reported
Cetirizine [Cetirizine Hydrochloride]	N	S		Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Ascorbic Acid/Macrogol/Potassium Chloride/Sodium Ascorbate/Sodium Chloride/Sodium Sulfate	N	S	Urethral	Unk	Not Reported
Ascorbic Acid/Macrogol/Potassium Chloride/Sodium Ascorbate/Sodium Chloride/Sodium Sulfate	N	S	Urethral	Unk	Not Reported
Pms Azithromycin	N	S	Unknown	Unk	Not Reported
Nicomorphine	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole, Trimethoprim, Bromhexine Hydrochloride And Clorprena	N	S	Unknown	Unk	Not Reported

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Note: If the field is blank, there is no data.



Cholecalciferol	N	S	Unknown	Unk	Not Reported
Pseudoephedrine	N	S	Unknown	Unk	Not Reported
Gramicidin\Neomycin\Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Nasal	Unk	Not Reported
Sodium Chloride	N	S	Endosinusial	Unk	Not Reported
Potassium Chloride	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	N	S	Ophthalmic	Unk	Not Reported
Acetylsalicylic Acid/Citric Acid/Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Betamethasone/Mupirocin	N	S	Topical	Unk	Not Reported
Dexpanthenol	N	S	Unknown	Unk	Not Reported
DI-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
Dulcolax	N	S	Unknown	Unk	Not Reported
Sulfatrim	N	S	Unknown	Unk	Not Reported
Apo-Hydrochlorothiazide	N	S	Endocervical	100 Mg	Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Apo-Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
Salix [Salix Alba Extract]	N	S	Intramuscular	Solution (Except Syrup)	Not Reported
Dimethyl Sulfoxide	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Oral	Unk	Takeda
Budesonide	N	S	Cutaneous	Unk	Takeda
Budesonide	N	S	Other	Unk	Takeda
Budesonide	N	S	Subcutaneous	Unk	Takeda
Caltrate + D [Calcium Carbonate;Colecalciferol]	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk Unk, Tid	Not Reported



				<u> </u>	
Acetaminophen	N	S	Unknown	Unk	Not Reported
Diphenoxylate/Atropine	N	S	Oral	Unk	Not Reported
Diphenoxylate/Atropine	N	S	Unknown	1 Df	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Transplacental	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Fluticasone Propionate	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole/Trimethoprim	N	S	Unknown	200 Milligram	Not Reported
Sulfamethoxazole/Trimethoprim	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk, Suspension For Infusion	Not Reported
Triamcinolone Acetonide	N	S	Intraocular	Unk	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk	Not Reported
Nicotine [Nicotine Polacrilex]	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Glycerol	N	S	Oral	Unk	Not Reported
Tocopherols Mixed	N	S	Unknown	Unk	Not Reported
Bifidobacterium Infantis	N	S		Unk	Not Reported
Bifidobacterium Infantis	N	S		Unk	Not Reported
Empracet [Paracetamol]	N	S		Unk	Not Reported
Flagyl [Metronidazole Benzoate]	N	S		Unk	Not Reported
Imovan	N	S		Unk	Not Reported
Sulcrate	N	S		Unk	Not Reported
Zopiclone	N	S		Unk	Not Reported
Cortenema	N	S		Unk	Not Reported
Oxybutynin Hydrochloride	N	S		Unk	Not Reported
Fentanyl [Fentanyl Citrate]	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Ciprofloxacin Hydrochloride	N	S	Intravenous (not	Unk	Not Reported



			otherwise specified)		
Entyvio	N	S	Intravenous (not otherwise specified)	200 Mg, 3x/Day	Not Reported
Versed	N	S	, ,	2 Df	Not Reported
Salofalk [Mesalazine]	N	S		Unk Unk, 3x/Day	Not Reported
Ditropan	N	S		Unk	Not Reported
Infliximab Bs Pfizer	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	N	S	Unknown	Unk	Not Reported
Amoxicillin [Amoxicillin	N	S	Unknown	Unk	Not Reported
Trihydrate] Gramicidin/Neomycin Sulfate/Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole/Trimethoprim	N	S	Unknown	200 Milligram	Not Reported
Sulfamethoxazole/Trimethoprim	N	S		Unk	Not Reported
Isoniazid	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Endocervical	100 Milligram	Not Reported
Ambroxol [Ambroxol Hydrochloride]	N	S	Unknown	Unk	Not Reported
Calcium & Vitamin D3	N	S	Unknown	Unk	Not Reported
Atropine Sulfate/Diphenoxylate Hydrochloride	N	S	Oral	1 Dosage Form	Not Reported
Atropine Sulfate/Diphenoxylate Hydrochloride	N	S	Oral	4 Dosage Form, Qd	Not Reported
Atropine Sulfate/Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Azithromycin Dihydrate	N	S	Unknown	Unk	Not Reported
Ambroxol/Cetirizine	N	S	Unknown	Unk	Not Reported
Hydrochloride Calcitriol/Calcium Carbonate/Zinc	N	S	Unknown	Unk	Not Reported
Calcium Carbonate/Ergocalciferol	N	S	Unknown	Unk	Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported



			201411041	· · · · · · · · · · · · · · · · · · ·	
Triamcinolone [Triamcinolone Diacetate]	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Endocervical	Unk	Not Reported
Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Macrogol/Potassium Chloride/Sodium Bicarbonate/Sodium Chloride	N	S	Unknown	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Loperamide [Loperamide Hydrochloride]	N	S	Oral	Unk	Not Reported
Loperamide [Loperamide Hydrochloride]	N	S	Oral	1 Dosage Form, Q6hr	Not Reported
Loperamide [Loperamide Hydrochloride]	N	S	Oral	1 Dosage Form	Not Reported
Loperamide [Loperamide Hydrochloride]	N	S	Oral	4 Dosage Form, Qd	Not Reported
Imodium	N	S	Unknown	Unk	Not Reported
Moviprep [Ascorbic Acid; Macrogol 3350;Potassium Chloride;Sodium Ascorb	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride + Ammonium Chloride + Sodium Citrate	N	S	Unknown	Unk	Not Reported
Glycerol/Sodium Stearate	N	S	Unknown	Unk	Not Reported
Mupirocin Calcium	N	S	Topical	Unk	Not Reported
Cupric Oxide/Folic Acid/Nicotinic Acid/Zinc	N	S	Unknown	Unk	Not Reported
Calcium Carbonate; Cholecalciferol;Sodium	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown	Unk	Not Reported
Glycerin [Glycerol]	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Fructose/Glycerol/Sodium Chloride	N	S	Unknown	Unk	Not Reported
Fructose/Glycerol/Sodium	N	S	Oral	Unk	Not Reported



0.1.1.1					
Chloride Vedolizumab	N	S	Unknown	200 Milligram, Tid	Not Reported
Align	N	S	Unknown	Unk	Not Reported
Calcium Citrate	N	S	Unknown	Unk	Not Reported
Gramicidin/Polymyxin B	N	S	Unknown	Unk	Not Reported
Atropine Sulfate	N	S	Oral	1 Dosage Form	Not Reported
Atropine Sulfate	N	S	Oral	Unk	Not Reported
Atropine Sulfate	N	S	Oral	4 Dosage Form	Not Reported
Atropine Sulfate	N	S	Unknown	Unk	Not Reported
Mezavant	N	S	Unknown	Unk	Not Reported
Benzydamine Hydrochloride	N	S	Unknown	Unk	Not Reported
Calcitriol	N	S	Intra-articular	Unk	Not Reported
Mentha Arvensis	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium Anhydrous	Ν	S	Unknown	Unk	Not Reported
Zinc Chloride	Ν	S	Unknown	Unk	Not Reported
Macrogol/Propylene	N	S	Other	Unk	Not Reported
Glycol/Sodium Chloride Benzydamine	N	S	Unknown		Not Reported
Bifidobacterium Longum	N	s			Not Reported
Ciprofloxacin	N	S	Unknown		Not Reported
Magnesium Carbonate	N	S	Unknown		Not Reported
Magnesium Hydroxide	N	S	Unknown		Not Reported
Ubidecarenone	N	S	Unknown		Not Reported
Fentanyl	N	S	Unknown		Not Reported
Apo-Alpraz	N	S	Unknown	0.25 Milligram	Not Reported
Empracet	N	S	Unknown		Not Reported
Valsartan	N	S	Unknown	Unk	Not Reported
Valsartan	N	S	Unknown	4 Dosage Form, Qd	Not Reported
Calcium Gluconate Cox	Ν	С		Unk	Not Reported
Calcium And Ergocalciferol	N	С	Unknown	Unk	Not Reported



Procedural Pain; Proctitis;

Paraesthesia Oral;

Maxeran

Metronidazole

Lomotil [Atropine Sulfate;

Diphenoxylate Hydrochloride]

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) **Detailed Report**

Unk Unk, Qid

10 Mg, Unk

		Benadryl Allergy [Diphenhydramine Hydrochloride]		N	С	Unknown	Unk			Not Reported
		Metoclopramide Hydrochloride		N	С	Unknown	Unk			Not Reported
		Benadryl		N	С	Unknown	Unk			Not Reported
		Sodium Stearate		N	С	Unknown	Unk			Not Reported
		Calcium Carbonate/Vitamin D Nos		N	С	Unknown	Unk			Not Reported
Mupirocin Calcium Mupirocin Calcium Hydrocortisone Antipyrine Pseudoephedrine. Tetrahydrozoline			N	С	Unknown	Unk			Not Reported	
			N	С	Topical	Unk			Not Reported	
		Antipyrine Pseudoephedrine.			S S S					Not Reported Not Reported Not Reported Not Reported
FDA Received Date	Case #	Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
23-Mar-2023	207111	30 EXPEDITED (15-DAY)	Υ		но, от	CA-TAKEDA- 2022TUS02466	6	71 YR	Female	CAN
Preferred Term		Product	Comp.	OTC	<u>Role</u>	Route	Dosage Text	Duration		Mfr
Abdominal Pain; Anaemia	,	Mesalazine		N	S	Unknown	Unk Unk, Tid			Takeda
Chronic Sinusitis; Colitis; Colitis Ulcerative; Constipation; Drug Ineffective; Dyspepsia; Erythema; Female Genital Tract Fistula; Frequent Bowel Movements; Haematochezia; Headache; Infusion Related Reaction; Macular Degeneration; Malaise; Nausea; Off Label Use; Oral Candidiasis; Pain;		Mesalazine		N	S	Unknown	Unk			Takeda
		Pantoprazole Sodium		N	S	Unknown	Unk			Not Reported
		Calcium Carbonate		N	S	Unknown	Unk			Not Reported
		Pantoprazole		N	S	Unknown	Unk			Not Reported
		Amoxicillin		N	S	Unknown	Unk			Not Reported
		Vedolizumab		N	S	Unknown	200 Milligram, Tid			Takeda
		Entyvio		N	S	Intravenous (not otherwise specified)	200 Milligram, Tid			Takeda
		Midazolam Hydrochloride		N	DS	Unknown	2 Dosage Form			Takeda

Unknown

Unk

С

С

Oral

Oral

Ν

Ν

Ν

S

Not Reported

Not Reported

Not Reported



Pyrexia; Radiculopathy; Rectal Haemorrhage; Therapeutic Product Effect Incomplete; Vaginal Discharge; Vaginal Flatulence; Weight Decreased

Betalled Report											
Flagyl	N	S	Unknown	Unk	Not Reported						
Calcium Carbonate, Cholecalciferol	N	S	Unknown	Unk	Not Reported						
Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported						
Acetaminophen W/Codeine Phosphate	N	S	Unknown	Unk	Not Reported						
Macrogol	N	S	Unknown	Unk	Not Reported						
Midazolam	N	S	Unknown	2 Dosage Form	Not Reported						
Acetylsalicylic Acid	N	S	Unknown	Unk	Not Reported						
Sodium Chloride	N	S	Respiratory (inhalation)	Unk	Not Reported						
Sodium Chloride	N	S	Unknown	Unk	Not Reported						
Moviprep	N	S	Unknown	Unk	Not Reported						
Acetaminophen	N	S	Unknown	Unk	Not Reported						
Adalimumab	N	S	Subcutaneous	Unk	Not Reported						
Alprazolam	N	S	Unknown	0.25 Milligram	Not Reported						
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported						
Diphenoxylate/Atropine	N	S	Oral	Unk	Not Reported						
Diphenoxylate/Atropine	N	S	Unknown	1 Dosage Form	Not Reported						
Azithromycin	N	S	Unknown	Unk	Not Reported						
Azithromycin	N	S	Oral	Unk	Not Reported						
Bisacodyl	N	S	Unknown	Unk	Not Reported						
Bisacodyl	N	S	Transdermal	Unk	Not Reported						
Betamethasone	N	S	Unknown	Unk	Not Reported						
Budesonide	N	S	Respiratory (inhalation)	Unk	Not Reported						
Budesonide	N	S	Oral	Unk	Not Reported						
Budesonide	N	S	Unknown	Unk	Not Reported						
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported						
Clarithromycin	N	S	Unknown	Unk	Not Reported						

Ν

S

Unknown

Unk

Clotrimazole

Not Reported



Cupric Oxide	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Oral	50 Milligram	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Ertapenem Sodium	N	S	Intramuscular	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Fluticasone Propionate	N	S	Unknown	Unk	Not Reported
Glycerin	N	S	Unknown	Unk	Not Reported
Glycerin	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Glycerin	N	S	Oral	Unk	Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Infliximab	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Infliximab	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Intramuscular	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Mupirocin	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	40 Milligram	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Transdermal	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported



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Potassium Chloride	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Unknown	150 Milligram	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	200 Milligram	Not Reported
Glycerol	N	S	Oral	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Flovent	N	S	Unknown	Unk	Not Reported
Isoniazid	N	S	Unknown		Not Reported
Humira	N	S	Subcutaneous	Unk	Not Reported
Entocort	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Oral	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Subcutaneous	Unk	Not Reported
Hydrochlorothiazide	N	S	Endocervical	100 Milligram	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Oral	Unk	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Ambroxol	N	S	Unknown		Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	0.122 Gram	Not Reported
Loperamide	N	S	Unknown	Unk	Not Reported
Loperamide	N	S	Oral	Unk	Not Reported
Tocopherols Mixed	N	S	Unknown		Not Reported



				<u> </u>	
Sodium Bicarbonate	N	S	Unknown		Not Reported
Acetaminophen;	N	S	Unknown	Unk	Not Reported
Dextropropoxyphene Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	1 Dosage Form	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	4 Dosage Form	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	4 Dosage Form, Qd	Not Reported
Azithromycin Dihydrate	N	S	Unknown	Unk	Not Reported
Ambroxol;Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Calcitriol;Calcium Carbonate; Zinc	N	S	Unknown	Unk	Not Reported
Calcium Carbonate; Ergocalciferol	N	S	Unknown		Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported
Triamcinolone	N	S	Unknown		Not Reported
Sinus Rinse	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic		Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Fentanyl	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Zopiclone	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	S	Unknown		Not Reported
Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate; Sodium Chloride;So	N	S	Unknown		Not Reported
Macrogol;Potassium Chloride; Sodium Bicarbonate	N	S	Unknown		Not Reported
Macrogol;Potassium Chloride; Sodium Bicarbonate;Sodium Chloride	N	S	Unknown		Not Reported



	Glycerine		N	S	Oral	Unk			Not Reported
	Glycerine		N	S	Unknown	Unk			Not Reported
	Ergocalciferol		Ν	S	Unknown	Unk			Not Reported
	Loperamide Hydrochloride		Ν	S	Oral	Unk			Not Reported
	Loperamide Hydrochloride		Ν	S	Unknown	Unk			Not Reported
	Loperamide Hydrochloride		N	S	Oral	1 Dosage Form, Qd			Not Reported
	Loperamide Hydrochloride		N	S	Oral	4 Dosage Form, Qd			Not Reported
	Cupric Oxide;Folic Acid;Nicotinic Acid;Zinc		N	S	Unknown	Unk			Not Reported
	Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate		N	S	Unknown	Unk			Not Reported
	Isoniazid;Pyridoxine Hydrochloride;		N	S	Unknown	Unk			Not Reported
	Sulfamethoxazole;Trimethoprim Gramicidin		N	S	Unknown	Unk			Not Reported
	Glycerol;Sodium Stearate		N	S	Unknown	Unk			Not Reported
	Diphenhydramine		N	S	Unknown	Unk			Not Reported
	Atropine Sulfate		N	S	Unknown	Unk			Not Reported
	Glyceryl Trinitrate		N	S	Unknown	Unk			Not Reported
FDA Received Date Case #	<u>Case Type</u>	<u>Health</u>	Prof	Outcomes	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2023 213087	741 EXPEDITED (15-DAY)	Υ		HO, OT	CA-SANOFI US 2022SA237087		71 YR	Female	e CAN
Preferred Term	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	Duration		Mfr
Chronic Sinusitis; Colitis	Alprazolam		N	S		Unk			Not Reported
Ulcerative; Constipation; Erythema; Female Genital	Alprazolam		N	S		Unk			Not Reported
Tract Fistula; Frequent	Alprazolam		N	S		Unk			Not Reported
Bowel Movements; Haematochezia;	Alprazolam		N	S		Unk			Not Reported
Headache; Macular	Alprazolam		N	S		Unk			Not Reported
Degeneration; Oral	Amoxicillin Trihydrate		N	S		Unk			Not Reported
Candidiasis; Proctitis; Radiculopathy; Rectal Haemorrhage;	Amoxicillin Trihydrate		N	S		Unk			Not Reported



Therapeutic Product Effect Incomplete; Vaginal Discharge; Vaginal Flatulence

			2010110011		
Amoxicillin Trihydrate	N	S		Unk	Not Reported
Hydrochlorothiazide	N	S		Unk	Not Reported
Hydrochlorothiazide	N	S		Unk	Not Reported
Hydrochlorothiazide	N	S		Unk	Not Reported
Hydrochlorothiazide	N	S		Unk	Not Reported
Atorvastatin	N	S		Unk	Not Reported
Azithromycin	N	S		Unk	Not Reported
Azithromycin	N	S		Unk	Not Reported
Azithromycin	N	S		Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Mupirocin	N	S		Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S		Unk	Not Reported
Betamethasone Dipropionate	N	S		Unk	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Transplacental	Unk	Sanofi
Bisacodyl	N	S		Unk	Sanofi
Bisacodyl	N	S	Unknown	Unk	Sanofi
Bisacodyl	N	S		Unk	Sanofi
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S		Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Unk	Not Reported
Diphenhydramine	N	S	Unknown	Unk	Sanofi
Budesonide	N	S	Oral	1 Df	Not Reported
Budesonide	N	S		Unk	Not Reported
Budesonide	N	S			Not Reported
Budesonide	N	S		2. Inhalation	Not Reported



Budesonide	N	S	Oral		Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Metronidazole	N	S			Sanofi
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
·			Unknown	Unk	
Morphine Sulfate	N	S		Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	Ν	S	Oral	Unk	Not Reported
Nadolol	N	S	Oral	Unk	Not Reported
Nicoderm	N	S	Transdermal	Unk	Sanofi
Nicoderm	Ν	S	Transdermal	Unk	Sanofi
Nicoderm	N	S			Sanofi
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	Ν	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Pantoprazole	Ν	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported



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Mesalazine	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Mesalazine Prednisone	N N	S S	Unknown	Unk	Not Reported Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Topical	Unk	Not Reported
Pregabalin	N	S	Topical	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S		Unk	Not Reported
Sodium Chloride	N	S		Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Sanofi
Acetylsalicylic Acid	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole/Trimethoprim	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole/Trimethoprim	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole/Trimethoprim	N	S	Unknown	Unk	Not Reported
Carmellose Sodium	N	S	Ophthalmic	Unk	Not Reported
Carmellose Sodium	N	S	Ophthalmic	Unk	Not Reported
Carmellose Sodium	N	S	Ophthalmic		Not Reported
Carmellose Sodium Atorvastatin Calcium	N N	S S	Unknown	Unk	Not Reported Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported



Fluocinolone N S Unk Acetonide/Neomycin Sulfate/Polymyxin B Sulfate	Not Reported
Loperamide Hydrochloride N S Oral Unk	Not Reported
Loperamide Hydrochloride N S Oral Unk, Qm	Not Reported
Macrogol 4000 N S Unknown Unk	Not Reported
Macrogol 4000 N S Unknown Unk	Not Reported
Macrogol 4000 N S Oral Unk	Not Reported
Macrogol 4000 N S Endocervical Unk	Not Reported
Colecalciferol N S Unknown Unk	Not Reported
Colecalciferol N S Unknown Unk	Not Reported
Betamethasone Valerate N S Topical Unk	Not Reported
Betamethasone Valerate N S Unknown Unk	Not Reported
Betamethasone Valerate N S Unknown Unk	Not Reported
Diphenhydramine Hydrochloride N S Unk	Sanofi
Diphenhydramine Hydrochloride N S Unknown Unk	Sanofi
Diphenhydramine Hydrochloride N S Unk	Sanofi
Diphenhydramine Hydrochloride N S Unk	Sanofi
Glycerol N S Oral Unk	Not Reported
Glycerol N S Oral Unk	Not Reported
Glycerol N S Oral Unk	Not Reported
Glycerol N S Unk	Not Reported
Magnesium Sulfate N S Unknown Unk	Not Reported
Magnesium Sulfate N S Unknown Unk	Not Reported
Magnesium Sulfate N S Unknown Unk	Not Reported
Magnesium Sulfate N S Unknown Unk	Not Reported
Zinc Oxide N S Unknown Unk	Sanofi
Zinc Oxide N S Unknown Unk	Sanofi
Zinc Oxide N S Unknown Unk	Sanofi
Zinc Oxide N S _{Unknown} Unk	Sanofi



				•	
Zinc Oxide	N	S	Unknown	Unk	Sanofi
Zinc Oxide	N	S	Unknown	Unk	Sanofi
Zinc Oxide	N	S	Unknown	Unk	Sanofi
Amoxicillin	N	S	Unknown	Unk	Not Reported
Amoxicillin	N	S	Unknown	Unk	Not Reported
Amoxicillin	N	S	Unknown	Not Specified	Not Reported
Paracetamol	N	S	Unknown	Unk	Not Reported
Paracetamol	N	S	Unknown	Unk	Not Reported
Paracetamol	N	S	Unknown	Unk	Not Reported
Paracetamol	N	S	Unknown	Unk	Not Reported
Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Potassium Chloride	N	S		Unk	Not Reported
Pantoprazole Sodium	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S		Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Sodium Bicarbonate	N	S		Unk	Not Reported
Atropine/Diphenoxylate	N	S	Unknown	Unk	Not Reported
Trimethoprim	N	S		Unk	Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported
Trimethoprim Simvastatin	N N	S S		Unk	Not Reported Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Simvastatin	N	S		Unk	Not Reported
Simvastatin	N	S		Unk	Not Reported



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Fluticasone Propionate/Salmeterol Xinafoate	N	S	Unknown	Unk	Not Reported
Neomycin Sulfate	N	S	Unknown	Unk	Not Reported
Loperamide	N	S	Unknown	Unk	Not Reported
Loperamide	N	S	Oral	4 Df, Cont	Not Reported
Loperamide	N	S	Unknown	Cyclical	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate Calcium Citrate	N N	S S		Not Specified	Not Reported Not Reported
Framycetin Sulfate	N	S		Unk	Not Reported
Isoniazid	N	S		Unk	Not Reported
Pyridoxine	N	S		Unk	Not Reported
Atropine Sulfate	N	S	Oral	Unk	Not Reported
Atropine Sulfate	N	S	Oral		Not Reported
Nicotine	N	S	Unknown	Unk	Sanofi
Calcium Carbonate	N	S	Intra-articular	Unk	Not Reported
Hydrocortisone	N	S	Oral	9 Mg	Sanofi
Benzydamine Hydrochloride	N	S	Unknown	Unk	Not Reported
Cholecalciferol	N	S	Unknown	Unk	Not Reported
Dulcolax	N	S	Unknown	Unk	Sanofi
Calcium Phosphate/Colecalciferol	N	S	Unknown	Unk	Not Reported
Zopiclone	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk	Sanofi
Difenoxin Hydrochloride	N	S	Unknown	Unk	Not Reported
Ertapenem	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Lomotil	N	S	Unknown	Unk	Not Reported



	Lomotil [Atropine Sulfate;		N	S	Unknown	Unk			Not Reported
	Diphenoxylate Hydrochloride] Moviprep [Ascorbic Acid; Macrogol 4000;Potassium		N	S	Unknown	Unk			Not Reported
	Chloride;Sodium Ascorb Neomycin B Sulfate		N	S	Unknown	Unk			Not Reported
	Vitamin E [Vitamin E Nos]		N	S	Unknown	Unk			Not Reported
	Furosemide Sucralfate		N N	S S	Unknown	Unk			Sanofi Sanofi
	Midazolam		N	S	Unknown	Unk			Not Reported
	Oxybutynin Hydrochloride		N	S	Unknown	Unk			Sanofi
	Ciprofloxacin Salt Not Specified		N	S		Unk			Not Reported
	Azithromycin Dihydrate Cupric Oxide Calcium		N N N	S S S	Unknown	Unk			Not Reported Not Reported Sanofi
	Habitrol [Nicotine] Polymyxin Zeaxanthin Triamcinolone		N N N	\$ \$ \$ \$					Not Reported Not Reported Not Reported Not Reported
			N	S	Unknown	Unk			Not Reported
	Azathioprine Refresh Tears		N	S	Unknown	Unk			•
							_	_	Not Reported
FDA Received Date Case	# Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Co	ntrol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
4-Mar-2023 17965	EXPEDITED (15-DAY)	N		HO, OT	NVSC20	20CA180005	71 YR	Female	e CAN
referred Term	<u>Product</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
hronic Sinusitis; Drug	Amoxicillin Trihydrate		N	S	Unknown	Unk			Novartis
effective; Dyspepsia; fusion Related Reaction; acular Degeneration;	Amoxicillin Trihydrate		N	S	Unknown	Unk (Powder For Oral Suspension)			Novartis
alaise; Nausea; Off	Amoxicillin Trihydrate		N	S	Unknown	Unk (Oral Suspension)			Novartis
ibel Use; Pain;	Azithromycin Dihydrate		N	S	Unknown	Unk			Novartis
araesthesia Oral; rocedural Pain; Pyrexia;	Atorvastatin		N	S	Unknown	Unk			Novartis
herapeutic Product Effect complete; Weight	Valsartan		N	S	Unknown	Unk			Novartis



ADMINISTRATION						
Decreased	Clarithromycin	N	S	Oral	Unk	Novartis
	Clarithromycin	N	S	Oral	Unk	Novartis
	Diphenhydramine	N	S	Unknown	Unk	Novartis
	Sodium Chloride	N	S	Nasal	Unk (Intranasal)	Not Reported
	Triamcinolone Acetonide	N	S	Intra-articular	Unk (Suspension Intra- Articular))	Novartis
	Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
	Metoclopramide Hydrochloride	N	S	Unknown	Unk	Not Reported
	Pantoprazole	N	S	Unknown	Unk	Novartis
	Pantoprazole Sodium	N	S	Unknown	Unk	Novartis
	Pregabalin	N	S	Unknown	Unk (Capsules Hard)	Not Reported
	Pregabalin	N	S	Unknown	Unk (Capsule)	Not Reported
	Ergocalciferol	N	S	Unknown	Unk	Not Reported
	Potassium Chloride	N	S	Unknown	Unk	Novartis
	Potassium Chloride	N	S	Urethral	Unk	Novartis
	Potassium Chloride	N	S	Urethral	Unk	Novartis
	Potassium Chloride	N	S	Urethral	Unk	Novartis
	Potassium Chloride	N	S	Urethral	Unk	Novartis
	Potassium Chloride	N	S	Unknown	Unk	Novartis
	Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
	Avamys	N	S	Unknown	Unk (Spray, Metered Dose)	Not Reported
	Avamys	N	S	Unknown	Unk (Spray, Metered Dose)	Not Reported
	Bactroban	N	S	Topical	Unk	Not Reported
	Acetaminophen	N	S	Unknown	Unk	Not Reported
	Acetaminophen	N	S	Unknown	Unk	Not Reported
	Acetaminophen	N	S	Unknown	Unk	Not Reported
	Acetaminophen	N	S	Unknown	Unk	Not Reported

