

Selection Criteria:

Product Name:				
Product Active Ingredient:				
Active Ingredient:	CARBOXYMETHYLCELLULOSE 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.

*. "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.

** "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.

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

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).

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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.
OTC	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.

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2021	20185068	EXPEDITED (15-DAY)	Y	OT	CA-SANOFI US-2021SA411345			Female	
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Bisacodyl	N		S				Sanofi	
	Metronidazole	N		S				Sanofi	
	Paracetamol	N		S				Not Reported	
	Atorvastatin Calcium	N		S				Not Reported	
	Alprazolam	N		S				Not Reported	
	Amoxicillin Trihydrate	N		S				Not Reported	
	Azithromycin	N		S		Unk		Not Reported	
	Betamethasone Dipropionate	N		S				Not Reported	
	Betamethasone Valerate	N		S				Not Reported	
	Budesonide	N		S				Not Reported	
	Budesonide	N		S				Not Reported	
	Budesonide	N		S		Unk		Not Reported	
	Calcium Carbonate	N		S		Unk		Not Reported	
	Carmellose Sodium	N		S		Unk		Not Reported	
	Cetirizine Hydrochloride	N		S		Unk		Not Reported	
	Clarithromycin	N		S		Unk		Not Reported	
	Clarithromycin	N		S		Unk		Not Reported	
	Clotrimazole	N		S		Unk		Not Reported	
	Desonide	N		S		Unk		Not Reported	
	Diphenhydramine Hydrochloride	N		S		Unk		Sanofi	
	Ergocalciferol	N		S		Unk		Sanofi	
	Fluticasone Furoate	N		S		Unk		Not Reported	
	Fluticasone Furoate	N		S		Unk		Not Reported	
	Glycerine	N		S	Oral	Unk		Not Reported	
	Hydrochlorothiazide	N		S		Unk		Not Reported	
	Hydrochlorothiazide	N		S		Unk		Not Reported	
	Magnesium Sulfate	N		S		Unk		Not Reported	
	Magnesium Oxide	N		S		Unk		Not Reported	

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Mesalazine	N	S		Unk	Sanofi
Mesalazine	N	S		Unk	Sanofi
Morphine Sulfate	N	S		Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Nadolol	N	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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Potassium Sulfate;S									
Mupirocin Calcium	N	S			Unk				Not Reported
Xantofyl Palmitate	N	S			Unk				Not Reported
Zeaxanthin	N	S			Unk				Not Reported
Acetaminophen	N	S			Unk				Not Reported
Calcium Carbonate/Vitamin D3	N	C							Not Reported
Valsartan	N	C							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2022	19711612	EXPEDITED (15-DAY)	Y	OT	CA-AstraZeneca-2021A674515			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Azithromycin	N	S		Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jan-2022	20214770	EXPEDITED (15-DAY)	Y	OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-VDP-2021-014753			Unknown	

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Ergocalciferol	N	S		Unknown	Unknown		Validus
	Bisacodyl	N	S		Unknown			Not Reported
	Metronidazole	N	S		Unknown			Not Reported
	Paracetamol	N	S		Unknown			Not Reported
	Atorvastatin Calcium	N	S		Unknown			Not Reported
	Alprazolam	N	S		Unknown			Not Reported
	Amoxicillin Trihydrate	N	S		Unknown			Not Reported
	Azithromycin	N	S		Unknown			Not Reported
	Betamethasone Dipropionate	N	S		Unknown	Unk		Not Reported
	Betamethasone Valerate	N	S		Unknown			Not Reported
	Budesonide	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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Sulfamethoxazole And Trimethoprim	N	S	Unknown	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Not Reported
Zinc Oxide	N	S	Unknown	Not Reported
Ertapenem Sodium	N	S	Unknown	Not Reported
Fluticasone Propionate	N	S	Unknown	Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown	Not Reported
Sinus Rinse	N	S	Nasal	Not Reported
Humira	N	S	Subcutaneous	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Unknown	Not Reported
Calcium Carbonate/Vitamin D3	N	S	Unknown	Not Reported
Vitamin D3	N	S	Unknown	Not Reported
Cupric Oxide	N	S	Unknown	Not Reported
Dilaudid	N	S	Unknown	Not Reported
Flovent	N	S	Unknown	Not Reported
Imodium	N	S	Unknown	Not Reported
Macrogol 3350;Magnesium Sulfate;Potassium Chloride; Potassium Sulfate;S	N	S	Unknown	Not Reported
Mupirocin Calcium	N	S	Unknown	Not Reported
Xantofyl Palmitate	N	S	Unknown	Not Reported
Zeaxanthin	N	S	Unknown	Not Reported
Acetaminophen	N	S	Unknown	Unk
Calcium Carbonate/Vitamin D3	N	C	Unknown	Unknown
Valsartan	N	C	Unknown	Unk

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2022	20340268	EXPEDITED (15-DAY)	N	OT	CA-GLENMARK PHARMACEUTICALS- 2022GMK069753			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2022	20340686	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2201685US			Female	USA
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Discharge; Eye Irritation; Macular Degeneration	Regener-Eyes Lite		N	C	Ophthalmic	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2022	20344634	EXPEDITED (15-DAY)	Y	OT	CA-GLENMARK PHARMACEUTICALS-2022GMK069761			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2022	20344747	EXPEDITED (15-DAY)	N	OT	CA-GLENMARK PHARMACEUTICALS-2022GMK069749			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2022	20349431	EXPEDITED (15-DAY)	N	OT	CA-GLENMARK PHARMACEUTICALS-2022GMK069756			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>		<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown	Unk			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2022	20350084	EXPEDITED (15-DAY)	N	OT	CA-GLENMARK PHARMACEUTICALS- 2022GMK069752			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2022	20354622	EXPEDITED (15-DAY)	N	OT	CA-GLENMARK PHARMACEUTICALS- 2022GMK069750			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jan-2022	20386254	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN- 2202500US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cerebrovascular Accident; Covid-19; Off Label Use	Walgreens Brand Eye Emollient		N	C		Unk, Bid			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2022	15660222	NON-EXPEDITED	N	HO, OT	US-ICU MEDICAL, INC.- ICU2018US00055			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Atrial Fibrillation; Diarrhoea; Hypersensitivity; Insomnia; Mastication Disorder; Product Dose Omission Issue; Sepsis; Skin Exfoliation; Speech Disorder; Stomatitis;	Super B Complex /01995301/		N	C	Unknown	Unk			Not Reported

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Thyroid Mass; Vomiting

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2022	19611752	EXPEDITED (15-DAY)	N	OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-VDP-2021- 000217			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown	Unk			Not Reported
	Azithromycin		N	S	Unknown	Unk			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2022	20496957	EXPEDITED (15-DAY)	Y	OT	CA-BRISTOL-MYERS SQUIBB COMPANY- BMS-2022-020350			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2022	20512841	DIRECT		DS			62 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Alopecia; Back Pain; Chills; Dysphonia; Eye Swelling; Fatigue; Ocular Hyperaemia; Palpitations; Peripheral Swelling; Peripheral Swelling; Peripheral Swelling; Respiratory Tract Congestion; Seborrhoea; Skin Exfoliation; Throat Tightness; Umbilical Erythema; Vision Blurred	Winen'S Multivitamin Probiotic			C C					Not Reported Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2022	20546961	EXPEDITED (15-DAY)	Y	OT	CA-009507513-2203CAN000824			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown	Dosage Form: Not Specified		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2022	20548417	NON-EXPEDITED	N		US-ALLERGAN-2108671US		90 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blindness Transient; Device Delivery System Issue; Eye Inflammation; Eye Irritation; Eye Pain; Eyelid Ptosis; Liquid Product Physical Issue; Ocular Hyperaemia; Product Packaging Quantity Issue	Nifepine		N	C	Oral	Unk		Not Reported	
	Multivitamin /00097801/		N	C		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Mar-2022	20584379	EXPEDITED (15-DAY)		HO, OT	CA-B.Braun Medical Inc. -2126691		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
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	Macrogol/Potassium/Sodium Bicarbonate		N	S				Not Reported	

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Decreased

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Apr-2022	19420055	EXPEDITED (15-DAY)	Y	OT	CA-AstraZeneca-2021A509529			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown				Not Reported
	Azithromycin		N	S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
06-May-2022	19888005	EXPEDITED (15-DAY)	Y	OT	CA-GLENMARK PHARMACEUTICALS-2021GMK068040			Unknown	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown	Unk			Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
30-May-2022	20891706	EXPEDITED (15-DAY)	Y	OT	CA-JNJFOC-20220550680			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
31-May-2022	20892479	EXPEDITED (15-DAY)	Y	OT	CA-JNJFOC-20220553090			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown				Not Reported
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Jun-2022	20171525	EXPEDITED (15-DAY)	Y	OT	CA-SANOFI US-2021SA411798			Female	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jun-2022	20257544	EXPEDITED (15-DAY)	Y	HO, OT	CA-GLAXOSMITHKLINE-CACH2021AMR091370			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
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	Azithromycin		N	S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jun-2022	20190428	EXPEDITED (15-DAY)	Y	OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-VDP-2021-014737			Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2022	20156875	EXPEDITED (15-DAY)	N	OT	CA-SANOFI US-2021SA406867			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S		Unk		Not Reported	
	Azithromycin		N	S	Unknown			Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2022	20156876	EXPEDITED (15-DAY)	N	OT	CA-SANOFI US-2021SA407496			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S		Unk		Not Reported	
	Azithromycin		N	S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Jun-2022	20157047	EXPEDITED (15-DAY)	N	OT	CA-SANOFI US-2021SA407532			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S		Unk		Not Reported	
	Azithromycin		N	S	Unknown			Not Reported	
	Ertapenem		N	S				Not Reported	
	Ertapenem		N	S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Jun-2022	20989193	EXPEDITED (15-DAY)	N	OT	CA-009507513-2206CAN005691			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown	Not Specified		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Jun-2022	20833155	EXPEDITED (15-DAY)	Y	HO, OT	CA-GLAXOSMITHKLINE-CACH2019AMR000333			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Sinusitis; Drug Ineffective; Dyspepsia; Infusion Related Reaction; Macular Degeneration; Malaise; Nausea; Off	Calcium Carbonate, Cholecalciferol		N	S	Unknown	Unk		Glaxosmithkline	
	Calcium Carbonate, Cholecalciferol		N	S		Unk		Glaxosmithkline	

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Label Use; Pain;	Habitrol	N	S		Unk	Glaxosmithkline
Paraesthesia Oral;	Nicotine	N	S		Unk (Transdermal Patch)	Glaxosmithkline
Procedural Pain; Pyrexia;	Nicoderm	N	S	Topical	Unk	Glaxosmithkline
Therapeutic Product Effect	Nicoderm	N	S	Unknown	Unk	Glaxosmithkline
Incomplete; Weight	Nicoderm	N	S	Unknown	Unk	Glaxosmithkline
Decreased	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	Y	S		Unk	Glaxosmithkline
	Zinc Oxide	Y	S		Unk	Glaxosmithkline
	Acetaminophen + Pseudoephedrine	N	S		Unk	Not Reported
	Salinex	N	S	Nasal	Unk	Not Reported
	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
	Magnesium Hydroxide	N	S		Unk	Not Reported
	Avamys	N	S		Unk, Spray Meter Dose	Not Reported
	Avamys	N	S		Unk	Not Reported
	Ergocalciferol	N	S		3000 Iu	Not Reported
	Ergocalciferol	N	S	Unknown	Unk	Not Reported

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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

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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)	N	S	Unknown	Unk		Not Reported

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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

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Chloride						
Glyceryl Trinitrate	N	S	Oral	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
Hydrochlorothiazide	N	S	Endocervical	100 Mg		Not Reported
Hydrochlorothiazide	N	S	Subcutaneous	Unk		Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk		Not Reported
Hydrochlorothiazide	N	S	Endocervical	Unk		Not Reported
Hydrochlorothiazide	N	S		Unk		Not Reported
Sodium Chloride	N	S	Nasal	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
Zinc Oxide	N	S	Oral	Unk		Not Reported
Calcium Carbonate + Calcium Gluconate + Vitamin D	N	S		Unk		Not Reported
Gramicidin/Neomycin Sulfate/Polymyxin B Sulfate	N	S		Unk		Not Reported
Macrogol 3350 + Potassium Chloride + Sodium Ascorbate + Sodium Chlorid	N	S				Not Reported
Macrogol 3350 + Potassium Chloride + Sodium Bicarbonate + Sodium Chlor	N	S		Unk		Not Reported
Vitamin D3	N	S		Unk		Not Reported
Magnesium Carbonate	N	S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Jun-2022	20995740	EXPEDITED (15-DAY)	N	OT	CA-ORGANON-Q2206CAN001920			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown	Not Specified			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Jun-2022	21000654	EXPEDITED (15-DAY)	N	OT	CA-009507513-2206CAN005397			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown	Unk; Dosage Form: Not Specified			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jun-2022	21017853	EXPEDITED (15-DAY)	N	OT	CA-ORGANON-O2206CAN002340			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown	Unk; Dosage Form: Not Specified			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jun-2022	20169179	EXPEDITED (15-DAY)	Y	OT	CA-SANOFI US-2021SA411340			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown	Unk			Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jul-2022	21033716	EXPEDITED (15-DAY)	Y	OT	CA-PURDUE-USA-2022-0294868			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown	Unk			Not Reported
	Calcium;Calcium Carbonate; Colecalciferol		N	C	Unknown	Unk			Not Reported

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FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2022	20126840	EXPEDITED (15-DAY)	Y	OT	CA-AstraZeneca-2021A821591			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown	Unknown		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Jul-2022	20198439	EXPEDITED (15-DAY)	N	OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-VDP-2021-014727			Unknown	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown			Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2022	21064881	EXPEDITED (15-DAY)	Y	OT	CA-PURDUE-USA-2022-0295088			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown	Unk		Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
11-Jul-2022	21064882	EXPEDITED (15-DAY)	Y	OT	CA-PURDUE-USA-2022-0294949			Female	CAN
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown	Unk		Not Reported	
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-CA2022AMR021799			Unknown	CAN

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Jul-2022	20495962	EXPEDITED (15-DAY)	N	OT	CA-GLAXOSMITHKLINE-CA2022AMR028721			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jul-2022	21043081	EXPEDITED (15-DAY)	Y	OT	CA-BAYER-2022A090356			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Jul-2022	16679201	EXPEDITED (15-DAY)	Y	HO, OT	CA-GLAXOSMITHKLINE-CA2019AMR133655			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
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	Calcium Carbonate, Cholecalciferol		N	S	Unknown	Unk		Glaxosmithkline	
	Calcium Carbonate, Cholecalciferol		N	S		Unk		Glaxosmithkline	
	Habitrol		N	S		Unk		Glaxosmithkline	
	Nicotine		N	S		Unk		Glaxosmithkline	
	Nicoderm		N	S	Topical	Unk		Glaxosmithkline	
	Nicotine Polacrilex		N	S		Unk		Glaxosmithkline	
	Pantoprazole		N	S	Unknown	Unk		Not Reported	
	Diphenhydramine		Y	S		Unk		Glaxosmithkline	

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Multivitamins	N	S		Unk	Glaxosmithkline
Zinc Oxide	Y	S		Unk	Glaxosmithkline
Acetaminophen + Pseudoephedrine	Y	S		Unk	Glaxosmithkline
Salinex	Y	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

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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	N	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	N	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

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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

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Trimethoprim					
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/Triamcinolone	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	N	S			Not Reported
Benzylamine	N	S		Unk	Not Reported
Amoxicillin	N	C		Unk	Not Reported
Valsartan	N	C		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)	N	S		Unk	Not Reported
Niquitin 4 Mg Mint Lozenge	N	S		Unk	Not Reported
Trimethoprim	N	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

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Salinex (Macrogol + Propylene Glycol + Sodium Chloride)	N	S		Unk	Not Reported
Alka-Seltzer (Acetylsalicylic Acid + Citric Acid + Sodium Bicarbonate)	N	S		Unk	Not Reported
Vitamin E	N	S		Unk	Not Reported
Calcium Carbonate + Cholecalciferol	N	S		Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Glaxosmithkline
Mupirocin	N	S	Topical	Unk	Glaxosmithkline
Mupirocin Calcium	N	S		Unk	Not Reported
Gramicidin/Neomycin Sulfate/Polymyxin B Sulfate	N	S		Unk	Not Reported
Potassium Chloride	N	S		Unk	Glaxosmithkline
Magnesium Sulfate Injection	N	S		Unk	Not Reported
Moviprep (Ascorbic Acid + Kcl + Macrogol 3350 + Nacl + Sodium Ascorbat	N	S			Not Reported
Magnesium Clofibrate	N	S		Unk	Not Reported
Ubidecarenone	N	S		Unk	Not Reported
Promethazine Hydrochloride		S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2022	21143884	EXPEDITED (15-DAY)	N	OT	CA-PURDUE-USA-2022-0295563			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Jul-2022	21143885	EXPEDITED (15-DAY)	Y	OT	CA-PURDUE-USA-2022-0295557			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S		Unk		Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Aug-2022	21160831	EXPEDITED (15-DAY)	Y	OT	CA-PURDUE-USA-2022-0295672			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Aug-2022	19431517	EXPEDITED (15-DAY)	Y	OT	CA-TAKEDA-2021TUS037838			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Aug-2022	21239521	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2222542US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Accidental Exposure To Product; Product Use Complaint; Skin Cancer	Pravastatinum Natricum		N	C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2022	16599628	EXPEDITED (15-DAY)	Y	OT	CA-AUROBINDO-AUR-APL-2019-040214			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Drug Interaction; Drug Level Increased;	Amoxicillin		N	S	Unknown	Unk		Aurobindo	
Electrocardiogram Qt Prolonged; Macular Degeneration;	Amlodipine Tablets		N	S	Unknown	1 Dosage Form, Once A Day		Aurobindo	
Schizoaffective Disorder	Aripiprazole		N	S	Unknown	Unk		Aurobindo	
	Atorvastatin		N	S	Unknown	Unk		Not Reported	
	Atorvastatin Tablets		N	S	Unknown	Unk		Not Reported	