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S

Unknown

Unk

Dextropropoxyphene

Not Reported



Alprazolam	N	S	Unknown	Unk		Not Reported
Alprazolam	N	S	Oral	Unk		Not Reported
Alprazolam	N	S	Oral	Unk		Not Reported
Betamethasone Diproprionate	N	S	Unknown	Unk		Not Reported
Betamethasone Diproprionate	N	S	Unknown	Unk		Not Reported
Biaxin XI	N	S	Oral	Unk (Extended Release	e)	Not Reported
Biaxin XI	N	S	Unknown	Unk	,	Not Reported
Biaxin XI	N	S	Unknown	Unk		Not Reported
Bisacodyl	N	S	Unknown	Unk		Not Reported
Cetrizin	N	S	Unknown	Unk		Not Reported
Clotrimazole	N	S	Unknown	Unk		Not Reported
Desonide	N	S	Unknown	Unk		Not Reported
Dilaudid	N	S	Unknown	Unk		Not Reported
Entocort	N	S	Oral	Unk (Capsule, Sustaine Release)	ed	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk		Not Reported
Flovent	N	S	Unknown	Unk		Not Reported
Glycerine	N	S	Oral	Unk		Not Reported
Habitrol	N	S	Transdermal	Unk (Patch)		Not Reported
Humira	N	S	Subcutaneous	Unk	6 YR	Not Reported
Humira	N	S	Subcutaneous	Unk	5 YR	Not Reported
Humira	N	S	Subcutaneous	Unk		Not Reported
Kenalog	N	S	Intra-articular	Unk		Not Reported
Kenalog	N	S	Intra-articular	Unk		Not Reported
Kenalog	N	S	Intra-articular	Unk (Suspension Intraarticular)		Not Reported
Lomotil	N	S	Oral	Unk (4 Every 1 Days)		Not Reported
Lomotil	N	S	Oral	Unk		Not Reported
Metronidazole	N	S	Unknown	Unk		Not Reported
Metronidazole	N	S	Unknown	Unk		Not Reported



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Ms Ir	N	S	Unknown	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Nadolol	N	S	Oral	Unk	Not Reported
Nadolol	N	S	Oral	Unk	Not Reported
Nicoderm	N	S	Transdermal	Unk (Patch)	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S		Unk	Not Reported
Bactrim	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk (Drops Opthalmic)	Not Reported
Sinus Rinse	N	S	Nasal	Unk (Intra-Nasal)	Not Reported
Sinus Rinse	N	S	Intra-articular	Unk (Intra-Nasal)	Not Reported
Trimethoprim Sulfamethoxazole	N	S	Unknown	Unk	Not Reported
Vitamin D	N	S	Unknown	Unk	Not Reported
Gramicidin;Polymyxin B	N	S	Ophthalmic	Unk	Not Reported
Calcium Carbonate/Vitamin D3	N	S	Unknown	Unk	Not Reported
Diphenoxylate Hcl And Atropine Sulfate	N	S	Oral	Unk	Not Reported
Azithromycin	N	S	Unknown	Unk	Not Reported
Azithromycin	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Topical	Unk	Not Reported
Budesonide	N	S		Unk	Not Reported
Budesonide	N	S	Other	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Calcium Citrate	N	S	Unknown	Unk	Not Reported



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Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
Vitamiin C	N	S	Unknown	Unk	Not Reported
Dulcolax	N	S	Unknown	Unk	Not Reported
Emser Salt	N	S	Unknown	Unk	Not Reported
Glycerol	N	S	Oral	Unk	Not Reported
Glyceryl Trinitrate	N	S	Unknown	Unk	Not Reported
Hctz	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
Imodium	N	S	Unknown	Unk	Not Reported
Loperamide	N	S	Oral	4 Dosage Form, Qd	Not Reported
Loperamide	N	S	Oral	Unk	Not Reported
Loperamide	N	S	Oral	1 Dosage Form, Qd	Not Reported
Loperamide	N	S	Oral	Unk	Not Reported
Loperamide	N	S	Oral	Unk	Not Reported
Sodium Ascorbate	N	S	Unknown	Unk	Not Reported
Sodium Ascorbate	N	S	Urethral	Unk	Not Reported
Sodium Ascorbate	N	S	Urethral	Unk	Not Reported
Sodium Ascorbate	N	S	Urethral	Unk	Not Reported
Sodium Ascorbate	N	S	Urethral	Unk	Not Reported
Sodium Chloride	N	S	Nasal	Unk (Intranasal)	Not Reported
Sodium Chloride	N	S	Urethral	Unk	Not Reported
Sodium Chloride	N	S	Urethral	Unk	Not Reported
Sodium Chloride	N	S	Urethral	Unk	Not Reported
Sodium Chloride	N	S	Urethral	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Sulfate	N	S	Unknown	Unk	Not Reported
Sodium Sulfate	N	S	Urethral	Unk	Not Reported



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Sodium Sulfate	N	S	Urethral	Unk	Not Reported
Sodium Sulfate	N	S	Urethral	Unk	Not Reported
Sodium Sulfate	N	S	Urethral	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Pms Azithromycin	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Mezavant	N	S	Unknown	Unk (Delayed And Extended Release)	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Neomycin Sulfate	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Transdermal	Unk	Not Reported
Paracetamol And Pseudoephedrine Hydrochloride	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Statex	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole And Trimethoprim	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole And Trimethoprim	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Calcium	N	S	Unknown	Unk	Not Reported
Betaderm	N	S	Unknown	Unk	Not Reported
Vitamin E	N	S	Unknown	Unk	Not Reported
Vitamins Nos	N	S	Oral	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Oral	Unk	Not Reported



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Zeaxanthin	N	S	Oral	Unk	Not Reported
Zinc Oxide	N	S	Oral	Unk	Not Reported
Cupric Oxide;Folic Acid; Nicotinamide;Zinc	N	S	Unknown	Unk	Not Reported
Cetirizine	N	S	Unknown	Unk	Not Reported
Macrogol 3350	N	S	Unknown	Unk	Not Reported
Macrogol	N	S	Unknown	Unk	Not Reported
Acetaminophen	N	S	Unknown	Unk	Not Reported
Bromhexine Hydrochloride	N	S	Unknown		Not Reported
Clofibrate	N	S	Unknown	Unk	Not Reported
Fluticasone	N	S	Unknown	Unk	Not Reported
Ichthammol	N	S	Unknown	Unk	Not Reported
Isoniazide	N	S	Unknown	Unk	Not Reported
Magnesium	N	S	Unknown	Unk	Not Reported
Mentha Arvensis	N	S	Unknown	Unk	Not Reported
Mentha Arvensis	N	S	Unknown	Unk	Not Reported
Nicomorphine	N	S	Unknown	Unk	Not Reported
Pyridoxine	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	С	Unknown		Not Reported
Calcium Phosphate	N	С	Unknown	Unk	Not Reported
Calcium Citrate	N	С	Unknown	Unk	Not Reported
Colecalciferol	N	С	Unknown	Unk	Not Reported
Cupric Oxide	N	С	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	С	Unknown	Unk	Not Reported
Vitamiin C	N	С	Unknown	Unk	Not Reported
Zinc	N	С	Unknown	Unk	Not Reported
Valsartan	N	С	Unknown	Unk	Not Reported
Apo Hydro	N	С	Endocervical	Unk	Not Reported



		Calcium Carbonate And Vita D	amin	N	С	Unknown	Unk		١	lot Reported
FDA Received Date	Case #	Case Type	<u>Hea</u>	th Prof	Outcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Mar-2023	177307	751 EXPEDITED (15-E	OAY) Y		HO, OT	NVSC20200	CA113431	71 YR	Female	USA
Preferred Term		<u>Product</u>	Comp	<u>. OT</u>	C Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Chronic Sinusitis; Drug		Adalimumab		Ν	S	Subcutaneous	Unk		١	lovartis
Ineffective; Drug Ineffective; Dyspepsia;		Amoxicillin Trihydrate		Ν	S	Unknown	Unk		١	lovartis
Infusion Related Reacti	ion;	Amoxicillin Trihydrate		Ν	S	Unknown	Unk		١	lovartis
Macular Degeneration; Malaise; Nausea; Off		Atropine Sulfate		Ν	S	Oral	Unk		١	lot Reported
Label Use; Pain;		Sodium Bicarbonate		Ν	S	Unknown	Unk		١	lot Reported
Paraesthesia Oral; Procedural Pain; Pyrexia; Therapeutic Product Effect Incomplete; Weight Decreased		Clarithromycin		N	S	Unknown	Unk (Modified-Release Tablet)	•	N	lovartis
	ieci	Clarithromycin		N	S	Unknown	Unk (Modified-Release Tablet)	•	N	lovartis
		Clarithromycin		N	S	Unknown	Unk (Modified-Release Tablet)	•	N	lovartis
		Clarithromycin		Ν	S	Unknown	Unk		١	lovartis
		Clarithromycin		Ν	S	Unknown	Unk		N	lovartis
		Atorvastatin Calcium		Ν	S	Unknown	Unk		N	lovartis
		Atorvastatin Calcium		Ν	S	Unknown	Unk		N	lovartis
		Atorvastatin Calcium		Ν	S	Unknown	Unk		N	lovartis
		Atorvastatin Calcium		Ν	S	Unknown	Unk		N	lovartis
		Ergocalciferol		Ν	S	Unknown	Unk		١	lot Reported
		Pantoprazole		Ν	S	Unknown	Unk		N	lovartis
		Pantoprazole		Ν	S	Unknown	Unk		١	lovartis
		Pantoprazole		Ν	S	Unknown	Unk		١	lovartis
		Pantoprazole		Ν	S	Unknown	Unk		١	lovartis
		Pregabalin		Ν	S	Unknown	Unk		١	lot Reported
		Pregabalin		Ν	S	Unknown	Unk		N	lot Reported



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Pregabalin	N	S	Topical	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Novartis
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Novartis
Valsartan	N	S	Unknown	Unk	Novartis
Valsartan	N	S	Unknown	Unk	Novartis
Sodium Chloride	N	S	Nasal	Unk	Not Reported
Azithromycin Dihydrate	N	S	Unknown	Unk	Novartis
Azithromycin Dihydrate	N	S	Oral	Unk	Novartis
Azithromycin Dihydrate	N	S	Unknown	Unk	Novartis
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Novartis
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Acetaminophen	N	S	Unknown	Unk	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Alprazolam	N	S		Unk	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Atropine Sulfate	N	S	Oral	Unk	Not Reported
Atropine Sulfate	N	S	Oral	Unk	Not Reported
Atropine Sulfate	N	S	Unknown	Unk	Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Apo-Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
Ascorbic Acid	N	S	Unknown	Unk (Copper, Xantofyl, Zeaxanthin, Zinc)	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Avamys	N	S	Unknown	Unk (Spray, Metered Dose)	Not Reported



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Avamys	N	S	Ophthalmic	Unk (Spray, Metered Dose)	Not Reported
Betaderm	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk (Extended Release)	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Transplacental	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Nasal	Unk	Not Reported
Sodium Chloride	N	S	Other	Unk(Intranasal)	Not Reported
Sodium Chloride	N	S	Other	Unk (Intranasal)	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Cetirizine	N	S	Unknown	Unk	Not Reported
Cetirizine	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Dilaudid	N	S	Unknown	Unk	Not Reported
Entocort	N	S	Unknown	Unk (Sustained Release)	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Ertapenem Sodium	N	S	Nasal	Unk (Powder For Solution)	Not Reported
Ertapenem Sodium	N	S	Nasal	Unk (Powder For Solution)	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported



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Flovent	N	S	Unknown	Unk		Not Reported
Glycerine	N	S	Oral	Unk (Liquid)		Not Reported
Glycerine	N	S	Unknown	Unk		Not Reported
Glycerine	N	S	Oral	Unk		Not Reported
Glycerine	N	S	Unknown	Unk		Not Reported
Gramicidin	N	S	Unknown	Unk		Not Reported
Humira	N	S	Subcutaneous	Unk	2190 DAY	Not Reported
Humira	N	S	Subcutaneous	Unk	2190 DAY	Not Reported
Humira	N	S	Unknown	Unk		Not Reported
Humira	N	S	Unknown	Unk		Not Reported
Kenalog	N	S	Unknown	Unk		Not Reported
Kenalog	N	S	Intra-articular	Unk		Not Reported
Lomotil	N	S	Oral	4 Dosage Form, Qd (4 Every 1 Days)		Not Reported
Lomotil	N	S	Oral	Unk		Not Reported
Macrogol	N	S	Unknown	Unk (Macrogol 3350, Potassium Chloride, Sodium Biocarbonate, Sodium Chloride, So)		Not Reported
Macrogol	N	S	Unknown	Unk		Not Reported
Metronidazole	N	S	Unknown	Unk		Not Reported
Metronidazole	N	S	Unknown	Unk		Not Reported
Mupirocin	N	S	Topical	Unk		Not Reported
Mupirocin	N	S	Unknown	Unk		Not Reported
Mupirocin	N	S	Unknown	Unk		Not Reported
Mupirocin	N	S	Unknown	Unk		Not Reported
Mupirocin Calcium	N	S	Unknown	Unk (Mupirocin Calcium Dihydrate)		Not Reported
Mupirocin Calcium	N	S	Topical	Unk		Not Reported
Mupirocin Calcium	N	S	Topical	Unk		Not Reported
Nadolol	N	S	Unknown	40 Mg		Not Reported



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Nadolol	N	S	Unknown	40 Mg	Not Reported
Nadolol	N	S	Intra-arterial	Unk	Not Reported
Nadolol	N	S	Oral	Unk	Not Reported
Nicoderm	N	S	Transdermal	Unk	Not Reported
Nicoderm	N	S	Transdermal	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Transdermal	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Subcutaneous	Unk	Not Reported
Pulmicort	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S	Other	Unk	Not Reported
Pulmicort	N	S		Unk	Not Reported
Pulmicort	N	S		Unk	Not Reported
Pulmicort	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk (Drops Opthalmic)	Not Reported
Refresh Tears	N	S	Unknown	Unk	Not Reported
Sinus Rinse	N	S	Nasal	Unk (Solution)	Not Reported
Sinus Rinse	N	S	Unknown	Unk (Solution Nasal)	Not Reported
Sinus Rinse	N	S	Unknown	Unk (Solution Nasal)	Not Reported
Statex	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported



				•	
Vitamin D3	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole And	N	S	Unknown	Unk	Not Reported
Trimethoprim Sulfamethoxazole And Trimethoprim	N	S	Unknown	Unk	Not Reported
Ambroxol Hydrochloride	N	S	Unknown	Unk	Not Reported
DI-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
DI-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
DI-Alpha Tocopheryl Acetate	N	S	Intracardiac	Unk	Not Reported
Bactrim	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Topical	Unk	Not Reported
Calcium Gluconate	N	S	Unknown	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Ophthalmic	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk (Nasal Spray)	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk (Nasal Spray)	Not Reported
Glycerol	N	S	Unknown	Unk	Not Reported
Glycerol	N	S	Oral	Unk	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported



Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	100 Mg	Not Reported
Hydromorphone Hydrochloride	N	S		•	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
			Unknown	Unk	
Hydromorphone Hydrochloride	N	S	Endocervical	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Unk	Not Reported
Gramicidin\Neomycin\Polymyxin B Sulfate	N	S	Unknown	Unk (Dental Ointment)	Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Dosage Form, Qmo (1 Every For1 Months)	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk, Q4w	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Ms Ir	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Intraocular	Unk	Not Reported
Sodium Stearate	N	S	Oral	Unk	Not Reported
Sodium Stearate	N	S	Unknown	Unk	Not Reported
Triamcinolone	N	S	Intra-articular	Unk, Suspension Intra- Articular	Not Reported
Triamcinolone	N	S	Unknown	Unk	Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported
Zinc Chloride	N	S	Unknown	Unk	Not Reported
Azithromycin	N	S	Oral	Unk	Not Reported
Azithromycin	N	S	Unknown	Unk	Not Reported
Budesonide	N	S		Unk	Not Reported



				- 1	
Budesonide	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Oral	1 Dosage Form	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Copper Gluconate	N	S	Unknown	Unk	Not Reported
Habitrol	N	S	Unknown	Unk (Patch)	Not Reported
Imodium	N	S	Unknown	Unk	Not Reported
Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Nystatin	N	S	Unknown	Unk	Not Reported
Potassium Phosphate Monobasic	N	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	N	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	N	S	Unknown	Unk	Not Reported
Vitamin C	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk (Calcium Carbonate, Vitamin D3)	Not Reported
Acetylsalicylic Acid	N	S	Oral	Unk	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Unk	Not Reported
Vitamin E	N	S	Unknown	Unk	Not Reported
Potassium Chloride	N	S	Unknown	Unk	Not Reported
Potassium Chloride	N	S	Endocervical	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Endocervical	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Oral	Unk	Not Reported
Neomycin Sulfate	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	N	S	Ophthalmic	Unk	Not Reported



				•	
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium Anhydrous	N	S	Unknown	Unk	Not Reported
Diphenoxylate Hydrochloride And Atropine Sulf	N	S	Oral	Unk	Not Reported
Diphenoxylate Hydrochloride And Atropine Sulf	N	S	Oral	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D3	N	S	Unknown	Unk	Not Reported
Mentha Arvensis	N	S	Unknown	Unk	Not Reported
Magnesium	N	S	Unknown	Unk	Not Reported
Magnesium Clofibrate	N	S	Unknown	Unk	Not Reported
Benzydamine	N	S	Unknown	Unk	Not Reported
Clobetasol;Clotrimazole	N	S	Unknown	Unk	Not Reported
Fluticasone Propionate	Ν	S	Unknown	Unk	Not Reported
Fluticasone Propionate	N	S	Unknown	Unk	Not Reported
Macrogol;Potassium;Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk (Suspension Intra Articular)	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk (Suspension Intra Articular)	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk (Suspension Intra Articular)	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk (Suspension Intra Articular)	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk	Not Reported
Vitamins Nos	N	S	Unknown	Unk	Not Reported
Vitamins Nos	N	S	Unknown	Unk	Not Reported
Ambroxol;Cetirizine	N	S	Unknown	Unk	Not Reported



				•	
Benzydamine Hydrochloride	N	S	Unknown	Unk	Not Reported
Calcium Citrate	N	S	Unknown	Unk	Not Reported
Cholecalciferol	N	S	Unknown	Unk	Not Reported
Ichthammol And Zinc Oxide	N	S	Unknown	Unk	Not Reported
Ichthammol And Zinc Oxide	N	S	Unknown	Unk	Not Reported
Macrogol 3350	N	S	Unknown	Unk	Not Reported
Macrogol 3350	N	S	Unknown	Unk	Not Reported
Macrogol	N	S	Unknown	Unk	Not Reported
Mesalamine	N	S	Unknown	Unk (Mezavant)	Not Reported
Prednisone Acetate	N	S	Unknown	Unk	Not Reported
Prednisone Acetate	N	S	Unknown	Unk	Not Reported
Vitamin D	N	S	Unknown	Unk (Jamieson)	Not Reported
Vitamin E Natural	N	S	Unknown	Unk	Not Reported
Fructose	N	S	Oral	Unk	Not Reported
Fructose	N	S	Oral	Unk	Not Reported
Fructose	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Pms Azithromycin	N	S	Unknown	Unk	Not Reported
Vitamin E Nos	N	S	Unknown	Unk	Not Reported
Cupric Oxide;Folic Acid;Nicotinic Acid;Zinc	N	S	Unknown	Unk	Not Reported
Bromhexine Hydrochloride	N	S	Unknown	Unk	Not Reported
Bromhexine Hydrochloride	N	S	Unknown	Unk	Not Reported
Glyceryl Trinitrate	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Nicomorphine	N	S	Unknown	Unk	Not Reported
Nicomorphine	N	S	Unknown	Unk	Not Reported
Acetaminophene	N	S	Unknown	Unk	Not Reported
Dulcolax	N	S	Unknown	Unk	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported



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Glycerol

Betamethasone Dipropionate

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Unk

Unk

Unknown

Unknown

					OTIKITOWIT	Olik			
	Valsartan		Ν	S	Vaginal	Unk			Not Reported
	Valsartan		Ν	S	Intracardiac	Unk			Not Reported
	Neomycin		Ν	S	Unknown	Unk			Not Reported
	Neomycin		Ν	S	Unknown	Unk			Not Reported
	Vitamin D		Ν	S	Unknown	Unk			Not Reported
	Framycetin Sulfate		Ν	S	Unknown	Unk			Not Reported
	Isoniazid		Ν	S	Unknown	Unk			Not Reported
	Glycerol		Ν	S	Oral				Not Reported
	Loperamide		Ν	S	Oral	4 Dosage Form, Q24h			Not Reported
	Loperamide		Ν	S	Unknown	Unk			Not Reported
	Loperamide		Ν	S	Unknown	1 Dosage Form			Not Reported
	Pyridoxine		Ν	S	Unknown	Unk			Not Reported
	Fluocinolone Acetonide		Ν	S	Unknown	Unk			Not Reported
	Atorvastatin Calcium		Ν	С	Unknown	Unk			Not Reported
	Calcium Carbonate		Ν	С	Unknown	Unk			Not Reported
	Sulfamethoxazole\Trimethoprim			S					Not Reported
FDA Received Date Case #	Case Type	<u>Health</u>	Prof	<u>Outcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Mar-2023 205188	EXPEDITED (15-DAY)	Υ	I	HO, OT	CA-TEVA-2022 2011562	2-CA-	71 YR	Female	CAN
Preferred Term	Product	Comp.	OTC	Role	<u>Route</u>	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Chronic Sinusitis; Drug	Acetaminophen		Ν	S	Unknown				Not Reported
Ineffective; Dyspepsia; Infusion Related Reaction;	Amoxicillin Trihydrate		Ν	S	Unknown				Teva
Macular Degeneration;	Atorvastatin Calcium		Ν	S	Unknown				Teva
Malaise; Nausea; Off Label Use; Pain;	Atorvastatin Calcium		Ν	S	Unknown				Teva
Paraesthesia Oral;	Calcium Carbonate		Ν	S	Unknown				Not Reported
Procedural Pain; Pyrexia;	Clarithromycin		N	S	Unknown				Actavis
Therapeutic Product Effect Incomplete; Weight	Diphenhydramine Hydrochloride		N	S	Unknown				Not Reported

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Note: If the field is blank, there is no data.

Not Reported

Not Reported



Decreased	Magnesium Sulfate	N	S	Unknown			Not Reported
	Nicotine	N	S	Unknown			Not Reported
	Pantoprazole	N	S	Unknown			Teva
	Sodium Chloride	N	S	Unknown			Not Reported
	Prednisone	N	S	Unknown			Actavis
	Pregabalin	N	S	Unknown			Teva
	Zinc Oxide	N	S	Unknown			Not Reported
	Avamys	N	S	Unknown			Not Reported
	Bactrim	N	S	Unknown			Not Reported
	Benadryl	N	S	Oral	50.0 Milligram		Not Reported
	Biaxin XI	N	S	Unknown			Not Reported
	Bisacodyl	N	S	Unknown			Not Reported
	Cetirizine Hydrochloride	N	S	Unknown			Not Reported
	Cetirizine Hydrochloride	N	S	Unknown			Not Reported
	Cholecalciferol	N	S	Unknown			Not Reported
	Clotrimazole	N	S	Unknown			Not Reported
	Cupric Oxide	N	S	Unknown			Not Reported
	D-Alpha Tocopherol	N	S	Unknown			Not Reported
	Desonide	N	S	Unknown			Not Reported
	Dilaudid	N	S	Unknown			Not Reported
	Entocort	N	S	Oral			Not Reported
	Entocort	N	S	Unknown			Not Reported
	Ertapenem Sodium	N	S	Unknown			Not Reported
	Flovent	N	S	Unknown			Not Reported
	Glycerol	N	S	Oral			Not Reported
	Gramicidin/Neomycin Sulfate/Polymyxin B Sulfate	N	S	Unknown			Not Reported
	Humira	N	S	Unknown	Solution Subcutaneous	6 YR	Not Reported
	Humira	N	S	Subcutaneous		6 YR	Not Reported
	Hydromorphone Hydrochloride	N	S	Endocervical			Not Reported



				-p-:-	
Infliximab	N	S	Intravenous (not otherwise specified	(E	Not Reported
Isoniazid/Pyridoxine Hydrochloride/Sulfa Methoxazole/Trimethoprim	N	S	Unknown	•	Not Reported
Lomotil	N	S	Oral		Not Reported
Polyethylene Glycol\Potassium Chloride\Sodium Bicarbonate	N	S	Unknown		Not Reported
Metronidazole	N	S	Unknown		Not Reported
Mupirocin	N	S	Topical		Not Reported
Mupirocin	N	S	Unknown	Ointment Topical	Not Reported
Nadolol	N	S	Unknown		Not Reported
Nicoderm	N	S	Unknown	Patch	Not Reported
Pentasa	N	S	Unknown		Not Reported
Pms-Azithromycin	N	S	Unknown		Not Reported
Pulmicort	N	S	Respiratory (inhalation)		Not Reported
Refresh Tears	N	S	Ophthalmic		Not Reported
Triamcinolone Acetonide	N	S	Unknown	Suspension Intra Articular	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular		Not Reported
Triamcinolone Acetonide	N	S	Unknown		Not Reported
Xantofyl Palmitate	N	S	Unknown		Not Reported
Zeaxanthin	N	S	Unknown		Not Reported
Alprazolam	N	S	Unknown		Actavis
Alprazolam	N	S	Unknown		Actavis
Azithromycin	N	S	Unknown		Not Reported
Betamethasone	N	S	Unknown		Actavis
Betamethasone	N	S	Unknown		Actavis
Betamethasone	N	S	Unknown		Actavis
Budesonide	N	S	Unknown		Ivax
Calcium & Vitamin D3	N	S	Unknown		Not Reported



Fluticasone Furoate	N	S	Unknown	Teva
Glycerin	N	S	Oral	Not Reported
Glycerin	N	S	Unknown	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Actavis
Hydromorphone Hydrochloride	N	S	Endocervical	Actavis
Loperamide	N	S	Unknown	Not Reported
Loperamide	N	S	Oral	Not Reported
Mesalazine	N	S	Unknown	Actavis
Morphine Sulfate	N	S	Unknown	Actavis
Sulfamethoxazole /Trimethoprim	N	S	Unknown	Teva
Adalimumab	N	S	Subcutaneous	Not Reported
Atropine/Diphenoxylate	N	S	Unknown	Not Reported
Hydrochloride Atropine/Diphenoxylate Hydrochloride	N	S	Oral	Not Reported
Macrogol	N	S	Unknown	Not Reported
Mixed Tocopherol Vitamin E	N	S	Unknown	Not Reported
Nicotine Polacrilex	N	S	Unknown	Not Reported
Potassium Chloride	N	S	Unknown	Not Reported
Sodium Bicarbonate	N	S	Unknown	Not Reported
Sodium Carboxymethyl Cellulos	Ν	S	Unknown	Not Reported
Vitamin D3	Ν	S	Unknown	Not Reported
Vitamin D3	Ν	S	Unknown	Not Reported
Atropine Sulfate	Ν	S	Unknown	Not Reported
Atropine Sulfate	Ν	S	Oral	Not Reported
Atropine Sulfate	Ν	S	Oral	Not Reported
Atropine Sulfate	N	S	Oral	Not Reported
Benzydamine Hydrochloride	Ν	S	Unknown	Not Reported
Calcitriol	N	S	Intra-articular	Not Reported
Cupric Oxide/Folic Acid/Nicotinic Acid/Zinc	N	S	Unknown	Not Reported