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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	Unknown	Unk		Not Reported
Aluminium	N	S	Unknown	30.0 Milliliter		Not Reported
Hydroxide/Magnesium						
Hydroxide/Simethicone						
Ambroxol Hydrochloride;	N	S	Unknown	Unk		Not Reported
Cetirizine Hydrochloride						
Atropine Sulfate\Diphenoxylate	N	S	Oral	Unk		Not Reported
Hydrochloride						
Atropine Sulfate	N	S	Oral	Unk		Not Reported
Apo-Ranitidine	N	S	Unknown	1 Dosage Form, Two Times A Day		Not Reported
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	Oral	Unk		Not Reported
Calcium Carbonate	N	S	Unknown	Unk		Not Reported
Calcium Carbonate;Vitamin D	N	S	Unknown	Unk		Not Reported
Nos						
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; Ergocalciferol	N	S	Unknown	Unk	Not Reported
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

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

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	C	Unknown	Unk	Not Reported
Valsartan	N	C	Unknown	Unk	Not Reported
Brexpiprazole	N	S	Unknown		Not Reported
Neomycin Sulfate		S			Not Reported
Sulfamethoxazole\Trimethoprim		S			Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2022	21242211	NON-EXPEDITED	Y		ALC2021US005793			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Product Administration Error	Omega-3-Acid Ethyl Ester		N	S	Oral	Take 2 Capsule (2 G Total) By Mouth Every Morning And Evening		Not Reported	
	Oxybutynin		N	S	Oral	Take 0.5-1 Tablet(2.5-5 Mg Total) By Mouth 3 Times A Day		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Aug-2022	21244536	EXPEDITED (15-DAY)	N	OT	CA-BAXTER-2022BAX017703			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown	Dosage Form Was Not Specified		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Aug-2022	21246694	EXPEDITED (15-DAY)	Y	OT	CA-BAXTER-2022BAX017701			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Azithromycin		N	S	Unknown	Dosage Form: Not Specified		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Aug-2022	21260656	EXPEDITED (15-DAY)	Y	OT	CA-BAXTER-2022BAX017704			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Metronidazole		N	S	Unknown	Unk		Baxter	
	Sodium Chloride		N	S	Endosinusal	Unk		Baxter	

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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 XL	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

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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 Magnesium Sulfate	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
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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Refresh Tears	N	S	Ophthalmic	Specified Dosage Form: Drops Ophthalmic	Not Reported
Salinex	N	S	Endosinusial	Dosage Form: Solution Nasal	Not Reported
Sinus Rinse	N	S	Endosinusial	Dosage Form: Solution Nasal	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
Statex	N	S	Unknown	Dosage Form Not Specified	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	Dosage Form Not Specified	Not Reported
Triamcinolone	N	S	Intra-articular	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Dosage Form: Suspension Intra-Articular	Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported
Valsartan	N	S	Unknown	Dosage Form Not Specified	Not Reported
Valsartan	N	S	Intracardiac	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
Zinc Oxide	N	S	Unknown	Dosage Form Not Specified	Not Reported
Calcium	N	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Aug-2022	21264552	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN- 2227275US			Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Macular Degeneration; Visual Impairment	Refresh Classic		N	S	Ophthalmic			Allergan	
	Refresh Optive		N	S	Ophthalmic			Allergan	
	Restasis		N	S	Ophthalmic			Allergan	
	Cellufresh		N	S	Ophthalmic			Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2022	21274558	EXPEDITED (15-DAY)	Y	OT	CA-AstraZeneca- 2022A297877			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Pulmicort		N	S	Unknown			Astrazeneca	
	Budesonide		N	S	Unknown			Not Reported	
	Entocort		N	S	Unknown			Not Reported	
	Acetaminophene		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	
	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			Not Reported	
	Azithromycin		N	S	Oral			Not Reported	
	Azithromycin Dihydrate		N	S	Unknown			Not Reported	
	Azithromycin Dihydrate		N	S	Oral			Not Reported	
	Bactrim		N	S	Unknown			Not Reported	
	Betamethasone		N	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

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Kenalog	N	S	Intra-articular	Not Reported
Lomotil	N	S	Oral	Not Reported
Loperamide	N	S	Oral	Not Reported
Hydrochloride/Simeticone				
Polyethylene Glycol	N	S	Unknown	Not Reported
3350\Potassium				
Chloride\Sodium				
Bicarbonate\Sodium Chloride				
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	Endosinusal	Not Reported
Sinus Rinse	N	S	Endosinusal	Not Reported
Sodium Carboxymethyl	N	S	Ophthalmic	Not Reported
Cellulose				
Sodium Carboxymethyl	N	S	Unknown	Not Reported
Cellulose				

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Sodium Chloride	N	S	Endosinusial	Not Reported
Sodium Stearate	N	S	Oral	Not Reported
Statex	N	S	Unknown	Not Reported
Sulfamethoxazole/Trimethoprim	N	S	Unknown	Not Reported
Triamcinolone	N	S	Intra-articular	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Not Reported
Trimethoprim	N	S	Unknown	Not Reported
Valsartan	N	S	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	N	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Aug-2022	21280026	DIRECT		RI			75 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Infection Bacterial	Theratears Extra Dry Eye Therapy		Y	S	Ophthalmic	Frequency : As Needed;		Akorn
	Cpap	N		C				Not Reported
	Micardis	N		C				Not Reported
	Mitazapine	N		C				Not Reported
	Morphine Sulfate Er	N		C				Not Reported
	Flomax	N		C				Not Reported
	Various Nutritional Supplements	N		C				Not Reported
	Turmeric	N		C				Not Reported
	B12	N		C				Not Reported
	B1	N		C				Not Reported
	B6	N		C				Not Reported
	C	N		C				Not Reported
	D3	N		C				Not Reported

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

K	N	C	Not Reported
Ashwaganda	N	C	Not Reported
Boswellia	N	C	Not Reported
Zinc	N	C	Not Reported
Copper	N	C	Not Reported
Rutin	N	C	Not Reported
Melatonin	N	C	Not Reported
Alpha Lipoid Acid	N	C	Not Reported
Astaxanthin	N	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Sep-2022	20290023	EXPEDITED (15-DAY)	Y	HO, OT	CA-GLAXOSMITHKLINE-CA2021AMR262195		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; 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	Amoxicillin Trihydrate	N		S	Unknown	Unk		Not Reported
	Betamethasone	N		S	Unknown	Unk		Not Reported
	Betamethasone Valerate	N		S	Unknown	Unk		Not Reported
	Metronidazole	N		S	Unknown	Unk		Not Reported
	Fluticasone Furoate	N		S	Unknown	Unk, Spray Metered Dose		Glaxosmithkline
	Sulfamethoxazole + Trimethoprim	N		S	Unknown	200 Mg		Not Reported
	Sulfamethoxazole + Trimethoprim	N		S	Unknown	Unk		Not Reported
	Avamys	N		S	Unknown	Unk		Glaxosmithkline
	Clotrimazole	Y		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	N		S	Transplacental	Unk		Not Reported

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

Bisacodyl	N	S	Unknown	Unk	Not Reported
Cetirizin	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

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

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	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	N	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

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

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

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

Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Sinus Rinse	N	S	Unknown	Unk	Not Reported
Triamcinolone	N	S	Unknown	Unk	Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk	Not Reported
Acetaminophen + Codeine Phosphate	N	S		Unk	Not Reported
Nicotinamide	N	S	Unknown	Unk	Not Reported
Metoclopramide Hydrochloride	N	C	Oral	Unk	Not Reported
Loperamide	N	C	Oral	4 Df, Qd	Not Reported
Calcium	N	C	Unknown	Unk	Not Reported
Calcium Carbonate + Vitamin D	N	C	Unknown	Unk	Not Reported
Calcium & Ergocalciferol	N	C		Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Sep-2022	21309575	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2228854US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abnormal Sensation In Eye; Blindness Transient; Eye Swelling; Ocular Hyperaemia	Refresh Optive		Y	S	Ophthalmic	2 Gtt, Qd		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Sep-2022	21327107	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2229615US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataract; Therapeutic Product Effect Incomplete	Refresh Optive		Y	S		Unk		Allergan	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Sep-2022	21338414	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2229532US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataract; Eye Irritation	Refresh Optive Gel Drops		Y	S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Sep-2022	20169617	EXPEDITED (15-DAY)	Y	OT	CA-SANOFI US-2021SA411702			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Triamcinolone Acetonide		N	S	Intra-articular	Unk		Sanofi	
	Paracetamol		N	S		Unk		Not Reported	
	Alprazolam		N	S	Unknown	Unk		Not Reported	
	Sulfamethoxazole/Trimethoprim		N	S				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		Sanofi	
	Budesonide		N	S	Respiratory (inhalation)	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	
	Desonide		N	S	Unknown	Unk		Not Reported	
	Hydrochlorothiazide		N	S	Unknown	Unk		Not Reported	
	Carmellose Sodium		N	S				Not Reported	
	Mesalazine		N	S	Unknown	Unk		Sanofi	

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

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	Sanofi
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	Sanofi
Ergocalciferol	N	S	Unknown	Unk	Sanofi
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Azithromycin Dihydrate	N	S	Unknown	Unk	Not Reported
Benzydamine	N	S	Unknown	Unk	Not Reported
Adalimumab	N	S	Subcutaneous	Unk	Not Reported
Macrogol;Potassium Chloride; Sodium Bicarbonate;Sodium Chloride	N	S	Unknown	Unk	Not Reported
Fluticasone Propionate	N	S	Unknown	Unk	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Vitamins Nos	N	S	Unknown	Unk	Not Reported
Acetaminophen	N	S	Unknown	Unk	Not Reported
Benzydamine	N	S			Not Reported
Refresh Tears	N	S	Ophthalmic	Ophthalmic Drops	Not Reported
Metronidazole	N	C	Unknown	Unk	Not Reported
Valsartan	N	C	Unknown	Unk	Not Reported
Sulfamethoxazole\Trimethoprim		S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Sep-2022	20208262	EXPEDITED (15-DAY)	Y	OT	US-VALIDUS PHARMACEUTICALS LLC-CA-VDP-2021- 014728			Unknown	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Ergocalciferol	N		S	Unknown	Unk		Validus
	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		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

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Fluticasone Furoate	N	S	Other	Unk, Nasal Spray	Not Reported
Azithromycin Dihydrate	N	S	Unknown	Unk	Not Reported
Benzydamine	N	S	Unknown	Unk	Not Reported
Adalimumab	N	S	Subcutaneous	Unk	Not Reported
Macrogol;Potassium Chloride; Sodium Bicarbonate;Sodium Chloride	N	S	Unknown	Unk	Not Reported
Fluticasone Propionate	N	S	Unknown	Unk	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Vitamins Nos	N	S	Unknown	Unk	Not Reported
Acetaminophen	N	S	Unknown	Unk	Not Reported
Benzydamine	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole And Trimethoprim	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk, Ophthalmic Drops	Not Reported
Metronidazole	N	C	Unknown	Unk	Not Reported
Valsartan	N	C	Unknown	Unk	Not Reported
Sulfamethoxazole\Trimethoprim		S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2022	21372107	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN- 2230307US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataract	Refresh Tears		Y	S	Ophthalmic			Not Reported	
	Refresh Optive		N	S	Ophthalmic	Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2022	21372111	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN- 2229990US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Neovascular Age-Related Macular Degeneration	Refresh Tears		Y	S	Ophthalmic	Unk		Allergan	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Sep-2022	21372129	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2230426US			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cataract; Product Container Issue	Refresh Plus		Y	S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
26-Sep-2022	20488075	EXPEDITED (15-DAY)	Y	HO, OT	CA-APOTEX-2022AP003249		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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	Amoxicillin Trihydrate		N	S	Unknown	Unk		Not Reported
	Atorvastatin		N	S	Unknown	Unk		Apotex
	Acetaminophen		N	S	Unknown	Unk		Apotex
	Bisacodyl		N	S	Unknown	Unk		Not Reported
	Cetirizine		N	S	Unknown	Unk		Apotex
	Calcium Carbonate		N	S	Unknown	Unk		Not Reported
	Clarithromycin		N	S	Unknown	Unk		Apotex
	Diphenhydramine		N	S	Unknown	Unk		Apotex
	Diphenhydramine		N	S	Oral	50 Milligram		Apotex
	Metronidazole		N	S	Unknown	Unk		Not Reported
	Nicotine		N	DS	Unknown	Unk		Apotex
	Nadolol		N	S	Unknown	40 Milligram		Not Reported
	Prednisone		N	S	Unknown	Unk		Not Reported
	Pantoprazole		N	S	Unknown	Unk		Apotex
	Pregabalin		N	S	Unknown	150 Milligram		Apotex
	Fluticasone		N	DS	Unknown	Unk		Apotex
	Alprazolam		N	S	Unknown	0.25 Milligram		Apotex
	Azithromycin		N	S	Unknown	Unk		Apotex

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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 Hydrochloride]	N	S	Oral	50 Milligram	Not Reported
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

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

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

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

Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Acetaminophen; Dextropropoxyphene	N	S	Unknown	Unk	Not Reported
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

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

Hydrochloride]						
Lomotil [Loperamide	N	C	Unknown	Unk		Not Reported
Hydrochloride]						
Loperamide	N	C	Oral	4 Milligram, Qd		Not Reported
Loperamide	N	C	Oral	4 Dosage Form, Qd		Not Reported
Benadryl [Diphenhydramine	N	C	Unknown	Unk		Not Reported
Hydrochloride]						
Metoclopramide Hydrochloride	N	C	Oral	Unk		Not Reported
Valsartan	N	C	Oral	4 Dosage Form, Qd		Not Reported
Valsartan	N	C	Oral	40 Milligram, Qd		Not Reported
Calcium;Ergocalciferol	N	C	Unknown	Unk		Not Reported
Calcium Gluconate	N	C	Unknown	Unk		Not Reported
Diphenoxylate Hydrochloride	N	C	Unknown	Unk		Not Reported
Neomycin Sulfate	N	C	Unknown	Unk		Not Reported
Calcium Carbonate/Vitamin D3	N	C	Unknown	Unk		Not Reported
Sodium Stearate	N	C	Unknown	Unk		Not Reported
Calcium;Colecalciferol	N	C	Unknown	Unk		Not Reported
Lomotil [Atropine Sulfate;	N	C	Unknown	Unk		Not Reported
Diphenoxylate Hydrochloride]						
Calcium Lactate;Calcium	N	C	Unknown	Unk		Not Reported
Phosphate;Ergocalciferol						
Benadryl Allergy	N	C	Unknown	Unk		Not Reported
[Diphenhydramine						
Hydrochloride]						

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Sep-2022	21379728	EXPEDITED (15-DAY)	Y	HO, OT	CA-AstraZeneca-2022A323944		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chronic Sinusitis; Drug	Budesonide	N	S	Unknown				Not Reported
Ineffective; Dyspepsia;	Acetaminophen	N	S	Unknown				Not Reported
Infusion Related Reaction;	Adalimumab	N	S	Subcutaneous				Not Reported
Macular Degeneration;	Alprazolam	N	S	Unknown		0.25mg Unknown		Not Reported
Malaise; Nausea; Off								
Label Use; Pain;								

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

Paraesthesia Oral; Procedural Pain; Pyrexia; Therapeutic Product Effect Incomplete; Weight Decreased	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	N	S	Oral	1.0df Unknown	Not Reported
	Hydrochloride/Atropine Sulfate					
	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

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

Magnesium Sulfate	N	S	Unknown		Not Reported
Mesalazine	N	S	Unknown		Not Reported
Metronidazole	N	S			Not Reported
Morphine Sulfate	N	S			Not Reported
Mupirocin	N	S	Topical		Not Reported
Nadolol	N	S	Unknown	40.0mg Unknown	Not Reported
Nicoderm	N	S	Unknown		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		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		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	C	Unknown		Not Reported
Lomotil	N	C	Unknown		Not Reported
Benadryl Allergy	N	C	Unknown		Not Reported
Calcium Gluconate	N	C	Unknown		Not Reported
Calcium Lactate/Ergocalciferol/Calcium Phosphate	N	C	Unknown		Not Reported
Metoclopramide Hydrochloride	N	C	Unknown		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Oct-2022	21404601	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2231339US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Expired Product Administered; Eye Pain; Macular Degeneration	Refresh Optive Sensitive		Y	S	Ophthalmic	Unk		Allergan	
	Hydroxychloroquine		N	S				Not Reported	
	Preservision		N	C		Unk		Not Reported	
	Multivitamins		N	C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Oct-2022	21407923	EXPEDITED (15-DAY)	Y	OT	ALC2022CA004488			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Atropine Sulfate		N	S	Unknown			Alcon	
	Adalimumab		N	S	Subcutaneous	Unk		Not Reported	
	Amoxicillin Trihydrate		N	S	Unknown	Unk		Not Reported	
	Atorvastatin Calcium		N	S	Unknown	Unk		Not Reported	
	Clarithromycin		N	S	Unknown	Unk		Not Reported	
	Diphenhydramine Hydrochloride		N	S	Unknown	Unk		Not Reported	
	Hydromorphone Hydrochloride		N	S	Unknown			Not Reported	
	Magnesium Sulfate		N	S	Unknown			Not Reported	
	Morphine Sulfate		N	S	Unknown			Not Reported	
	Pantoprazole Sodium		N	S	Unknown			Not Reported	
	Pregabalin		N	S	Unknown			Not Reported	
	Triamcinolone Acetonide		N	S	Intra-articular	Unk		Not Reported	
	Acetaminophen		N	S	Unknown			Not Reported	
	Acetylsalicylic Acid		N	S	Unknown			Not Reported	
	Alprazolam		N	S		Unk		Not Reported	
	Alprazolam		N	S	Unknown	Unk		Not Reported	

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

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

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

	Polymyxin B Sulfate	N	S	Unknown		Not Reported
	Prednisone	N	S	Unknown		Not Reported
	Sodium Carboxymethylcellulose	N	S	Ophthalmic		Not Reported
	Sodium Chloride	N	S	Unknown		Not Reported
	Sulfamethoxazole	N	S	Unknown		Not Reported
	Vitamin D Nos	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
	Hyrimoz [Adalimumab]	N	C	Unknown		Not Reported
	Valsartan	N	C	Unknown		Not Reported
	Vitamin A [Retinol]	N	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Oct-2022	21416087	DIRECT						Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Theratears	N	S					Not Reported
	Theratears	N	C					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Oct-2022	21374054	EXPEDITED (15-DAY)	Y	OT	NVSC2022CA214430			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Adalimumab	N	S	Subcutaneous	Unk			Novartis
	Amoxicillin	N	S	Unknown	Unk			Novartis
	Amoxicillin Trihydrate	N	S	Unknown	Unk			Novartis
	Atorvastatin Calcium	N	S	Unknown	Unk			Novartis
	Atropine Sulfate	N	S	Unknown	Unk			Not Reported
	Clarithromycin	N	S	Unknown	Unk			Novartis

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

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

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

Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
Ichthammol And Zinc Oxide	N	S	Unknown	Unk	Not Reported
Macrogol	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Metronidazole	N	S	Unknown	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
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Prednisone	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole	N	S	Unknown	Unk	Not Reported
Vitamin D	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
Valsartan	N	C	Unknown	Unk	Not Reported
Vitamin A	N	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Oct-2022	21414166	EXPEDITED (15-DAY)	N	HO, OT	CA-JNJFOC-20220962772		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chronic Sinusitis; Drug Ineffective; Dyspepsia; Infusion Related Reaction; Macular Degeneration; Malaise; Nausea; Off	Remicade	N	S		Intravenous drip			Not Reported
	Cetirizine Hydrochloride	N	S		Unknown			Not Reported
	Acetaminophen	N	S		Unknown			Not Reported

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

Label Use; Pain;	Adalimumab	N	S	Subcutaneous	Not Reported
Paraesthesia Oral;	Alprazolam	N	S	Unknown	Not Reported
Procedural Pain; Pyrexia;	Amoxicillin	N	S	Unknown	Not Reported
Therapeutic Product Effect	Atorvastatin Calcium	N	S	Unknown	Not Reported
Incomplete; Weight	Atropine	N	S	Oral	Not Reported
Decreased	Azithromycin	N	S	Unknown	Not Reported
	Betamethasone	N	S	Unknown	Not Reported
	Betamethasone Dipropionate	N	S	Unknown	Not Reported
	Betamethasone Valerate	N	S	Unknown	Not Reported
	Bisacodyl	N	S	Unknown	Not Reported
	Budesonide	N	S	Unknown	Not Reported
	Calcium & Vitamin D3	N	S		Not Reported
	Calcium Carbonate	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	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

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

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	N	S		Not Reported
Potassium Chloride	N	S	Unknown	Not Reported
Prednisone	N	S	Unknown	Not Reported
Pregabalin	N	S	Unknown	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Not Reported
Sodium Chloride	N	S		Not Reported
Sodium Chloride	N	S	Unknown	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	C	Unknown	Not Reported
Calcium Lactate	N	C	Unknown	Not Reported
Lomotil [Atropine Sulfate; Diphenoxylate Hydrochloride]	N	C	Unknown	Not Reported
Lomotil [Loperamide Hydrochloride]	N	C	Unknown	Not Reported
Metoclopramide Hydrochloride	N	C	Unknown	Not Reported
Valsartan	N	C	Unknown	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Oct-2022	16835715	EXPEDITED (15-DAY)	Y	OT	CA- GLAXOSMITHKLINE- CA2019168899			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Paracetamol		Y	S	Unknown	Unk		Glaxosmithkline
	Paracetamol		Y	S	Unknown	Unk		Glaxosmithkline
	Nicoderm		N	S	Transdermal	Unk, Patch		Not Reported
	Nicoderm		N	S	Unknown	Unk		Not Reported
	Nicoderm		N	S		Unk		Not Reported
	Cetirizine Hydrochloride		N	S	Unknown	Unk		Not Reported
	Cetirizine Hydrochloride		N	S	Unknown	Unk		Not Reported
	Fluticasone Furoate		N	S	Unknown	Unk		Not Reported
	Fluticasone Furoate		N	S	Ophthalmic	Unk		Not Reported
	Diphenhydramine Hydrochloride		N	S	Unknown	Unk		Not Reported
	Mupirocin		N	S	Topical	Unk		Not Reported
	Mupirocin		N	S	Topical	Unk		Not Reported
	Paracetamol + Pseudoephedrine Hydrochloride		N	S	Unknown	Unk		Not Reported
	Imodium		N	S	Oral	Unk		Not Reported
	Zinc Oxide		N	S	Unknown	Unk		Not Reported
	Alprazolam		N	S	Unknown	Unk		Not Reported
	Alprazolam		N	S	Unknown	Unk		Not Reported
	Alprazolam		N	S	Respiratory (inhalation)	Unk		Not Reported
	Alprazolam		N	S	Unknown	Unk		Not Reported
	Apo Hydro		N	S	Unknown	Unk		Not Reported
	Amoxicillin Trihydrate		N	S	Unknown	Unk		Not Reported
	Atorvastatin Calcium		N	S	Unknown	Unk		Not Reported
	Atorvastatin Calcium		N	S	Unknown	Unk		Not Reported

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

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

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

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 + 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

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

Trimethoprim And Sulfamethoxazole	N	S	Unknown	Unk	Not Reported
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

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

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	C	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 Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2022	20695565	EXPEDITED (15-DAY)	N	OT	ALC2022CA001693			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Atropine Sulfate		N	S	Unknown	Unk		Alcon
	Atropine Sulfate		N	S	Oral			Not Reported
	Acetaminophen		N	S	Unknown	Unk		Not Reported
	Acetaminophen		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
	Azithromycin		N	S	Oral	Unk		Not Reported
	Azithromycin		N	S	Oral	Unk		Not Reported
	Azithromycin		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
	Bisacodyl		N	S	Unknown	Unk		Not Reported
	Budesonide		N	S	Respiratory (inhalation)	Unk		Not Reported
	Budesonide		N	S	Respiratory (inhalation)	Unk		Not Reported
	Clarithromycin		N	S	Unknown	Unk		Not Reported
	Clarithromycin		N	S	Unknown	Unk		Not Reported
Clarithromycin		N	S	Unknown			Not Reported	
Clotrimazole		N	S	Unknown	Unk		Not Reported	

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

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

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

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	Endosinusal	Unk	Not Reported
Sodium Chloride	N	S	Endosinusal	Unk	Not Reported
Sulfamethoxazole And Trimethoprim	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole And	N	S	Unknown	Unk	Not Reported

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

Trimethoprim						
Triamcinolone Acetonide	N	S	Intra-articular	Unk		Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk		Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk		Not Reported
Vitamin D [Vitamin D Nos]	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			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	C	Unknown			Not Reported
Valsartan	N	C	Vaginal	Unk		Not Reported
Acetaminophen; Dextropropoxyphene	N	S	Unknown	Unk		Not Reported
Amoxicillin	N	S	Unknown	Unk		Not Reported
Amoxicillin	N	S	Unknown	Unk		Not Reported
Calcium Carbonate/Vitamin D3	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

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

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	N	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	N	S	Unknown	Unk	Not Reported
Glycerol	N	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

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

Neomycin Sulfate	N	S	Unknown	Unk	Not Reported
Macrogol	N	S	Unknown	Unk	Not Reported
Bactrim	N	S	Unknown	Unk	Not Reported
Entocort	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Oct-2022	21480497	EXPEDITED (15-DAY)	Y	OT	CA-AstraZeneca-2022A345167			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Pulmicort	N	S	Unknown				Not Reported
	Budesonide	N	S	Unknown				Not Reported
	Entocort	N	S	Unknown				Not Reported
	Acetaminophen	N	S	Unknown				Not Reported
	Adalimumab	N	S	Subcutaneous				Not Reported
	Alprazolam	N	S	Unknown				Not Reported
	Ambroxol Hydrochloride	N	S	Unknown				Not Reported
	Apohydrochlorothiazide	N	S	Unknown				Not Reported
	Atorvastatin Calcium	N	S	Unknown				Not Reported
	Atorvastatin Calcium	N	S	Unknown				Not Reported
	Atropine Sulfate	N	S	Unknown				Not Reported
	Azithromycin	N	S	Oral		Dose Unkwnon		Not Reported
	Bactrim	N	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	N	S	Unknown				Not Reported

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

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 Cellulose	N	S	Unknown	Not Reported
Sodium Chloride	N	S	Unknown	Not Reported

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

Sodium Stearate	N	S	Oral	Not Reported
Sulfamethoxazole/Trimethoprim	N	S	Unknown	Not Reported
Triamcinolone	N	S	Intra-articular	Not Reported
Trimethoprim	N	S	Unknown	Not Reported
Valsartan	N	S	Intracardiac	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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Oct-2022	21481021	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2234087US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cataract; Eye Irritation; Hypersensitivity; Medical Device Implantation; Thinking Abnormal	Refresh Optive Advanced Preservative-Free		Y	S	Ophthalmic	Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Oct-2022	21493223	NON-EXPEDITED	N		US-ALLERGAN-2205203US			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Pruritus	Combigan[R]		N	S		Unk, Bid		Allergan
	Refresh Tears		N	S		Unk		Allergan
	Latanoprost		N	S		0.005% Eye Drops, Once A Day At Bedtime		Not Reported
	Dorzolamide Hcl		N	S		Unk		Not Reported
	Vyndamax		N	C		61 Mg, Qd		Not Reported
	Benazepril		N	C		40 Mg, Qd		Not Reported

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Levothyroxine	N	C	100 Mg, Qd	Not Reported
Simvastatin	N	C	40 Mg, Qd	Not Reported
Baby Aspirin	N	C	81 Mg, Qd	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Oct-2022	20741566	EXPEDITED (15-DAY)	N	HO, OT	CA-009507513-2204CAN007107		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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	Invanz	N		S				Merck
	Remicade	N		S	Intravenous (not otherwise specified)			Not Reported
	Acetaminophen	N		S	Unknown			Not Reported
	Acetylsalicylic Acid	N		S	Unknown	Not Specified		Not Reported
	Adalimumab	N		S	Subcutaneous			Not Reported
	Alprazolam	N		S	Unknown	0.25 Milligram		Not Reported
	Amoxicillin	N		S	Unknown			Not Reported
	Atorvastatin Calcium	N		S	Unknown			Not Reported
	Atropine;Diphenoxylate	N		S	Oral			Not Reported
	Avamys	N		S	Unknown			Not Reported
	Azithromycin	N		S	Unknown			Not Reported
	Benadryl [Diphenhydramine Hydrochloride]	N		S				Not Reported
	Betamethasone	N		S	Unknown			Not Reported
	Betamethasone Valerate	N		S	Unknown	0.122 Gram		Not Reported
	Biaxin XI	N		S				Not Reported
	Bisacodyl	N		S	Unknown			Not Reported
	Budesonide	N		S	Unknown			Not Reported
	Calcium;Colecalciferol	N		S	Unknown			Not Reported
	Calcium Carbonate	N		S	Unknown			Not Reported
	Calcium Citrate	N		S	Unknown	Not Specified		Not Reported
	Cetirizine Hydrochloride	N		S	Unknown			Not 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	N	S			Not Reported
Fluticasone Furoate	N	S	Unknown		Not Reported
Fluticasone Propionate	N	S			Not Reported
Glycerine	N	S	Unknown		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	N	S			Not Reported
Hydrochlorothiazide	N	S	Endocervical		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	N	S				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	150 Milligram		Not Reported
Pulmicort	N	S				Not Reported
Sodium Bicarbonate	N	S	Unknown	Not Specified		Not Reported
Carboxy Methyl Cellulose Sodium	N	S	Unknown			Not Reported
Sodium Chloride	N	S	Nasal			Not Reported
Sulfamethoxazole And Trimethoprim	N	S	Unknown	200 Milligram		Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Dosage Form: Suspension Intraarticular		Not Reported
Valsartan	N	S				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;Ergocalciferol	N	C				Not Reported
Loperamide	N	C	Unknown			Not Reported
Metoclopramide Hydrochloride	N	C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Oct-2022	21499441	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2233583US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cataract; Eye Irritation; Eye Pain; Product Delivery Mechanism Issue; Product Quality Issue; Product Use Complaint; Strabismus	Refresh Relieva Pf	Y	S		Ophthalmic	One Drop Per Eye , 3 To 6 Times A Day		Not Reported
	Refresh Relieva Pf	Y	S		Ophthalmic	One Drop Per Eye , 3 To 6 Times A Day		Not Reported
	Prednisone	N	C		Ophthalmic	Unk		Not Reported
	Vitamin D3	N	C					Not Reported
	Colace	N	C					Not Reported

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	Psyllium Fibre		N	C					Not Reported
	Restasis Multidose		N	DS					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2022	21521873	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2235484US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataract; Erythema Of Eyelid; Eye Irritation; Eye Pain; Ocular Hyperaemia	Refresh Digital Pf		Y	S	Ophthalmic	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Nov-2022	21530938	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2235535US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataract Operation	Refresh Tears		Y	S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2022	19013615	EXPEDITED (15-DAY)	Y	OT	CA-AstraZeneca-2021A116631			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Entocort		N	S	Oral				Not Reported
	Pulmicort		N	S	Respiratory (inhalation)				Not Reported
	Acetaminophen		N	S	Unknown				Not Reported
	Alprazolam		N	S	Unknown				Not Reported
	Amoxicillin Trihydrate		N	S	Unknown				Not Reported
	Atorvastatin		N	S	Unknown				Not Reported
	Avamys		N	S	Unknown				Not Reported
	Azithromycin Dihydrate		N	S	Unknown				Not Reported
	Bactroban		N	S	Unknown				Not Reported
	Betaderm		N	S	Unknown				Not Reported

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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/Potassium Chloride	N	S	Unknown	Not Reported

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Prednisone	N	S	Unknown	Not Reported
Pregabalin	N	S	Unknown	Not Reported
Refresh Tears	N	S	Unknown	Not Reported
Sodium Chloride	N	S	Unknown	Not Reported
Sinus Rinse	N	S	Unknown	Not Reported
Statex	N	S	Unknown	Not Reported
Bactrim	N	S	Unknown	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Not Reported
Vitamin D3	N	S	Unknown	Not Reported
Humira	N	S	Subcutaneous	Not Reported
Cupric Oxide	N	S	Unknown	Not Reported
Neomycin/Gramicidin/Polymyxin B Sulfate	N	S	Unknown	Not Reported
Macrogol 3350/Sodium Chloride/Sodium Bicarbonate/Potassium Chloride	N	S		Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Not Reported
Diphenoxylate Hydrochloride And Atropine Sulphate	N	S		Not Reported
Xantofyl Palmitate	N	S	Unknown	Not Reported
Zeaxanthin	N	S		Not Reported
Zinc Oxide	N	S	Unknown	Not Reported
Magnesium Sulfate	N	S		Not Reported
Valsartan	N	C	Unknown	Not Reported
Calcium Carbonate With Vit D	N	C		Not Reported
Apo Hydro	N	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Nov-2022	21550779	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2235750US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataract	Refresh Relieva		Y	S				Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Nov-2022	21568012	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2236281US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Glaucoma; Macular Degeneration; Multiple Allergies; Reaction To Preservatives	Refresh Optive Sensitive		Y	S		Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Nov-2022	20178153	EXPEDITED (15-DAY)	N	HO, OT	CA-SANOFI US-2021SA412083		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
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	Triamcinolone Acetonide		N	S		Unk		Sanofi	
	Triamcinolone Acetonide		N	S	Intra-articular	Unk		Sanofi	
	Triamcinolone Acetonide		N	S		Unk		Sanofi	
	Triamcinolone Acetonide		N	S	Intra-articular	Unk		Sanofi	
	Triamcinolone Acetonide		N	S	Intra-articular	Unk		Sanofi	
	Amoxicillin (Salt Not Specified)		N	S		Unk		Not Reported	
	Amoxicillin Trihydrate		N	S		Unk		Not Reported	
	Amoxicillin Trihydrate		N	S				Not Reported	
	Amoxicillin Trihydrate		N	S				Not Reported	
	Budesonide		N	S	Oral	Unk		Not Reported	
	Budesonide		N	S		Unk		Not Reported	
	Budesonide		N	S	Oral	Not Specified		Not Reported	
	Budesonide		N	S	Oral	Unk		Not Reported	
	Bisacodyl		N	S		Unk		Sanofi	
	Bisacodyl		N	S				Sanofi	
	Bisacodyl		N	S		Not Specified		Sanofi	
	Bisacodyl		N	S				Sanofi	
	Cetirizine Hydrochloride		N	S		Unk		Not Reported	