				<u> </u>	
Diphenoxylate Hydrochloride	N	S	Unknown		Not Reported
Ergocalciferol	Ν	S	Unknown		Not Reported
Glycerol/Sodium Stearate	Ν	S	Unknown		Not Reported
Glyceryl Trinitrate	Ν	S	Unknown		Not Reported
Gramicidin	N	S	Unknown		Not Reported
Gramicidin/Polymyxin B	N	S	Unknown		Not Reported
Hydrochlorothiazide	Ν	S	Unknown		Ivax
Imodium	N	S	Unknown		Not Reported
Cefixime	N	S	Unknown		Not Reported
Magnesium Oxide	N	S	Unknown		Not Reported
Mentha Arvensis	N	S	Unknown		Not Reported
Nicomorphine	N	S	Unknown		Not Reported
Nicotinamide	N	S	Unknown		Not Reported
Nicotine	N	S	Unknown		Not Reported
Polyethylene Glycol 4000	N	S	Unknown		Not Reported
Furosemide	N	S	Unknown		Not Reported
Simvastatin	N	S	Unknown		Ivax
Sinus Rinse	N	S	Unknown		Not Reported
Sodium Carboxymethyl	N	S	Ophthalmic		Not Reported
Cellulose Sodium Carboxymethyl	N	S	Ophthalmic		Not Reported
Cellulose Sulfamethoxazole	N	S	Unknown		Not Reported
Sulfamethoxazole	N	S	Unknown		Teva
W/Trimethoprim					
Trimethoprim	N	S	Unknown		Not Reported
Zinc Chloride	N	S	Unknown		Not Reported
Calcium Carbonate/Vitamin D Loperamide	N N	C C	Oral	4 Dosage Forms Daily;	Not Reported Not Reported
Metoclopramide Hydrochloride	N	С	Oral	2	Not Reported
Metoclopramide Hydrochloride	N	С			Not Reported
Valsartan	N	С	Oral	4 Dosage Forms Daily;	Not Reported



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		Benadry	1		N	С	Unknown			١	lot Reported
		Calcium			N	С	Unknown			١	lot Reported
			Lactate/Calcium ate/Ergocalciferol		N	С	Unknown			١	lot Reported
		Lomotil	ate/Ligocalcherol		N	С	Unknown			١	lot Reported
		Amoxicil Diphenh	llin ydramine Hydrochloride		N N	C C	Unknown				lot Reported lot Reported
		Neomyc	in Calcium Dihydrate in Sulfate Stearate		N N N	C C C				١	lot Reported lot Reported lot Reported
FDA Received Date	Case #		Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Control :	503B Facility	<u>Age</u>	<u>Sex</u>	Country
27-Mar-2023	212798	328	EXPEDITED (15-DAY)	N		ОТ	US-ALLERGAN 2228095US	N -		Male	USA
referred Term		Product	<u>t</u>	Comp.	OTC	Role	Route	Dosage Text	<u>Duration</u>	<u>M</u>	<u>fr</u>
Arthritis; Device Difficu To Use; Frustration	ait	Kenesn	Optive Sensitive		Υ	S	Ophthalmic	Unk		,	llergan
olerance Decreased; Myocardial Infarction; Neoplasm Malignant; Product Quality Issue; Mascular Graft											
olerance Decreased; Myocardial Infarction; Jeoplasm Malignant; Product Quality Issue; Pascular Graft			Case Type	Health	Prof	<u>Outcomes</u>	Mfr Control :	<u> 503B Facility</u>	Age	<u>Sex</u>	<u>Country</u>
olerance Decreased; lyocardial Infarction; leoplasm Malignant; roduct Quality Issue; ascular Graft FDA Received Date			Case Type EXPEDITED (15-DAY)	<u>Health</u> Y		Outcomes HO, OT	Mfr Control at CA-CELLTRIO -2019CA02067	N INC.	<u>Age</u>	<u>Sex</u> Unknown	<u>Country</u> CAN
olerance Decreased; lyocardial Infarction; eoplasm Malignant; roduct Quality Issue; ascular Graft FDA Received Date 28-Mar-2023	Case #		EXPEDITED (15-DAY)			HO, OT	CA-CELLTRIO	N INC.	Age Duration		CAN
folerance Decreased; Myocardial Infarction; Meoplasm Malignant; Product Quality Issue; Mascular Graft FDA Received Date 28-Mar-2023 Preferred Term Abdominal Pain; Anae Chronic Sinusitis; Colid	Case # 162592 emia;	298	EXPEDITED (15-DAY)	Y		HO, OT	CA-CELLTRIO -2019CA02067	N INC. 2 Dosage Text 5 Mg/Kg, Every 6 Weeks		Unknown	CAN
olerance Decreased; lyocardial Infarction; lyocardial Infarction; lyocardial Infarction; lyocardial Infarction; leoplasm Malignant; roduct Quality Issue; lascular Graft TDA Received Date least Paraceles Paraceles araceles Paraceles Parac	Case # 162592 emia; tis;	298 Product	EXPEDITED (15-DAY)	Y	OTC	HO, OT	CA-CELLTRIO -2019CA02067 Route Intravenous (not	N INC. 2 Dosage Text 5 Mg/Kg, Every 6 Weeks 5 Mg/Kg, Every 6 Weeks		Unknown M	CAN <u>fr</u>
olerance Decreased; Myocardial Infarction; Jeoplasm Malignant; Product Quality Issue; Vascular Graft	Case # 162592 emia; tis; ; nital	Product Inflectra	EXPEDITED (15-DAY)	Y	OTC N	HO, OT Role S	CA-CELLTRIO -2019CA02067 Route Intravenous (not otherwise specified) Intravenous (not	N INC. Dosage Text 5 Mg/Kg, Every 6 Weeks 5 Mg/Kg, Every 6 Weeks 5 Mg/Kg, Every 6 Weeks		Unknown M C	CAN fr Celltrion

Note: If the field is blank, there is no data.



			•		
Inflectra	N	S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks	Celltrion
Inflectra	N	S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks	Celltrion
Inflectra	N	S	Intravenous (not otherwise specified)	10 Mg/Kg, Every 6 Weeks	Celltrion
Inflectra	N	S	Intravenous (not otherwise specified)	10 Mg/Kg, Every 6 Weeks 132 DAY	Celltrion
Pantoprazole	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Oral	Unk	Not Reported
Alprazolam	N	S	Unknown	0.25 Mg	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Diflucan	N	S		Unk	Not Reported
Solu-Medrol	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Methylprednisolone Sodium Succinate	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Midazolam	N	S	,	2 Df	Not Reported
Midazolam	N	S		2 Df (Pre-Filled Syringe)	Not Reported
Pregabalin	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Unknown	150 Mg	Not Reported
Azithromycin	N	S	Unknown	Unk	Not Reported
Lomotil	N	S	Oral	Unk, Unk, Qid	Not Reported
Lomotil	N	S	Oral	4 Df, 1x/Day, Qd	Not Reported
Lomotil	N	S	Unknown	Unk	Not Reported
Nitroglycerin	N	S	Oral	Unk	Not Reported
Pronutrients Calcium + D	N	S	Unknown	Unk	Not Reported
Bacteriostatic Sodium Chloride	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Unk	Not Reported

Date - Time: 11-Apr-2023 10:56:54 AM EST Note: If the field is blank, there is no data.



Adalimumab	N	S	Subcutaneous	Unk Solution (Except	Not Reported
D OII		0		Syrup)	N (D
Potassium Chloride	N	S	Unknown	Unk	Not Reported
Potassium Chloride	N	S		Unk	Not Reported
Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Neomycin Sulfate	N	S	Unknown	Unk	Not Reported
Fluconazole	N	S	Unknown		Not Reported
Hydrocortisone	N	S	Unknown		Not Reported
Sertraline Hcl	N	S	Unknown	25 Milligram, Qd	Not Reported
Acetaminophen And Codeine Phosphate	N	S		Unk	Not Reported
Sodium Chloride	N	S	Nasal	Formulation:Pellet	Not Reported
Sodium Chloride	N	S	Nasal	Unk	Not Reported
Sodium Chloride	N	S	Respiratory (inhalation)	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Other	Unk	Not Reported
Bactrim	N	S	Unknown	Unk	Not Reported
Bactrim	N	S	Nasal	Unk	Not Reported
Apo Hydromorphone	N	S	Endocervical	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Acetaminophen; Dextropropoxyphene	N	S	Oral	Unk	Not Reported
Avamys	N	S	Unknown	Unk (Spray, Metered)	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	0.122 Gram	Not Reported
Biaxin XI	N	S	Unknown	Unk (Tablet, Extended	Not Reported



				Release)		
Clarithromycin	N	S	Unknown	Unk		Not Reported
Clotrimazole	N	S	Unknown	Unk		Not Reported
Cupric Oxide	N	S	Unknown	Unk		Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk		Not Reported
Desonide	N	S	Unknown	Unk		Not Reported
Dilaudid	N	S	Unknown	Unk		Not Reported
Dilaudid	N	S	Unknown	1 Dosage Form, Bid		Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk		Not Reported
Entocort	N	S	Unknown	Unk, Extended		Not Reported
Entocort	N	S	Oral	Unk		Not Reported
Ertapenem Sodium	N	S	Unknown	Unk		Not Reported
Nadolol	N	S		Unk		Not Reported
Nadolol	N	S	Unknown	40 Milligram		Not Reported
Flovent	N	S	Unknown	Unk		Not Reported
Humira	N	S	Subcutaneous	Unk Solution (Except Syrup)	2190 DAY	Not Reported
Humira	N	S	Unknown	Unk Solution (Except Syrup)		Not Reported
Macrogol, Potassium Chloride, Sodium Bicarbonate	N	S	Unknown	Unk		Not Reported
Magnesium Sulfate	N	S	Unknown	Unk		Not Reported
Magnesium Sulfate	N	S	Intramuscular	Unk		Not Reported
Nicoderm	N	S	Transdermal	Unk		Not Reported
Nicoderm	N	S	Unknown	Unk		Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk		Not Reported
Prednisone	N	S	Unknown	Unk		Not Reported
Pulmicort	N	S	Unknown	Unk		Not Reported
Pulmicort	N	S	Oral	Unk		Not Reported
Refresh Tears	N	S	Intraocular	Unk		Not Reported



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Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Refresh Tears	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Loperamide	N	S	Oral	4 Dosage Form, Qd	Not Reported
Loperamide	N	S	Oral	1 Dosage Form, Q6hr	Not Reported
Vitamin E [Tocopheryl Acetate]	N	S		Unk	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Unk	Not Reported
Glycerinum	N	S	Oral	Unk	Not Reported
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate; Sodium Chloride;So	N	S	Urethral	Unk	Not Reported
Difenoxin Hydrochloride	N	S	Unknown	Unk	Not Reported
Isoniazid;Pyridoxine Hydrochloride; Sulfamethoxazole;Trimethoprim	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Glycerine	N	S	Unknown	Unk	Not Reported
Gramicidin\Neomycin\Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Ms Ir	N	S		Unknown	Not Reported
Sinus Rinse	N	S	Unknown	Unk	Not Reported
Sinus Rinse	N	S	Nasal	Unk	Not Reported
Sinus Rinse	N	S	Other	Unk	Not Reported
Vitamin D3	N	S		Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Mupirocin	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Habitrol	N	S	Other	Unk	Not Reported
Kenalog	N	S	Intra-articular	Unk	Not Reported
Statex	N	S	Unknown	Unk	Not Reported



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Betaderm	N	S	Unknown	Unk	Not Reported
Calcium Amino Acid Chelate; Calcium Carbonate; Colecalciferol;Magnesium	N	S	Unknown	Unk	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Acetaminophene	N	S	Unknown	Unk	Not Reported
Calcium Carbonate; Colecalciferol;Zinc	N	S	Intra-articular	Unknown	Not Reported
Sulfamethoxazole	N	S	Unknown	Unknown	Not Reported
Lutein\Zeaxanthin	N	S	Unknown	Unk	Not Reported
Lutein\Zeaxanthin	N	S	Oral	Unk	Not Reported
Atorvastatin	N	S	Unknown	Unknown	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S		Unk	Not Reported
Gramicidin	N	S		Unk	Not Reported
Macrogol	N	S	Urethral	Unk	Not Reported
Macrogol	N	S	Urethral	Unk	Not Reported
Pms Azithromycin	N	S		Unk	Not Reported
Glyceryl Trinitrate	N	S	Oral	Unk	Not Reported
Nicomorphine	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole, Trimethoprim, Bromhexine Hydrochloride And Clorprena	N	S	Unknown	Unk	Not Reported
Cholecalciferol	N	S		Unk	Not Reported
Pseudoephedrine	N	S	Unknown	Unk	Not Reported
Gramicidin\Neomycin\Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Nasal	Unk	Not Reported
Sodium Chloride	N	S	Endosinusial	Unk	Not Reported
Potassium Chloride	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	Ν	S	Ophthalmic	Unk	Not Reported



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Acetylsalicylic Acid;Citric Acid; Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Betamethasone;Mupirocin	N	S	Topical	Unk	Not Reported
Dexpanthenol	N	S	•	Unk	Not Reported
DI-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
Dulcolax	N	S	Unknown	Unk	Not Reported
Sulfatrim	N	S	Unknown	Unk	Not Reported
Apo-Hydrochlorothiazide	N	S	Endocervical	100 Mg	Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Apo-Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
Salix [Salix Alba Extract]	N	S	Intramuscular	Solution (Except Syrup)	Not Reported
Dimethyl Sulfoxide	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Oral	Unk	Not Reported
Budesonide	N	S	Cutaneous	Unk	Not Reported
Budesonide	N	S	Other	Unk	Not Reported
Budesonide	N	S	Subcutaneous	Unk	Not Reported
Caltrate + D [Calcium Carbonate;Colecalciferol]	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk Unk, Tid	Not Reported
Acetaminophen	N	S	Unknown	Unk	Not Reported
Diphenoxylate/Atropine	N	S	Oral	Unk	Not Reported
Diphenoxylate/Atropine	N	S	Unknown	1 Df	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Transplacental	Unk	Not Reported
Betamethasone Dipropionate	N	S		Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Fluticasone Propionate	N	S	Unknown	Unk	Not Reported



Sulfamethoxazole;Trimethoprim	N	S	Unknown	200 Milligram	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intraocular	Unk	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk	Not Reported
Nicotine [Nicotine Polacrilex]	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Glycerol	N	S	Oral	Unk	Not Reported
Tocopherols Mixed	N	S	Unknown	Unk	Not Reported
Bifidobacterium Infantis	N	S		Unk	Not Reported
Bifidobacterium Infantis	N	S		Unk	Not Reported
Empracet [Paracetamol]	N	S		Unk	Not Reported
Flagyl [Metronidazole Benzoate]	N	S		Unk	Not Reported
Imovan	N	S		Unk	Not Reported
Sulcrate	N	S		Unk	Not Reported
Zopiclone	N	S		Unk	Not Reported
Cortenema	N	S		Unk	Not Reported
Oxybutynin Hydrochloride	N	S		Unk	Not Reported
Fentanyl [Fentanyl Citrate]	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Ciprofloxacin Hydrochloride	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Entyvio	N	S	Intravenous (not otherwise specified)	200 Mg, 3x/Day	Not Reported
Versed	N	S		2 Df	Not Reported
Salofalk [Mesalazine]	N	S		Unk Unk, 3x/Day	Not Reported
Ditropan	N	S		Unk	Not Reported
Infliximab Bs Pfizer	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Remicade	Ν	S	Unknown	Unk	Not Reported



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Amoxicillin	N	S	Unknown	Unk	Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	200 Milligram	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	Unk	Not Reported
Isoniazid	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Endocervical	100 Milligram	Not Reported
Ambroxol Hydrochloride	N	S	Unknown	Unk	Not Reported
Calcium & Vitamin D3	N	S	Unknown	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	1 Df	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	4 Dosage Form, Qd	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Azithromycin Dihydrate	N	S	Unknown	Unk	Not Reported
Ambroxol;Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Calcitriol;Calcium Carbonate; Zinc	N	S	Unknown	Unk	Not Reported
Calcium Carbonate; Ergocalciferol	N	S	Unknown	Unk	Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported
Triamcinolone [Triamcinolone Diacetate]	Ν	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Endocervical	Unk	Not Reported
Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Macrogol;Potassium Chloride; Sodium Bicarbonate;Sodium Chloride	N	S	Unknown	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Dosage Form, Q6hr	Not Reported



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Loperamide Hydrochloride	N	S	Oral	1 Dosage Form	Not Reported
Loperamide Hydrochloride	N	S	Oral	4 Dosage Form, Qd	Not Reported
Imodium	N	S	Unknown	Unk	Not Reported
Moviprep [Ascorbic Acid; Macrogol 3350;Potassium Chloride;Sodium Ascorb	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride + Ammonium Chloride + Sodium Citrate	N	S	Unknown	Unk	Not Reported
Glycerol;Sodium Stearate	N	S	Unknown	Unk	Not Reported
Mupirocin Calcium	N	S	Topical	Unk	Not Reported
Cupric Oxide;Folic Acid;Nicotinic Acid;Zinc	N	S	Unknown	Unk	Not Reported
Calcium Carbonate; Cholecalciferol;Sodium	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown	Unk	Not Reported
Glycerin [Glycerol]	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Fructose;Glycerol;Sodium Chloride	N	S	Unknown	Unk	Not Reported
Fructose;Glycerol;Sodium Chloride	N	S	Oral	Unk	Not Reported
Vedolizumab	N	S	Unknown	200 Milligram, Tid	Not Reported
Align	N	S	Unknown	Unk	Not Reported
Calcium Citrate	N	S	Unknown	Unk	Not Reported
Gramicidin;Polymyxin B	N	S	Unknown	Unk	Not Reported
Atropine Sulfate	N	S	Oral	1 Dosage Form	Not Reported
Atropine Sulfate	N	S	Oral	Unk	Not Reported
Atropine Sulfate	N	S	Oral	4 Dosage Form	Not Reported
Atropine Sulfate	N	S	Unknown	Unk	Not Reported
Mezavant	N	S	Unknown	Unk	Not Reported
Benzydamine Hydrochloride	N	S	Unknown	Unk	Not Reported



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Calcitriol	N	S	Intra-articular	Unk	Not Reported
Mentha Arvensis	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium Anhydrous	N	S	Unknown	Unk	Not Reported
Zinc Chloride	N	S	Unknown	Unk	Not Reported
Macrogol;Propylene Glycol; Sodium Chloride	N	S	Other	Unk	Not Reported
Benzydamine	N	S	Unknown		Not Reported
Bifidobacterium Longum	N	S	Unknown		Not Reported
Ciprofloxacin	N	S	Unknown		Not Reported
Magnesium Carbonate	N	S	Unknown		Not Reported
Magnesium Hydroxide	N	S	Unknown		Not Reported
Ubidecarenone	N	S	Unknown		Not Reported
Fentanyl	Ν	S	Unknown		Not Reported
Apo-Alpraz	N	S	Unknown	0.25 Milligram	Not Reported
Empracet	N	S	Unknown	-	Not Reported
Valsartan	Ν	С	Unknown	Unk	Not Reported
Valsartan	Ν	С	Unknown	4 Dosage Form, Qd	Not Reported
Calcium Gluconate Cox	Ν	С		Unk	Not Reported
Calcium And Ergocalciferol	Ν	С	Unknown	Unk	Not Reported
Lomotil [Atropine Sulfate; Diphenoxylate Hydrochloride]	N	С	Oral	Unk Unk, Qid	Not Reported
Maxeran	N	С	Oral	10 Mg, Unk	Not Reported
Benadryl Allergy [Diphenhydramine Hydrochloride]	N	С	Unknown	Unk	Not Reported
Metoclopramide Hydrochloride	N	С	Unknown	Unk	Not Reported
Benadryl	N	С	Unknown	Unk	Not Reported
Sodium Stearate	N	С	Unknown	Unk	Not Reported
Calcium Carbonate;Vitamin D Nos	N	С	Unknown	Unk	Not Reported
Mupirocin Calcium	N	С	Unknown	Unk	Not Reported
Mupirocin Calcium	N	С	Topical	Unk	Not Reported



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	Antipyri Pseudo	ortisone ine ephedrine. drozoline			\$ \$ \$ \$					Not Not	Reported Reported Reported Reported	
FDA Received Date	Case #	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Co	ntrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country	
28-Mar-2023	21238409	EXPEDITED (15-DAY)	Y		HO, OT		IDUS ACEUTICALS -VDP-2022-			Unknown	USA	
Preferred Term	Produc	<u>et</u>	Comp.	OTC	Role	Route	Dosage	e Text	Duration	<u>Mfr</u>		
Abdominal Pain; Anae	emia; Ergocal	lciferol		N	S	Unknown	Unk			Vali	dus	

Preferred Term	Product	Comp.	<u>otc</u>	Role	Route	Dosage Text	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Anaemia;	Ergocalciferol		N	S	Unknown	Unk		Validus
Chronic Sinusitis; Colitis; Colitis Ulcerative;	Furosemide		N	S	Unknown	Unk		Validus
Constipation; Drug	Alprazolam		N	S	Unknown	Unk		Not Reported
Ineffective; Dyspepsia; Erythema; Female Genital	Alprazolam		N	S	Unknown	Unk		Not Reported
Tract Fistula; Frequent	Alprazolam		N	S	Unknown	Unk		Not Reported
Bowel Movements; Haematochezia;	Alprazolam		N	S	Unknown	Unk		Not Reported
Headache; Infusion	Alprazolam		N	S	Unknown	Unk		Not Reported
Related Reaction; Macular	Amoxicillin Trihydrate		N	S	Unknown	Unk		Not Reported
Degeneration; Malaise; Nausea; Off Label Use;	Amoxicillin Trihydrate		N	S	Unknown	Unk		Not Reported
Oral Candidiasis; Pain;	Amoxicillin Trihydrate		N	S	Unknown	Unk		Not Reported
Paraesthesia Oral; Procedural Pain; Proctitis;	Hydrochlorothiazide		N	S	Unknown	Unk		Not Reported
Pyrexia; Radiculopathy;	Hydrochlorothiazide		N	S	Unknown	Unk		Not Reported
Rectal Haemorrhage; Therapeutic Product Effect	Hydrochlorothiazide		N	S	Unknown	Unk		Not Reported
Incomplete; Treatment	Hydrochlorothiazide		N	S	Unknown	Unk		Not Reported
Failure; Vaginal Discharge; Vaginal	Atorvastatin		N	S	Unknown	Unk		Not Reported
Flatulence; Weight	Azithromycin		N	S	Unknown	Unk		Not Reported
Decreased	Azithromycin		N	S	Unknown	Unk		Not Reported
	Azithromycin		N	S	Unknown	Unk		Not Reported
	Mupirocin		N	S	Topical	Unk		Not Reported
	Mupirocin		N	S	Unknown	Unk		Not Reported
	Betamethasone Dipropionate		N	S	Unknown	Unk		Not Reported



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Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Transplacental	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Unk	Not Reported
Diphenhydramine	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Oral	1 Dosage Form	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Unknown	2. Inhalation	Not Reported
Budesonide	N	S	Oral	Unk	Not Reported
Glycerin [Glycerol]	N	S	Oral	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown		Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Oral	Unk	Not Reported
Nadolol	N	S	Oral	Unk	Not Reported



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Nicoderm	N	S	Transdermal	Unk	Not Reported
Nicoderm	N	S	Transdermal	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Topical	Unk	Not Reported
Pregabalin	N	S	Topical	Unk	Not Reported



Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole; Trimethoprim	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	Unk	Not Reported
Carmellose Sodium	N	S	Ophthalmic	Eye Drops, Solution, Unk	Not Reported
Carmellose Sodium	N	S	Ophthalmic	Eye Drops, Solution, Unk	Not Reported
Carmellose Sodium	N	S	Ophthalmic	Eye Drops, Solution, Unk	Not Reported
Carmellose Sodium	N	S	Unknown	Eye Drops, Solution, Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Fluocinolone Acetonide; Neomycin Sulfate;Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk, Qmo	Not Reported
Macrogol 4000	N	S	Unknown	Unk	Not Reported
Macrogol 4000	N	S	Unknown	Unk	Not Reported
Macrogol 4000	N	S	Oral	Unk	Not Reported
Macrogol 4000	N	S	Endocervical	Unk	Not Reported
Colecalciferol	N	S	Unknown	Unk	Not Reported
Colecalciferol	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Topical	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported



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Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Glycerol	N	S	Oral	Unk	Not Reported
Glycerol	N	S	Oral	Unk	Not Reported
Glycerol	N	S	Oral	Unk	Not Reported
Glycerol	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Amoxicillin	N	S	Unknown	Unk	Not Reported
Amoxicillin	N	S	Unknown	Unk	Not Reported
Amoxicillin	N	S	Unknown	Not Specified	Not Reported
Paracetamol	N	S	Unknown	Unk	Not Reported
Paracetamol	N	S	Unknown	Unk	Not Reported
Paracetamol	N	S	Unknown	Unk	Not Reported
Paracetamol	N	S	Unknown	Unk	Not Reported
Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Potassium Chloride	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium	N	S	Unknown	Unk	Not Reported



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Betamethasone	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Atropine;Diphenoxylate	N	S	Unknown	Unk	Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Fluticasone Propionate; Salmeterol Xinafoate	N	S	Unknown	Unk	Not Reported
Neomycin Sulfate	N	S	Unknown	Unk	Not Reported
Loperamide	N	S	Unknown	Unk	Not Reported
Loperamide	N	S	Oral	4 Df, Cont	Not Reported
Loperamide	N	S	Unknown	Cyclical	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Nasal Spray, Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Nasal Spray, Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Nasal Spray, Unk	Not Reported
Calcium Citrate	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk	Not Reported
Framycetin Sulfate	N	S	Unknown	Unk	Not Reported
Isoniazid	N	S	Unknown	Unk	Not Reported
Pyridoxine	N	S	Unknown	Unk	Not Reported
Atropine Sulphate	N	S	Oral	Unk	Not Reported



Atropine Sulphate	N	S	Oral	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Intra-articular	Unk	Not Reported
Hydrocortisone	N	S	Oral	9 Mg	Not Reported
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate; Sodium Chloride;So	N	S	Unknown	Unk	Not Reported
Kenalog [Triamcinolone Acetonide]	N	S	Unknown		Not Reported
Lomotil [Loperamide Hydrochloride]	N	S	Oral	Unk	Not Reported
Ambroxol;Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Diphenoxylate Hydrochloride And Atropine Sulfate	N	S	Unknown	Unk	Not Reported
Glycerol; Sodium Stearate	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium Anhydrous	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Sulfamethoxazole	N	S	Unknown	Unk	Not Reported
Ertapenem	N	S	Unknown	Unk	Not Reported
Mupirocin Calcium	N	S	Unknown	Unk	Not Reported
Azithromycin Monohydrate	N	S	Unknown	Unk	Not Reported
Vitamin E [Tocopherol]	N	S	Unknown	Unk	Not Reported
Cholecalciferol	N	S	Unknown	Unk	Not Reported
Difenoxin Hydrochloride	N	S	Unknown	Unk	Not Reported
Calcimax-Op [Calcitriol;Calcium Carbonate;Zinc]	N	S	Intra-articular	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate, Unspecified\Polyethylene Glycol 3350\Potassium Chloride\Potassium Sulfate\Sodium Bicarbonate\Sodium Chloride\Sodium Sulfate	N	S	Unknown	Unk	Not Reported