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

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Clarithromycin	N	S			Not Reported
Clarithromycin	N	S		Not Specified	Not Reported
Clarithromycin	N	S			Not Reported
Clarithromycin	N	S			Not Reported
Sodium Chloride	N	S		Unk	Not Reported
Sodium Chloride	N	S	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

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Morphine Sulfate	N	S		Not Specified	Not Reported
Morphine Sulfate	N	S		Unk	Not Reported
Fluticasone Furoate	N	S		Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Mupirocin	N	S		Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Mupirocin	N	S		Unk	Not Reported
Nadolol	N	S		Unk	Not Reported
Nadolol	N	S			Not Reported
Nadolol	N	S			Not Reported
Nadolol	N	S			Not Reported
Nadolol	N	S			Not Reported
Nicotine	N	S		Unk	Sanofi
Nicotine	N	S		Unk	Sanofi
Nicotine	N	S		Not Specified	Sanofi
Nicotine	N	S		Unk	Sanofi
Nicotine	N	S		Unk	Sanofi
Pantoprazole	N	S		Unk	Not Reported
Pantoprazole	N	S		Unk	Not Reported
Pantoprazole	N	S		Not Specified	Not Reported
Pantoprazole	N	S			Not Reported
Prednisone	N	S		Unk	Not Reported
Prednisone	N	S		Unk	Not Reported
Prednisone	N	S		Not Specified	Not Reported
Prednisone	N	S		Unk	Not Reported
Prednisone	N	S		Unk	Not Reported
Pregabalin	N	S		Unk	Not Reported
Pregabalin	N	S		Unk	Not Reported
Pregabalin	N	S		Unk	Not Reported
Pregabalin	N	S		150 Mg	Not Reported

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Sodium Bicarbonate	N	S		Unk	Not Reported
Simvastatin	N	S		Unk	Not Reported
Simvastatin	N	S			Not Reported
Simvastatin	N	S			Not Reported
Simvastatin	N	S			Not Reported
Simvastatin	N	S			Not Reported
Potassium Chloride	N	S		Unk	Not Reported
Colecalciferol	N	S		Unk	Not Reported
Colecalciferol	N	S			Not Reported
Colecalciferol	N	S			Not Reported
Nicoderm	N	S		Unk	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	N	S			Sanofi
Zinc Oxide	N	S			Sanofi
Cupric Oxide	N	S		Unk	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

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

Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S		Unk	Not Reported
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	N	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
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

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

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Carbonate;Zinc]						
Refresh Tears	N	S	Ophthalmic	Unk		Not Reported
Refresh Tears	N	S	Ophthalmic			Not Reported
Refresh Tears	N	S	Ophthalmic			Not Reported
Acetaminophen	N	S		Not Specified		Not Reported
Acetaminophen	N	S				Not Reported
Avamys	N	S		Spray, Metered Dose		Not Reported
Avamys	N	S				Not Reported
Avamys	N	S				Not Reported
Vitamin D3	N	S		Unk		Not Reported
Vitamin D3	N	S				Not Reported
Xantofyl Palmitate	N	S		Unk		Not Reported
Xantofyl Palmitate	N	S		Unk		Not Reported
Xantofyl Palmitate	N	S		Unk		Not Reported
Zeaxanthin Forte	N	S		Not Specified		Not Reported
Zeaxanthin Forte	N	S		Unk		Not Reported
Valsartan	N	C		Unk		Not Reported
Valsartan	N	C		Unk		Not Reported
Benadryl Allergy	N	C		Unk		Not Reported
[Diphenhydramine						
Hydrochloride]						
Calcium Gluconate	N	C		Unk		Not Reported
Calcium Lactate;Calcium	N	C		Unk		Not Reported
Phosphate;Colecalciferol						
Lomotil [Loperamide	N	C		Unk		Not Reported
Hydrochloride]						
Metoclopramide Hydrochloride	N	C		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Nov-2022	21579963	EXPEDITED (15-DAY)	Y	OT	CA-BAUSCHBL-BL-2022-021079			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Neomycin And Polymyxin B Sulfates And Gramicidin		N	S	Unknown			Bausch And Lomb

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Ophthalmic Soln Sodium Chloride	N	S	Endosinusal		Not Reported
Budesonide	N	S	Unknown		Not Reported
Mesalazine	N	S	Unknown		Not Reported
Metronidazole	N	S	Unknown		Not Reported
Triamcinolone	N	S	Intra-articular		Not Reported
Triamcinolone Acetonide	N	S	Intra-articular		Not Reported
Acetaminophene	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
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

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

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

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

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	Endosinusal	Solution Nasal	Not Reported
Sinus Rinse	N	S	Endosinusal	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	C	Unknown		Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Nov-2022	17929893	EXPEDITED (15-DAY)	N	OT	CA-Accord-186201			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Atorvastatin		N	S	Unknown			Not Reported
	Pregabalin		N	S				Not Reported
	Hydrochlorothiazide		N	S				Not Reported
	Pantoprazole		N	S				Not Reported
	Simvastatin		N	S				Accord
	Acetaminophen		N	S	Unknown			Not Reported
	Alprazolam		N	S	Unknown			Not Reported
	Amoxicillin		N	S				Not Reported
	Apo Hydro		N	S	Unknown			Not Reported
	Avamys		N	S	Unknown	Spray, Metered Dose		Not Reported
	Betamethasone		N	S	Unknown	Also Received Betamethasone Dipropionate		Not Reported
	Biacin XI		N	S		Tablet (Extended-Release)		Not Reported
	Bisacodyl		N	S				Not Reported
	Calcium Carbonate W/Vitamin D		N	S				Not Reported
	Cetirizine		N	S				Not Reported
	Clarithromycin		N	S				Not Reported
	Clotrimazole		N	S				Not Reported
	Desonide		N	S				Not Reported
	Diphenhydramine		N	S				Not Reported
	Entocort		N	S		Capsule Sustainedrelease		Not Reported
	Ertapenem Sodium		N	S				Not Reported
	Flovent		N	S				Not Reported
	Glycerin		N	S	Oral	Liquid Oral		Not Reported
	Gramicidin		N	S				Not Reported
	W/Neomycin/Polymyxin B							
	Humira		N	S	Subcutaneous	Solution Subcutaneous	6 YR	Not Reported
	Kenalog		N	S	Intra-articular	Suspension Intra- Articular		Not Reported

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

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	N	S			Not Reported
Pentasa	N	S	Unknown		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	C	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

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

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

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

	Fructose W/Glycerin/Sodium Chloride	N	S	Oral				Not Reported
	Potassium Chloride	N	S					Not Reported
	Ambroxol,Cetirizine Hydrochloride	N	S					Not Reported
	Valsartan	N	S					Not Reported
	Glycerin\Ichthammol	N	S					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Nov-2022	21611343	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2237597US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataract; Conjunctivitis	Refresh Digital Pf		Y	S	Ophthalmic	Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Nov-2022	18328537	EXPEDITED (15-DAY)	Y	HO, OT	CA-AstraZeneca-2020SF24442			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
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	Budesonide		N	S	Other			Not Reported	
	Entocort		N	S	Oral			Not Reported	
	Pulmicort		N	S	Respiratory (inhalation)			Astrazeneca	
	Atorvastatin Calcium		N	S	Unknown			Not Reported	
	Alprazolam		N	S	Oral	0.25 Mg		Not Reported	
	Alprazolam		N	S	Oral			Not Reported	
	Calcium Carbonate		N	S	Unknown			Not Reported	
	Magnesium Sulfate		N	S	Unknown			Not Reported	
	Metronidazole		N	S	Unknown			Not Reported	
	Metronidazole		N	S	Unknown			Not Reported	
	Morphine Sulfate		N	S	Unknown			Not Reported	
	Pregabalin		N	S	Oral			Not Reported	
	Pregabalin		N	S	Oral	150 Mg		Not Reported	

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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 Hydrochloride/Atropine Sulfate	N	S	Oral		Not Reported
Avamys	N	S	Unknown	Metered Dose	Not Reported
Avamys	N	S	Unknown		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	Oral	Tablet (Extendedrelease)	Not Reported
Biaxin XI	N	S	Unknown	Tablet (Extendedrelease)	Not Reported
Biaxin XI	N	S	Unknown	Tablet (Extendedrelease)	Not Reported
Dulcolax	N	S	Unknown		Not Reported
Cetirizine Hydrochloride	N	S	Unknown		Not Reported
Clarithromycin	N	S	Oral		Not Reported
Clarithromycin	N	S	Oral		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
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

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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

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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 Days	Not Reported
Sodium Chloride	N	S	Nasal		Not Reported
Statex	N	S	Unknown		Not Reported
Ergocalciferol	N	S	Unknown	3000 Iu	Not Reported
Alka-Seltzer	N	S	Unknown		Not Reported
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 Carbonate	N	S	Unknown		Not Reported
Pentasa	N	S	Unknown		Not Reported
Sodium Chloride	N	S	Nasal		Not Reported
Mesalazine	N	S	Unknown		Not Reported

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Pms Azithromycin	N	S	Unknown		Not Reported
Hctz	N	S	Unknown		Not Reported
Acetylsalicylic Acid	N	S	Unknown		Not Reported
Azithromycin	N	S	Unknown		Not Reported
Glycerol	N	S	Oral		Not Reported
Moviprep	N	S	Unknown		Not Reported
Metoclopramide Hydrochloride	N	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	N	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	N	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

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

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 Chloride/Glycerol/Fructose	N	S	Unknown	Not Reported
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/Dextropropoxyphene	N	S	Unknown	Not Reported
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	N	S	Unknown	Not Reported
Zinc Chloride	N	S	Unknown	Not Reported
Sodium Stearate	N	S	Unknown	Not Reported
Sodium Carboxymethyl Cellulose	N	S	Unknown	Not Reported
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

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

Calcium Citrate/Magnesium Oxide/Calcium Carbonate/Colecalciferol/Calcium Phosphate	N	S	Unknown	Not Reported
Simvastatin	N	S	Unknown	Not Reported
Minerals/Vitamins	N	S	Unknown	Not Reported
Valsartan	N	C	Unknown	Not Reported
Atropine Sulfate		S		Not Reported
Sulfamethoxazole/Trimethoprim		S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Nov-2022	21635581	EXPEDITED (15-DAY)	N		US-ALLERGAN-2235429US			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Contamination Microbial; Product Delivery Mechanism Issue	Refresh Tears	Y	S			Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2022	16815325	EXPEDITED (15-DAY)	Y	OT	CA-JNJFOC-20190913993			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Nicoderm	N	S		Transdermal			Not Reported
	Nicoderm	N	S		Unknown			Not Reported
	Nicoderm	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
	Nicotine	N	S		Unknown			Not Reported
	Budesonide	N	S		Unknown			Not Reported
	Budesonide	N	S		Other			Not Reported
	Paracetamol	N	S		Unknown			Not Reported



Detailed Report

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	Transdermal		Not Reported
Kenalog [Triamcinolone Acetonide]	N	S	Unknown		Not Reported

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

Kenalog [Triamcinolone Acetonide]	N	S	Intra-articular		Not Reported
Kenalog [Triamcinolone Acetonide]	N	S	Intra-articular		Not Reported
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; Diphenoxylate Hydrochloride]	N	S	Oral		Not Reported
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

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

Biaxin XL	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

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

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

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

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]	N	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	N	S	Unknown	Not Reported
Aspirin\Caffeine	N	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

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

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

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

	Mezavant	N	S	Unknown		Not Reported
	Simvastatin	N	S	Unknown		Not Reported
	Simvastatin	N	S	Unknown		Not Reported
	Glycerol;Ichthammol	N	S	Unknown		Not Reported
	Calcium Carbonate/Vitamin D3	N	C	Unknown		Not Reported
	Valsartan	N	C	Unknown		Not Reported
	Vitamin A [Retinol]	N	C	Unknown		Not Reported
	Neomycin Sulfate		S			Not Reported
	Sulfamethoxazole\Trimethoprim		S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Nov-2022	21640103	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2238234US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dry Eye; Glaucoma;	Refresh Optive	Y	S					Allergan
Product Availability Issue;	Refresh Optive Advanced	Y	S					Allergan
Therapy Interrupted								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Nov-2022	16038950	EXPEDITED (15-DAY)	Y	OT	CA-ABBVIE-19K-028-2688707-00			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Macular Degeneration; Therapeutic Product Effect Decreased	Humira	N	S		Subcutaneous			Abbvie
	Humira	N	S		Subcutaneous			Abbvie
	Humira	N	S		Unknown	Solution Subcutaneous		Abbvie
	Lomotil	N	S		Oral	0.025 + 2.5 Mg/ 1 Tablet Times A Day Or As Needed Every 6 Hours		Not Reported
	Diphenhydramine	N	S		Unknown			Not Reported
	Clotrimaderm	N	S		Unknown			Not Reported
	Apo Sulfatrim	N	S		Unknown			Not Reported
	Invanz	N	S		Unknown			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	Endosinusal		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

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

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	N	S	Unknown		Not Reported
Atropine Sulfate Diphenoxylate Hydrochloride	N	S	Oral		Unknown
Diphenoxylate Hydrochloride	N	S	Oral		Unknown
Diphenoxylate Hydrochloride	N	S	Unknown		Unknown

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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

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

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
Cetirizine	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

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

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 Trimethoprim	N	S	Unknown		Unknown
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

FDA Adverse Event Reporting System

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Detailed Report

Sodium Chloride						
Atropine Sulphate	N	S	Oral			Not Reported
Atropine Sulphate	N	S	Unknown	Not Specified		Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Eye Drops		Unknown
Difenoxin Hydrochloride	N	S	Oral			Unknown
Citric Acid;Sodium Bicarbonate	N	S	Unknown			Unknown
Macrogol;Potassium Chloride; Sodium Bicarbonate	N	S	Unknown			Unknown
Calcium Carbonate And Vitamin D	N	S	Unknown			Unknown
Atropine Sulfate\Diphenoxylate Hydrochloride	N	S	Unknown			Unknown
Mupirocin Calcium	N	S	Topical	Dihydrate		Glenmark
Potassium;Sodium Bicarbonate; Sodium Sulfate	N	S	Unknown			Not Reported
Fluticasone Propionate	N	S	Unknown			Unknown
Polyethylene Glycol 4000	N	S	Unknown			Unknown
Pantoprazole Sodium	N	S	Unknown			Not Reported
Fructose;Glycerol;Sodium Chloride	N	S	Oral			Unknown
Ambroxol Hydrochloride	N	S	Unknown			Not Reported
Sodium Stearate	N	S	Oral			Unknown
Nicotinamide	N	S	Unknown			Not Reported
Inflectra	N	C	Intravenous (not otherwise specified)			Not Reported
Valsartan	N	C	Unknown			Not Reported
Adalimumab	N	S	Subcutaneous	Solution Subcutaneous		Unknown
Zinc Chloride	N	S	Unknown			Unknown
Sulfamethoxazole\Trimethoprim		S				Not Reported
Neomycin Sulfate		S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2022	17921729	EXPEDITED (15-DAY)	Y	OT	CA-APOTEX- 2020AP012302			Female	CAN

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Alprazolam		N	S	Unknown	Unk		Apotex
	Acetaminophen		Y	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		N	S				Apotex
	Clarithromycin		N	S	Unknown	Unk		Apotex
	Diphenhydramine		Y	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 6 Hours		Apotex
	Loperamide		N	S	Oral	1 Dosage Form, Cyclical		Apotex

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

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 XL	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

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

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

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

Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Unk Unk, Qid	Not Reported
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

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

Vitamin D3	N	S	Unknown	Unk	Not Reported
Adalimumab	N	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

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

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

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

Calcium Carbonate; Colecalciferol	N	C	Unknown	Unk	Not Reported
Valsartan	N	C	Unknown	Unk	Not Reported
Valsartan	N	C	Vaginal	Unk	Not Reported
Calcium Carbonate W/Vitamin D [Calcium Carbonate; Colecalciferol]	N	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	C	Unknown	Unk	Not Reported
Calcium Carbonate And Vitamin D	N	C	Unknown	Unk	Not Reported
Vitamin D3	N	C	Unknown	Unk	Not Reported
Sulfamethoxazole\Trimethoprim		S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Nov-2022	19708623	EXPEDITED (15-DAY)	Y	OT	CA-AstraZeneca- 2021A674528			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Budesonide	N		S	Unknown			Astrazeneca
	Acetaminophen	N		S	Unknown			Not Reported
	Adalimumab	N		S	Subcutaneous			Not Reported
	Alprazolam	N		S	Unknown			Not Reported
	Amoxicillin Trihydrate	N		S	Unknown			Not Reported
	Atorvastatin Calcium	N		S	Unknown			Not Reported
	Avamys	N		S	Ophthalmic			Not Reported
	Benzydamine Hydrochloride	N		S	Unknown			Not Reported
	Betamethasone Dipropionate	N		S	Unknown			Not Reported
	Betamethasone Valerate	N		S	Unknown			Not Reported
	Cetirizine Hydrochloride	N		S	Unknown			Not Reported
	Clarithromycin	N		S	Unknown			Not Reported
	Clotrimazole	N		S	Unknown			Not Reported
	Desonide	N		S	Unknown			Not Reported
	Diphenhydramine	N		S	Unknown			Not Reported