Triamcinolone	N	S	Unknown		Not Reported
Vitamin D [Vitamin D Nos]	N	S	Unknown	Unk	Not Reported
Macrogol;Potassium Chloride; Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Fructose;Glycerol;Sodium Chloride	N	S	Oral	Unk	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	Ν	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	Ν	S	Ophthalmic	Unk	Not Reported
Vitamin E Nos	Ν	S	Unknown	Unk	Not Reported
Zeaxanthin	Ν	S	Unknown	Unk	Not Reported
Sulfamethoxazole	Ν	S	Unknown		Not Reported
Flovent	Ν	S	Unknown		Not Reported
Benzydamine Hydrochloride	Ν	S	Unknown	Unk	Not Reported
Dulcolax [Bisacodyl]	Ν	S	Unknown	Unk	Not Reported
Calcium Phosphate; Colecalciferol	N	S	Unknown	Unk	Not Reported
Difenoxin Hydrochloride	Ν	S	Unknown	Unk	Not Reported
Ertapenem	Ν	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Lomotil [Loperamide Hydrochloride]	N	S	Unknown	Unk	Not Reported
Lomotil [Atropine Sulfate; Diphenoxylate Hydrochloride]	N	S	Unknown	Unk	Not Reported
Moviprep [Ascorbic Acid; Macrogol 4000;Potassium Chloride;Sodium Ascorb	N	S	Unknown	Unk	Not Reported
Neomycin B Sulfate	Ν	S	Unknown	Unk	Not Reported
Vitamin E [Vitamin E Nos]	Ν	S	Unknown	Unk	Not Reported
Sucralfate	N	S	Unknown	Unk	Not Reported
Midazolam	N	S	Unknown	Unk	Not Reported
Oxybutynin Hydrochloride	N	S	Unknown	Unk	Not Reported



	Ciproflo	oxacin		N	S	Unknown		Unk		I	Not Reported
	Zopiclo	ne		N	S	Unknown		Unk		1	Not Reported
	Azathio	prine		N	S	Unknown		Unk		I	Not Reported
	Azithro	mycin Dihydrate		N	S	Unknown		Unk		I	Not Reported
	Cupric	Oxide		N	S	Unknown		Unk		I	Not Reported
	Calcium	า		N	S	Unknown		Unk		I	Not Reported
	Habitro	[Nicotine]		N	S	Unknown		Unk		I	Not Reported
	Polymy	xin		N	S	Unknown		Unk		I	Not Reported
	Salinex	[Sodium Chloride]		N	S	Unknown		Unk (Nasal Drop)		I	Not Reported
	Diphenl	hydramine Hydrochloride		N	S	Unknown		Unk		1	Not Reported
	Diphenl	hydramine Hydrochloride		N	S	Unknown		Unk		I	Not Reported
	Diphenl	hydramine Hydrochloride		N	S	Unknown		Unk		I	Not Reported
	Diphenl	hydramine Hydrochloride		Ν	S	Unknown		Unk		I	Not Reported
	Refresh	Tears		N	S	Unknown		Unk		I	Not Reported
	Valsarta	an		N	С	Unknown		Unk		I	Not Reported
	Mesala	zine		N	С	Oral		1.2 Gram		I	Not Reported
	Diphenl	hydramine Hydrochloride		N	С	Unknown		Unk		I	Not Reported
	Calcium D3	n Carbonate And Vitamin		N	С	Unknown		Unk		I	Not Reported
	Neomy	cin Sulfate		N	С	Unknown		Unk		I	Not Reported
	Sodium	Stearate		N	С	Unknown		Unk		I	Not Reported
	Amoxic	illin		N	С	Unknown		Unk (Amoxicillin; Calciun Carbonate)	n	I	Not Reported
	Calcium	n Carbonate		N	С	Unknown		Unk		I	Not Reported
FDA Received Date Ca	se #	Case Type	Health	Prof	Outcomes	Mfr C	Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
28-Mar-2023 213	384118	EXPEDITED (15-DAY)	Υ		HO, OT	NVSC	2022CA21	5906	71 YR	Female	CAN
Preferred Term	Produc	<u>et</u>	Comp.	ото	Role	Route	<u></u>	<u>Dosage Text</u>	<u>Duration</u>	<u>N</u>	<u>lfr</u>
Abdominal Pain; Anaemia; Chronic Sinusitis; Colitis;	; Pantopi	razole		N	S	Unknown		Unk		l	Novartis



Colitis Ulcerative; Constipation; Drug
Ineffective; Dyspepsia;
Erythema; Female Genital
Tract Fistula; Frequent
Bowel Movements;
Haematochezia;
Headache; Infusion
Related Reaction; Macular
Degeneration; Malaise;
Nausea; Off Label Use;
Oral Candidiasis; Pain;
Paraesthesia Oral;
Procedural Pain; Proctitis;
Pyrexia; Radiculopathy;
Rectal Haemorrhage;
Therapeutic Product Effect
Incomplete; Vaginal
Discharge; Vaginal
Flatulence; Weight
Decreased
Doorodood

Pantoprazole N S Unknown Unk Novartis Adalimumab N S Subcutaneous Unk Novartis Atorvastatin N S Unknown Unk Novartis Diphenhydramine Hydrochloride N S Unknown Unk Not Reported Betamethasone N S Unknown Unk Novartis Clarithromycin N S Unknown Unk Novartis Sodium Bicarbonate N S Unknown Unk Not Reported Potassium Chloride N S Unknown Unk Not Reported Pregabalin N S Unknown Unk Not Reported Amoxicillin Trihydrate N S Unknown Unk Novartis Amoxicillin Trihydrate N S Unknown Unk Novartis Hydromorphone Hydrochloride N S Unknown Unk Not Reported Morphire Sulfate				Detailed Ke	port	
Atoryastatin N S Unknown Unk Novartis Diphenhydramine Hydrochloride N S Unknown Unk Novartis Betamethasone N S Unknown Unk Novartis Clarithromycin N S Unknown Unk Novartis Pantoprazole Sodium N S Unknown Unk Novartis Sodium Bicarbonate N S Unknown Unk Not Reported Potassium Chloride N S Unknown Unk Not Reported Pregabalin N S Unknown Unk Not Reported Pregabalin N S Unknown Unk Not Reported Amoxicillin Trihydrate N S Unknown Unk Novartis Amoxicillin Trihydrate N S Unknown Unk Novartis Hydromorphone Hydrochloride N S Endocervical Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Azithromycin Dihydrate N S Unknown Unk Not Reported Azithromycin Dihydrate N S Unknown Unk Not Reported Infliximab N S Unknown Unk Not Reported Atoryastatin Calcium N S Unknown Unk Not Reported Atoryastatin Calcium N S Unknown Unk Not Reported Atoryastatin Calcium N S Unknown Unk Not Reported Amoxicillin N S Unknown Unk Not Reported Atoryastatin Calcium N S Unknown Unk Not Reported Atoryastatin Calcium N S Unknown Unk Novartis Fentanyl N S Unknown Unk Novartis Midazolam N S Unknown Unk Novartis Midazolam N S Unknown Unk Novartis Midazolam N S Unknown Unk Not Reported	Pantoprazole	N	S	Unknown	Unk	Novartis
Diphenhydramine Hydrochloride Betamethasone N S Unknown Unk Novartis Clarithromycin N S Unknown Unk Novartis Pantoprazole Sodium N S Unknown Unk Novartis Pantoprazole Sodium N S Unknown Unk Novartis Pantoprazole Sodium N S Unknown Unk Not Reported Potassium Chloride N S Unknown Unk Not Reported Pregabalin N S Unknown Unk Not Reported Amoxicillin Trihydrate N S Unknown Unk Novartis Amoxicillin Trihydrate N S Unknown Unk Novartis Hydromorphone Hydrochloride N S Endocervical Unk Not Reported Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Worphine Sulfate N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Not Reported Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Unk Not Reported Not Reported Not Reported Morphine Sulfate N S Unknown Unk Not Reported Unk Novartis Novartis Unk Novartis Unk Novartis Unk Novartis Unk Novartis Unk Novartis Unk Novartis Novartis Novartis Unk Not Reported	Adalimumab	N	S	Subcutaneous	Unk	Novartis
Betamethasone N S Unknown Unk Novartis Clarithromycin N S Unknown Unk Novartis Pantoprazole Sodium N S Unknown Unk Novartis Sodium Bicarbonate N S Unknown Unk Not Reported Potassium Chloride N S Unknown Unk Not Reported Pregabalin N S Unknown 150 Mg Not Reported Pregabalin N S Unknown Unk Not Reported Pregabalin N S Unknown Unk Not Reported Amoxicillin Trihydrate N S Unknown Unk Novartis Amoxicillin Trihydrate N S Unknown Unk Novartis Hydromorphone Hydrochloride N S Endocervical Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Not Reported Azithromycin Dihydrate N S Unknown Unk Not Reported Azithromycin Dihydrate N S Unknown Unk Not Reported Infliximab N S Intravenous (not otherwise specified) Infliximab N S Unknown Unk Not Reported Atorvastatin Calcium N S Unknown Unk Not Reported Amoxicillin N S Unknown Unk Not Reported Amoxicillin N S Unknown Unk Not Reported Atorvastatin Calcium N S Unknown Unk Novartis Fentanyl N S Unknown Unk Novartis Unknown Unk Novartis Fentanyl N S Unknown Unk Novartis Unknown Unk Novartis Unknown Unk Novartis Unknown Unk Novartis Unk Novartis Unknown Unk Novartis Unknown Unk Novartis	Atorvastatin	N	S	Unknown	Unk	Novartis
Clarithromycin N S Unknown Unk Novartis Pantoprazole Sodium N S Unknown Unk Novartis Sodium Bicarbonate N S Unknown Unk Not Reported Potassium Chloride N S Unknown Unk Not Reported Pregabalin N S Unknown Unk Not Reported Pregabalin N S Unknown Unk Not Reported Amoxicillin Trihydrate N S Unknown Unk Novartis Amoxicillin Trihydrate N S Unknown Unk Novartis Hydromorphone Hydrochloride N S Endocervical Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Not Reported Milliximab N S Unknown Unk Novartis Infliximab N S Unknown Unk Novartis Infliximab N S Unknown Unk Novartis Infliximab Novartis Fergocalciferol N S Unknown Unk Novartis Amoxicillin N S Unknown Unk Novartis Amoxicillin N S Unknown Unk Novartis Amoxicillin N S Unknown Unk Novartis Pertanyl Novartis Midazolam N S Unknown Unk Novartis Midazolam N S Unknown Unk Not Reported Midazolam N S Unknown Unk Not Reported Midazolam N S Unknown Unk Novartis Not Reported	Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium N S Unknown Unk Not Reported Not Repo	Betamethasone	N	S	Unknown	Unk	Novartis
Sodium Bicarbonate N S Unknown Unk Not Reported Potassium Chloride N S Unknown Unk Not Reported Pregabalin N S Unknown 150 Mg Not Reported Pregabalin N S Unknown Unk Not Reported Pregabalin N S Unknown Unk Not Reported Amoxicillin Trihydrate N S Unknown Unk Novartis Amoxicillin Trihydrate N S Unknown Unk Novartis Hydromorphone Hydrochloride N S Endocervical Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Not Reported Azithromycin Dihydrate N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Not Reported Azithromycin Dihydrate N S Unknown Unk Not Reported Otherwise specified) Infliximab N S Unknown Unk Not Reported Otherwise specified) Infliximab N S Unknown Unk Not Reported Otherwise specified) Ergocalciferol N S Unknown Unk Not Reported Otherwise specified) Ergocalciferol N S Unknown Unk Not Reported Otherwise specified) Amoxicillin N S Unknown Unk Novartis Amoxicillin N S Unknown Unk Novartis Fentanyl N S Unknown Unk Novartis Midazolam N S Unknown Unk Novartis Midazolam N S Unknown Unk Not Reported Otherwise specified) Midazolam N S Unknown Unk Not Reported Otherwise specified)	Clarithromycin	N	S	Unknown	Unk	Novartis
Potassium Chloride N S Unknown Unk Not Reported Pregabalin N S Unknown 150 Mg Not Reported Pregabalin N S Unknown Unk Not Reported Amoxicillin Trihydrate N S Unknown Unk Novartis Amoxicillin Trihydrate N S Unknown Unk Novartis Hydromorphone Hydrochloride N S Endocervical Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Novartis Infliximab N S Intravenous (not otherwise specified) Unk Not Reported Infliximab N S Unknown Unk Not Reported	Pantoprazole Sodium	N	S	Unknown	Unk	Novartis
Pregabalin N S Unknown 150 Mg Not Reported Pregabalin N S Unknown Unk Not Reported Amoxicillin Trihydrate N S Unknown Unk Novartis Amoxicillin Trihydrate N S Unknown Unk Novartis Hydromorphone Hydrochloride N S Endocervical Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Not Reported Azirknomycin Dihydrate N S Unknown Unk Not Reported Infliximab N S Intravenous (not otherwise specified) Unk Not Reported Infliximab N S Unknown Unk Not Reported Atorvastatin Calcium N S Unknown Unk Novartis Amoxicillin N S Unknown Unk Not R	Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Pregabalin N S Unknown Unk Not Reported Amoxicillin Trihydrate N S Unknown Unk Novartis Amoxicillin Trihydrate N S Unknown Unk Novartis Hydromorphone Hydrochloride N S Endocervical Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Not Reported Azithromycin Dihydrate N S Unknown Unk Novartis Infliximab N S Intravenous (not otherwise specified) Unk Not Reported Infliximab N S Unknown Unk Not Reported Atorvastatin Calcium N S Unknown Unk Novartis Amoxicillin N S Unknown Unk Novartis Fentanyl N S Unknown Unk Not Reported	Potassium Chloride	N	S	Unknown	Unk	Not Reported
Amoxicillin Trihydrate N S Unknown Unk Novartis Amoxicillin Trihydrate N S Unknown Unk Novartis Hydromorphone Hydrochloride N S Endocervical Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Not Reported Azithromycin Dihydrate N S Unknown Unk Novartis Infliximab N S Intravenous (not otherwise specified) Infliximab N S Intravenous (not otherwise specified) Ergocalciferol N S Unknown Unk Not Reported Atorvastatin Calcium N S Unknown Unk Novartis Fentanyl N S Unknown Unk Novartis Midazolam N S Unknown Unk Novartis Midazolam N S Unknown Unk Novartis Midazolam N S Unknown Unk Novartis Mot Reported Not Reported	Pregabalin	N	S	Unknown	150 Mg	Not Reported
Amoxicillin Trihydrate N S Unknown Unk Novartis Hydromorphone Hydrochloride N S Endocervical Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Not Reported Azithromycin Dihydrate N S Unknown Unk Novartis Infliximab N S Unknown Unk Novartis Infliximab N S Intravenous (not otherwise specified) Infliximab N S Unknown Unk Not Reported Ergocalciferol N S Unknown Unk Not Reported Atorvastatin Calcium N S Unknown Unk Novartis Amoxicillin N S Unknown Unk Novartis Fentanyl N S Unknown Unk Novartis Midazolam N S Unknown 2 Dosage Form Not Reported Midazolam N S Unknown 2 Dosage Form Not Reported Midazolam N S Unknown 2 Dosage Form Not Reported	Pregabalin	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride N S Endocervical Unk Not Reported Hydromorphone Hydrochloride N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Not Reported Azithromycin Dihydrate N S Unknown Unk Novartis Infliximab N S Unknown Unk Novartis Infliximab N S Intravenous (not otherwise specified) Infliximab N S Unknown Unk Not Reported Otherwise specified) Infliximab Not Reported Unk Novartis Unk Not Reported	Amoxicillin Trihydrate	N	S	Unknown	Unk	Novartis
Hydromorphone Hydrochloride N S Unknown Unk Not Reported Morphine Sulfate N S Unknown Unk Not Reported Magnesium Sulfate N S Unknown Unk Not Reported Azithromycin Dihydrate N S Unknown Unk Novartis Infliximab N S Intravenous (not otherwise specified) Infliximab N S Unknown Unk Not Reported Infliximab N S Intravenous (not otherwise specified) Infliximab N S Unknown Unk Not Reported Ergocalciferol N S Unknown Unk Not Reported Atorvastatin Calcium N S Unknown Unk Novartis Amoxicillin N S Unknown Unk Novartis Fentanyl N S Unknown Unk Novartis Intravenous (not otherwise specified)	Amoxicillin Trihydrate	N	S	Unknown	Unk	Novartis
Morphine SulfateNSUnknownUnkNot ReportedMagnesium SulfateNSUnknownUnkNot ReportedAzithromycin DihydrateNSUnknownUnkNovartisInfliximabNSIntravenous (not otherwise specified)UnkNot ReportedInfliximabNSIntravenous (not otherwise specified)5 Mg/KgNot ReportedErgocalciferolNSUnknownUnkNot ReportedAtorvastatin CalciumNSUnknownUnkNovartisAmoxicillinNSUnknownUnkNovartisFentanylNSIntravenous (not otherwise specified)UnkNot ReportedMidazolamNSUnknown2 Dosage FormNot ReportedAtropine SulfateNSOralUnkNot Reported	Hydromorphone Hydrochloride	N	S	Endocervical	Unk	Not Reported
Magnesium SulfateNSUnknownUnkNot ReportedAzithromycin DihydrateNSUnknownUnkNovartisInfliximabNSIntravenous (not otherwise specified)UnkNot ReportedInfliximabNSIntravenous (not otherwise specified)5 Mg/KgNot ReportedErgocalciferolNSUnknownUnkNovartisAtorvastatin CalciumNSUnknownUnkNovartisAmoxicillinNSUnknownUnkNovartisFentanylNSIntravenous (not otherwise specified)UnkNot ReportedMidazolamNSUnknown2 Dosage FormNot ReportedAtropine SulfateNSOralUnkNot Reported	Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Azithromycin Dihydrate N S Unknown Unk Infliximab N S Intravenous (not otherwise specified) Infliximab N S Intravenous (not otherwise specified) Infliximab N S Unknown Unk Atorvastatin Calcium N S Unknown Unk Amoxicillin N S Unknown Unk Novartis Amoxicillin N S Unknown Unk Novartis Fentanyl N S Unknown Unk Novartis Intravenous (not otherwise specified) Unk Novartis Novartis Novartis Amoxicillin N S Unknown Unk Novartis Fentanyl N S Unknown Unk Novartis Fentanyl Not Reported	Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Infliximab N S Intravenous (not otherwise specified) Unk Not Reported Infliximab N S Intravenous (not otherwise specified) 5 Mg/Kg Not Reported Ergocalciferol N S Unknown Unk Not Reported Atorvastatin Calcium N S Unknown Unk Novartis Amoxicillin N S Unknown Unk Novartis Fentanyl N S Intravenous (not otherwise specified) Unk Not Reported Midazolam N S Unknown 2 Dosage Form Not Reported Atropine Sulfate N S Oral Unk	Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Infliximab N S Intravenous (not otherwise specified) Ergocalciferol Atorvastatin Calcium N S Unknown Unk Novartis Amoxicillin N S Unknown Unk Novartis N S Unknown Unk Novartis Novartis Intravenous (not otherwise specified) N S Unknown Unk Novartis Novartis Fentanyl N S Unknown Unk Novartis Fentanyl N S Unknown Unk Novartis Fontanyl Not Reported N S Unknown Unk Not Reported	Azithromycin Dihydrate	N	S	Unknown	Unk	Novartis
Ergocalciferol N S Unknown Unk Not Reported Atorvastatin Calcium N S Unknown Unk Novartis Amoxicillin N S Unknown Unk Novartis Fentanyl N S Intravenous (not otherwise specified) Midazolam N S Unknown 2 Dosage Form Not Reported Atropine Sulfate N S Oral Unk	Infliximab	N	S		Unk	Not Reported
Atorvastatin Calcium N S Unknown Unk Novartis Novartis Fentanyl N S Intravenous (not otherwise specified) Midazolam N S Unknown Vnk Novartis Not Reported	Infliximab	N	S		5 Mg/Kg	Not Reported
Amoxicillin N S Unknown Unk Novartis Fentanyl N S Intravenous (not otherwise specified) Midazolam N S Unknown 2 Dosage Form Not Reported Atropine Sulfate N S Oral Unk Not Reported	Ergocalciferol	N	S	Unknown	Unk	Not Reported
Fentanyl N S Intravenous (not otherwise specified) Midazolam N S Unknown 2 Dosage Form Not Reported Atropine Sulfate N S Oral Unk Not Reported	Atorvastatin Calcium	N	S	Unknown	Unk	Novartis
Midazolam N S Unknown 2 Dosage Form Not Reported Atropine Sulfate N S Oral Unk Not Reported	Amoxicillin	N	S	Unknown	Unk	Novartis
Atropine Sulfate N S Oral Unk Not Reported	Fentanyl	N	S		Unk	Not Reported
Oldi Olik	Midazolam	N	S	Unknown	2 Dosage Form	Not Reported
Atropine Sulfate N S Oral 4 Dosage Form Not Reported	Atropine Sulfate	N	S	Oral	Unk	Not Reported
	Atropine Sulfate	N	S	Oral	4 Dosage Form	Not Reported



				•		
Atropine Sulfate	N	S	Oral	1 Dosage Form		Not Reported
Atropine Sulfate	N	S	Unknown	Unk		Not Reported
Atropine Sulfate	N	S	Unknown	1 Dosage Form		Not Reported
Acetaminophen	N	S	Unknown	Unk		Not Reported
Acetaminophen	N	S	Unknown	Unk		Not Reported
Glycerine	N	S	Oral	Unk		Not Reported
Glycerine	N	S	Unknown	Unk		Not Reported
Glycerine	N	S	Unknown	Unk (Oral Liquid)		Not Reported
Alprazolam	N	S	Unknown	0.25 Mg		Not Reported
Sulfamethoxazole And Trimethoprim	N	S	Unknown	200 Mg		Not Reported
Azithromycin	N	S	Unknown	Unk		Not Reported
Biaxin XI	N	S	Unknown	Unk (Extended Release)		Not Reported
Calcitriol	N	S	Intra-articular	Unk		Not Reported
Diphenoxylate Hydrochloride	N	S	Oral	Unk		Not Reported
Diphenoxylate Hydrochloride	N	S	Oral	1 Dosage Form		Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown	Unk		Not Reported
Entocort	N	S	Unknown	Unk (Sustained Release))	Not Reported
Entocort	N	S	Oral	Unk		Not Reported
Flovent	N	S	Unknown	Unk		Not Reported
Glyceryl Trinitrate	N	S	Unknown	Unk		Not Reported
Humira	N	S	Subcutaneous	Unk	6 YR	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk		Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk		Not Reported
Imodium	N	S	Unknown	Unk		Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk		Not Reported
Nicotine	N	S	Transdermal	Unk		Not Reported
Sinus Rinse	N	S	Nasal	Unk		Not Reported
Sinus Rinse	N	S	Other	Unk		Not Reported
Statex	N	S	Unknown	Unk		Not Reported



Benzalkonium Chloride	N	S	Nasal	Unk (Intranasal)	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	0.122 G	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Calcium Carbonate And Vitamin D	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Metronidazole	Ν	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk, Suspension	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Fluticasone Propionate	N	S	Unknown	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Glycerol	N	S	Oral	Unk	Not Reported
Glycerol	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown		Not Reported
Gramicidin;Polymyxin B	N	S	Unknown	Unk	Not Reported
Loperamide	N	S	Unknown	Unk	Not Reported
Loperamide	N	S	Oral	4 Dosage Form, Qd	Not Reported
Loperamide	N	S	Oral	1 Dosage Form, Cyclical	Not Reported



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Mesalazine	N	S	Unknown	Unk	Not Reported
Macrogol	N	S	Urethral	Unk	Not Reported
Macrogol	N	S	Unknown	Unk	Not Reported
Tocopherols Mixed	N	S	Unknown	Unk	Not Reported
Gramicidin\Neomycin\Polymyxin B Sulfate	N	S	Unknown	Unk (Dental)	Not Reported
Nadolol	N	S	Unknown	40 Mg	Not Reported
Nicoderm	N	S	Transdermal	Unk (Patch)	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Oral	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S		Unk	Not Reported
Sodium Chloride	N	S	Nasal	Unk	Not Reported
Sodium Chloride	N	S	Nasal	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Cupric Oxide;Folic Acid;Nicotinic Acid;Zinc	N	S	Unknown	Unk	Not Reported
Benzydamine Hydrochloride	N	S	Unknown	Unk	Not Reported
Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Mentha Arvensis	N	S	Unknown	Unk	Not Reported



Nicomorphine	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium Anhydrous	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole	N	S	Unknown	200 Mg	Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported
Zinc Chloride	N	S	Unknown	Unk	Not Reported
Acetaminophen And Codeine Phosphate	N	S	Unknown	Unk	Not Reported
Dextropropoxyphene	N	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Unk	Not Reported
Ambroxol Hydrochloride	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Ambroxol	N	S	Unknown	Unk	Not Reported
Ammonium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Citrate	N	S	Unknown	Unk	Not Reported
Entyvio	N	S	Intravenous (not otherwise specified)	200 Mg, Tid	Not Reported
Entyvio	N	S	Intravenous (not otherwise specified)	200 Mg, Tid	Not Reported
Flagyl	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 3350\Potassium\Sodium	N	S	Unknown	Unk	Not Reported
Chloride\Sodium Sulfate Polyethylene Glycol 3350\Potassium\Sodium Chloride\Sodium Sulfate	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 3350\Potassium\Sodium	N	S	Unknown	Unk	Not Reported
Chloride\Sodium Sulfate Polyethylene Glycol 3350\Potassium\Sodium Chloride\Sodium Sulfate	N	S	Unknown	Unk	Not Reported

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Note: If the field is blank, there is no data.



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Isoniazid	N	S	Unknown	Unk		Not Reported
Midazolam Hydrochloride	N	S	Unknown	2 Dosage Form		Not Reported
Nicotinamide	N	S	Unknown	Unk		Not Reported
Zopiclone	N	S	Unknown	Unk		Not Reported
Refresh Tears	N	S	Ophthalmic	Unk (Eye Drops)		Not Reported
Refresh Tears	N	S	Intraocular	Unk (Drops Ophthalmic)		Not Reported
Lomotil	N	S	Unknown	Unk		Not Reported
Lomotil	N	S	Oral	Unk, 4 Every One Day		Not Reported
Lomotil	N	S	Oral	4 Dosage Form, 1 Every 1 Day		Not Reported
Valsartan	N	С	Unknown	Unk		Not Reported
Amoxicillin	N	С	Unknown	Unk		Not Reported
Pulmicort	N	S		Unk		Not Reported
Pulmicort	N	S	Oral	Unk		Not Reported
Infliximab	N	S	Intravenous (not otherwise specified)	5 Mg/Kg		Not Reported
Infliximab	N	S	Intravenous (not otherwise specified)	10 Mg/Kg	132 DAY	Not Reported
Infliximab	N	S	Intravenous (not otherwise specified)	5 Mg/Kg		Not Reported
Infliximab	N	S	Intravenous (not otherwise specified)	5 Mg/Kg		Not Reported
Infliximab	N	S	Intravenous (not otherwise specified)	5 Mg/Kg		Not Reported
Infliximab	N	S	Intravenous (not otherwise specified)	5 Mg/Kg		Not Reported
Infliximab	N	S	Intravenous (not otherwise specified)	10 Mg/Kg	132 DAY	Not Reported
Avamys	N	S	Unknown	Unk		Not Reported
Methylprednisolone Sodium Succinate	N	S	Intravenous (not otherwise specified)	Unk		Not Reported
Pentasa	N	S	Unknown	Unk		Not Reported

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Dilaudid

FDA Adverse Event Reporting System Freedom of Information Act (FOIA) **Detailed Report**

Unknown

1 Dosage Form, 2 Every 1

Day

							Day			
		Diflucan		Ν	S	Unknown	Unk			Not Reported
Solu-Medrol Bactrim			N	S	Intravenous (not otherwise specifie	Unk d)			Not Reported	
			Ν	S	Unknown	Unk			Not Reported	
		Glycerinum		Ν	S	Oral	Unk (Drops Oral)			Not Reported
		Bactrim		Ν	S	Nasal	Unk			Not Reported
		Calcium		Ν	S	Unknown	Unk			Not Reported
		Calcium Lactate		Ν	С	Unknown	Unk			Not Reported
		Sodium Stearate		Ν	С	Unknown	Unk			Not Reported
		Calcium Gluconate		Ν	С	Unknown	Unk			Not Reported
		Metoclopramide Hydrochloride		Ν	С	Unknown	Unk			Not Reported
		Benadryl		Ν	С	Unknown	Unk			Not Reported
		Benadryl Allergy		Ν	С	Oral	Unk			Not Reported
		Neomycin Sulfate		Ν	С	Unknown	Unk			Not Reported
		Diphenhydramine Hydrochloride		N	С	Unknown	Unk			Not Reported
FDA Received Date	Case :	# Case Type	<u>Health</u>	<u>Prof</u>	Outcomes	Mfr Contro	1# 503B Facility	<u>Age</u>	<u>Sex</u>	Country
29-Mar-2023	21985	846 EXPEDITED (15-DAY)	Υ		HO, OT	NVSC2023C	A027221	65 YR	Female	CAN
Preferred Term		Product	Comp.	OTO	Role	Route	<u>Dosage Text</u>	<u>Duration</u>		<u>Mfr</u>
Abdominal Pain; Anae		Adalimumab		N	S	Subcutaneous	Unk			Novartis
Chronic Sinusitis; Colin Colitis Ulcerative;	tis;	Atorvastatin Calcium		N	S	Unknown	Unk			Novartis
Constipation; Drug Ineffective; Dyspepsia		Atorvastatin Calcium		N	S	Unknown	Unk (Dosage Form: No Specified)	t		Novartis
Erythema; Female Ge Tract Fistula; Frequen		Azithromycin		N	S	Unknown	Unk			Novartis
Bowel Movements;	ι	Azithromycin		N	S	Oral	Unk			Novartis
Haematochezia;		Ciprofloxacin		N	S	Unknown	Unk			Novartis
Headache; Infusion Related Reaction; Mad Degeneration; Malaise		Sodium Bicarbonate		N	S	Unknown	Unk			Not Reported

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Note: If the field is blank, there is no data.