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Dulcolax	N	S	Unknown	Not Reported
Ergocalciferol	N	S	Unknown	Not Reported
Ertapenem Sodium	N	S	Unknown	Not Reported
Flovent	N	S	Unknown	Not Reported
Glycerine	N	S	Oral	Not Reported
Humira	N	S	Subcutaneous	Not Reported
Hydrochlorothiazide	N	S	Unknown	Not Reported
Macrogol 3350/Potassium/Sodium Chloride/Sodium Bicarbonate	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	Unknown	Not Reported
Nadolol	N	S	Intra-articular	Not Reported
Nicoderm	N	S	Unknown	Not Reported
Nicotine Polacrilex	N	S	Unknown	Not Reported
Pms-Azithromycin	N	S	Unknown	Not Reported
Prednisone	N	S	Subcutaneous	Not Reported
Pregabalin	N	S	Topical	Not Reported
Refresh Tears	N	S	Ophthalmic	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Not Reported
Valsartan	N	S	Unknown	Not Reported
Valsartan	N	C	Unknown	Not Reported
Sulfamethoxazole/Trimethoprim		S		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Dec-2022	21675228	EXPEDITED (15-DAY)	Y	HO, OT	CA-AstraZeneca-2022A204396		71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Sinusitis; Drug	Budesonide		N	S	Nasal			Not Reported	

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

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	Not Reported
	Nicotine	N	S	Unknown	Not Reported
	Nicotine	N	S	Unknown	Not Reported
	Paracetamol	N	S	Unknown	Not Reported
	Cetirizine Hydrochloride	N	S	Unknown	Not Reported
	Diphenhydramine Hydrochloride	N	S	Unknown	Not Reported
	Infliximab, Recombinant	N	S	Intravenous (not otherwise specified)	Not Reported
	Zinc Oxide	N	S	Unknown	Not Reported
	Imodium	N	S	Unknown	Not Reported
	Adalimumab	N	S	Subcutaneous	Not Reported
	Amoxicillin Trihydrate	N	S	Unknown	Not Reported
	Atorvastatin Calcium	N	S	Unknown	Not Reported
	Alprazolam	N	S	Unknown	Not Reported
	Diphenoxylate Hydrochloride/Atropine Sulfate	N	S	Oral	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
	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
	Ertapenem Sodium	N	S	Unknown	Not Reported
	Fluticasone Furoate	N	S	Unknown	Not Reported
	Fluticasone Propionate	N	S	Unknown	Not Reported
	Glycerol	N	S	Oral	Not Reported
	Neomycin Sulfate/Gramicidin/Polymyxin B	N	S	Unknown	Not Reported

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

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	N	S	Unknown		Not Reported
Sodium Bicarbonate	N	S	Unknown		Not Reported
Sodium Carboxymethyl Cellulose	N	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	N	S	Unknown		Not Reported
Loperamide	N	S	Unknown		Not Reported
Nicotine Polacrilex	N	S	Unknown		Not Reported
Calcium Citrate	N	S			Not Reported
Sodium Sulfate/Macrogol 3350/Sodium Chloride/Sodium Bicarbonate/Potassium Chloride	N	S			Not Reported
Hydrochlorothiazide	N	S			Not Reported

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

Natural Vitamin E	N	S							Not Reported
Isoniazid/Pyridoxine	N	S							Not Reported
Hydrochloride/Sulfamethoxazole /Trimethoprim									
D-Alpha Tocopherol	N	S							Not Reported
Biaxin XI	N	S							Not Reported
Entocort	N	S							Not Reported
Pulmicort	N	S							Not Reported
Triamcinolone Acetonide	N	S							Not Reported
Lomotil	N	S							Not Reported
Acetaminophen/Dextropropoxyphene	N	S							Not Reported
Ambroxol	N	S							Not Reported
Hydrochloride/Cetirizine Hydrochloride									
Calcitriol/Calcium Carbonate/Zinc	N	S							Not Reported
Glycerine	N	S							Not Reported
Gramicidin	N	S							Not Reported
Magnesium Oxide	N	S							Not Reported
Simvastatin	N	S							Not Reported
Sinus Rinse	N	S							Not Reported
Triamcinolone	N	S							Not Reported
Trimethoprim	N	S							Not Reported
Loperamide Hydrochloride	N	S							Not Reported
Nicotinamide	N	S							Not Reported
Benadryl [Diphenhydramine Hydrochloride]	N	C	Unknown						Not Reported
Metoclopramide Hydrochloride	N	C	Unknown						Not Reported
Valsartan	N	C	Unknown						Not Reported
Ergocalciferol/Calcium Carbonate	N	C							Not Reported
Calcium & Ergocalciferol	N	C							Not Reported
Calcium	N	C	Unknown						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Dec-2022	21172982	EXPEDITED (15-DAY)	Y	HO, OT	CA-SSP- 2022SA302125AA		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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

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	Ergocalciferol	N	S	Unknown	Unk	Sanofi
	Alprazolam	N	S	Unknown	0.25 Mg	Not Reported
	Atorvastatin	N	S	Unknown	Unk	Not Reported
	Atropine Sulfate	N	S	Oral	Unk	Not Reported
	Atropine Sulfate	N	S	Oral	4 Df	Not Reported
	Atropine Sulfate	N	S	Oral	1 Df	Not Reported
	Atropine Sulfate	N	S	Unknown	Unk	Not Reported
	Fluticasone Furoate	N	S	Unknown	Metered Dose	Not Reported
	Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
	Betamethasone Valerate	N	S	Unknown	Unk	Not Reported
	Bisacodyl	N	S	Unknown	Unk	Sanofi
	Budesonide	N	S	Oral	Unk	Not Reported
	Budesonide	N	S	Respiratory (inhalation)	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
	Desonide	N	S	Unknown	Unk	Not Reported
	Diphenhydramine Hydrochloride	N	S	Oral	50 Mg	Sanofi
	Glycerine	N	S	Oral	Unk	Not Reported
	Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
	Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
	Mesalazine	N	S	Unknown	Unk	Sanofi
	Metronidazole	N	S	Unknown	Unk	Sanofi
	Morphine Sulfate	N	S	Unknown	Unk	Not Reported
	Mupirocin	N	S	Unknown	Unk	Not Reported
	Mupirocin	N	S	Topical	Unk	Not Reported
	Nadolol	N	S	Unknown	40 Mg	Not Reported

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

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

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

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

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

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	C		Unk		Not Reported
Amoxicillin	N	C		Unk		Not Reported
Amoxicillin Trihydrate	N	C		Unk		Not Reported
Neomycin Sulfate	N	C		Unk		Not Reported
Sodium Stearate	N	C		Unk		Not Reported
Calcium Carbonate And Vitamin D3	N	C		Unk		Not Reported
Diphenhydramine Hydrochloride	N	C		Unk		Not Reported
Mupirocin Calcium	N	C		Unk		Not Reported
Acetylsalicylic Acid	N	S		Unk		Not Reported
Calcium Citrate	N	S		Unk		Not Reported

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

	Diphenhydramine	N	S		Unk	Sanofi
	Lomotil [Loperamide Hydrochloride]	N	S	Oral	Unk	Not Reported
	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	C	Oral	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Dec-2022	21690182	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2239648US			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cataract	Refresh Optive Mega-3		Y	S		Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Dec-2022	20710671	EXPEDITED (15-DAY)	Y	OT	CA-JNJFOC-20220419307			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Imodium	N	S	Unknown				Not Reported
	Cetirizine Hydrochloride	N	S	Unknown				Not Reported
	Diphenhydramine Hydrochloride	Y	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
	Hydrochlorothiazide	N	S	Unknown				Not Reported
	Atorvastatin Calcium	N	S	Unknown				Not Reported

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Diphenoxylate Hydrochloride And Atropine Sulfate	N	S	Unknown	Not Reported
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

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

Refresh Tears Plus	N	S	Ophthalmic	Not Reported
Sinus Rinse	N	S		Not Reported
Sodium Chloride	N	S	Unknown	Not Reported
Oriprim	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
Metronidazole	N	S	Unknown	Not Reported
Valsartan	N	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Dec-2022	21698534	EXPEDITED (15-DAY)	Y	OT	FR-JNJFOC-20221216183		44 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Leukopenia; Neutropenia	Tramadol Hydrochloride	N	S		Oral	Unk		Not Reported
	Celluvisc [Carmellose Sodium]	N	S			1 Drop, 4/Day		Not Reported
	Paracetamol	N	S		Oral	1 Dosage Form, 4/Day		Not Reported
	Laroxyl	N	S		Oral	5 Drop, 5/Day		Not Reported
	Gabapentine	N	S		Oral	1200 Milligram, 1/Day		Not Reported
	Cyanocobalamin	N	S			1 Drop, 4/Day		Not Reported
	Duloxetine	N	S		Unknown	60 Milligram, 1/Day		Not Reported
	Lovenox [Enoxaparin Sodium]	N	S		Subcutaneous	Unk		Not Reported
	Levothyrox	N	S		Oral	1 Dosage Form, 1/Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Dec-2022	21309147	EXPEDITED (15-DAY)	Y	HO, OT	CA-GLAXOSMITHKLINE-CACH2022AMR031535			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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Detailed Report

Abdominal Pain; Anaemia; Chronic Sinusitis; Colitis; Colitis Ulcerative;	Calcium Carbonate, Cholecalciferol Habitrol	N	S		Unk	Glaxosmithkline
Constipation; Drug	Nicotine	N	S		Unk	Glaxosmithkline
Ineffective; Dyspepsia;	Nicoderm	N	S		Unk	Glaxosmithkline
Erythema; Female Genital Tract Fistula; Frequent Bowel Movements;	Nicotine Polacrilex	N	S		Unk	Glaxosmithkline
Haematochezia;	Pantoprazole	N	S		Unk	Not Reported
Headache; Infusion Related Reaction; Macular Degeneration; Malaise;	Diphenhydramine Multivitamins	N	S		Unk	Not Reported Glaxosmithkline
Nausea; Off Label Use;	Zinc Oxide	Y	S		Unk	Glaxosmithkline
Oral Candidiasis; Pain; Paraesthesia Oral;	Acetaminophen + Pseudoephedrine	N	S		Unk	Not Reported
Procedural Pain; Proctitis; Pyrexia; Radiculopathy;	Sodium Chloride	N	S		Unk	Not Reported
Rectal Haemorrhage;	Magnesium Sulfate	N	S		Unk	Not Reported
Therapeutic Product Effect Incomplete; Vaginal Discharge; Vaginal Flatulence; Weight Decreased	D-Alpha Tocopherol Niquitin 4 Mg Mint Lozenge Magnesium Oxide Magnesium Sulfate Inj Vitamin E Nicotinamide Magnesium Hydroxide Acetaminophen	N N N N N N N Y	S S S S S S S S		Unk Unk Unk Unk Unk Unk Unk Unk	Glaxosmithkline Glaxosmithkline Not Reported Not Reported Glaxosmithkline Not Reported Not Reported Glaxosmithkline
	Bactroban (Mupirocin)	N	S		Unk	Not Reported
	Fluticasone Propionate	N	S		Unk	Glaxosmithkline
	Magnesium (Magnesium Salt)	N	S		Unk	Not Reported
	Empracet	N	S			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
	Azithromycin Dihydrate	N	S		Unk	Not Reported
	Clotrimazole	N	S			Not Reported

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Metronidazole	N	S		Unk	Not Reported
Alprazolam Tablet	N	S		0.25 Mg	Not Reported
Biaxin XL	N	S			Not Reported
Clarithromycin	N	S		Unk	Not Reported
Desonide	N	S		Unk	Not Reported
Ertapenem Sodium	N	S		Unk	Not Reported
Glycerine	N	S			Not Reported
Humira	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
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	N	S			Not Reported
Mesalazine	N	S		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		Unk	Not Reported
Zeaxanthin	N	S			Not Reported
Xantofyl Palmitate	N	S			Not Reported

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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
Glycerol 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

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Glycerol	N	S		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		Not Reported
Fructose	N	S		Not Reported
Solu Medrol	N	S	Unk	Not Reported
Align	N	S	Unk	Not Reported
Ciprofloxacin	N	S		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

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Dec-2022	21708455	NON-EXPEDITED	N		US-UNITED THERAPEUTICS-UNT- 2022-025556			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Contact; Device Allergy	Remodulin Sq		N	S	Subcutaneous	Unk, Continuing		Not Reported	
	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 Eliquis		N	S	Unknown	Unk		Not Reported	
			N	C	Unknown	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Dec-2022	21722234	EXPEDITED (15-DAY)	Y	OT	FR-MYLANLABS- 2022M1137349		44 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Leukopenia; Neutropenia	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	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Dec-2022	21724926	EXPEDITED (15-DAY)	Y	OT	FR-SA-2022SA504550		44 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Leukopenia; Neutropenia	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		N	S	Oral	1200 Mg, Qd		Not Reported
	Duloxetine Hydrochloride		N	S		60 Mg, Qd		Not Reported
	Lovenox		N	S	Subcutaneous	Unk		Sanofi
	Levothyroxine Sodium		N	S	Oral	Unk, Qd		Not Reported
	Tramadol Hydrochloride		N	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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Dec-2022	21743755	EXPEDITED (15-DAY)	Y	OT	FR-AUROBINDO-AUR-APL-2022-052968		44 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Leukopenia; 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		N	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

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Laroxyl	N	S	Oral	5 Drops 5 Times A Day	Not Reported
Lovenox	N	S	Subcutaneous	Unk	Not Reported
Levothyrox	N	S	Oral	1 Dosage Form, Once A Day (1 Tablet/Day)	Not Reported
Vitamine B12 Chauvin	N	S		1 Drop 3 To 4 Times A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Dec-2022	20487629	EXPEDITED (15-DAY)	Y	HO, OT	CA-ABBVIE-22K-028-4281888-00		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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	Humira		N	S	Subcutaneous			Abbvie
	Pulmicort		N	S	Respiratory (inhalation)			Not Reported
	Infliximab		N	S	Intravenous (not otherwise specified)			Not Reported
	Mupirocin		N	S	Topical			Not Reported
	Atorvastatin Calcium		N	S	Unknown			Not Reported
	Bactrim		N	S	Unknown			Not Reported
	Cetirizine Hydrochloride		N	S	Unknown			Not Reported
	Cholecalciferol		N	S	Unknown			Not Reported
	Cupric Oxide		N	S	Unknown			Not Reported
	Dilaudid		N	S	Unknown			Not Reported
	Diphenhydramine Hydrochloride		N	S	Unknown			Not Reported
	Flovent		N	S	Unknown			Not Reported
	Macrogol;Potassium;Sodium Bicarbonate		N	S	Unknown			Not Reported
	Magnesium Sulfate		N	S	Unknown			Not Reported
	Nadolol		N	S	Oral			Not Reported
	Pantoprazole		N	S	Unknown			Not Reported
	Prednisone		N	S	Unknown			Not Reported

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

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; Polymyxin B Sulfate	N	S	Unknown		Not Reported
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 Hydrochloride/Sulfamethoxazole /Trimethoprim	N	S	Unknown		Not Reported
Xantofyl Palmitate	N	S	Unknown		Not Reported

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

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	N	S	Unknown		Not Reported
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate;	N	S	Unknown	Sodium Sulfate	Not Reported

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Sodium Chloride									
Pantoprazole Sodium Anhydrous	N	S	Unknown						Not Reported
Glycerol;Sodium Stearate	N	S	Unknown						Not Reported
Sinus Rinse	N	S	Unknown						Not Reported
Loperamide	N	C							Not Reported
Metoclopramide Hydrochloride	N	C	Oral						Not Reported
Calcium Carbonate And Vitamin D3	N	C							Not Reported
Valsartan	N	C							Not Reported
Sodium Stearate	N	C							Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2022	21763886	EXPEDITED (15-DAY)	Y	OT	FR-SUN PHARMACEUTICAL INDUSTRIES LTD- 2022RR-369620		44 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Leukopenia; Neutropenia	Gabapentine	N	S	Oral		1200 Milligram		Sun
	Celluvisc	N	S	Ophthalmic		Unk		Not Reported
	Dafalgan	N	S	Oral		Unk		Not Reported
	Laroxyl	N	S	Oral		Unk		Not Reported
	Vitamine B12 Chauvin	N	S	Ophthalmic		Unk		Not Reported
	Duloxetine Base	N	S	Unknown		60 Milligram		Not Reported
	Lovenox	N	S	Subcutaneous		Unk		Not Reported
	Levothyrox	N	S	Oral		Unk		Not Reported
	Tramadol Base	N	S	Oral		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2022	21764428	EXPEDITED (15-DAY)	Y	OT	FR-TEVA-2022-FR-2837071		44 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Leukopenia; Neutropenia	Gabapentin		N	S		1200 Milligram Daily; 1200mg/Day , Therapy		Ivax	

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

Duloxetine	N	S	End Date : Nask 60 Milligram Daily; 60mg/Day , Therapy End Date : Nask	Teva
Tramadol Base	N	S	Therapy End Date : Nask	Teva
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 Reported
Dafalgan	N	S	4 Dosage Forms Daily; 1 Tablet 4 Times A Day , Form Strength : 1 Gram , Therapy Start Date : Asku	Not Reported
Laroxyl	N	S	25 Gtt Daily; 5 Drops 5 Times A Day , Form Strength : 40 Mg/MI , Therapy End Date : Nask	Not 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 Reported
Lovenox	N	S	Therapy End Date : Nask	Not Reported
Levothyrox	N	S	1 Dosage Forms Daily; 1 Tablet/Day , Therapy End Date : Nask	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2022	21767074	DIRECT						Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Refresh Tears	N	S					Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2022	21767144	DIRECT						Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Refresh Relieva		N	S					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Dec-2022	21768562	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2241714US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataract; Impaired Healing	Refresh Optive Mega-3		Y	S					Allergan
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Dec-2022	21297993	EXPEDITED (15-DAY)	Y	HO, OT	CA-AstraZeneca-2022A299284		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
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	Budesonide		N	S	Unknown				Astrazeneca
	Budesonide		N	S	Unknown				Not Reported
	Entocort		N	S	Unknown				Not Reported
	Paracetamol/Dextropropoxyphene		N	S	Unknown				Not Reported
	Acetaminophen		N	S	Unknown				Not Reported
	Adalimumab		N	S					Not Reported
	Alprazolam		N	S	Unknown				Not Reported
	Atorvastatin Calcium		N	S	Unknown				Not Reported
	Diphenoxylate Hydrochloride/Atropine Sulfate		N	S	Oral				Not Reported
	Azithromycin		N	S	Unknown				Not Reported
	Betamethasone Dipropionate		N	S	Unknown				Not Reported
	Betamethasone Dipropionate		N	S	Unknown				Not Reported
	Betamethasone Valerate		N	S	Unknown				Not Reported

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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	N	S		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
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 Carboxymethyl 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

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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)		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 Hydrochloride	N	S	Unknown		Not Reported
Sodium Citrate/Diphenhydramine Hydrochloride/Ammonium Chloride	N	S	Unknown	1.0df Unknown	Not Reported
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 Carbonate/Zinc	N	S	Unknown		Not Reported
Ergocalciferol/Calcium Carbonate	N	S	Unknown		Not Reported

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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 Sodium Bicarbonate/Macrogol/Potassium 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	N	S	Unknown	Not Reported
Neomycin Sulfate	N	S	Unknown	Not Reported
Nicoderm	N	S	Unknown	Not Reported
Nicotinamide	N	S	Unknown	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Not Reported
Refresh Tears	N	S	Unknown	Not Reported
Simvastatin	N	S	Unknown	Not Reported
Sinus Rinse	N	S	Unknown	Not Reported
Sodium Bicarbonate	N	S	Unknown	Not Reported
Sodium Stearate	N	S	Unknown	Not Reported
Sulfamethoxazole/Tri Methoprim	N	S	Unknown	Not Reported
Triamcinolone	N	S	Unknown	Not Reported
Trimethoprim	N	S	Unknown	Not Reported
Bactrim	N	S	Unknown	Not Reported
Metoclopramide Hydrochloride	N	C	Unknown	Not Reported
Benadryl	N	C	Unknown	Not Reported
Valsartan	N	C	Unknown	Not Reported
Lomotil	N	C	Unknown	Not Reported
Calcium Lactate/Ergocalciferol/Calcium Phosphate	N	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Dec-2022	21790071	EXPEDITED (15-DAY)	Y	HO, OT	CA-AstraZeneca-2022A412818		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chronic Sinusitis; Drug Ineffective; Dyspepsia; Infusion Related Reaction; Macular Degeneration; Malaise; Nausea; Off Label Use; Pain;	Budesonide	N	S	Unknown				Astrazeneca
	Entocort	N	S	Unknown				Not Reported
	Clarithromycin	N	S	Unknown				Not Reported
	Hydrochlorothiazide	N	S	Unknown				Not Reported

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

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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
Cetirizine 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

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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 Cellulose	N	S	Ophthalmic	Not Reported
Sodium Carboxymethyl Cellulose	N	S	Ophthalmic	Not Reported
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

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

Zinc Oxide	N	S	Unknown	Not Reported
Diphenhydramine Hydrochloride	N	C		Not Reported
Calcium Carbonate And Vitamin D3	N	C		Not Reported
Amoxicillin	N	C	Unknown	Not Reported
Valsartan	N	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Jan-2023	21810768	DIRECT		DS			76 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Keratitis	Refresh Digital Pf Multi Vitamin Mineral		Y	S C				Allergan Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2023	20499775	EXPEDITED (15-DAY)	Y	HO, OT	CA-AUROBINDO-AUR- APL-2022-004685		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
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	Atorvastatin		N	S	Unknown	Unk		Not Reported	
	Amoxicillin		N	S	Unknown	Unk		Aurobindo	
	Atorvastatin Tablets		N	S	Unknown	Unk		Not Reported	
	Azithromycin		N	S	Unknown	Unk		Eugia Pharma	
	Ertapenem		N	S	Unknown	Unk		Eugia Pharma	
	Metronidazole		N	S	Unknown	Unk		Aurobindo	
	Pantoprazole		N	S	Unknown	Unk		Aurobindo	
	Pregabalin Capsules		N	S	Oral	150 Milligram		Not Reported	
	Sulfamethoxazole+Trimethoprim		N	S	Unknown	200 Milligram		Aurobindo	
	Simvastatin Tablet		N	S	Unknown	Unk		Aurobindo	
	Acetaminophen		N	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	N	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	N	S			Not Reported
Glycerol	N	S	Oral	Unk	Not Reported
Gramicidin;Polymyxin B	N	S			Not Reported
Glycerol;Sodium Stearate	N	S	Unknown	Unk	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	N	S			Not Reported
Sinus Rinse	N	S	Unknown	Unk	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

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Vitamin E Mixed Tocopherols	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
Benadryl	N	C	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D3	N	C	Unknown	Unk	Not Reported
Calcium	N	C	Unknown	Unk	Not Reported
Calcium Lactate;Calcium Phosphate;Ergocalciferol	N	C	Unknown	Unk	Not Reported
Diphenoxylate Hydrochloride	N	C	Unknown	Unk	Not Reported
Neomycin Sulfate	N	C	Unknown	Unk	Not Reported
Sodium Stearate	N	C	Unknown	Unk	Not Reported
Valsartan	N	C	Oral	4 Dosage Form, Once A Day	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Jan-2023	21165041	EXPEDITED (15-DAY)	Y	OT	CA-AUROBINDO-AUR-APL-2022-029356			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Amoxicillin	N	S	Unknown	Unk			Aurobindo
	Atorvastatin	N	S	Unknown	Unk			Not Reported
	Atorvastatin	N	S	Unknown	Unk			Not Reported
	Atorvastatin	N	S	Unknown	Unk			Not Reported
	Atorvastatin	N	S	Unknown	Unk			Not Reported
	Azithromycin	N	S	Oral	Unk			Eugia Pharma
	Azithromycin	N	S	Unknown	Unk			Eugia Pharma
	Azithromycin	N	S	Oral	Unk			Eugia Pharma
	Metronidazole	N	S	Unknown	Unk			Aurobindo
	Pregabalin Capsules	N	S	Unknown	Unk			Not Reported
	Pantoprazole	N	S	Unknown	Unk			Aurobindo

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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

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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

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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	C	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	Endosinusal		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	Endosinusal	Unk	Not Reported

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Sinus Rinse	N	S	Unknown	Unk	Not Reported
Sodium Stearate	N	S	Unknown	Unk	Not Reported
Sodium Stearate	N	S	Oral	Unk	Not Reported
Sodium Chloride	N	S	Nasal	Unk	Not Reported
Triamcinolone Acetonide	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Vitamin D	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Vitamin E	N	S	Unknown	Unknown	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
Potassium Chloride	N	S	Unknown	Unknown	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Zinc Chloride	N	S	Unknown	Unk	Not Reported
Calcium	N	C	Unknown	Unk	Not Reported
Valsartan	N	C	Vaginal	Unk	Not Reported
Valsartan	N	C	Intracardiac	Unk	Not Reported
Vitamine A	N	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Jan-2023	21824734	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2242813US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataract	Refresh Optive Mega-3		Y	S		Unk Unk, Qid		Allergan	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Jan-2023	20698577	EXPEDITED (15-DAY)	Y	OT	NVSC2022CA080548			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Adalimumab		N	S	Subcutaneous	Unk		Novartis
	Hydromorphone		N	S	Unknown	Unk, Qw		Not Reported
	Hydromorphone		N	S	Unknown	Unk		Not Reported
	Atorvastatin Calcium		N	S	Unknown	Unk		Novartis
	Atorvastatin Calcium		N	S	Unknown	Unk		Novartis
	Atorvastatin Calcium		N	S	Unknown	Unk		Novartis
	Atorvastatin Calcium		N	S	Unknown	Unk		Novartis
	Azithromycin		N	S	Oral	Unk		Novartis
	Valsartan		N	S	Intracardiac	Unk		Novartis
	Ergocalciferol		N	S	Unknown	Unk		Not Reported
	Clarithromycin		N	S	Unknown	Unk		Novartis
	Morphine Sulfate		N	S	Unknown	Unk		Not Reported
	Amoxicillin		N	S	Unknown	Unk		Novartis
	Diphenhydramine Hydrochloride		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
	Magnesium Sulfate		N	S	Unknown	Unk		Not Reported
	Sodium Bicarbonate		N	S	Unknown	Unk		Not Reported
	Pantoprazole Sodium		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		Novartis
	Atropine Sulfate		N	S	Unknown	Unk		Not Reported

**FDA Adverse Event Reporting System
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Detailed Report**

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

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

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

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

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 Adverse Event Reporting System

Freedom of Information Act (FOIA)

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Jan-2023	21838009	EXPEDITED (15-DAY)	N	OT	ALC2023CA000442			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Atropine Sulfate	N		S	Oral	Unk		Alcon
	Acetaminophen	N		S	Unknown			Not Reported
	Acetaminophen	N		S	Unknown	Unk		Not Reported
	Adalimumab	N		S	Subcutaneous	Unk		Not Reported
	Alprazolam	N		S	Unknown	Unk		Not Reported
	Amoxicillin Trihydrate	N		S	Unknown			Not Reported
	Apo-Hydrochlorothiazide	N		S	Unknown			Not Reported
	Atorvastatin Calcium	N		S	Unknown			Not Reported
	Atropine Sulfate;Diphenoxylate Hydrochloride	N		S	Unknown	Unk		Not Reported
	Avamys	N		S	Unknown			Not Reported
	Azithromycin	N		S	Unknown			Not Reported
	Azithromycin	N		S	Unknown			Not Reported
	Bactrim	N		S	Unknown	Unk		Not Reported
	Betamethasone Dipropionate	N		S	Unknown			Not Reported
	Betamethasone Valerate	N		S	Unknown			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	Unknown			Not Reported
	Calcium Carbonate	N		S	Intra-articular	Unk		Not Reported
	Cetirizine Hydrochloride	N		S	Unknown	Unk		Not Reported
	Clarithromycin	N		S	Unknown			Not Reported
	Clotrimazole	N		S	Unknown	Unk		Not Reported
	Desonide	N		S	Unknown	Unk		Not Reported

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

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

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

Sodium Chloride	N	S	Unknown		Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular		Not Reported
Vitamin D3	N	S	Unknown		Not Reported
Vitamin E Nos	N	S	Unknown		Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown		Not Reported
Zinc Oxide	N	S	Unknown		Not Reported
Valsartan	N	C	Vaginal		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2023	21844015	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2236274US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Hypersensitivity; Eye Pruritus; Retinal Haemorrhage	Refresh Relieva Pf	Y	S		Ophthalmic	2 Gtt		Allergan	
	Coenzyme Q10	N	S			Unk		Not Reported	
	Refresh Optive Mega-3	N	C			Unk		Not Reported	
	Gentel [Hypromellose]	N	C			Unk		Not Reported	
	Similasan	N	C			Unk		Not Reported	
	Calcium	N	C			Unk		Not Reported	
	Magnesium	N	C			Unk		Not Reported	
	Vitamin D [Colecalciferol]	N	C			Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Jan-2023	21845115	EXPEDITED (15-DAY)	N	OT	CA-BAXTER-2023BAX010003			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Sodium Chloride	N	S		Unknown	(Dosage Form: Not Specified)		Baxter	
	Metronidazole	N	S		Unknown	(Dosage Form: Not Specified)		Baxter	

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

Acetaminophen	N	S	Unknown	Specified) (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

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

Clotrimazole	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
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
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
Gramicidin;Neomycin	N	S	Unknown	Unk	Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Humira	N	S	Unknown	(Dosage Form: Solurion Subcutaneous)	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
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
Nadolol	N	S	Unknown	Unk	Not Reported

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Nicoderm	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Unknown	(Dosage Form: Not Specified)	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 Specified)	Not Reported
Refresh Tears	N	S	Ophthalmic	(Dosage Form: Drops Ophthalmic)	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Sinus Rinse	N	S	Unknown	(Dosage Form: Solution Nasal)	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	(Dosage Form: Suspension Intra-Articular)	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Vitamin E Nos	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	(Dosage Form: Not Specified)	Not Reported
Valsartan	N	C	Vaginal	(Dosage Form: Not Specified)	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Jan-2023	21849449	DIRECT					64 YR	Female	USA

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective	Refresh Solution Nos		N	S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jan-2023	21284458	EXPEDITED (15-DAY)	Y	OT	FR-BRISTOL-MYERS SQUIBB COMPANY- 2022-099280		76 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mouth Ulceration	Istodax		N	S	Intravenous drip			Not Reported	
	Lasilix [Furosemide]		N	S	Oral	One Tablet In The Morning		Not Reported	
	Hydrocortisone		N	S	Oral	Two In The Morning		Not Reported	
	Januvia		N	S	Oral	Once In The Morning		Not Reported	
	Vitamine B12		N	S	Oral	Two Ampoules Weekly, 1000 Microg / 2 MI Oral Solution		Not Reported	
	Venlafaxine		N	S	Oral	Once In The Morning		Not Reported	
	Clopidogrel		N	S	Oral	Once In The Morning		Not Reported	
	Diffu K		N	S	Oral	Two Tablets In The Morning, One At Midday		Not Reported	
	Oracilline [Phenoxymethylpenicillin Benzathine]		N	S	Oral	1000000 Iu		Not Reported	
	Levothyrox		N	S	Oral	Once In The Morning		Not Reported	
	Atorvastatine		N	S	Oral	Once In The Evening		Not Reported	
	Paracetamol		N	S	Oral	1 G, One Tablet Every 8 H		Not Reported	
	Bronchodual		N	S	Respiratory (inhalation)	50 Microg / 20 Microg Per Dose (Inns: Fenoterol Hydrobromide / Ipratropium Bromide) Two Puffs In The		Not Reported	
	Bisoprolol		N	S	Oral	One Tablet In The Morning		Not Reported	
	Zymad		N	S	Oral	In Ampoules		Not Reported	
	Amlor		N	S	Oral	Once In The Morning		Not Reported	

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

Dexeryl [Glycerol;Paraffin, Liquid;White Soft Paraffin]	N	S	One Daily Application On The Whole Body, 2 Tubes Weekly.	Not Reported
Optive	N	S	Lubricating And Osmoprotective Ocular Solution 1-2 Drops Per Day Depending On Discomfort	Not Reported
Clarelux	N	C	2 Tubes Weekly: One Weekly Application On The Whole Body, Space Out Applications For Few Days, Even	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Jan-2023	21861690	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN- 2300183US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Allergy To Chemicals; Cataract; Conjunctivitis; Cough; Covid-19; Eye Contusion; Eye Irritation; Incorrect Dose Administered; Ocular Hyperaemia; Photophobia	Refresh Plus		Y	S	Ophthalmic	4-5 Times Daily		Not Reported	
	Children'S Chewable Complete Multivitamins		N	C				Not Reported	
	Tums [Calcium Carbonate]		N	C		Unk		Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Jan-2023	21873582	EXPEDITED (15-DAY)	N	DS	US-ALLERGAN- 2300539US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Disability; Expired Product Administered; Eye Injury; Eye Irritation; Gait Inability; Vision Blurred; Visual Impairment	Refresh Optive		Y	S	Ophthalmic	2 Drop Per Eye		Allergan	

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Jan-2023	21880256	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2300879US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataract; Expired Product Administered	Refresh Tears		Y	S		Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2023	20213444	EXPEDITED (15-DAY)	N	OT	CA-PFIZER INC-202101810635			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Alprazolam Mylan		N	S	Unknown	Unk		Mylan	
	Pregabalin Mylan		N	S	Unknown	Unk		Mylan	
	Atorvastatin Calcium		N	S	Unknown	Unk		Mylan	
	Pantoprazole		N	S	Unknown	Unk		Not Reported	
	Amoxicillin Trihydrate		N	S	Unknown	Unk		Not Reported	
	Metronidazole		N	S	Unknown	Unk		Not Reported	
	Azithromycin		N	S	Unknown	Unk		Not Reported	
	Sodium Chloride Bacteriostatic		N	S	Unknown	Unk		Not Reported	
	Triamcinolone Acetonide		N	S	Unknown	Unk		Not Reported	
	Triamcinolone Acetonide		N	S	Intra-arterial	Unk		Not Reported	
	Morphine Sulfate		N	S	Unknown	Unk		Not Reported	
	Hydromorphone Hydrochloride		N	S	Unknown	Unk		Not Reported	
	Diphenhydramine Hcl		N	S	Unknown	Unk		Not Reported	
	Calcium Carbonate		N	S	Unknown	Unk		Not Reported	
	Atropine Sulfate		N	S	Oral	Unk		Not Reported	
	Adalimumab		N	S	Subcutaneous	Unk		Not Reported	
	Mezavant		N	S	Unknown	Unk		Not Reported	
	Pentasa		N	S	Unknown	Unk		Not Reported	

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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	C	Unknown	Unk	Not Reported