Not Reported



Nausea; Off Label Use; Oral Candidiasis; Pain; Paraesthesia Oral; Procedural Pain; Proctitis; Pyrexia; Radiculopathy; Rectal Haemorrhage; Therapeutic Product Effect Incomplete; Vaginal Discharge; Vaginal Flatulence; Weight Decreased

Ciprofloxacin Hydrochloride	N	S	Unknown	Unk
Clarithromycin	N	S	Unknown	Unk
Clarithromycin	N	S	Unknown	Unk
Diphenhydramine	N	S	Unknown	Unk
Diphenhydramine	N	S	Unknown	Unk
Diphenhydramine Hydrochloride	N	S	Unknown	Unk
Diphenhydramine Hydrochloride	N	S	Oral	50 Mg
Diphenhydramine Hydrochloride	N	S	Unknown	Unk
Fentanyl	N	S	Unknown	Unk
Fentanyl Citrate	N	S	Unknown	Unk
Fluconazole	N	S	Unknown	Unk
Hydrocortisone	N	S	Unknown	Unk
Magnesium	N	S	Unknown	Unk
Hydromorphone Hydrochloride	N	S	Unknown	Unk
Hydromorphone Hydrochloride	N	S	Endocervical	Unk
Hydromorphone Hydrochloride	N	S	Unknown	Unk
Hydromorphone Hydrochloride	N	S	Unknown	Unk
Hydromorphone Hydrochloride	N	S	Unknown	Unk
Magnesium Sulfate	N	S	Unknown	Unk
Magnesium Sulfate	N	S	Unknown	Unk, Strength (50%) (Formulation: Liquid Intramuscular)
Magnesium Sulfate	N	S	Unknown	Unk
Pantoprazole	N	S	Unknown	Unk
Dentenrazala	NI	C		

Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk, Strength (50%) (Formulation: Liquid Intramuscular)	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Novartis
Pantoprazole	N	S	Unknown	Unk	Novartis
Potassium Chloride	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Unknown	150 Mg	Not Reported
Acetaminophen	N	S	Unknown	Unk	Not Reported
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Novartis

Novartis

Novartis

Not Reported

Not Reported

Not Reported

Not Reported

Not Reported
Not Reported
Not Reported
Not Reported
Novartis
Not Reported



				<u> </u>	
Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Dosage Form, Qd	Not Reported
Loperamide Hydrochloride	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Dosage Form, Qid	Not Reported
Loperamide Hydrochloride	N	S	Oral	4 Dosage Form, Qd	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk	Not Reported
Bisacodyl	N	S	Transplacental	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Unknown	Unk (Modified-Release Capsule, Hard)	Not Reported
Budesonide	N	S		Unk	Not Reported
Budesonide	N	S	Oral	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Fluticasone Propionate	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Topical	Unk	Not Reported
Sodium Chloride	Ν	S	Nasal	Unk (Intra-Nasal)	Not Reported
Zinc Oxide	Ν	S	Unknown	Unk	Not Reported
Zopiclone	Ν	S	Unknown	Unk	Not Reported
Magnesium Oxide	Ν	S	Unknown	Unk	Not Reported
Magnesium Carbonate	Ν	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Unk	Not Reported



Magnesium Hydroxide	N	S	Unknown	Unk		Not Reported
Align	N	S	Unknown	Unk		Not Reported
Apo-Alpraz	N	S	Unknown	0.25 Mg		Not Reported
Apo-Alpraz	N	S	Unknown	Unk		Not Reported
Apo-Alpraz	N	S	Unknown	Unk		Not Reported
Benzydamine	N	S	Unknown	Unk		Not Reported
Betamethasone Valerate	N	S	Unknown	Unk		Not Reported
Biaxin XI	N	S	Unknown	Unk (Extended Release)		Not Reported
Biaxin XI	N	S	Unknown	Unk		Not Reported
Clotrimazole	N	S	Unknown	Unk		Not Reported
Clotrimazole	N	S	Unknown	Unk		Not Reported
Cortenema	N	S	Unknown	Unk (Suspension)		Not Reported
Desonide	N	S	Unknown	Unk		Not Reported
Desonide	N	S	Unknown	Unk		Not Reported
Empracet	N	S	Unknown	Unk		Not Reported
Entyvio	N	S	Intravenous (not otherwise specified)	Unk (Powder For Solution Intravenous)	า	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk (Route: Intra-Nasal)		Not Reported
Ertapenem Sodium	N	S	Intramuscular	Unk		Not Reported
Fructose	N	S	Unknown	Unk		Not Reported
Glycerin	N	S	Unknown	Unk		Not Reported
Glycerin	N	S	Oral	Unk		Not Reported
Glycerin	N	S	Oral	Unk		Not Reported
Glycerol	N	S	Unknown	Unk		Not Reported
Glyceryl Trinitrate	N	S	Oral	Unk		Not Reported
Habitrol	N	S	Unknown	Unk		Not Reported
Humira	N	S	Subcutaneous	Unk	6 YR	Not Reported
Humira	N	S	Subcutaneous	Unk		Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk		Not Reported



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Hydrochlorothiazide	N	S	Subcutaneous	Unk	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
Hydrochlorothiazide	N	S	Endocervical	100 Mg	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Methylprednisolone Sodium Succinate	N	S	Unknown	Unk	Not Reported
Methylprednisolone Sodium Succinate	N	S	Unknown	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Midazolam	N	S	Unknown	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Mupirocin	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	40 Mg	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Topical	Unk (Patch)	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported



Nicotine	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Oxybutynin Hydrochloride	N	S	Unknown	Unk	Not Reported
Oxybutynin Hydrochloride	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Refresh Tears	N	S	Unknown	Unk	Not Reported
Sucralfate	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk (Suspension Intra- Articular)	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk	Not Reported
Ubidecarenone	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Oral	Unk	Not Reported
Zeaxanthin	N	S	Oral	Unk	Not Reported
Flovent	N	S	Unknown	Unk	Not Reported
Flovent	N	S	Unknown	Unk	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Sinus Rinse	N	S	Nasal	Unk (Solution Nasal)	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole And Trimethoprim	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole And Trimethoprim	N	S	Unknown	200 Mg	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Alprazolam Teva	N	S	Unknown	0.25 Mg	Not Reported



Alprazolam	N	S	Unknown	0.25 Mg	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Framycetin Sulfate	N	S	Unknown	Unk	Not Reported
Pyridoxine	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Acetaminophene	N	S	Unknown	Unk	Not Reported
Apo Hydro	N	S	Endocervical	Unk	Not Reported
Avamys	N	S	Unknown	Unk (Spray, Metered Dose)	Not Reported
Bactrim	N	S	Unknown	Unk	Not Reported
Bactroban	N	S	Unknown	Unk	Not Reported
Betaderm	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Betamethasone Sodium Phosphate	N	S	Unknown	Unk	Not Reported
Cetirizine	N	S	Unknown	Unk	Not Reported
Dexpantenol	N	S	Unknown	Unk	Not Reported
Difenoxin Hydrochloride	N	S	Unknown	Unk	Not Reported
Dilaudid	N	S	Unknown	Unk	Not Reported
Dimethyl Sulfoxide	N	S	Unknown	Unk	Not Reported
Entocort	N	S	Oral	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Fluticasone	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Kenalog	N	S	Intra-articular	Unk (Suspension)	Not Reported
Lomotil	N	S	Oral	Unk, Qid	Not Reported
Loperamide	N	S	Oral	4 Dosage Form, Qd	Not Reported
Neomycin Sulfate	N	S	Unknown	Unk	Not Reported



		Nicotine	Polacrilex		N	S	Unknown	Unk			Not Reported
		Pentasa			Ν	S	Unknown	Unk			Not Reported
		Polymyx	in B Sulfate		Ν	S	Unknown	Unk			Not Reported
		Pulmico	rt		Ν	S	Unknown	Unk			Not Reported
		Sodium	Chloride		Ν	S	Other	Unk			Not Reported
		Sodium	Chloride		Ν	S	Unknown	Unk			Not Reported
		Sodium	Chloride		Ν	S	Nasal	Unk			Not Reported
		Statex			N	S	Unknown	Unk			Not Reported
FDA Received Date	Case #	<u>#</u>	Case Type	<u>Health</u>	Prof	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
31-Mar-2023	212603	399	EXPEDITED (15-DAY)	Υ		HO, OT	CA-BAXTER- 2022BAX01769	6	71 YR	Female	CAN
Preferred Term		Produc	<u>t</u>	Comp.	OTO	Role	Route	Dosage Text	Duration]	<u>Mfr</u>
Chronic Sinusitis; Drug Ineffective; Dyspepsia; Infusion Related React	ion;	Sodium	Chloride		N	S	Nasal	Dosage Form: Not Specified, Intranasal Route			Baxter
Macular Degeneration; Malaise; Nausea; Off Label Use; Pain;	; Nausea; Off	Sodium	Chloride		N	S	Other	Dosage Form: Not Specified			Baxter
Paraesthesia Oral; Procedural Pain; Pyrex		Sodium	Chloride		N	S		Dosage Form: Not Specified			Baxter
Therapeutic Product Ef Incomplete; Weight Decreased	fect	Metronio	dazole		N	S	Unknown	Dosage Form: Not Specified			Baxter
Decreased		Magnes	ium Sulfate		N	S	Unknown	Dosage Form: Not Specified			Baxter
		Potassiu	ım Chloride		N	S	Endocervical	Dosage Form: Not Specified			Baxter
		Sodium Concent	Bicarbonate rate		N	S	Unknown	Dosage Form: Not Specified			Baxter
		Acetami	nophen Injection		N	S	Unknown	Dosage Form: Not Specified			Baxter
		Alprazol	am		Ν	S	Unknown	0.25 Milligrams (Mg)			Not Reported
		Alprazol	am		Ν	S		Via Inhalation Route			Not Reported



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Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
Atropine Sulfate	N	S	Oral	Dosage Form: Not Specified	Not Reported
Atorvastatin Calcium	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Avamys	N	S	Unknown	Dosage Form: Spray Metered Dose	Not Reported
Azithromycin	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Adalimumab	N	S	Subcutaneous	Dosage Form: Solution Subcutaneous	Not Reported
Adalimumab Azithromycin Monohydrate	N N	S S	Unknown		Not Reported Not Reported
Atorvastatin	N	S	Unknown		Not Reported
Acetylsalicylic Acid	N	S	Oral	Dosage Form: Not Specified	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Azithromycin Dihydrate	N	S	Unknown		Not Reported
Ambroxol;Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Bactrim	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Betamethasone	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Biaxin XI	N	S	Unknown	Extended Release	Not Reported
Bisacodyl	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Bisacodyl	N	S	Transplacental	Dosage Form: Not Specified	Not Reported
Betamethasone Valerate	N	S	Unknown	0.122 Gram	Not Reported



Budesonide	N	S	Oral	1 Dosage Form (Dosage Form: Not Specified)	Not Reported
Budesonide	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Clarithromycin	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Citric Acid;Sodium Bicarbonate	N	S	Unknown		Not Reported
Calcium Carbonate	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Calcium Carbonate/Vitamin D3	N	S	Unknown		Not Reported
Calcium Citrate	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Cetirizine	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Cholecalciferol	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Clotrimazole	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Calcitriol;Calcium Carbonate; Zinc	N	S	Intra-articular		Not Reported
Cupric Oxide	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Cetirizine Hydrochloride	N	S	Unknown		Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Dosage Form: Not Specified	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Dosage Form: Not Specified	Not Reported
D-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
Difenoxin Hydrochloride	N	S	Oral		Not Reported
Diphenhydramine Hydrochloride	N	S	Oral	Dosage Form: Not Specified, 50 Milligram	Not Reported



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Diphenhydramine Hydrochloride Diphenhydramine	N N	S S	Unknown	Dosage Form: Not Specified		Not Reported Not Reported
Dilaudid	N	S	Unknown	Dosage Form: Not Specified		Not Reported
Ertapenem Sodium	N	S	Unknown	Unk		Not Reported
Ertapenem Sodium	N	S	Nasal	Via Intranasal		Not Reported
Ertapenem	N	S	Unknown	Single Use Vial, Dosage Form: Powder For Soluti Intramuscular		Not Reported
Ergocalciferol	N	S	Unknown	Dosage Form: Not Specified		Not Reported
Entocort	N	S	Oral	Capsule, Sustained Release		Not Reported
Flovent	N	S	Unknown	Dosage Form: Not Specified		Not Reported
Fluticasone Furoate	N	S	Unknown	Unk		Not Reported
Fructose;Glycerol;Sodium Chloride	N	S	Oral	Unk		Not Reported
Fluticasone	N	S	Unknown	Dosage Form: Not Specified		Not Reported
Glycerol	N	S	Oral	Unk		Not Reported
Glycerol	Ν	S	Unknown	Unk		Not Reported
Glycerol;Sodium Stearate	Ν	S	Oral	Unk		Not Reported
Glycerine	N	S	Oral	Unk		Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown	Unk		Not Reported
Gramicidin	N	S	Unknown	Unk		Not Reported
Humira	N	S	Subcutaneous	Dosage Text: Solution Subcutaneous	6 YR	Not Reported
Humira	N	S	Subcutaneous	Unk	6 YR	Not Reported
Hydrochlorothiazide	N	S	Endocervical			Not Reported
Hydromorphone	N	S	Unknown	Dosage Form: Not Specified		Not Reported



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Hydromorphone Hydrochloride	N	S	Endocervical	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Ichthammol;Zinc Oxide	N	S	Unknown	Unk	Not Reported
Lomotil	N	S	Oral		Not Reported
Mupirocin	N	S	Topical	Dosage Form: Ointment Topical	Not Reported
Macrogol 3350	N	S	Unknown	Unk	Not Reported
Macrogol;Potassium Chloride; Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Macrogol 3350;Potassium Chloride;Sodium Chloride; Sodium Sulfate	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Moviprep	N	S	Unknown	Dosage Text: Powder For Solution For Oral	Not Reported
Morphine Sulfate	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Magnesium Oxide	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Nadolol	N	S	Unknown	40 Milligrams	Not Reported
Neomycin	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Neomycin B Sulfate	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Neomycin Sulfate	N	S	Unknown	Unk	Not Reported
Neomycin Sulfate	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Patch	Not Reported
Nicotine	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Nicotine Polacrilex	N	S	Unknown	Dosage Form: Not Specified	Not Reported



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Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium	N	S	Unknown		Not Reported
Pentasa	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Polyethylene Glycol 4000	N	S	Endocervical	Unk	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Pregabalin	N	S	Unknown	150 Milligrams	Not Reported
Prednisone Acetate	N	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S		Dosage Form: Not Specified	Not Reported
Refresh Tears	N	S	Ophthalmic	Drops Ophthalmic	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Simvastatin	N	S	Unknown		Not Reported
Sulfamethoxazole	N	S	Unknown		Not Reported
Sulfamethoxazole And Trimethoprim	N	S	Oral	Dosage Form: Not Specified, 1 Dosage Form	Not Reported
Sulfamethoxazole And Trimethoprim	N	S	Unknown	200 Milligram	Not Reported
Sinus Rinse	N	S	Nasal	Solution Nasal Via Intranasal	Not Reported
Triamcinolone	N	S	Intra-articular	Unk	Not Reported
Triamcinolone	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Dosage Form: Suspension	Not Reported



				Intra-Articular	
Triamcinolone Acetonide	N	S	Intra-articular	Dosage Form: Suspension Intra Articular	Not Reported
Trimethoprim	N	S	Unknown		Not Reported
Vitamin D	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Vitamin E Nos	N	S	Intracardiac		Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Zinc Oxide	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Acetaminophen	N	S	Unknown		Not Reported
Acetaminophen; Dextropropoxyphene	N	S	Unknown		Not Reported
Amoxicillin	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Atorvastatin Calcium	N	S	Unknown		Not Reported
Calcium Carbonate; Ergocalciferol	N	S	Unknown		Not Reported
Cupric Oxide;Folic Acid;Nicotinic Acid;Zinc	N	S	Unknown		Not Reported
Fluticasone Proprionate	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown		Not Reported
Infliximab	N	S	Intravenous (not otherwise specified)	Dosage Form: Not Specified	Not Reported
Isoniazid/Pyridoxine Hydrochloride/Sulfamethoxazole /Trimethoprim	N	S	Unknown		Not Reported
Loperamide Hydrochloride	N	S	Oral		Not Reported
Magnesium Sulfate	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Loperamide	N	S	Unknown		Not Reported
Calcium;Colecalciferol	N	S	Unknown	Dosage Form: Not	Not Reported



						Specified	
	Nicot	tinamide	N	S	Unknown		Not Reported
	Glyce	erin	N	S	Unknown	Dosage Form: Not Specified	Not Reported
	Pante	oprazole Sodium Anhydrous	N	S	Unknown		Not Reported
	Diph	enhydramine Hydrochloride	N	С	Unknown		Not Reported
	Calci	ium Carbonate/Vitamin D3	N	С	Unknown		Not Reported
	Valsa	artan	N	С	Oral	Dosage Form: Not Specified, 4 Dosage Form, One Every One Days	Not Reported
	Valsa	artan	N	С	Unknown	40 Milligrams, One Every One Days	Not Reported
	Valsa	artan	N	С	Unknown	Dosage Form: Not Specified	Not Reported
	Sodi	um Stearate	N	С	Unknown		Not Reported
	Calci	ium Ergocalciferol	N	С	Unknown		Not Reported
	Meto	clopramide Hydrochloride	N	С	Oral		Not Reported
	Meto	clopramide Hydrochloride	N	С	Unknown	Unk	Not Reported
	Calci	ium	N	С	Unknown	Dosage Form: Not Specified	Not Reported
		ium Carbonate; calciferol	N	С	Unknown		Not Reported
	Lope	ramide	N	С	Oral	4 Dosage Forms, One Every One Days	Not Reported
	Bena	adryl	N	С	Unknown	Dosage Form: Not Specified	Not Reported
	Lomo	otil	N	С	Unknown		Not Reported
		ium Lactate;Calcium phate;Ergocalciferol	N	С	Unknown		Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility Age	Sex Country
04-Apr-2023	17954704	EXPEDITED (15-DAY)	Υ	но, от	CA-GLENMARK PHARMACEUTI 2020GMK04830	ICALS-	Unknown CAN



Preferred Term	<u>Product</u>	Comp.	<u>OTC</u>	<u>Role</u>	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaemia; Mupirocin Chronic Sinusitis; Colitis;	Mupirocin		N	S	Unknown	Unk (Formulation: Unknown)		Glenmark
Colitis Ulcerative; Constipation; Drug Ineffective; Dyspepsia;	Mupirocin		N	S	Unknown	Unk (Formulation: Unknown)		Glenmark
Erythema; Female Genital Tract Fistula; Frequent	Mupirocin		N	S	Topical	Unk (Formulation: Unknown)		Glenmark
Bowel Movements; Haematochezia; Headache; Hypotension;	Mupirocin		N	S	Unknown	Unk (Formulation: Unknown)		Glenmark
Infusion Related Reaction; Macular Degeneration;	Mupirocin		N	S	Topical	Unk (Formulation: Unknown)		Glenmark
Malaise; Nausea; Off Label Use; Oral Candidiasis; Pain;	Mupirocin		N	S	Topical	Unk (Formulation: Ointment)		Glenmark
Paraesthesia Oral; Procedural Pain; Proctitis;	Mupirocin		N	S	Topical	Unk (Formulation: Ointment)		Glenmark
Pyrexia; Radiculopathy; Rectal Haemorrhage; Therapeutic Product Effect	Pyrexia; Radiculopathy; Mupirocin Rectal Haemorrhage;		N	S	Topical	Unk (Formulation: Ointment)		Glenmark
Incomplete; Vaginal Discharge; Vaginal	Mupirocin		N	S	Unknown	Unk (Formulation: Ointment)		Glenmark
Flatulence; Weight	Amoxicillin Trihydrate		N	S	Unknown	Unk		Not Reported
Decreased; Weight Decreased	Amoxicillin Trihydrate		N	S	Unknown	Unk		Not Reported
Dooreaseu	Atropine Sulfate;Diphenoxylate Hydrochloride		N	S	Oral	Unk		Not Reported
	Atropine Sulfate;Diphenoxylate Hydrochloride		N	S	Oral	4 Dosage Form, 1 Eve Day	ry 1	Not Reported
	Atropine Sulfate;Diphenoxylate Hydrochloride		N	S	Oral	4 Dosage Form 1 Ever Day	y 1	Not Reported
	Atropine Sulfate;Diphenoxylate Hydrochloride		N	S	Oral	Unk (Formulation: Unknown)		Not Reported
	Atropine Sulfate;Diphenoxylate Hydrochloride		N	S	Oral	1 Dosage Form		Not Reported
	Atropine Sulfate;Diphenoxylate Hydrochloride		N	S	Oral	Unk		Not Reported
	Atropine Sulfate;Diphenoxylate Hydrochloride		N	S	Oral	Unk		Not Reported



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Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Azithromycin Dihydrate	N	s	Unknown	Unk	Not Reported
Azithromycin Dihydrate	N	S	Oral	Unk	Not Reported
Betaderm /00008501/	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Transplacental	Unk	Not Reported
Calcium, Magnesium & Vitamin D3	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Dilaudid	N	S	Unknown	Unk	Not Reported
Dilaudid	N	S	Unknown	Unk	Not Reported
Dilaudid	N	S	Oral	Unk	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid	N	S	Oral	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported



Diphophydramina Hydrochlorida	N	S			Not Reported
Diphenhydramine Hydrochloride			Oral	50 Milligram	•
Calcium Carbonate; Ergocalciferol	N	S	Unknown	Unk	Not Reported
Calcium Carbonate;	N	S	Unknown	Unk	Not Reported
Ergocalciferol					N . B
Calcium Carbonate; Ergocalciferol	N	S	Unknown	Unk	Not Reported
Calcium Carbonate;	N	S	Unknown	Unk	Not Reported
Ergocalciferol					N . B
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Flovent	Ν	S	Unknown	Unk	Not Reported
Gramicidin W/Neomycin	N	S	Unknown	Unk	Not Reported
Sulfate/Polymycin B Gramicidin W/Neomycin	N	S			Not Reported
Sulfate/Polymycin B	IN	3	Unknown	Unk	Not Neported
Macrogol 3350 W/Potassium	N	S	Unknown	Unk	Not Reported
Chloride//01618701/ Humira	N	S		11.1.75 1.17 0.1.17 0.400.74.17	Not Reported
Humma	IN	3	Subcutaneous	Unk (Forulation: Solution 2190 DAY Subcutaneous)	Not Nepotted
Humira	N	S	Unknown	Unk (Forulation: Solution 6 YR	Not Reported
			OTIKHOWH	Subcutaneous)	
Humira	N	S	Unknown	Unk (Forulation: Solution	Not Reported
				Subcutaneous)	
Humira	Ν	S	Subcutaneous	Unk	Not Reported
Humira	Ν	S	Subcutaneous	Unk (Forulation: Solution 2190 DAY	Not Reported
				Subcutaneous)	
Metronidazole	N	S	Unknown	Unk	Not Reported
Metronidazole	Ν	S	Unknown	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
morphino Canato	11		UNKNOWN	UTIK	. tot reported



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Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Oral	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Neomycin Sulfate	N	S	Unknown	Unk	Not Reported
Glycerol;Sodium Stearate	N	S	Oral	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Transdermal	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Nasal	Unk	Not Reported
Sodium Chloride	N	S	Other	Unk	Not Reported
Sodium Chloride	N	S	Nasal	Unk	Not Reported
Sodium Chloride	N	S	Endosinusial	Unk	Not Reported
Habitrol [Nicotine]	N	S	Unknown	Unk	Not Reported
Habitrol [Nicotine]	N	S	Transdermal	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Glycerol	N	S	Oral	Unk	Not Reported
Glycerol	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Vitamin E [Vitamin E Nos]	N	S	Unknown	Unk	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported



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Prednisone	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Potassium Chloride	N	S	Unknown	Unk	Not Reported
Potassium Chloride	N	S	Endocervical	Unk	Not Reported
Pulmicort	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S		Unk	Not Reported
Pulmicort	N	S	Other	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk (Formulation: Ophthalmic Drops)	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk (Formulation: Ophthalmic Drops)	Not Reported
Refresh Tears	N	S	Unknown	Unk	Not Reported
Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Nasal	Unk; Route: Intra-Nasal	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Other	Unk	Not Reported
Statex /00036302/	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole And Trimethoprim	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole And Trimethoprim	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole And Trimethoprim	N	S	Oral	1 Dosage Form	Not Reported
Sulfamethoxazole And Trimethoprim	N	S	Unknown	200 Milligram	Not Reported

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Sulfamethoxazole And	N	S	Unknown	200 Milligram	Not Reported
Trimethoprim Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Oral	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Oral	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Bactroban [Mupirocin]	N	S	Unknown	Unk	Not Reported
Acetaminophen	N	S	Unknown	Unk (Formulation Unknown)	Not Reported
Acetaminophen	N	S	Unknown	Unk	Not Reported
Acetaminophen	N	S	Unknown	Unk (Formulation Tablet)	Not Reported
Acetaminophen	N	S	Unknown	Unk	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Alprazolam	N	S	Oral	Unk	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Alprazolam	N	S		Unk	Not Reported
Apo Hydro	N	S	Endocervical	Unk	Not Reported
Apo Hydro	N	S	Unknown	Unk	Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Avamys	N	S	Unknown	Unk (Spray, Metered Dose)	Not Reported
Avamys	N	S	Ophthalmic	Unk (Spray, Metered Dose)	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Oral	Unk	Not Reported

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Biaxin XI	N	S	Unknown	Unk	Not Reported
Cetirizine	N	S	Unknown	Unk	Not Reported
Entocort	N	S	Unknown	Unk	Not Reported
Entocort	N	S	Oral	Unk	Not Reported
Glycerine	N	S	Oral	Unk; Dosage Form: Liquid Oral	Not Reported
Kenalog /00031902/	N	S	Unknown	Unk	Not Reported
Kenalog /00031902/	N	S	Intra-articular	Unk	Not Reported
Lomotil	N	S	Oral	Unk Unk, 4 Every 1 Day	Not Reported
Lomotil	N	S	Oral	Unk	Not Reported
Lomotil	N	S	Oral	Unk, 1 Every 6 Hours	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Transdermal	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Oral	Unk	Not Reported
Pregabalin	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Unknown	Unk	Not Reported
Sinus Rinse	N	S	Nasal	Unk; (Formulation: Powder For Solution Nasal) Route: Intra-Nasal	Not Reported
Sinus Rinse	N	S	Unknown	Unk (Formulation: Unknown)	Not Reported
Sinus Rinse	N	S	Nasal	Unk (Formulation: Solution Nasal)	Not Reported
Sinus Rinse	N	S	Other	Unk	Not Reported
Sinus Rinse	N	S	Nasal	Unk (Formulation: Unknown)	Not Reported
Sinus Rinse	N	S	Endosinusial	Unk (Formulation: Solution Nasal)	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported

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Zeaxanthin	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
DI-Alpha Tocopherol Acetate	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Ms Ir	N	S	Unknown	Unk	Not Reported
Pms Azithromycin	N	S	Unknown	Unk	Not Reported
Amoxicillin	N	S	Unknown	Unk	Not Reported
Amoxicillin	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Diphenhydramine	N	S	Unknown	Unk	Not Reported
Diphenhydramine	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk (4 Every 1 Days)	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Dosage Form 1 Every 1 Days	Not Reported
Loperamide Hydrochloride	N	S	Oral	4 Dosage Form, Od	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk, 1 Every 1 Days	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Intra-articular	Unk	Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium Anhydrous	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium Anhydrous	N	S	Unknown	Unk	Not Reported



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Pantoprazole Sodium Anhydrous	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium Anhydrous	N	S	Unknown	Unk	Not Reported
Triamcinolone	N	S	Unknown	Unk	Not Reported
Triamcinolone	N	S	Intra-articular	Unk	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Atorvastatin	N	S	Unknown	Unk	Not Reported
Avamys	N	S	Unknown	Unk	Not Reported
Avamys	N	S	Nasal	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Oral	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Subcutaneous	Unk	Not Reported
Budesonide	N	S		Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Cetrizine	N	S	Unknown	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Oral	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Subcutaneous	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	100 Milligram	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported



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Mesalazine	N	S	Unknown	Unk		Not Reported
Alka-Seltzer	N	S	Unknown	Unk		Not Reported
Bactrim	N	S	Unknown	Unk		Not Reported
Bactrim	N	S	Unknown	Unk		Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk		Not Reported
Cupric Oxide	N	S	Unknown	Unk		Not Reported
Macrogol;Potassium Chloride; Sodium Bicarbonate	N	S	Unknown	Unk		Not Reported
Vitamin-E [Tocopheryl Acetate]	N	S	Unknown	Unk		Not Reported
Calcium Carbonate/Vitamin D3	N	S	Unknown	Unk		Not Reported
Calcium Carbonate/Vitamin D3	N	S	Unknown	Unk		Not Reported
Humira	N	S	Unknown	Unk		Not Reported
Humira	N	S	Subcutaneous	Unk	2190 DAY	Not Reported
Atorvastatin	N	S	Unknown	Unk		Not Reported
Azithromycin	N	S	Unknown	Unk		Not Reported
Azithromycin	N	S	Oral	Unk		Not Reported
Azithromycin	N	S	Unknown	Unk		Not Reported
Betamethasone Valerate	Ν	S	Unknown	Unk		Not Reported
Betamethasone Valerate	Ν	S	Topical	Unk		Not Reported
Betamethasone Valerate	N	S	Unknown	Unk		Not Reported
Cetirizine	N	S	Unknown	Unk		Not Reported
Glycerine	N	S	Oral	Unk		Not Reported
Glycerine	N	S	Oral	Unk		Not Reported
Glycerine	N	S	Unknown	Unk		Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk		Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Unk		Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk		Not Reported
Macrogol	N	S	Unknown	Unk		Not Reported
Macrogol;Potassium Chloride; Sodium Bicarbonate;Sodium Chloride	N	S	Unknown	Unk		Not Reported



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Ac	dalimumab	N	S	Subcutaneous	Unk (Formulation: Subcutaneous Solution)	Not Reported
Ac	dalimumab	N	S	Unknown	Unk	Not Reported
Ac	dalimumab	N	S	Unknown	Unk (Formulation: Subcutaneous Solution)	Not Reported
Vi	tamin D3	N	S	Unknown	Unk	Not Reported
De	cetaminophen; extropropoxyphene	N	S	Unknown	Unk	Not Reported
	ezavant	N	S	Unknown	Unk	Not Reported
Kε	enalog /00031902/	N	S	Intra-articular	Unk (Formulation: Suspension Intra-Articular)	Not Reported
	enalog [Triamcinolone cetonide]	N	S	Intra-articular	Unk, Suspension Intraarticular	Not Reported
Sc	odium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Sc	odium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Sc	odium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Sc	odium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Ca	alcium Carbonate	N	S	Unknown	Unk	Not Reported
Ca	alcium Carbonate	N	S	Unknown	Unk	Not Reported
Er	tapenem	N	S	Intramuscular	Unk	Not Reported
Fle	ovent	N	S	Unknown	Unk	Not Reported
Fle	ovent	N	S	Unknown	Unk	Not Reported
Gı	ramicidin;Polymyxin B	N	S	Unknown	Unk	Not Reported
M	etronidazole	Ν	S	Unknown	Unk	Not Reported
M	ultivitamin [Vitamins Nos]	N	S	Unknown	Unk	Not Reported
Ni	quitin Mint	Ν	S	Unknown	Unk	Not Reported
Cł	olyethylene Glycol;Potassium nloride;Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Hy	ropine Sulfate;Difenoxin /drochloride	N	S	Oral	Unk	Not Reported
	ropine Sulfate;Difenoxin /drochloride	N	S	Oral	Unk	Not Reported
At	ropine Sulfate;Difenoxin	N	S	Oral	4 Dosage Form 1 Every 1	Not Reported



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Hydrochloride				Days	
Atropine Sulfate;Difenoxin Hydrochloride	N	S	Oral	1 Dosage Form 1 Every 1 Days	Not Reported
Calcium Carbonate/Vitamin D3	N	S	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D3	N	S	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D3	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Calcium Carbonate;Calcium Citrate;Calcium Phosphate; Colecalciferol;Mag	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Triamcinolone	N	S	Intra-articular	Unk	Not Reported
Pregabalin	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Dosage Form (1 Every 6 Hours)	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk Unk (1 Every 6 Hours)	Not Reported
Loperamide Hydrochloride	N	S	Oral	4 Dosage Form 1 Every 1 Days	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk Unk, 1 Every 1 Week	Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Dosage Form, Cyclical	Not Reported
DI-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
Acetaminophen; Dextropropoxyphene	N	S	Unknown	Unk	Not Reported
Acetaminophen; Dextropropoxyphene	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Habitrol [Nicotine]	N	S	Unknown	Unk	Not Reported
Apo Hydro	N	S	Endocervical	Unk	Not Reported



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Apo Hydro	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk (Formulation Reported; Suspension Intra- Articular)	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Ophthalmic	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Ambroxol Hydrochloride; Cetirizine	N	S	Unknown	Unk	Not Reported
Valsartan	N	S	Intracardiac	Unk	Not Reported
Valsartan	N	S	Unknown	Unk	Not Reported
Infliximab	N	S	Intravenous (not otherwise specified)	5 Milligram Per Kilogram	Not Reported
Infliximab	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Cholecalciferol	N	S	Unknown	Unk	Not Reported
Mesalamine	N	S	Unknown	Unk	Not Reported



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Sulfamethoxazole And	N	S	Unknown	Unk	Not Reported
Trimethoprim Sulfamethoxazole And	N	S	Unknown	Unk	Not Reported
Trimethoprim			OHKHOWH	Olik	-
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Dulcolax [Bisacodyl]	N	S	Unknown	Unk	Not Reported
Paracetamol And	N	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride Fructose;Glycerol;Sodium Chloride	N	S	Unknown	Unk	Not Reported
Fructose;Glycerol;Sodium Chloride	N	S	Oral	Unk	Not Reported
Atropine Sulfate	N	S	Oral	Unk	Not Reported
Atropine Sulfate	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Endocervical	Unk	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Infa-3 [Gramicidin;Neomycin Sulfate;Polymyxin B]	N	S	Unknown	Unk (Ointment Dental)	Not Reported
Magnesium	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Diphenoxylate Hydrochloride And Atropine Sulfate	N	S	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D3	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported



Calcium & Vitamin D3	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Oral	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Fluticasone Propionate	N	S	Unknown		Not Reported
Isoniazid;Pyridoxine; Sulfamethoxazole;Trimethoprim	N	S	Endocervical	Unk	Not Reported
Loperamide	N	S	Oral	1 Dosage Form Cyclical	Not Reported
Loperamide	N	S	Oral	4 Dosage Form 1 Every 1 Days	Not Reported
Loperamide	N	S	Oral	Unk	Not Reported
Nitroglycerin	N	S	Oral	Unk	Not Reported
Glycerinum	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Unk	Not Reported
Nystatin	N	S	Unknown	Unk	Not Reported
Pseudoephedrine	N	S	Unknown	Unk	Not Reported
Zinc	N	S	Unknown	Unk	Not Reported
Imodium	N	S	Unknown	Unk	Not Reported
Glycerol;Ichthammol	N	S	Unknown	Unk	Not Reported
Metronidazole Benzoate	N	S	Unknown	Unk	Not Reported
Luxat	N	S	Unknown	Unk	Not Reported
Benzydamine Hydrochloride	N	S	Unknown	Unk	Not Reported
Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Fluticasone	N	S	Unknown	Unk	Not Reported
Hydromorphone	N	S	Unknown	Unk	Not Reported



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Moviprep [Ascorbic Acid; Macrogol 3350;Potassium Chloride;Sodium Ascorb	N	S	Oral	Unk	Not Reported
Sodium Stearate	N	S	Oral	Unk	Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported
Calcium Gluconate	N	S	Unknown	Unk	Not Reported
Zinc Chloride	N	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid;Citric Acid; Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Difenoxin Hydrochloride	N	S	Oral	Unk	Not Reported
Atropine	N	S	Oral	Unk	Not Reported
Atropine	N	S	Unknown	Unk	Not Reported
Copper Gluconate;Zinc	N	S	Unknown	Unk	Not Reported
Glyceryl Trinitrate	N	S	Oral	Unk	Not Reported
Acetaminophen; Pseudoephedrine	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	С	Unknown	Unk	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	N	С	Oral	50 Milligram	Not Reported
Metoclopramide Hydrochloride	N	С	Oral	10 Milligram	Not Reported
Vitamin D3	N	С	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D3	N	С	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D3	N	С	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	С	Endocervical	Unk	Not Reported
Clotrimazole	N	С	Unknown	Unk	Not Reported
Valsartan	N	С	Unknown	Unk	Not Reported
Valsartan	N	С	Intracardiac	Unk	Not Reported
Valsartan	N	С	Vaginal	Unk	Not Reported
Valsartan	N	С	Unknown	Unk	Not Reported
Sulfamethoxazole\Trimethoprim		S			Not Reported



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FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

FDA Received Date	Case #	1	Case Type	<u>Health</u>	Prof Ou	tcomes	Mfr Control	<u>l #</u>	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Apr-2023	199305	588	EXPEDITED (15-DAY)	N	НС	, OT	CA-PURDUE 2021-028568			71 YR	Female	e CAN
Preferred Term		Produc	<u>et</u>	Comp.	<u>OTC</u>	Role	Route	Dos	sage Text	<u>Duration</u>		Mfr
Chronic Sinusitis; Drug		Dilaudio	d		N	S	Unknown	Un	ıknown			Rhodes
Ineffective; Dyspepsia; Infusion Related React		Ms Ir			N	S	Unknown	Un	known			Not Reported
Macular Degeneration;		Acetam	inophen		N	S	Unknown	Un	known			Not Reported
Malaise; Nausea; Off Label Use; Pain;		Acetam	inophen		N	S	Unknown	Un	nk			Not Reported
Paraesthesia Oral;		Acetam	inophen		N	S	Unknown	Un	nk			Not Reported
Procedural Pain; Pyrex Therapeutic Product Et		Acetyls	alicylic Acid		N	S	Oral	Un	nknown			Not Reported
Incomplete; Weight	nect	Acetyls	alicylic Acid		N	S	Unknown	Un	nk			Not Reported
Decreased		Alprazo	lam		N	S	Unknown	Un	ıknown			Not Reported
		Alprazo	lam		N	S	Unknown	0.2	25 Milligram			Not Reported
		Amoxic	illin Trihydrate		N	S	Unknown	Un	ıknown			Not Reported
		Amoxic	illin Trihydrate		N	S	Unknown	Un	nk			Not Reported
		Amoxic	illin Trihydrate		N	S	Unknown	Un	nk			Not Reported
		Betame	thasone Valerate		N	S	Unknown	Un	ıknown			Not Reported
		Betame	thasone Valerate		N	S	Topical	Un	nk			Not Reported
		Betame	thasone Valerate		N	S	Unknown	0.1	122 Gram			Not Reported
		Bisacoo	dyl		N	S	Unknown	Un	ıknown			Not Reported
		Bisacoo	dyl		N	S	Unknown	Un	nk			Not Reported
		Bisacoo	dyl		N	S	Unknown	Un	nk			Not Reported
		Budeso	nide		N	S	Unknown	Un	ıknown			Not Reported
		Budeso	nide		N	S	Respiratory (inhalation)	Un	nk			Not Reported
		Budeso	nide		N	S	Oral	Un	nk			Not Reported
		Budeso	nide		N	S	Respiratory (inhalation)	Un	nk			Not Reported
		Budeso	nide		N	S	Oral	1 [Dosage Form			Not Reported



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Budesonide	N	S	Unknown	Unk		Not Reported
Budesonide	N	S	Unknown	Unk		Not Reported
Budesonide	N	S	Unknown	Unk		Not Reported
Budesonide	N	S	Unknown	Unk		Not Reported
Budesonide	N	S	Unknown	Unk		Not Reported
Clarithromycin	N	S	Unknown	Unknown		Not Reported
Clarithromycin	N	S	Subcutaneous	Unk		Not Reported
Clarithromycin	N	S	Unknown	Unk		Not Reported
Clotrimazole	N	S	Unknown	Unknown		Not Reported
Clotrimazole	N	S	Unknown	Unk		Not Reported
Cupric Oxide	N	S	Unknown	Unknown		Not Reported
Cupric Oxide	N	S	Unknown	Unk		Not Reported
D-Alpha Tocopheryl Acetate	N	S	Unknown	Unknown		Not Reported
Desonide	N	S	Unknown	Unknown		Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unknown		Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unknown		Not Reported
Ertapenem	N	S	Unknown	Unknown		Not Reported
Fluticasone Furoate	N	S	Unknown	Unknown		Not Reported
Fluticasone Furoate	N	S	Ophthalmic	Unk		Not Reported
Glycerol	N	S	Oral	Unknown		Not Reported
Gramicidin W/Neomycin Sulfate/Polymycin B	N	S	Unknown	Unknown		Not Reported
Humira	N	S	Subcutaneous	Unk	2190 DAY	Not Reported
Humira	N	S	Unknown	Unknown		Not Reported
Magnesium Sulfate	N	S	Unknown	Unknown		Not Reported
Mesalazine	N	S	Unknown	Unknown		Not Reported
Metronidazole	N	S	Unknown	Unknown		Not Reported
Mupirocin	N	S	Topical	Unk		Not Reported
Nadolol	N	S	Unknown	Unknown		Not Reported
Nadolol	N	S	Intra-articular	Unk		Not Reported



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Nadolol	N	S	Unknown	40 Milligram	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unknown	Not Reported
Pantoprazole	N	S	Unknown	Unknown	Not Reported
Prednisone	N	S	Unknown	Unknown	Not Reported
Pregabalin	N	S	Unknown	Unknown	Not Reported
Pregabalin	N	S	Topical	Unk	Not Reported
Pregabalin	N	S	Unknown	150 Milligram	Not Reported
Refresh Tears	N	S	Ophthalmic	Unknown	Not Reported
Sodium Chloride	Ν	S	Unknown	Unknown	Not Reported
Sodium Chloride	N	S	Nasal	Unk	Not Reported
Sulfamethoxazol W/Trimetoprim	N	S	Endocervical	Unk	Not Reported
Triamcinolone	N	S	Intra-articular	Unk	Not Reported
Vitamin E /00110501/	N	S	Unknown	Unk	Not Reported
Vitamin E /00110501/	N	S	Intracardiac	Unk	Not Reported
Vitamine E	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unknown	Not Reported
Zinc	N	S	Unknown	Unknown	Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Avamys	N	S	Unknown	Unk	Not Reported
Atropine Sulfate	N	S	Oral	Unk	Not Reported
W/Diphenoxylate Hydrochlor. Atropine Sulfate W/Diphenoxylate Hydrochlor.	N	S	Oral	4 Df,1every 1day	Not Reported
Atropine Sulfate W/Diphenoxylate Hydrochlor.	N	S	Unknown	1 Df, Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Adalimumab	N	S	Subcutaneous	Unk	Not Reported
Adalimumab Adalimumab	N	S S			Not Reported
Adailmumab Amoxicillin	N N	S	Unknown	Unk	Not Reported Not Reported
			=:::::::::::::::::::::::::::::::::::::	= = = =	•



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Acetaminophen W/Pseudoephedrine	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Bactroban /00753901/	N	S	Unknown	Unk	Not Reported
Cetirizine	N	S	Unknown	Unk	Not Reported
Cetirizine Diphenhydramine	N N	S S	Unknown	Unk	Not Reported Not Reported
Dulcolax /00064401/	N	S	Unknown	Unk	Not Reported
Entocort	N	s	Unknown	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Fluticasone Propionate	N	S	Unknown	Unk	Not Reported
Flovent	N	S	Unknown	Unk	Not Reported
Glycerin /00200601/	N	S	Oral	Unk	Not Reported
Gramicidin	N	s	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk (1 Every 1 Weeks)	Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Df, Q6h	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk Unk, Qid	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk (1 Every 1 Weeks)	Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Df, Q6h	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk, Qid	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Transdermal	Unk	Not Reported
Pulmicort	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S	Respiratory (inhalation)	Unk	Not Reported
Pantoprazole Sodium Anhydrous	N	S	Unknown	Unk	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Pms Azithromycin	N	S	Unknown	Unk	Not Reported



Not Reported Not Reported Not Reported Not Reported
Not Reported
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Not Reported
Not Reported



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Aspirin\Caffeine	N	S	Endocervical	Unk	Not Reported
Valsartan	N	S	Unknown	Unk	Not Reported
Valsartan	N	S	Intracardiac	Unk	Not Reported
Valsartan	N	S	Intracerebral	Unk	Not Reported
Gramicidin W/Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Multivitamines And Minerals	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol\Potassium Chloride\Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Potassium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Neomycin Sulfate	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unknown	Not Reported
Hydrochlorothiazide	N	S	Unknown	100 Milligram	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	4 Df,1every 1day	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Unknown	1 Dosage Form	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Endocervical	Unk	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Endocervical	200 Milligram	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	1 Dosage Form	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Endocervical	Unk	Not Reported
Infliximab	N	S	Unknown	5 Milligram/Kilogram	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Trimethoprim	N	S	Unknown	Unknown	Not Reported
Loperamide	N	S	Oral	Unk	Not Reported
Loperamide	N	S	Oral	Unk	Not Reported
Loperamide	N	S	Oral	1 Df, Q6h	Not Reported
Loperamide	N	S	Oral	Unk, Qid	Not Reported
Loperamide	N	S	Oral	4 Dosage Form, Daily	Not Reported



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		Loperan	nide		N	S	Oral	1 Dosage Form, Cyclical		N	lot Reported
		Loperan	nide		Ν	S	Oral	Unk, Weekly		N	lot Reported
	Loperamide				Ν	S	Oral	Unk, Monthly		N	lot Reported
		Atropine	Sulfate		Ν	S	Unknown	Unknown		N	lot Reported
		Calcitrio	I		N	S	Unknown	Unknown		N	lot Reported
		Loperan	nide		N	С	Oral	4 Dosage Form, Daily		N	lot Reported
		Valsarta	n		N	С	Intracardiac	Unk		N	lot Reported
		Valsarta	n		N	С	Unknown	40 Milligram, Daily		N	lot Reported
		Valsarta	n		N	С	Unknown	4 Dosage Form, Daily		N	lot Reported
FDA Received Date	Case #		Case Type	Health	<u>Prof</u>	Outcomes	Mfr Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
05-Apr-2023	208446	559	EXPEDITED (15-DAY)	Y		HO, OT	CA- GLAXOSMITHI CA2019AMR24			Unknown	CAN
Preferred Term		Produc	<u>t</u>	Comp.	OTO	Role Role	Route	Dosage Text	Duration	<u>M</u> 1	<u>fr</u>
Abdominal Pain; Anaen Chronic Sinusitis; Coliti		Avamys			N	S	Unknown	Unk (Spray, Metered Dose)		G	Blaxosmithkline
Colitis Ulcerative; Constipation; Drug		Avamys			N	S	Unknown	Unk		G	Blaxosmithkline
Ineffective; Dyspepsia;		Flovent			N	S		Unk		G	Blaxosmithkline
Erythema; Female Gen Tract Fistula; Frequent		Flovent			N	S	Unknown	Unk (Spray Metered Dose	e)	G	Blaxosmithkline
Bowel Movements;		Fluticas	one Propionate		N	S	Unknown	Unk			Glaxosmithkline
Haematochezia; Headache; Infusion		Betamet	hasone Valerate		N	S	Unknown	Unk		N	lot Reported
Related Reaction; Mac		Betamet	hasone Valerate		N	S	Topical	Unk			lot Reported
Degeneration; Malaise; Nausea; Off Label Use;		Betamet	hasone Valerate		N	S	Unknown	Unk		N	lot Reported
Oral Candidiasis; Pain;		Potassiu	ım Chloride		N	S	Unknown	Unk			lot Reported
Paraesthesia Oral; Procedural Pain; Procti Pyrexia; Radiculopathy		Fluticaso Propiona Xinafoat	ate+Salmeterol		N	S	Unknown	Unk		G	Blaxosmithkline
Rectal Haemorrhage;		Mupiroc			N	S	Unknown	Unk		G	Blaxosmithkline
Therapeutic Product Ef Incomplete; Vaginal	fect	Mupiroc	in		N	S	Topical	Unk		G	Blaxosmithkline
Discharge; Vaginal		Sulfame	thoxazole +		N	S	Unknown	Unk		N	lot Reported

Date - Time: 11-Apr-2023 10:56:54 AM EST Note

Trimethoprim

Flatulence; Weight

Note: If the field is blank, there is no data.

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Sulfamethoxazole +	Ν	S		Unk	Not Reported
Trimethoprim Bactroban (Mupirocin)	N	S	Topical	Unk	Glaxosmithkline
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Bisacodyl	Ν	S	Transplacental	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Cetirizine	N	S	Unknown	Unk	Not Reported
Clotrimazole	Υ	S	Unknown	Unk	Glaxosmithkline
Clotrimazole	Υ	S	Unknown	Unk	Glaxosmithkline
Triamcinolone	N	S	Intra-articular	Unk	Not Reported
Triamcinolone	N	S	Unknown	Unk	Not Reported
Ubidecarenone	N	S	Unknown	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Glyceryl Trinitrate	N	S	Oral	Unk	Not Reported
Dulcolax	N	S	Unknown	Unk	Not Reported
Magnesium	N	S	Unknown	Unk	Not Reported
Vitamin D	Ν	S	Unknown	Unk	Not Reported
Magnesium Hydroxide	Ν	S	Unknown	Unk	Not Reported
Metoclopramide Hydrochloride	Ν	S	Oral	Unk	Not Reported
Calcium Carbonate, Cholecalciferol	N	S	Unknown	Unk	Glaxosmithkline
Tocopheryl Acetate-D-Alpha	N	S			Not Reported
Mepolizumab	N	S		100 Mg	Glaxosmithkline
Sulfamethoxazole + Trimethoprim	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole +	N	S	Unknown	Unk	Not Reported
Trimethoprim Sulfamethoxazole +	N	S	Unknown	Unk	Not Reported
			O I II II I I I I I I I I I I I I I I I	····	•



Trimethoprim Fluticasone Furoate	N	S	Unknown	Unk	Glaxosmithkline
Fluticasone Furoate	N	S	Unknown	Unk	Glaxosmithkline
Paracetamol	N	S	Unknown	Unk	Not Reported
Paracetamol	N	S	Unknown	Unk	Not Reported
Diphenhydramine	N	S	Unknown	Unk	Not Reported
Diphenhydramine	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Transdermal	Unk	Not Reported
Nicotine	N	S	Intramuscular	Unk	Not Reported
Nicotine Transdermal Patch	N	S	Unknown	Unk	Not Reported
Salinex (Macrogol + Propylene	N	S	Nasal	Unk	Not Reported
Glycol + Sodium Chloride) Nicotinamide	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate Injection	N	S	Unknown	Unk	Not Reported
Acetaminophen +	N	S	Unknown	Unk	Not Reported
Pseudoephedrine Magnesium Sulfate	N	S			Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Niquitin	N	S	Unknown	Unk	Not Reported
•			Unknown	4 Mg	·
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Vitamin E	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Azithromycin Dihydrate	N	S	Oral	Unk	Not Reported
Azithromycin Dihydrate	N	S	Unknown	Unk	Not Reported



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Diphenhydramine Hydrochloride	N	S	Unknown	Unk		Not Reported
Diphenhydramine Hydrochloride	N	S	Oral	50 Mg		Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk		Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk		Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk		Not Reported
Habitrol	N	S	Unknown	Unk		Not Reported
Pantoprazole	N	S	Unknown	Unk		Not Reported
Pantoprazole	N	S	Unknown	Unk		Not Reported
Pantoprazole	N	S	Unknown	40 Mg, Qd		Not Reported
Nicoderm	N	S	Topical	Unk		Not Reported
Nicoderm	N	S	Topical	Unk		Not Reported
Nicoderm	N	S	Unknown	Unk		Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk		Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk		Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk		Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk		Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk		Not Reported
Alprazolam	N	S	Respiratory (inhalation)	Unk		Not Reported
Alprazolam	N	S	Unknown	Unk		Not Reported
Alprazolam	N	S	Unknown	0.25 Mg		Not Reported
Biaxin XI	N	S	Unknown	Unk		Not Reported
Clarithromycin	N	S	Unknown	Unk		Not Reported
Clarithromycin	N	S		Unk		Not Reported
Ertapenem Sodium	N	S	Respiratory (inhalation)	Unk		Not Reported
Humira	N	S	Subcutaneous	Unk	2190 DAY	Not Reported
Humira	N	S	Unknown	Unk		Not Reported
Humira	N	S	Subcutaneous	Unk		Not Reported
Humira	N	S	Subcutaneous	Unk		Not Reported



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Humira	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	40 Mg	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Oral	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Refresh Tears	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Sinus Rinse	N	S	Nasal	Unk	Not Reported
Calcium Carbonate + Vitamin D3	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk, 1 Every 6 Hours	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk, Q 4 Week	Not Reported
Loperamide Hydrochloride	N	S		Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	4 Df, Qd	Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Df, 1 In 1 Cyclical	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk, 0.025+2.5 Mg	Not Reported
Dextropropoxyphene + Acetaminophen	N	S	Unknown	Unk	Not Reported
Atropine Sulphate + Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Atropine Sulphate + Diphenoxylate Hydrochloride	N	S	Oral	1 Df	Not Reported
Atropine Sulphate + Diphenoxylate Hydrochloride	N	S	Oral	4 Df, Qd	Not Reported
Atropine Sulphate +	N	S	Oral	Unk, Qid	Not Reported