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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2023	20378873	EXPEDITED (15-DAY)	N	OT	CA-PFIZER INC-202200122423			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Macular Degeneration	Alprazolam Mylan		N	S	Unknown	Unk		Mylan	
	Atorvastatin Calcium		N	S	Unknown	Unk		Mylan	
	Pregabalin Mylan		N	S	Unknown	Unk		Mylan	
	Pantoprazole		N	S	Unknown	Unk		Not Reported	
	Amoxicillin Trihydrate		N	S	Unknown	Unk		Not Reported	
	Metronidazole		N	S	Unknown	Unk		Not Reported	
	Calcium Carbonate		N	S	Unknown	Unk		Not Reported	
	Atropine Sulfate, Diphenoxylate Hcl		N	S	Unknown	Unk		Not Reported	
	Atropine Sulfate, Diphenoxylate Hcl		N	S	Oral	Unk		Not Reported	
	Azithromycin		N	S	Unknown	Unk		Not Reported	
	Morphine Sulfate		N	S	Unknown	Unk		Not Reported	
	Paracetamol		N	S	Unknown	Unk		Not Reported	
	Adalimumab		N	S	Subcutaneous	Unk		Not Reported	
	Dilaudid		N	S	Unknown	Unk		Not Reported	
	Mesalazine		N	S	Unknown	Unk		Not Reported	
	Prednisone		N	S	Unknown	Unk		Not Reported	
	Triamcinolone Acetonide Acetate		N	S	Intra-articular	Unk		Not Reported	
	Bactrim		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	
	Ergocalciferol		N	S	Unknown	Unk		Not Reported	

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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 Hydrochloride	N	S	Unknown	Unk	Not Reported
Entocort	N	S	Oral	Unk	Not Reported
Ertapenem Sodium	N	S	Unknown	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Gramicidin;Neomycin	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Subcutaneous	Unk	Not Reported
Mupirocin	N	S	Topical	Unk	Not Reported
Nadolol	N	S	Unknown	Unk	Not Reported
Nicoderm	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Sinus Rinse	N	S	Nasal	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Valsartan	N	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2023	21886721	EXPEDITED (15-DAY)	N	OT	CA-PFIZER INC-202200920173			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Pregabalin Mylan	N	S	Unknown	Unk			Mylan
	Alprazolam Mylan	N	S	Unknown	Unk			Mylan
	Atorvastatin 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 XL	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

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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; Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Diphenoxylate Hydrochloride And Atropine Sulfate	N	S	Unknown	Unk	Not Reported

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Calcium Carbonate; Colecalciferol	N	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Unk	Not Reported
Ambroxol Hydrochloride	N	S	Unknown	Unk	Not Reported
Calcium Gluconate	N	S	Unknown	Unk	Not Reported
Cupric Oxide	N	S	Unknown	Unk	Not Reported
Fructose	N	S	Unknown	Unk	Not Reported
Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 4000	N	S	Unknown	Unk	Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported
Atropine Sulfate;Difenoxin Hydrochloride	N	S	Unknown	Unk	Not Reported
Calcium Citrate	N	S	Unknown	Unk	Not Reported
Fluocinolone Acetonide; Neomycin Sulfate;Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Ichthammol;Zinc Oxide	N	S	Unknown	Unk	Not Reported
Macrogol;Potassium Chloride; Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Valsartan	N	C	Vaginal	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2023	21886794	EXPEDITED (15-DAY)	N	HO, OT	US-ALLERGAN- 2300805US			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Amnesia; Disease	Refresh Relieva Pf		Y	S	Ophthalmic			Allergan
Recurrence; Eye	Refresh Optive		N	S	Ophthalmic	1 Drop Each Eye		Allergan
Discharge; Transient	Refresh Optive		N	S				Allergan
Ischaemic Attack; Vision	Metformin		N	C				Not Reported
Blurred								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Jan-2023	21886805	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN- 2300675US			Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataract; Swelling Of Eyelid	Refresh Liquigel Ophthalmic		Y	S	Ophthalmic	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2023	21314309	EXPEDITED (15-DAY)	Y	OT	NVSC2022FR200301		76 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mouth Ulceration	Atorvastatin		N	S	Oral	40 Mg, Qd		Novartis	
	Furosemide		N	S	Oral	40 Mg, Qd		Not Reported	
	Paracetamol		N	S	Oral	1 Dosage Form, Prn		Novartis	
	Bisoprolol Fumarate		N	S	Oral	5 Mg, Qd		Novartis	
	Venlafaxine		N	S	Oral	75 Mg, Qd		Not Reported	
	Amlodipine		N	S	Oral	5 Mg, Qd		Novartis	
	Vit B12		N	S	Oral	2 Dosage Form, Qw		Not Reported	
	Diffu K		N	S	Oral	1800 Mg, Qd (Two Tablets In The Morning, One At Midday)		Not Reported	
	Hydrocortisone		N	S	Oral	20 Mg, Qd (Two In The Morning)		Not Reported	
	Levothyrox		N	S	Oral	Once In The Morning		Not Reported	
	Oracilline		N	S	Oral	2 Dosage Form, Qd (Strength: 1 000 000 U.I. /10 MI)		Not Reported	
	Bronchodual		N	S		50 Microg / 20 Microg Per Dose (Inns: Fenoterol Hydrobromide / Ipratropium Bromide) Two Puffs In The		Not Reported	
	Januvia		N	S	Oral	1000 Mg, Qd		Not Reported	
	Januvia		N	S	Oral	100 Mg, Qd (Once In The Morning)		Not Reported	
	Istodax		N	S	Intravenous (not	53.1 Mg, Qmo		Not Reported	

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				otherwise specified)		
Zymad	N	S	Oral	1 Dosage Form, Qmo (Strength: 50 000 Ui)		Not Reported
Clopidogrel	N	S	Oral	75 Mg, Qd		Not Reported
Clopidogrel	N	S	Oral	75 Mg, Qd (Once In The Morning)		Not Reported
Atorvastatine	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
Bisoprolol	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 MI Oral Solution)		Not Reported
Lasilix	N	S	Oral	40 Mg, Qd (One Tablet In The Morning)		Not Reported
Glycerin\Mineral Oil\Petrolatum	N	S	Unknown	One Daily Application On The Whole Body, 2 Tubes Weekly.		Not Reported
Clarelux	N	C	Unknown	2 Tubes Weekly: One Weekly Application On The Whole Body, Space Out Applications For Few Days, Even		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2023	21890963	EXPEDITED (15-DAY)	Y	OT	CA-009507513- 2301CAN006853			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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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

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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	Endosinusal	Unk	Not Reported
Sinus Rinse	N	S	Endosinusal	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	Endosinusal	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

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

Zinc Oxide	N	S	Unknown	Unk	Not Reported
Calcium	N	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Jan-2023	21897598	DIRECT						Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective	Refresh Eye Drops	N	S					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2023	16797741	EXPEDITED (15-DAY)	N	HO, OT	CA-TEVA-2019-CA-1104790			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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	Azithromycin	N	S		Unknown			Not Reported
	Azithromycin	N	S		Unknown			Not Reported
	Azithromycin	N	S		Unknown			Not Reported
	Azithromycin	N	S		Unknown			Not Reported
	Acetaminophen	N	S		Unknown			Not Reported
	Acetaminophen	N	S		Unknown			Not Reported
	Acetaminophen	N	S		Unknown			Not Reported
	Acetaminophen	N	S		Unknown			Not Reported
	Acetaminophen	N	S		Unknown			Not Reported
	Alprazolam	N	S		Unknown			Actavis
	Alprazolam	N	S		Unknown			Actavis
	Alprazolam	N	S		Unknown			Actavis
	Alprazolam	N	S		Unknown			Actavis
	Amoxicillin Trihydrate	N	S		Unknown			Teva
	Atorvastatin Calcium	N	S		Unknown			Teva
	Atorvastatin Calcium	N	S		Unknown			Teva

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

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 Carbonate/Ergocalciferol	N	S	Unknown	Not Reported
Calcium Carbonate/Ergocalciferol	N	S	Unknown	Not Reported
Calcium Carbonate/Ergocalciferol	N	S	Unknown	Not Reported
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

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

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
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

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

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 W/Trimethoprim	N	S	Unknown		Teva
Sulfamethoxazole W/Trimethoprim	N	S	Unknown		Teva
Sulfamethoxazole W/Trimethoprim	N	S	Unknown		Teva
Sulfamethoxazole W/Trimethoprim	N	S	Unknown		Teva
Sulfamethoxazole W/Trimethoprim	N	S	Unknown		Teva
Sulfamethoxazole W/Trimethoprim	N	S	Unknown		Teva
Sulfamethoxazole W/Trimethoprim	N	S	Unknown		Teva
Sulfamethoxazole W/Trimethoprim	N	S	Unknown		Teva
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

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

Pantoprazole Sodium Anhydrous	N	S	Unknown	Teva
Glycerine	N	S	Unknown	Not Reported
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	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
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/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 Tocopheryl Acetate/Vitamin C / Xantofyl Palmitat	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

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

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

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

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

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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/Pseudoephedrine	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

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

Vitamins Nos	N	S	Unknown	Not Reported
Mezavant Also Known As	N	S	Unknown	Not Reported
Mesalamine				
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 Carbonate/Zinc	N	S	Intra-articular	Not Reported
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/Dextropropoxyphene	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/Sulfamethoxazole/Trimethoprim	N	S	Unknown	Not Reported
Butanediol/Dexpanthenol/Dimethylsulfoxide/Glycerol	N	S	Oral	Not Reported
Calcium Gluconate	N	S	Unknown	Not Reported
Calcium Carbonate\Calcium Citrate\Calcium Phosphate\Cholecalciferol\Vitamin D	N	S	Unknown	Not Reported
Clobetasol	N	S	Unknown	Not Reported
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/Triamcinolone	N	S	Unknown	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Not Reported
Isoniazid/Pyridoxine Hydrochloride/Sulfamethoxazole/Trimethoprim	N	S	Unknown	Not Reported

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

Gramicidin/Neomycin/Nystatin/Trimethoprim	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/Dimethylsulfoxide/Glycerol	N	S	Oral	Not Reported
Calcium Carbonate/Calcium Citrate/Calcium Phosphate/Cellulose - Microcrystalline	N	S	Unknown	Not Reported
Antipyrine	N	S	Unknown	Not Reported
Bromhexine	N	S	Unknown	Not Reported

FDA Adverse Event Reporting System

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Detailed Report

Hydrochloride/Clorprenaline					
Hydrochloride/Sulfamethoxazole					
/					
Calcium	N	S	Unknown		Not Reported
Carbonate/Ergocalciferol					
Valsartan	N	C	Unknown		Not Reported
Carbonate/Colecalciferol	N	C			Not Reported
Calcium Carbonate; Vitamin D	N	C	Unknown		Not Reported
Nos					
Benadryl	N	C	Unknown		Not Reported
Calcium & Ergocalciferol	N	C	Unknown		Not Reported
Lomotil	N	C	Unknown		Not Reported
Metoclopramide Hydrochloride	N	C	Unknown		Not Reported
Clotrimazole	N	C			Not Reported
Vitamin A	N	C	Unknown		Not Reported
Hydrochlorothiazide	N	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2023	20696193	EXPEDITED (15-DAY)	Y	OT	ALC2022CA001692			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Atropine Sulfate	N	S	Unknown	Unk			Alcon
	Atropine Sulfate	N	S	Oral				Not Reported
	Acetaminophen	N	S	Unknown	Unk			Not Reported
	Acetylsalicylic Acid	N	S	Oral	Unk			Not Reported
	Adalimumab	N	S	Subcutaneous	Solution Subcutaneous			Not Reported
	Alprazolam	N	S	Unknown	Unk			Not Reported
	Ambroxol Hydrochloride	N	S	Unknown	Unk			Not Reported
	Amoxicillin	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

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

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

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

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	N	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	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
Mupirocin	N	S	Topical	Unk	Not Reported
Mupirocin Calcium	N	S	Topical	Unk	Not Reported
Nadolol	N	S	Unknown		Not Reported
Neomycin Sulfate	N	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

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

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

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

Zinc Oxide	N	S	Unknown	Unk	Not Reported
Valsartan	N	C	Intracardiac	Unk	Not Reported
Biaxin XI	N	S	Unknown	Unk	Not Reported
Fructose;Glycerol;Sodium Chloride	N	S	Unknown	Unk	Not Reported
Ichthammol;Zinc Oxide	N	S	Unknown	Unk	Not Reported
Ichthammol;Zinc Oxide	N	S	Unknown	Unk	Not Reported
Magnesium Oxide	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
Pantoprazole Sodium	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Mezavant	N	S	Unknown		Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Zeaxanthin Forte	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Cupric Oxide;Folic Acid;Nicotinic Acid;Zinc Oxide	N	S	Unknown	Unk	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Jan-2023	21905773	EXPEDITED (15-DAY)	Y	HO, OT	CA-BAUSCH-BL-2023-000835		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Anaemia;	Budesonide	N	S		Unknown			Santarus
Chronic Sinusitis; Colitis;	Glyceryl Trinitrate	N	S		Unknown			Not Reported
Colitis Ulcerative;	Mesalazine	N	S		Unknown			Valeant
Constipation; Drug Ineffective; Dyspepsia;	Metronidazole	N	S		Unknown			Not Reported

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

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	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; Dextropropoxyphene	N	S	Unknown		Not Reported
	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
	Ciprofloxacin Hydrochloride	N	S	Unknown		Not Reported

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

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; Sulfamethoxazole;Trimethoprim	N	S	Endocervical	Prolonged-Release Tablet	Not Reported
Isoniazid;Pyridoxine Hydrochloride;	N	S	Unknown		Not Reported

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

Sulfamethoxazole;Trimethoprim	N	S	Unknown		Not Reported
Loperamide Hydrochloride	N	S	Unknown		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
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

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

Zeaxanthin	N	S	Unknown	Not Reported
Zinc Oxide	N	S	Unknown	Not Reported
Zopiclone	N	S	Unknown	Not Reported
Acetylsalicylic Acid;Citric Acid; Sodium Bicarbonate	N	S	Unknown	Not Reported
Apo Pregabalin	N	S	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2023	19330058	EXPEDITED (15-DAY)	Y	OT	CA-TAKEDA- 2021TUS033851			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	476 (Mesalazine/Mesalamine)	N	S	Unknown	Unk			Takeda
	Pentasa	N	S	Unknown	Unk			Takeda
	Pantoprazole	N	S	Unknown	Unk			Not Reported
	Pantoprazole Sodium	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
	Amoxicillin Trihydrate	N	S	Unknown	Unk			Not Reported
	Metronidazole	N	S	Unknown	Unk			Not Reported
	Acetylsalicylic Acid	N	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	N	S	Unknown	Unk			Not Reported
	Acetaminophen	N	S	Unknown	Unk			Not Reported
	Alprazolam	N	S	Respiratory	Unk			Not Reported

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

			(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	N	S	Unknown	Unk	Not Reported

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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 Trimethoprim	N	S	Unknown	Unk	Not Reported
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

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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

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

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	Endosinusal	Unk	Not Reported

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

Fructose;Glycerol;Sodium Chloride	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride; Simeticone	N	S	Unknown	Unk	Not Reported
Kenalog	N	S	Intra-articular	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2023	21327001	EXPEDITED (15-DAY)	Y	OT	FR-AUROBINDO-AUR-APL-2022-035600		76 YR	Male	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Mouth Ulceration	Amlodipine	N	S	Oral		5 Milligram, Once A Day		Aurobindo	
	Atorvastatin	N	S	Oral		40 Milligram, Once A Day (Once In The Evening)		Not Reported	
	Bisoprolol Film-Coated Tablets	N	S	Oral		5 Milligram, Once A Day		Aurobindo	
	Clopidogrel	N	S	Oral		75 Milligram, Once A Day		Aurobindo	
	Furosemide	N	S	Oral		40 Milligram, Once A Day		Eugia Pharma	
	Paracetamol Tablet	N	S	Oral		1 Dosage Form, As Necessary		Aurobindo	
	Venlafaxine	N	S	Oral		75 Milligram, Once A Day (Once In The Morning)		Aurobindo	
	Amlor	N	S	Oral		5 Milligram, Once A Day (Once In The Morning)		Not Reported	
	Bronchodual	N	S			1 Dosage Form, Once A Day		Not Reported	
	Glycerin\Mineral Oil\Petrolatum	N	S	Unknown		One Daily Application On The Whole Body, 2 Tubes Weekly		Not Reported	
	Diffu K	N	S	Oral		1800 Milligram, Once A Day		Not Reported	
	Hydrocortisone	N	S	Oral		20 Milligram, Once A Day		Not Reported	
	Istodax	N	S	Intravenous (not otherwise specified)		53.1 Milligram 1 Month		Not Reported	
	Lasilix	N	S	Oral		40 Milligram, Once A Day (One Tablet In The		Not Reported	

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Levothyrox	N	S	Oral	Morning) 1 Dosage Form, Once A Day	Not Reported
Januvia	N	S	Oral	1000 Milligram, Once A Day	Not Reported
Januvia	N	S	Oral	100 Milligram, Once A Day (Once In The Morning)	Not Reported
Optive	N	S	Unknown	Lubricating And Osmoprotective Ocular Solution 1-2 Drops Per Day Depending On Discomfort	Not Reported
Oracilline	N	S	Oral	2 Dosage Form, Once A Day	Not Reported
Vitamine B12	N	S	Oral	2 Dosage Form, Every Week	Not Reported
Zymad	N	S	Oral	1 Dosage Form (Every Month)	Not Reported
Clarelux	N	C	Unknown	2 Tubes Weekly: One Weekly Application On The Whole Body, Space Out Applications For Few Days, Even	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2023	21907338	EXPEDITED (15-DAY)	Y	OT	CA-ORGANON-O2301CAN001944			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Zocor	N	S	Unknown	Unk			Organon
	Invanz	N	S	Unknown	Unk			Not Reported
	Acetaminophene	N	S	Unknown	Unk			Not Reported
	Adalimumab	N	S	Subcutaneous	Unk, Solution Subcutaneous			Not Reported
	Alprazolam	N	S	Unknown	Unk			Not Reported