Diphenoxylate Hydrochloride Atorvastatin Calcium	N	s	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Anhydrous Pantoprazole Sodium	N	S	Unknown	Unk	Not Reported
Gramicidin + Polymyxin B	N	S	Unknown	Unk	Not Reported
Statex (Simvastatin)	N	S	Unknown	Unk	Not Reported
Statex (Simvastatin)	N	S	Unknown	Unk	Not Reported
Niquitin 4 Mg Mint Lozenge	N	S	Unknown	Unk	Not Reported
Cupric Oxide + Folic Acid +	N	S	Unknown	Unk	Not Reported
Nicotinamide + Zinc			OTIKITOWIT	OTIK	•
Jackson'S Mineral Salts Sodium Chloride	N	S	Unknown	Unk (Pellet)	Not Reported
Alka-Seltzer (Acetylsalicylic Acid + Citric Acid + Sodium	N	S	Unknown	Unk	Not Reported
Bicarbonate) Calcium Carbonate + Cholecalciferol	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	100 Mg	Not Reported
Hydrochlorothiazide	N	S	Subcutaneous	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
Sulfamethoxazole + Tmp	N	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Unk	Not Reported
Calcitriol + Calcium Carbonate +	N	S	Unknown	Unk	Not Reported
Zinc Acetic Acid + Triamcinolone Acetonide	N	S	Unknown	Unk	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Moviprep	N	S	Unknown	Unk	Not Reported
Amoxycillin	N	S	Unknown	Unk	Not Reported
Amoxycillin	N	S	Unknown	Unk	Not Reported



		Ambrox	kol/Cetirizine		N	S	Unknown	Unk			١	Not Reported
		Isoniaz	id		N	S	Unknown	Unk			1	Not Reported
		Magnes	sium Aspartate		N	S	Unknown	Unk			1	Not Reported
		Zinc Ch	nloride		N	S	Unknown	Unk			1	Not Reported
		Valsart	an		N	S	Unknown	Unk			1	Not Reported
FDA Received Date	Case #	<u> </u>	Case Type	Health	Prof	Outcomes	Mfr Con	trol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Apr-2023	21836	304	EXPEDITED (15-DAY)	Υ		ОТ	CA-GLEN PHARMA 2023GMK	CEUTICALS-			Unknown	CAN
Preferred Term		Produc	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u> Text</u>	Duration	<u>M</u>	<u>lfr</u>
Drug Ineffective; Macu Degeneration	ılar	Mupiro	cin		N	S	Topical		Formulation: ent Topical)		(Glenmark
		Acetam	ninophen		N	S	Unknown	Unk			1	Not Reported
		Acetyls	alicylic Acid		N	S	Oral	Unk			1	Not Reported
		Adalim	umab		N	S	Subcutaneous	Unk			1	Not Reported
		Alprazo	olam		N	S	Unknown	Unk			1	Not Reported
		Ambrox	col Hydrochloride		N	S	Unknown	Unk			1	Not Reported
		Amoxic	illin		N	S	Unknown	Unk			1	Not Reported
		Аро-Ну	drochlorothiazide		N	S	Unknown	Unk			1	Not Reported
		Atorvas	statin Calcium		N	S	Unknown	Unk			1	Not Reported
		Atorvas	statin Calcium		N	S	Unknown	Unk			1	Not Reported
		Atropin	e Sulfate		N	S	Oral	Unk			1	Not Reported
		Atropin	e Sulfate		N	S	Unknown	Unk			1	Not Reported
		Avamys	S		N	S	Unknown	Unk			1	Not Reported
		Azithro	mycin		N	S	Oral	Unk			1	Not Reported
		Bactrim	1		N	S	Unknown	Unk			1	Not Reported
		Betame	ethasone		N	S	Unknown	Unk			1	Not Reported
		Betame	ethasone Dipropionate		N	S	Unknown	Unk			1	Not Reported
		Betame	ethasone Valerate		N	S	Unknown	Unk			1	Not Reported



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Bisacodyl	N	S	Unknown	Unk	Not Reported
Budesonide	N	S		Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D3	N	S	Unknown	Unk	Not Reported
Calcium Gluconate	N	S	Unknown	Unk	Not Reported
Cetirizine	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk	Not Reported
Dilaudid	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Oral	Unk	Not Reported
Entocort	N	S	Unknown	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Flovent	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Glycerine	N	S	Unknown	Unk	Not Reported
Glycerol	N	S	Oral	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Humira	N	S	Subcutaneous	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Hydromorphone	N	S	Unknown	Unk (1 Every 1 Weeks)	Not Reported
Hydromorphone	N	S	Unknown	Unk	Not Reported



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Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk (1 Every 1 Weeks)	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk	Not Reported
Macrogol	N	S	Unknown	Unk	Not Reported
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate; Sodium Chloride;So	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Ms Ir	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Neomycin Sulfate	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Pantoprazole	N	S	Unknown	Unk	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Potassium Chloride	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S	Unknown	Unk	Not Reported
Sinus Rinse	N	S	Unknown	Unk (Solution Nasal)	Not Reported
Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
				-	



	Sodi	ium Chloride		N	S	Unknown	Unk			Not Reported
	Sodi	um Stearate		N	S	Oral	Unk			Not Reported
	Sulfa	amethoxazole;Trimethoprim		N	S	Unknown	Unk			Not Reported
	Triar	mcinolone		N	S	Intra-articular	Unk			Not Reported
	Trim	ethoprim		N	S	Unknown	Unk			Not Reported
	Vitar	min D3		N	S	Unknown	Unk			Not Reported
	Xant	tofyl Palmitate		N	S	Unknown	Unk			Not Reported
	Zeax	kanthin		N	S	Unknown	Unk			Not Reported
	Zinc	Chloride		N	S	Unknown	Unk			Not Reported
	Zinc	Oxide		N	S	Unknown	Unk			Not Reported
	Vals	artan		N	S	Intracardiac	Unk			Not Reported
		pine Sulfate;Diphenoxylate		N	S	Oral	Unk			Not Reported
		rochloride ium Carbonate/Vitamin D3		N	S	Unknown	Unk			Not Reported
	D-Al	pha Tocopherol		N	S	Unknown	Unk			Not Reported
FDA Received Date	Case #	Case Type	Health	Prof Ou	tcomes	Mfr Contro	ol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
06-Apr-2023	21948537	EXPEDITED (15-DAY)	Υ	ОТ	•	CA-ORGANO O2301CANO			Female	CAN
Preferred Term	Proc	duct	Comp.	<u>OTC</u>	Role	Route	Dosage Text	<u>Duration</u>		<u>Mfr</u>
Drug Ineffective; Maci Degeneration	ular Dipro	osone		N	S	Unknown	Unk, Dosage Form: Not Specified			Organon
										Organan
	Zoco	or		N	S	Unknown	Unk			Organon
		or aminophen		N N	S S	Unknown Unknown	·			Not Reported
	Acet						Unk Unk, Dosage Form: Not			•
	Acet Acet	aminophen		N	S	Unknown	Unk Unk, Dosage Form: Not Specified			Not Reported
	Acet Acet	aminophen		N N	s s	Unknown Unknown	Unk Unk, Dosage Form: Not Specified Unk Unk Unk, Dosage Form: Not			Not Reported



				Subcutaneous	
Alprazolam	N	S		Unk	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Ambroxol;Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Unknown	Unk	Not Reported
Avamys	N	S	Ophthalmic	Unk	Not Reported
Avamys	N	S	Unknown	Unk	Not Reported
Azithromycin Dihydrate	N	S	Unknown	Unk, Dosage Form: Not Specified; Also Reported As "Pms-Azithromycin"	Not Reported
Azithromycin Dihydrate	N	S	Unknown	Unk	Not Reported
Bactrim	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Bactrim	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Benzydamine Hydrochloride	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported



Biaxin XI	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Transplacental	Unk, Dosage Form: Not Specified	Not Reported
Bisacodyl	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Bisacodyl	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Budesonide	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Budesonide	N	S		Unk, Dosage Form: Not Specified	Not Reported
Calcium Carbonate And Vita	min N	S	Unknown	Unk	Not Reported
Calcium Carbonate And Vita D3	min N	S	Intra-articular	Unk	Not Reported
Calcium Carbonate And Vita D3	min N	S	Unknown	Dosage Form: Not Specified	Not Reported
Calcium Citrate	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Calcium Phosphate Dibasic; Colecalciferol	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S			Not Reported
Cholecalciferol	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Clarithromycin	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Clotrimazole	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Cupric Oxide	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopheryl Acetate	N	S	Intracardiac	Unk	Not Reported



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Desonide	N	S	Unknown	Unk, Dosage Form: Not Specified		Not Reported
Dilaudid	N	S	Unknown	Unk, Dosage Form: Not Specified		Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk, Dosage Form: Not Specified		Not Reported
Entocort	N	S	Unknown	Unk		Not Reported
Entocort	N	S	Oral	Unk		Not Reported
Ergocalciferol	N	S	Unknown	Unk, Dosage Form: Not Specified		Not Reported
Ertapenem Sodium	N	S	Unknown	Unk, Route:Intra-Nasal		Not Reported
Ertapenem Sodium	N	S	Unknown	Unk		Not Reported
Flovent	N	S	Unknown	Unk, Dosage Form: Not Specified		
Fluticasone Furoate	N	S	Ophthalmic	Unk		Not Reported
Fluticasone Furoate	N	S	Unknown	Jnknown Unk		Not Reported
Fluticasone Propionate	N	S	Unknown	Unk		Not Reported
Glycerine	N	S	Oral	Unk		Not Reported
Glycerine	N	S	Unknown	Unk		Not Reported
Glycerol	N	S	Oral	Unk		Not Reported
Glycerol	N	S	Unknown	Unk		Not Reported
Glycerol;Sodium Stearate	N	S	Oral	Unk		Not Reported
Gramicidin	N	S	Unknown	Unk		Not Reported
Humira	N	S	Unknown	Unk		Not Reported
Humira	N	S	Subcutaneous	Unk, Dosage Form: Solution Subcutaneous	2190 DAY	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk		Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk		Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk		Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Unk		Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Unk		Not Reported



				•	
Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Ichthammol;Zinc Oxide	N	S	Unknown	Unk	Not Reported
Infa-3 [Gramicidin;Neomycin Sulfate;Polymyxin B]	N	S	Unknown	Unk, Formulation: Ointment Dental	Not Reported
Lomotil [Loperamide Hydrochloride]	N	S	Oral	4 Every 1 Days	Not Reported
Lomotil [Loperamide Hydrochloride]	N	S	Oral	4 Dosage Form, 1 Every 1 Days	Not Reported
Lomotil [Loperamide Hydrochloride]	N	S	Oral	1 Every 1 Month	Not Reported
Lomotil [Loperamide Hydrochloride]	N	S	Oral	1 Dosage Form, Cyclical	Not Reported
Macrogol 3350	N	S	Urethral	Unk	Not Reported
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate; Sodium Chloride;So	N	S	Unknown	Unk	Not Reported
Macrogol 3350;Potassium Chloride;Sodium Chloride; Sodium Sulfate	N	S	Unknown	Unk	Not Reported
Macrogol;Potassium Chloride; Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Magnesium Oxide	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Mesalamine	N	S	Unknown	Unk, Dosage Form: Tablet (Delayed And Extended Release); Mezavant Also Known As Mesalamine	Not Reported
Metronidazole	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Morphine Sulfate	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Morphine Sulfate	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Mupirocin	N	S	Unknown	Unk	Not Reported

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Mupirocin N S Topical Unk	Not Reported
- Topical Olik	
Mupirocin N S Topical Unk, Dosage Form: Ointment Topical	Not Reported
Mupirocin Calcium Hydrate N S Topical Unk	Not Reported
Mupirocin Calcium Hydrate N S Unknown Unk	Not Reported
Mupirocin Calcium Hydrate N S Topical Unk	Not Reported
Nadolol N S Unknown Unk	Not Reported
Neomycin Sulfate N S Unknown Unk	Not Reported
Nicoderm N S Unknown Unk, Dosage Form: Patch	Not Reported
Nicoderm N S Unknown Unk	Not Reported
Nicotine N S Unknown Unk, Dosage Form: Not Specified	Not Reported
Nicotine Polacrilex N S Unknown Unk	Not Reported
Nicotine Polacrilex N S Unknown Unk	Not Reported
Nicotine Polacrilex N S Unknown Unk	Not Reported
Pantoprazole Sodium N S Unknown Unk, Dosage Form: Not [Pantoprazole Sodium Specified Monohydrate]	Not Reported
Pantoprazole Sodium N S Unknown Unk, Dosage Form: Not [Pantoprazole Sodium Specified Monohydrate]	Not Reported
Pentasa N S Unknown Unk, Dosage Form: Not Specified	Not Reported
Polyethylene Glycol 4000 N S Unknown Unk	Not Reported
Polyethylene Glycol 4000 N S Endocervical Unk	Not Reported
Polymyxin B Sulfate N S Unknown Unk, Dosage Form: Not Specified	Not Reported
Polymyxin B Sulfate N S Unknown Unk	Not Reported
Potassium Chloride N S Unknown Unk, Dosage Form: Not Specified	Not Reported
Prednisone N S Subcutaneous Unk, Dosage Form: Not Specified	Not Reported
Prednisone N S Unknown Unk, Dosage Form: Not	Not Reported

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				Specified	
Prednisone Acetate	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Topical	Unk(Also Reported As "Pregabalin (Manufacturer Unknown)")	Not Reported
Pregabalin	N	S	Unknown	Unk	Not Reported
Pseudoephedrine Hydrochloride	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S		Unk (Dosage Form: Not Specified)	Not Reported
Pulmicort	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk, Dosage Form: Ophthalmic Drops	Not Reported
Sinus Rinse	N	S	Unknown	Unk, Formulation: Solution Nasal, Route: Intra-Nasal	Not Reported
Sodium Bicarbonate	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk, Route: Intra-Nasal	Not Reported
Sodium Chloride	N	S	Other	Unk, Dosage Form: Not Specified	Not Reported
Sodium Chloride	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Sulfatrim [Sulfamethoxazole; Trimethoprim]	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk, Dosage Form: Suspension Intra-Articular	Not Reported
Kenalog [Triamcinolone Acetonide]	N	S	Intra-articular	Unk, Formulation: Suspension Intra-Articular	Not Reported
Valsartan	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Vitamin D [Colecalciferol]	N	S	Unknown	Unk	Not Reported

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	Vitamin	D3		Ν	S	Unknown	Unk			Not	t Reported
	Vitamin	D3		Ν	S	Unknown	Unk			Not	t Reported
	Vitamir Acetate	E Natural [Tocopheryl		N	S	Unknown	Unk			Not	t Reported
	Xantofy	n Palmitate		N	S	Unknown	Unk			Not	t Reported
	Lutein\2	Zeaxanthin		N	S	Unknown	Unk			Not	t Reported
	Zinc Ox	kide		N	S	Unknown	Unk, D Specif	osage Form: Not ied		Not	t Reported
	Fructos Chlorid	se;Glycerol;Sodium e		N	S	Oral	Unk			Not	t Reported
	Chlorid			N	S	Oral	Unk			Not	t Reported
	Chlorid			N	S	Unknown	Unk				t Reported
	Polymy	idin;Neomycin Sulfate; xin B Sulfate		N	S	Unknown	Unk				t Reported
	Dextrop	ninophen; oropoxyphene		N	S	Unknown	Unk				t Reported
		oan [Mupirocin]		N	S	Unknown	Unk				t Reported
	Mineral	ls\Vitamins		N	S	Unknown	Unk			Not	t Reported
	Betame	ethasone;Mupirocin		N	S	Unknown	Unk			Not	t Reported
	Betame	ethasone;Mupirocin		N	S	Topical	Unk			Not	t Reported
	Dimeth	andiol;Dexpanthenol; yl Sulfoxide;Glycerol		N	S	Oral	Unk				t Reported
	Dimeth	andiol;Dexpanthenol; yl Sulfoxide;Glycerol		N	S	Unknown	Unk				t Reported
	Hydroc	id/Pyridoxine hloride/Sulfamethoxazole		N	S	Unknown	Unk			Not	t Reported
	/Trimet Betame Phosph	ethasone Sodium		N	S	Unknown	Unk			Not	t Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr C	ontrol #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
07-Apr-2023	20561561	EXPEDITED (15-DAY)	Υ		ОТ		RGANON- CAN000535			Female	CAN
<u>Preferred Term</u>	Produc	<u>ct</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	



Drug Ineffective; Macular Degeneration

				•	
Diprosone	N	S	Unknown	Unk, Dosage Form: Not Specified	Organon
Diprosone	N	S	Unknown	Unk	Organon
Invanz	N	S	Unknown	Unk	Not Reported
Invanz	N	S	Unknown	Unk	Not Reported
Acetaminophen	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Avamys	N	S	Unknown	Unk; Dosage Form: Spray, Metered Dose	Not Reported
Azithromycin Dihydrate	N	S	Unknown	Unk	Not Reported
Bactrim	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Bisacodyl	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Calcium Carbonate	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Calcium Carbonate And Vitamin D3	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Cholecalciferol	N	S	Unknown	Unk,Dosage Form: Not Specified	Not Reported
Clarithromycin	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported



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Clotrimazole	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Dilaudid	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Entocort	N	S	Unknown	Unk, Formulation:Capsule, Sustained-Release	Not Reported
Flovent	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Fructose;Glycerol;Sodium Chloride	N	S	Oral	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Humira	N	S	Subcutaneous	Unk; Formulation: Solution Subcutaneous	Not Reported
Humira	N	S			Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Macrogol	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Metronidazole	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Morphine Sulfate	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Mupirocin Calcium Hydrate	N	S	Unknown	Unk; Dosage Form: Ointment Topical	Not Reported
Mupirocin Calcium Hydrate	N	S	Topical	Unk	Not Reported
Mupirocin Calcium Hydrate	N	S	Unknown	Unk	Not Reported

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Mupirocin Calcium Hydrate	N	S	Unknown	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Neomycin Sulfate	N	S	Unknown	Unk, Doage Form: Not Specified	Not Reported
Nicoderm	N	S	Unknown	Unk, Dosage Form: Patch	Not Reported
Nicotine	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Pantoprazole Sodium	N	S	Unknown	Unk, Doage Form: Not Specified	Not Reported
Pentasa	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Polymyxin B Sulphate	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Pregabalin	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Pulmicort	N	S		Dosage Form: Not Specified	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk, Dosage Form: Drops Ophthalmic	Not Reported
Sodium Chloride	N	S	Nasal	Dosage Form: Not Specified, Route Of Admisntration : Intra-Nasal	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk, Dosage Form: Suspension Intra-Articular	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported



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Zinc Oxide	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Acetaminophen; Dextropropoxyphene	N	S	Unknown	Unk	Not Reported
Apo Hydro	N	S	Unknown	Unk	Not Reported
Atropine	N	S	Oral	Dosage Form: Not Specified	Not Reported
Azithromycin	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Bactroban [Mupirocin]	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Budesonide	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Budesonide	N	S		Unk, Dosage Form: Not Specified	Not Reported
Minerals	N	S	Unknown	Unk	Not Reported
Ascorbic Acid;Copper;DI-Alpha Tocopherol;Xantofyl;Zeaxanthin; Zinc	N	S	Unknown	Unk	Not Reported
Diphenhydramine	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
DI-Alpha Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
Fluticasone	N	S	Unknown	Unk; Dosage Form: Not Specified	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Glycerine	N	S	Unknown	Unk	Not Reported
Habitrol [Nicotine Polacrilex]	N	S	Unknown	Formulation: Patch	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
Kenalog [Triamcinolone Acetonide]	N	S	Unknown	Unk	Not Reported
Lomotil [Loperamide Hydrochloride]	N	S	Oral	Unk	Not Reported
Loperamide	N	S	Oral	Unk	Not Reported



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Macrogol;Propylene Glycol; Sodium Chloride	N	S	Nasal	Unk,Route Of Admisntration: Intra-Nasal	Not Reported
Magnesium	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Mesalazine	N	S	Unknown	Unk, Doage Form: Not Specified	Not Reported
Mupirocin Calcium	N	S	Topical	Unk	Not Reported
Sinus Rinse	N	S	Nasal	Formulation: Solution Intra-Nasal	Not Reported
Statex [Morphine Sulfate]	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Vitamin D [Colecalciferol]	N	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Glycerol	N	S	Unknown	Unk	Not Reported
Pms Azithromycin	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Potassium Chloride	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Sodium Bicarbonate	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Betamethasone Sodium Phosphate	N	S	Unknown	Unk	Not Reported
Benzydamine	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate; Betamethasone Sodium Phosphate	N	S	Unknown	Unk	Not Reported
Clobetasol Propionate; Clotrimazole	N	S	Unknown	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Macrogol;Potassium Chloride; Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported



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FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

		Vitamins Nos		N	S	Unknown	Unk			Not Reported
		Valsartan		N	С	Unknown	Unk, Dosage Form: Not Specified			Not Reported
		Metronidazole		N	С	Unknown	Unk, Dosage Form: Not Specified			Not Reported
		Sulfamethoxazole\Trimethoprim			S					Not Reported
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	Outcome	s Mfr Co	ntrol # 503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Apr-2023	172001	194 EXPEDITED (15-DAY)	Υ		ОТ	CA-drred USA/CA	ddys- N/19/0117732		Female	e CAN
Preferred Term		<u>Product</u>	Comp.	OTO	C Role	Route	Dosage Text	<u>Duration</u>		Mfr
Drug Ineffective; Macu	ılar	Atorvastatin		N	S	Unknown				Not Reported
Degeneration		Atorvastatin		N	S	Unknown				Not Reported
		Ertapenem For Injection, 1 G/Vial		Ν	S	Unknown				Not Reported
		Ertapenem For Injection, 1 G/Vial		N	S	Unknown				Not Reported
		Alprazolam		N	S	Unknown				Not Reported
		Alprazolam		N	S	Unknown				Not Reported
		Amoxicillin Trihydrate		N	S	Unknown				Not Reported
		Amoxicillin Trihydrate		N	S	Unknown				Not Reported
		Acetaminophen		N	S	Oral				Not Reported
		Acetaminophen		Ν	S	Unknown				Not Reported
		Apo Hydro		Ν	S	Oral				Not Reported
		Apo Hydro		Ν	S	Endocervical				Not Reported
		Apo Hydro		Ν	S	Unknown				Not Reported
		Avamys		Ν	S	Ophthalmic				Not Reported
		Avamys		N	S	Unknown				Not Reported
		Azithromycin Dihydrate		Ν	S	Unknown				Not Reported
		Bactroban		Ν	S	Unknown				Not Reported
		Betaderm		Ν	S	Unknown				Not Reported



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Betar	nethasone Dipropionate	N	S	Unknown		Not Reported
Biaxir	n XI	N	S	Oral		Not Reported
Biaxir	n XI	N	S	Unknown		Not Reported
Bisac	odyl	N	S	Unknown		Not Reported
Bisac	odyl	N	S	Transplacental		Not Reported
Cetiri	zine	N	S	Unknown		Not Reported
Clarit	hromycin	N	S	Unknown		Not Reported
Clarit	hromycin	N	S	Unknown		Not Reported
Clotri	mazole	N	S	Unknown		Not Reported
Deso	nide	N	S	Unknown		Not Reported
Dilau	did	N	S	Unknown		Not Reported
Diphe	nhydramine Hydrochloride	N	S	Unknown		Not Reported
Diphe	nhydramine Hydrochloride	N	S	Unknown		Not Reported
Entoc	cort	N	S	Oral		Not Reported
Entoc	cort	N	S	Unknown		Not Reported
Flove	nt	N	S	Unknown		Not Reported
Flove	nt	N	S	Unknown		Not Reported
Glyce	rine	N	S	Oral		Not Reported
Glyce	rine	N	S	Unknown		Not Reported
	icidin/Neomycin	N	S	Unknown		Not Reported
Gram	re/Polymyxin B Sulfate icidin/Neomycin re/Polymyxin B Sulfate	N	S	Unknown		Not Reported
Gram	icidin/Neomycin re/Polymyxin B Sulfate	N	S	Unknown		Not Reported
Habit	rol	N	S	Unknown		Not Reported
Humi	ra	N	S	Subcutaneous	6 YR	Not Reported
Humi	ra	N	S	Subcutaneous	6 YR	Not Reported
Kena	log	N	S	Intra-articular		Not Reported
Lomo	til	N	S	Oral		Not Reported
Metro	nidazole	N	S	Unknown		Not Reported



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Metronidazole	N	S	Unknown	Not Reported
Ms Ir	N	S	Unknown	Not Reported
Mupirocin	N	S	Topical	Not Reported
Mupirocin	N	S	Unknown	Not Reported
Nadolol	Ν	S	Unknown	Not Reported
Nadolol	N	S	Intra-articular	Not Reported
Nadolol	N	S	Oral	Not Reported
Nicoderm	N	S	Unknown	Not Reported
Nicoderm	N	S	Unknown	Not Reported
Pantoprazole	N	S	Unknown	Not Reported
Pentasa	N	S	Unknown	Not Reported
Prednisone	N	S	Subcutaneous	Not Reported
Pregabalin	Ν	S	Topical	Not Reported
Pregabalin	N	S	Oral	Not Reported
Pregabalin	N	S	Unknown	Not Reported
Pulmicort	N	S	Unknown	Not Reported
Pulmicort	N	S	Other	Not Reported
Refresh Tears	N	S	Ophthalmic	Not Reported
Sodium Chloride	N	S	Unknown	Not Reported
Sodium Chloride	N	S	Unknown	Not Reported
Sodium Chloride	N	S	Other	Not Reported
Statex	N	S	Unknown	Not Reported
Sulfamethoxazole/Trimethoprim	N	S	Unknown	Not Reported
Sulfamethoxazole/Trimethoprim	N	S	Unknown	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Not Reported
Triamcinolone Acetonide	N	S		Not Reported
Triamcinolone Acetonide	N	S	Unknown	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Not Reported



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Vitamin D3	N	S	Unknown	Not Reported
Vitamin D3	N	S	Unknown	Not Reported
Vitamin D3	N	S	Unknown	Not Reported
Atropine Sulfate/Diphenoxylate Hydrochloride	N	S	Oral	Not Reported
Atropine Sulfate/Diphenoxylate Hydrochloride	N	S	Oral	Not Reported
Atropine Sulfate/Diphenoxylate Hydrochloride	N	S	Oral	Not Reported
Atropine Sulfate/Diphenoxylate Hydrochloride	N	S	Oral	Not Reported
Atropine Sulfate/Diphenoxylate Hydrochloride	N	S	Unknown	Not Reported
Diphenhydramine Hydrochloride	Ν	S		Not Reported
Diphenhydramine Hydrochloride	N	S		Not Reported
Morphine Sulfate	N	S	Unknown	Not Reported
Morphine Sulfate	N	S	Unknown	Not Reported
Nicotine	N	S	Unknown	Not Reported
Xantofyl Palmitate	N	S	Unknown	Not Reported
Zeaxanthin	N	S	Unknown	Not Reported
Zinc Oxide	N	S	Unknown	Not Reported
Calcium Carbonate	N	S	Unknown	Not Reported
Calcium Carbonate	N	S	Unknown	Not Reported
Alka-Seltzer Relief Chews	N	S	Unknown	Not Reported
Bactrim	N	S	Unknown	Not Reported
Betamethasone Valerate	N	S	Unknown	Not Reported
Betamethasone Valerate	N	S	Unknown	Not Reported
Cholecalciferol	N	S	Unknown	Not Reported
Cupric Oxide	N	S	Unknown	Not Reported
Magnesium Sulfate	N	S	Unknown	Not Reported
Vitamin-E	N	S	Unknown	Not Reported
Loperamide Hydrochloride	N	S	Oral	Not Reported
Loperamide Hydrochloride	N	S	Oral	Not Reported



Loperamide Hydrochloride	N	S	Unknown	Not Reported
Loperamide Hydrochloride	N	S	Oral	Not Reported
Loperamide Hydrochloride	N	S	Oral	Not Reported
Loperamide Hydrochloride	N	S	Oral	Not Reported
Loperamide Hydrochloride	N	S	Oral	Not Reported
Adalimumab	N	S	Subcutaneous	Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Not Reported
Mesalazine	N	S	Unknown	Not Reported
Pantoprazole Sodium Anhydrous	N	S	Unknown	Not Reported
Budesonide	N	S	Unknown	Not Reported
Budesonide Budesonide Budesonide Budesonide	N N N N	S S S	Oral	Not Reported Not Reported Not Reported Not Reported
Budesonide	N	S	Subcutaneous	Not Reported
Calcium Carbonate With Vitamin D3	N	S		Not Reported
Calcium Carbonate With Vitamin D3	N	S	Unknown	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Not Reported
Hydrochlorothiazide	N	S	Endocervical	Not Reported
Hydrochlorothiazide Hydrochlorothiazide	N N	S S	Subcutaneous	Not Reported Not Reported
Ergocalciferol	N	S	Unknown	Not Reported
Acetylsalicylic Acid	N	S	Oral	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Not Reported
Amoxicillin	N	S	Unknown	Not Reported
Fluticasone Furoate	N	S	Ophthalmic	Not Reported
Fluticasone Furoate	N	S	Unknown	Not Reported
Azithromycin	N	S	Unknown	Not Reported



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Clotrimazole	N	S	Unknown		Not Reported
Glycerol	N	S	Oral		Not Reported
Glycerol	N	S	Oral		Not Reported
Gramicidin/Neomycin Sulfate/Polymyxin B Sulfate	N	S	Unknown		Not Reported
Macrogol/Potassium Chloride/Sodium Bicarbonate	N	S	Unknown		Not Reported
Mesalazine	N	S	Unknown		Not Reported
Neomycin Sulfate	N	S	Unknown		Not Reported
Polymyxin B Sulfate	N	S	Unknown		Not Reported
Potassium Chloride	N	S	Unknown		Not Reported
Sodium Bicarbonate	N	S	Unknown		Not Reported
Vitamin D3	N	S	Unknown		Not Reported
Vitamin D3	N	S	Unknown		Not Reported
Triamcinolone	N	S	Unknown		Not Reported
Triamcinolone	N	S	Intra-articular		Not Reported
Simvastatin	N	S	Unknown		Not Reported
Vitamins Nos	N	S	Unknown		Not Reported
Prednisone Acetate	N	S	Unknown		Not Reported
Imodium Vitamin E Cap 400unit	N N	S S	Unknown	400unit	Not Reported Not Reported
Atropine Sulfate/ Difenoxin/ Hydrochloride	N	S	Oral	. 333	Not Reported
Betamethasone Sodium Phosphate	N	S	Unknown		Not Reported
Betamethasone Sodium Phosphate	N	S	Unknown		Not Reported
Atropine	N	S	Oral		Not Reported
Valsartan	N	S	Vaginal		Not Reported
Valsartan	N	S	Vaginal		Not Reported
Valsartan	N	S	Unknown		Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown		Not Reported



Sinus Rinse N S Other Not R	Penorted
Other	•
A L UO di i	Reported
Ambroxol/Cetirizine N S _{Unknown} Not R Hydrochloride	Reported
	Reported
Mupirocin Calcium Dihydrate N S Unknown Not R	Reported
Betamethasone Dipropionate N S Unknown Not R	Reported
Magnesium Oxide N S Unknown Not R	Reported
Calcium Carbonate N S Unknown Not R	Reported
Ertapenem N S Unknown Not R	Reported
Pseudoephedrine N S Unknown Not R	Reported
Pseudoephedrine N S Unknown Not R	Reported
Mezavant N S _{Unknown} Not R	Reported
Clarithromycin N S Unknown Not R	Reported
Calcium N S Not R	Reported
Carbonate/Ergocalciferol Glycerol/Sodium Stearate N S Not R	Reported
	Reported
CHATOWIT	Reported
	Reported
	Reported
	Reported
Betamethasone N S Unknown Not R	Reported
Gramicidin N S _{Unknown} Not R	Reported
Fluticasone Propionate N S Unknown Not R	Reported
Benzydamine Hydrochloride N S Unknown Not R	Reported
Dulcolax N S Unknown Not R	Reported
Pms-Azithromycin N S _{Unknown} Not R	Reported
Sulfamethoxazole N S Unknown Not R	Reported
Zinc N S Unknown Not R	Reported
Vitamins Nos N S _{Unknown} Not R	Reported



Vitamins Nos	N	S	Intra-articular	Not Reported
Acetic Acid/Triamcinolone	N	S	iiitia-articulai	Not Reported
Gramicidin/Neomycin Macrogol 3350/Potassium	N N	S S		Not Reported Not Reported
Chloride/Sodium Bicarbonate/Sodium Chloride				
Azithromycin Isopropanolate	N	S		Not Reported
Monohydrate Macrogol	N	S	Unknown	Not Reported
Acetaminophen/Dextr	N	S	Unknown	Not Reported
Opropoxyphene Minerals	N	S	Unknown	Not Reported
Dietary	N	S	Unknown	Not Reported
Supplement\Minerals\Vitamins Fructose/Glycerol/Sodium	N	S		-
Chloride	IN	5	Oral	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Not Reported
Sodium Carboxymethyl Cellulose	N	S	Ophthalmic	Not Reported
Sodium Carboxymethyl	N	S	Unknown	Not Reported
Cellulose Betamethasone/Mupirocin	N	S	Topical	Not Reported
Isoniazid/Pyridoxines/Sulfameth	N	S	Unknown	Not Reported
oxazole/Trimethoprim Polyethylene Glycol 4000	N	S	Urethral	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Not Reported
Gramicidin\Neomycin\Polymyxin	N	S		Not Reported
B Sulfate Mentha Arvensis	N	S	Unknown	Not Reported
Calcium Citrate	N	s	Unknown	Not Reported
Calcium Phosphate (Dibasic)/	N	S	Unknown	Not Reported
Vitamin D3 Ichthammol/Zinc Oxide	N	S	Unknown	Not Reported
Calcium Gluconate	N	S	Unknown	Not Reported
Calcium Gluconate	N	S	Unknown	Not Reported
Valsartan	N	С	Intracardiac	Not Reported



		Valsartan			N	С	Vaginal					Not Reported
		Valsartan			Ν	С	Unknown					Not Reported
		Calcium	1.76		Ν	С	Unknown					Not Reported
		Carbonate/Coled Hydrochlorothia:			N	С	Unknown					Not Reported
		Clotrimazole			N	С	Unknown					Not Reported
FDA Received Date	Case #	<u>Case 1</u>	<u>Гуре</u>	Health	Prof	Outcomes	Mfr (Control #	503B Facility	<u>Age</u>	<u>Sex</u>	Country
10-Apr-2023	20222	515 EXPE	DITED (15-DAY)	Υ		HO, OT		RGANON- CAN001744		71 YR	Female	CAN
Preferred Term		Product		Comp.	OTO	Role	Route	Dosage	e Text	Duration		<u>Mfr</u>
Abdominal Pain; Anae		Diprolene			N	S	Unknown	Unk				Organon
Chronic Sinusitis; Colit Colitis Ulcerative;	tis;	Diprolene			N	S	Unknown	Unk				Organon
Constipation; Drug		Diprolene			N	S	Unknown	Unk				Organon
Ineffective; Dyspepsia: Erythema; Female Ger		Diprolene			N	S	Unknown	Unk				Organon
Tract Fistula; Frequent		Diprolene			N	S	Unknown	Unk				Organon
Bowel Movements;		Zocor			N	S	Unknown	Unk				Organon
Haematochezia; Headache; Infusion		Zocor			N	S	Unknown	Unk				Organon
Related Reaction; Mad		Zocor			Ν	S	Unknown	Unk				Organon
Degeneration; Malaise Nausea; Off Label Use		Zocor			Ν	S	Unknown	Unk				Organon
Oral Candidiasis; Pain	,	Betamethasone	Dipropionate		Ν	S	Unknown	Unk				Not Reported
Paraesthesia Oral; Procedural Pain; Proc	titie:	Betamethasone			Ν	S	Unknown	Unk				Not Reported
Pyrexia; Radiculopathy		Betamethasone			Ν	S	Unknown	Unk				Not Reported
Rectal Haemorrhage; Therapeutic Product Effect Incomplete; Vaginal Discharge; Vaginal Flatulence; Weight	Effect	Betaderm Ointm	ent		N	S	Unknown	Unk, [Specit	Dosage Form: Not fied			Not Reported
		Betaderm Ointm	ent		Ν	S	Unknown	0.122	Gram			Not Reported
		Invanz			Ν	S	Unknown	Unk				Not Reported
Decreased		Invanz			Ν	S	Unknown	Unk				Not Reported
		Invanz			Ν	S	Unknown	Unk				Not Reported
		Invanz			Ν	S	Unknown	Unk				Not Reported



Paracetamol	N	S	Unknown	Unk	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Alprazolam	N	S	Unknown	0.25 Milligram	Not Reported
Alprazolam	N	S	Oral	Unk	Not Reported
Alprazolam	N	S	Oral	Unk	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Alprazolam	N	S	Unknown	Unk	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
Apo-Hydro	N	S	Endocervical	Unk	Not Reported
Apo-Hydro	N	S	Endocervical	Unk	Not Reported
Apo-Hydro	N	S	Endocervical	Unk	Not Reported
Apo-Hydro	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Avamys	N	S	Unknown	Unk, Dosage Form: Spray, Metered Dose	Not Reported
Avamys	N	S	Unknown	Unk, Dosage Form: Spray, Metered Dose	Not Reported
Azithromycin	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Azithromycin	N	S	Unknown	Unk	Not Reported
Azithromycin	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported



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Pulmicort	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S	Oral	Unk	Not Reported
Pulmicort	N	S	Cutaneous	Unk	Not Reported
Pulmicort	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S		Unk	Not Reported
Budesonide	N	S		Unk	Not Reported
Budesonide	N	S		Unk	Not Reported
Budesonide	N	S	Unknown	Unk	Not Reported
Benadryl Allergy [Cetirizine Hydrochloride]	N	S	Unknown	Unk	Not Reported
Benadryl Allergy [Cetirizine Hydrochloride]	N	S	Unknown	Unk	Not Reported
Benadryl Allergy [Cetirizine Hydrochloride]	N	S	Unknown	Unk	Not Reported
Clarithromycin	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Clotrimazole	N	S	Unknown	Unk	Not Reported
Desonide	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Desonide	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Diphenhydramine	N	S	Unknown	Unk	Not Reported
Entocort	N	S	Unknown	Unk	Not Reported
Entocort	N	S	Unknown	Unk	Not Reported
Entocort	N	S	Oral	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Flovent	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported



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N	S	Oral	Unk		Not Reported
N	S	Unknown	Unk		Not Reported
N	S	Unknown	Unk		Not Reported
N	S	Subcutaneous	Unk, Dosage Form: Solution Subcutaneous	6 YR	Not Reported
N	S	Subcutaneous	Unk, Dosage Form: Solution Subcutaneous	6 YR	Not Reported
N	S	Unknown	Unk	5 YR	Not Reported
N	S	Unknown	100 Milligram		Not Reported
N	S	Endocervical	Unk		Not Reported
N	S	Endocervical	Unk		Not Reported
N	S	Unknown	Unk		Not Reported
N	S	Unknown	Unk		Not Reported
N	S	Unknown	Unk, Dosage Form: Not Specified		Not Reported
N	S	Unknown	Unk, Dosage Form: Not Specified		Not Reported
N	S	Topical	Unk, Dosage Form: Ointment Topical		Not Reported
N	S	Unknown	Unk		Not Reported
N	S	Unknown	40 Milligram		Not Reported
N	S	Unknown	Unk		Not Reported
N	S	Unknown	Unk		Not Reported
N	S	Unknown	Unk		Not Reported
N	S	Unknown	Unk		Not Reported
N	S	Unknown	Unk, Dosage Form: Not Specified		Not Reported
N	S	Unknown	Unk, Dosage Form: Not Specified		Not Reported
N	S	Unknown	Dosage Form: Not Specified		Not Reported
N	S	Unknown	Dosage Form: Not		Not Reported
	N N N N N N N N N N N N N N N N N N N		N S Unknown N S Subcutaneous N S Subcutaneous N S Subcutaneous N S Unknown N S Unknown N S Endocervical N S Endocervical N S Unknown	N S Unknown Unk N S Unknown Unk N S Subcutaneous Unk, Dosage Form: Solution Subcutaneous N S Unknown Unk N S Unknown Unk N S Unknown 100 Milligram N S Endocervical Unk N S Unknown Unk, Dosage Form: Not Specified N S Unknown Unk, Dosage Form: Not Specified N S Unknown Unk Dosage Form: Not Specified N S Unknown Dosage Form: Not Specified	N S Unknown Unk N S Subcutaneous Unk, Dosage Form: 6 YR Solution Subcutaneous Onk, Dosage Form: 6 YR Solution Subcutaneous Onk N S Unknown Unk Onk N S Unknown Onk N S Endocervical Unk N S Endocervical Unk N S Unknown Unk N S Unknown Unk N S Unknown Unk N S Unknown Unk, Dosage Form: Not Specified N S Unknown Unk, Dosage Form: Not Specified N S Unknown Unk Dosage Form: Not Specified N S Unknown Dosage Form: Not Specified N S Unknown Dosage Form: Not Specified

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				Specified	
Pregabalin	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Topical	Unk	Not Reported
Pregabalin	Ν	S	Unknown	150 Milligram	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk, Dosage Form: Drops Opthalmic	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk, Dosage Form: Drops Opthalmic	Not Reported
Sulfamethoxazole;Trimethoprim	Ν	S	Unknown	Unk	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Suspension Intra-Articular	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Solution	Not Reported
Triamcinolone Acetonide	Ν	S	Intra-articular	Unk	Not Reported
Triamcinolone Acetonide	Ν	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	Ν	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	Ν	S	Intra-articular	Unk	Not Reported
Vitamine D	Ν	S	Unknown	Unk	Not Reported
Vitamine D	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Infa-3 [Gramicidin;Neomycin Sulfate;Polymyxin B]	N	S	Unknown	Unk, Ointment Dental	Not Reported
Infa-3 [Gramicidin;Neomycin Sulfate;Polymyxin B]	N	S	Unknown	Unk	Not Reported
Infa-3 [Gramicidin;Neomycin Sulfate;Polymyxin B]	N	S	Unknown	Unk	Not Reported
Mesalamine	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk, Dosage Form: Patch	Not Reported
Nicoderm	N	S	Topical	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Topical	Unk	Not Reported
Bactroban [Mupirocin]	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported



Bactroban [Mupirocin]	N	S	Unknown	Unk	Not Reported
Bactroban [Mupirocin]	N	S	Topical	Unk	Not Reported
Betaderm [lodine;Povidone-lodine]	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Betaderm [lodine;Povidone- lodine]	N	S	Unknown	Unk	Not Reported
Calcium;Magnesium;Vitamin D Nos	N	S	Unknown	Unk	Not Reported
Calcium Carbonate; Colecalciferol	N	S	Unknown	Unk	Not Reported
Calcium Carbonate; Colecalciferol	N	S	Unknown	Unk	Not Reported
Dilaudid	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Dilaudid	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Habitrol [Nicotine]	N	S	Unknown	Unk, Dosage Form: Patch	Not Reported
Habitrol [Nicotine]	N	S	Unknown	Unk	Not Reported
Kenalog [Triamcinolone Acetonide]	N	S	Intra-articular	Unk, Dosage Form: Suspension Intra-Articular	Not Reported
Kenalog [Triamcinolone Acetonide]	N	S	Intra-articular	Suspension Intra-Articular	Not Reported
Lomotil [Loperamide Hydrochloride]	N	S	Oral	Unk, Qid	Not Reported
Lomotil [Loperamide Hydrochloride]	N	S	Oral	4 Every 1 Days	Not Reported
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate; Sodium Chloride;So	N	S	Unknown	Unk	Not Reported
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate; Sodium Chloride;So	N	S	Unknown	Unk	Not Reported
Msir	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Msir	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Statex [Morphine Sulfate]	Ν	S	Unknown	Unk, Dosage Form: Not	Not Reported

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				Specified	
Statex [Morphine Sulfate]	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Salinex [Sodium Chloride]	N	S	Unknown	Unk, Dosage Form: Solution Nasal	Not Reported
Salinex [Sodium Chloride]	N	S	Unknown	Unk, Dosage Form: Solution Nasal	Not Reported
Pantoprazole	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Loperamide Hydrochloride	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	4 Every 1 Days	Not Reported
Loperamide Hydrochloride	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Dosage Form	Not Reported
Loperamide Hydrochloride	N	S	Unknown	4 Dosage Form, 1 Every 1 Days	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk, 1 Every 1 Months	Not Reported
Loperamide Hydrochloride	N	S	Oral	1.0 Dosage Form, 1 Every 1 Days	Not Reported
Triamcinolone	N	S	Unknown	Unk (Dosage Form: Suspension Intra-Articular)	Not Reported
Triamcinolone	N	S	Unknown	Unk	Not Reported
Triamcinolone	N	S	Intra-articular	Unk	Not Reported
Alka-Seltzer	N	S	Unknown	Unk	Not Reported
Alka-Seltzer	N	S	Unknown	Unk	Not Reported
Bactrim	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Bactrim	N	S	Unknown	Unk	Not Reported
Bactrim	N	S	Nasal	Unk	Not Reported
Bactrim	N	S	Nasal	Unk	Not Reported
Bactrim	N	S	Nasal	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported



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Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Xantofyl Palmitate	N	S	Oral	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Oral	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Zinc Oxide	N	S	Oral	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Atropine Sulfate;Diphenoxylate	N	S	Oral	1 Tablet, Q6h	Not Reported
Hydrochloride Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	1 Every 6 Hours	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	1 Every 1 Days	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	1 Every 6 Hours	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	4.0 Dosage Forms, 1 Every 1 Days	Not Reported
Sinus Rinse	N	S	Nasal	Solution Nasal	Not Reported
Sinus Rinse	N	S	Nasal	Solution Nasal	Not Reported
Morphine Sulphate	N	S	Unknown	Unk	Not Reported
Dulcolax [Sodium Picosulfate]	N	S	Unknown	Unk	Not Reported
Dulcolax [Sodium Picosulfate]	N	S	Unknown	Unk	Not Reported
Vitamin E [Tocopheryl Acetate]	N	S	Unknown	Unk, 400 Unit	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Benzydamine Hydrochloride	N	S	Unknown	Unk	Not Reported



Benzydamine Hydrochloride	N	S	Unknown	Unk	Not Reported
Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
Tocopheryl Acetate	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Nasal	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Intracardiac	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Unknown	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Unknown	Unk	Not Reported
Alrex [Loteprednol Etabonate]	N	S	Ophthalmic	Unk	Not Reported
Alrex [Loteprednol Etabonate]	N	S	Ophthalmic	Unk	Not Reported
Ascorbic Acid;Betacarotene; Cupric Oxide;DI-Alpha Tocopheryl Acetate;Zi	N	S	Unknown	Unk	Not Reported
Clobetasone Butyrate; Gentamicin Sulfate;Miconazole Nitrate	N	S	Unknown	Unk	Not Reported
Clobetasone Butyrate; Gentamicin Sulfate;Miconazole Nitrate	N	S	Unknown	Unk	Not Reported
Clobetasone Butyrate; Gentamicin Sulfate;Miconazole Nitrate	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Taro-Mupirocin	N	S	Unknown	Unk	Not Reported
Taro-Mupirocin	N	S	Unknown	Unk	Not Reported
Taro-Mupirocin	N	S	Unknown	Unk	Not Reported
Riva-Pantoprazole	N	S	Unknown	Unk	Not Reported
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Preferred Term	<u>Produ</u>	<u>ict</u>	Comp.	OTC	Role	Route	<u>Dosage</u>	<u>Text</u>	<u>Duration</u>	<u>Mfr</u>	
10-Apr-2023	21436605	EXPEDITED (15-DAY)	Υ		HO, OT		MITHKLINE- 22AMR037200			Unknown	CAN
FDA Received Date	Case #	Case Type	<u>Health</u>	<u>Prof</u>	<u>Outcomes</u>	Mfr Con	ntrol#	503B Facility	<u>Age</u>	<u>Sex</u>	Country
		ne Sulfate;Diphenoxylate chloride		N	S	Unknown	Unk			Not	Reported
	_	[Loteprednol Etabonate]		N	S	Unknown	Unk				Reported
		ne Polacrilex		N	S	Unknown	Unk				Reported
		ne Polacrilex		N	S	Unknown	Unk			Not	Reported
	Kenalo Acetor	og [Triamcinolone nide]		N	S	Unknown	Unk			Not	Reported
	Kenalo Acetor	og [Triamcinolone nide]		N	S	Intra-articular		osage Form: nsion Intra-Articula	·)		Reported
		ne Sulfate;Diphenoxylate chloride		N	S	Unknown	Unk			Not	Reported
	Imodiu			N	S	Unknown	Unk				Reported
	_	esium Oxide		N	S	Unknown	Unk				Reported
	Magne	esium Oxide		N	S	Unknown	Unk			Not	Reported
	D-Alph	na Tocopherol		N	S	Unknown	Unk			Not	Reported
		opropoxyphene na Tocopherol		N	S	Unknown	Unk			Not	Reported
	Acetar	ppropoxyphene minophen;		N	S	Unknown	Unk				Reported
	•	minophen;		N	S	Unknown	Unk				Reported
		de;Sodium Bicarbonate		N	S	Unknown	Unk				Reported
Isoniazid;Pyric Hydrochloride Sulfamethoxa		zid;Pyridoxine		N N	s s	Unknown	Unk Unk				Reported Reported
	Hydro	zid;Pyridoxine chloride; nethoxazole;Trimethoprim		N	S	Unknown	Unk			Not	Reported
	Riva-F	Pantoprazole		N	S	Unknown	Unk				Reported



0.25 Mg

Unk, Tid

Unk

Unk

Abdominal Pain; Anaemia;	Calcium Carbonate,	N	S		Unk	Glaxosmithkline
Chronic Sinusitis; Colitis; Colitis Ulcerative;	Cholecalciferol Nicotine	N	S			Glaxosmithkline
Constipation; Drug	Nicoderm	N	S		Unk	Glaxosmithkline
Ineffective; Dyspepsia;					Unk	
Erythema; Female Genital Tract Fistula; Frequent	Nicotine Polacrilex	N	S		Unk	Glaxosmithkline
Bowel Movements;	Pantoprazole	N	S		Unk	Not Reported
Haematochezia;	Zinc Oxide	Y	S		Unk	Glaxosmithkline
Headache; Infusion Related Reaction; Macular	Acetaminophen + Pseudoephedrine	N	S		Unk	Not Reported
Degeneration; Malaise; Nausea; Off Label Use;	Sodium Chloride	N	S		Unk	Not Reported
Oral Candidiasis; Pain; Paraesthesia Oral;	Magnesium Sulfate	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Procedural Pain; Proctitis;	D-Alpha Tocopherol	N	S		Unk	Glaxosmithkline
Pyrexia; Radiculopathy; Rectal Haemorrhage;	Magnesium Oxide	N	S		Unk	Not Reported
Therapeutic Product Effect	Cetirizine Hydrochloride	N	S		Unk	Not Reported
Incomplete; Vaginal Discharge; Vaginal	Magnesium Sulfate Inj	N	S		Unk	Not Reported
Flatulence; Weight	Vitamin E	N	S		Unk	Glaxosmithkline
Decreased	Nicotinamide	N	S		Unk	Not Reported
	Acetaminophen	Υ	S		Unk	Glaxosmithkline
	Bactroban (Mupirocin)	N	S	Topical	Unk	Not Reported
	Calcium Gluconate	N	S		Unk	Glaxosmithkline
	Fluticasone Propionate	N	S		Unk	Glaxosmithkline
	Azithromycin Dihydrate	N	S		Unk	Not Reported
	Fluticasone Furoate	N	S		Unk	Glaxosmithkline
	Clotrimazole	N	S		Unk	Not Reported
	Metronidazole	N	S		Unk	Not Reported
	Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported

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Alprazolam

Mesalazine

Clarithromycin

Biaxin XI

Not Reported

Not Reported

Not Reported

Not Reported



Desonide	N	S		Unk	Not Reported
Ertapenem Sodium	N	S		Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Humira	N	S		Unk	Not Reported
Nadolol	N	S		Unk	Not Reported
Prednisone	N	S		150 Mg	Not Reported
Pregabalin Capsule	N	S		Unk	Not Reported
Refresh Tears	N	S		Unk	Not Reported
Sinus Rinse	N	S		Unk	Not Reported
Hydromorphone Hydrochloride	N	S		Unk	Not Reported
Budesonide	N	S	Oral	Unk	Not Reported
Morphine Sulfate	N	S		Unk	Not Reported
Sulfamethoxazole + Tmp	N	S		200 Mg	Not Reported
Kenalog (Triamcinolone Acetonide)	N	S		Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Df, Qid	Not Reported
Zeaxanthin	N	S		Unk	Not Reported
Xantofyl Palmitate	N	S		Unk	Not Reported
Atorvastatin Calcium	N	S		Unk	Not Reported
Betamethasone Valerate	N	S		0.122 G	Not Reported
Cupric Oxide + Folic Acid + Nicotinamide + Zinc	N	S		Unk	Not Reported
Amoxicillin Trihydrate	N	S		Unk	Not Reported
Glyceryl Trinitrate	N	S		Unk	Not Reported
Calcium Carbonate + Colecalciferol + Zinc Oxide	N	S		Unk	Not Reported
Hydrochlorothiazide	N	S		100 Mg	Not Reported
Dulcolax (Bisacodyl)	N	S		Unk	Not Reported
Gramicidin/Neomycin Sulfate/Polymyxin B Sulfate	N	S		Unk	Not Reported
Vitamin D3	N	S		Unk	Not Reported
Magnesium Carbonate	N	S		Unk	Not Reported



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Diphenhydramine Hydrochloride	N	S		Unk	Not Reported
Dextropropoxyphene + Acetaminophen	N	S		Unk	Not Reported
Benzydamine	N	S		Unk	Not Reported
Atropine Sulphate + Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Magnesium Sulfate	N	S		Unk	Not Reported
Statex (Morphine Sulfate)	N	S		Unk	Not Reported
Isoniazid + Pyridoxine Hydrochloride + Sulfamethoxazole + Trimethoprim	N	S		Unk	Not Reported
Alka-Seltzer (Acetylsalicylic Acid + Citric Acid + Sodium Bicarbonate)	N	S		Unk	Not Reported
Potassium Chloride	N	S		Unk	Not Reported
Ubidecarenone	N	S		Unk	Not Reported
Glycerol	N	S		Unk	Not Reported
Macrogol 3350 + Potassium Chloride + Sodium Bicarbonate + Sodium Chlor	N	S		Unk	Not Reported
Sodium Carboxymethyl Cellulose	N	S		Unk	Not Reported
Acetylsalicylic Acid	N	S		Unk	Not Reported
Calcitriol + Calcium Carbonate + Zinc	N	S		Unk	Not Reported
Acetic Acid + Triamcinolone Acetonide	N	S		Unk	Not Reported
Fluconazole	N	S		Unk	Not Reported
Methylprednisolone Sodium Succinate	N	S		Unk	Not Reported
Midazolam	N	S		Unk	Not Reported
Bifidobacterium Infantis	N	S		Unk	Not Reported
Hydrocortisone	N	S		Unk	Not Reported
Zopiclone	N	S		Unk	Not Reported
Sucralfate	N	S		Unk	Not Reported



Oxybutynin Hydrochloride	N	S	Unk	Not Reported
Fentanyl Citrate	N	S	Unk	Not Reported
Ciprofloxacin Hydrochloride	N	S	Unk	Not Reported
Vedolizumab	N	S	Unk	Not Reported
Fructose	N	S	Unk	Not Reported
Solu Medrol	N	S	Unk	Not Reported
Ciprofloxacin	N	S	Unk	Not Reported
Oxybutynin Hydrochloride	N	S	Unk	Not Reported
Cortenema	N	S	Unk	Not Reported
Salinex (Furosemide)	N	S	Unk	Not Reported
Ambroxol Hydrochloride	N	S	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unk	Not Reported
Carboxymethylcellulose Sodium	N	S	Unk	Not Reported
Sodium Stearate	N	S	Unk	Not Reported
Triamcinolone	N	S	Unk	Not Reported
Trimethoprim	N	S	Unk	Not Reported
Moviprep	N	S	Unk	Not Reported
Acetic Acid Citric Acid	N N	S S	Unk	Not Reported Not Reported
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