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

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

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

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

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

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	Endosinusal	Unk, Nasal Solution	Not Reported
Sinus Rinse	N	S	Endosinusal	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	Endosinusal	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
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Calcium	N	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
25-Jan-2023	21911968	NON-EXPEDITED	N		US-ALLERGAN-2230989US			Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenopia; Burning	Botox Cosmetic		N	S		Unk Unk, Single	1 DAY	Allergan	
Sensation; Dry Eye;	Botox Cosmetic		N	S		Unk Unk, Single	1 DAY	Allergan	
Dysarthria; Dysphagia;	Botox Cosmetic		N	S		Unk Unk, Single	1 DAY	Allergan	
Eye Disorder; Facial	Botox Cosmetic		N	S		1.5 Units, Single	1 DAY	Allergan	
Paresis; Headache; Jaw	Botox Cosmetic		N	S		2 Units, Single	1 DAY	Allergan	
Clicking; Jaw Disorder;	Botox Cosmetic		N	S				Allergan	
Malocclusion; Muscle	Refresh Tears		N	S	Ophthalmic	Unk		Allergan	
Atrophy; Off Label Use;									
Pruritus; Tongue Disorder;									
Vision Blurred; Visual									
Impairment									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2023	21928058	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2302183US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataract	Refresh Tears		Y	S	Ophthalmic	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2023	21928067	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2213826US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blepharitis; Cataract;	Refresh Tears		Y	S		Unk		Allergan	
Epiretinal Membrane;									
Lacrimation Increased									
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
30-Jan-2023	21928088	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2302237US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataract	Refresh Tears		Y	S				Not Reported	

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2023	21931693	EXPEDITED (15-DAY)	Y	OT	CA-JNJFOC-20230153559			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Budesonide		N	S	Unknown			Not Reported
	Nicoderm		N	S	Unknown			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
	Loperamide/Simethicone		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
	Atorvastatin Calcium		N	S	Unknown			Not Reported
	Atropine		N	S	Unknown			Not Reported
	Atropine		N	S	Oral			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

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

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
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
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
Glycerine	N	S	Oral	Not Reported
Gramicidin	N	S	Unknown	Not Reported
Gramicidin;Neomycin Sulfate; 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

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

Mupirocin Calcium Hydrate	N	S	Topical	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
Pulmicort	N	S	Unknown	Not Reported
Refresh Tears	N	S	Ophthalmic	Not Reported
Salinex [Macrogol;Propylene Glycol;Sodium Chloride]	N	S	Endosinusal	Not Reported
Simvastatin	N	S	Unknown	Not Reported
Sinus Rinse	N	S	Endosinusal	Not Reported
Carmellose Sodium	N	S	Unknown	Not Reported
Carmellose Sodium	N	S	Ophthalmic	Not Reported
Sodium Chloride	N	S	Endosinusal	Not Reported
Sodium Stearate	N	S	Oral	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	Not Reported
Triamcinolone	N	S	Intra-articular	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Not Reported
Trimethoprim	N	S	Unknown	Not Reported
Valsartan	N	S	Intracardiac	Not Reported
Vitamin C [Ascorbic Acid]	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
Calcium	N	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2023	21932378	EXPEDITED (15-DAY)	Y	HO, OT	CA-AstraZeneca-2023A023914		65 YR	Female	CAN

FDA Adverse Event Reporting System

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaemia;	Budesonide		N	S				Not Reported
Chronic Sinusitis; Colitis;	Acetaminophen		N	S				Not Reported
Colitis Ulcerative;	Paracetamol/Dextropropoxyphen		N	S				Not Reported
Constipation; Drug	e							
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							
Related Reaction; Macular	Align		N	S				Not Reported
Degeneration; Malaise;	Amoxicillin Trihydrate		N	S				Not Reported
Nausea; Off Label Use;	Apo-Alpraz		N	S		0.25 Milligram		Not Reported
Oral Candidiasis; Pain;	Apo-Pregabalin		N	S		150 Milligram		Not Reported
Paraesthesia Oral;								
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

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Empracet	N	S		Not Reported
Entyvio	N	S		Not Reported
Ertapenem Sodium	N	S		Not Reported
Fentanyl	N	S		Not Reported
Fentanyl Citrate	N	S		Not Reported
Fluconazole	N	S		Not Reported
Fluticasone Propionate	N	S		Not Reported
Fructose	N	S		Not Reported
Glycerin	N	S		Not Reported
Glycerol	N	S		Not Reported
Glyceryl Trinitrate	N	S		Not Reported
Neomycin/Gramicidin/Polymyxin B Sulfate	N	S		Not Reported
Habitrol	N	S		Not Reported
Humira	N	S		Not Reported
Hydrochlorothiazide	N	S		Not Reported
Hydrochlorothiazide	N	S	Subcutaneous	Not Reported
Hydrochlorothiazide	N	S		Not Reported
Hydrochlorothiazide	N	S	Endocervical	Not Reported
Hydrocortisone	N	S		Not Reported
Hydromorphone Hydrochloride	N	S	Endocervical	Not Reported
Isoniazid/Pyridoxine Hydrochloride/Sulfa	N	S		Not Reported
Methoxazole/Trimethoprim				
Loperamide Hydrochloride	N	S		Not Reported
Macrogol 3350/Sodium Chloride/Sodium Bicarbonate/Potassium Chloride	N	S		Not Reported
Magnesium	N	S		Not Reported
Magnesium Carbonate	N	S		Not Reported
Magnesium Hydroxide	N	S		Not Reported
Magnesium Oxide	N	S		Not Reported
Magnesium Sulfate	N	S		Not Reported
Mesalazine	N	S		Not Reported
Methylprednisolone Sodium Succinate	N	S		Not Reported
Metronidazole	N	S		Not Reported
Midazolam	N	S		Not Reported
Morphine Sulfate	N	S		Not Reported
Mupirocin	N	S		Not Reported
Nadolol	N	S		Not Reported

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	Nicoderm	N	S						Not Reported
	Nicotinamide	N	S						Not Reported
	Nicotine	N	S						Not Reported
	Oxybutynin Hydrochloride	N	S						Not Reported
	Pantoprazole	N	S						Not Reported
	Potassium Chloride	N	S						Not Reported
	Prednisone	N	S						Not Reported
	Refresh Tears	N	S						Not Reported
	Polyethylene Glycol\Propylene Glycol\Sodium Chloride	N	S						Not Reported
	Sinus Rinse	N	S						Not Reported
	Sodium Carboxymethyl Cellulose	N	S						Not Reported
	Sucralfate	N	S						Not Reported
	Sulfamethoxazole/Trimethoprim	N	S		200 Milligram				Not Reported
	Triamcinolone Acetonide	N	S						Not Reported
	Ubidecarenone	N	S						Not Reported
	Vitamin D3	N	S						Not Reported
	Xantofyl Palmitate	N	S						Not Reported
	Zeaxanthin	N	S						Not Reported
	Zinc Oxide	N	S						Not Reported
	Zopiclone	N	S						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Jan-2023	21932928	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2302484US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Skin Cancer	Refresh Tears		Y	S	Ophthalmic			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2023	21264873	EXPEDITED (15-DAY)	Y	HO, OT	CA-Accord-275681		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chronic Sinusitis; Drug Ineffective; Dyspepsia;	Atorvastatin		N	S	Unknown			Not Reported
Infusion Related Reaction;	Pregabalin		N	S	Unknown			Not Reported
Macular Degeneration; Malaise; Nausea; Pain;	Pantoprazole		N	S	Unknown			Not Reported

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

Paraesthesia Oral; Procedural Pain; Pyrexia; Therapeutic Product Effect Incomplete; Weight Decreased	Simvastatin	N	S			Accord
	Acetaminophen	N	S	Unknown		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

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

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 W/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
Macrogol	N	S			Not Reported
Sodium Bicarbonate	N	S			Not Reported
Zinc Oxide	N	S	Unknown		Not Reported
Loperamide	N	S	Oral		Not Reported
Acetaminophen W/Dextropropoxyphene	N	S			Not Reported
Ambroxol,Cetirizine Hydrochloride	N	S			Not Reported
Calcitriol, Calcium Carbonate, Zinc	N	S			Not Reported

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

Hydrochlorothiazide	N	S			Not Reported
Humira	N	S	Subcutaneous	Solution Subcutaneous	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	C			Not Reported
Neomycin	N	C			Not Reported
Metoclopramide Hydrochloride	N	C	Oral		Not Reported
Calcium	N	C			Not Reported
Valsartan	N	C	Oral	1 Every 1 Days	Not Reported
Calcium And Ergocalciferol	N	C	Unknown		Not Reported
Amoxicillin	N	C			Not Reported
Calcium Gluconate	N	C			Not Reported
Calcium W/Colecalciferol	N	C			Not Reported
Diphenhydramine Hydrochloride	N	C			Not Reported
Mupirocin Calcium	N	C			Not Reported
Sodium	N	C			Not Reported
Benadryl	N	C			Not Reported
Atropine W/Diphenoxylate	N	S			Not Reported
Betamethasone	N	S	Unknown		Not Reported
Diphenhydramine Hydrochloride	N	S	Oral		Not Reported
Hydromorphone Hydrochloride	N	S			Not Reported
Sulfamethoxazole	N	S	Unknown		Not Reported
W/Trimethoprim					
Sulfamethoxazole	N	S	Oral		Not Reported
W/Trimethoprim					

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

Fluticasone	N	S	Unknown	Not Reported
Atropine Sulfate	N	S	Oral	Not Reported
Atropine Sulfate	N	S	Oral	Not Reported
Atropine Sulfate	N	S		Not Reported
Valsartan	N	C	Oral	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
01-Feb-2023	21886070	EXPEDITED (15-DAY)	N	OT	CA-PFIZER INC- 202101824569			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Alprazolam	N	S		Unknown	Unk		Not Reported
	Atorvastatin	N	S		Unknown	Unk		Not Reported
	Pregabalin Mylan	N	S		Unknown	Unk		Mylan
	Sertraline Hcl	N	S		Unknown	25 Milligram, Qd		Mylan
	Amlodipine Besilate	N	S		Unknown	5 Milligram, Qd		Mylan
	Pantoprazole	N	S		Unknown	40 Milligram, Qd		Not Reported
	Pantoprazole	N	S		Unknown	Unk		Not Reported
	Amoxicillin Trihydrate	N	S		Unknown	Unk		Not Reported
	Azithromycin	N	S		Unknown	Unk		Not Reported
	Atropine Sulfate	N	S		Oral	Unk		Not Reported
	Hydromorphone Hydrochloride	N	S		Unknown	Unk		Not Reported
	Morphine Sulfate	N	S		Unknown	Unk		Not Reported
	Sodium Bicarbonate	N	S		Unknown	Unk		Not Reported
	Sodium Chloride	N	S		Unknown	Unk		Not Reported
	Potassium Chloride	N	S		Unknown	Unk		Not Reported
	Atropine Sulfate, Diphenoxylate Hcl	N	S		Oral	Unk		Not Reported
	Bisoprolol Fumarate	N	S		Unknown	5 Milligram, Qd		Not Reported
	Triamcinolone Acetonide	N	S		Intra-articular	Unk		Not Reported
	Adalimumab	N	S		Subcutaneous	Unk		Not Reported

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

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	N	S	Unknown	Unk	Not Reported
Clotrimazole	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
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	N	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	N	S	Topical	Unk	Not Reported

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

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;	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	Unk	Not Reported
Amoxicillin	N	S	Unknown	Unk	Not Reported
Mupirocin Calcium	N	S	Unknown	Unk	Not Reported

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

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 XL	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
Trimethoprim	N	S	Unknown	Unk	Not Reported
Ergocalciferol	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported

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

Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate Glycerol	N	S	Unknown	Unk	Not Reported
Sodium Stearate	N	S	Unknown	Unk	Not Reported
Dilaudid	N	S	Unknown	Unk	Not Reported
Bactrim	N	S	Unknown	Unk	Not Reported
Ambroxol	N	S	Unknown	Unk	Not Reported
Diphenoxylate Hydrochloride	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Macrogol 3350;Potassium Chloride;Sodium Bicarbonate; Sodium Chloride Magnesium Sulphate	N	S	Unknown	Unk	Not Reported
Zinc Chloride	N	S	Unknown	Unk	Not Reported
Vitamin E	N	S	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D3	N	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2023	19362106	EXPEDITED (15-DAY)	Y	OT	CA-PFIZER INC- 2021619805			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Pantoprazole	N	S	Unknown	Unk			Unknown
	Pantoprazole	N	S	Unknown	Unk			Unknown
	Alprazolam	N	S	Respiratory (inhalation)	Unk			Pfizer
	Alprazolam	N	S	Unknown	Unk			Pfizer
	Azithromycin	N	S	Unknown	Unk			Pfizer
	Lomotil	N	S	Oral	Unk			Pfizer
	Hydromorphone Hydrochloride	N	S	Unknown	Unk, 1/Week			Pfizer
	Magnesium Sulfate	N	S	Unknown	Unk			Pfizer
	Metronidazole	N	S	Unknown	Unk			Pfizer

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

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 Hydrochloride	N	S	Oral	Unk	Pfizer
Atropine Sulfate/Diphenoxylate Hydrochloride	N	S	Unknown	Unk	Pfizer
Atropine Sulfate	N	S	Unknown	Unk	Pfizer
Calcium Carbonate	N	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	N	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

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

Chloride;Sodium Ascorb						
Acetaminophen	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
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 And Atropine Sulfate	N	S	Oral	Unk		Not Reported
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

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

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 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 [Cholecalciferol]	N	S	Unknown	Unk	Not Reported

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

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	N	S	Unknown	Unk	Not Reported
Chloride/Sodium Sulfate					
Glycerol/Sodium Stearate	N	S	Oral	Unk	Not Reported
Ambroxol/Cetirizine	N	S	Unknown	Unk	Not Reported
Hydrochloride					
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

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

[Calcium Carbonate; Colecalciferol]						
Ambroxol Hydrochloride	N	S	Unknown	Unk		Not Reported
Diphenoxylate Hydrochloride	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
Sodium Stearate	N	S	Oral	Unk		Not Reported
Trimethoprim	N	S	Unknown	Unk		Not Reported
Zinc Chloride	N	S	Unknown	Unk		Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk		Not Reported
Difenoxin Hydrochloride	N	S	Unknown	Unk		Not Reported
Vitamin A [Retinol]	N	S	Unknown	Unk		Not Reported
Loperamide Hydrochloride	N	S	Unknown	Unk		Not Reported
Vitamin C [Ascorbic Acid]	N	S	Unknown	Unk		Not Reported
Simvastatin	N	S	Unknown	Unk		Not Reported
Salinex [Sodium Chloride]	N	S	Endosinusal	Unk		Not Reported
Fructose/Glycerol/Sodium Chloride	N	S	Unknown	Unk		Not Reported
Loperamide Hydrochloride/Simeticone	N	S	Unknown	Unk		Not Reported
Kenalog [Triamcinolone Acetonide]	N	S	Intra-articular	Unk		Not Reported
Fructose	N	S				Not Reported
Simeticone	N	S				Not Reported
Loperamide	N	S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2023	21945525	EXPEDITED (15-DAY)	Y	OT	CA-AstraZeneca- 2023A026478			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Budesonide Pulmicort		N N	S S		Unknown		Not Reported Astrazeneca

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

Entocort	N	S		Not Reported
Nicoderm	N	S	Unknown	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

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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 Glycerine	N	S	Unknown	Not Reported
Gramicidin	N	S	Oral	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

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Salinex [Macrogol;Propylene Glycol;Sodium Chloride]	N	S	Endosinusal	Not Reported
Simvastatin	N	S	Unknown	Not Reported
Sinus Rinse	N	S	Endosinusal	Not Reported
Carmellose Sodium	N	S	Unknown	Not Reported
Carmellose Sodium	N	S	Ophthalmic	Not Reported
Sodium Chloride	N	S	Endosinusal	Not Reported
Sodium Stearate	N	S	Oral	Not Reported
Sulfamethoxazole/Trimethoprim	N	S	Unknown	Not Reported
Triamcinolone	N	S	Intra-articular	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Not Reported
Trimethoprim	N	S	Unknown	Not Reported
Valsartan	N	S	Intracardiac	Not Reported
Vitamin C [Ascorbic Acid]	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
Calcium	N	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
02-Feb-2023	21946648	DIRECT		DS, RI			67 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erythema Of Eyelid; Eyelids Pruritus; Swelling Of Eyelid; Therapy Non-Responder	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Frequency : Every 12 Hours;		Ezricare

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2023	21950639	DIRECT		RI			76 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Infection; Nausea; Recalled Product Administered	Refresh Liquigel		Y	S				Unknown	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2023	21950640	DIRECT		DS, RI			66 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctivitis; Instillation Site Reaction; Recalled Product Administered	Carboxymethylcellulose Sodium		Y	S	Ophthalmic	Other Quantity : 2 Drop(S); Frequency : As Needed;		Delsam Pharm	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2023	21951661	DIRECT	N	OT			46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blindness; Eye Irritation; Eye Pruritus; Foreign Body Sensation In Eyes; Ocular Hyperaemia; Periorbital Swelling; Therapy Cessation; Visual Impairment	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S				Ezricare	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2023	21951668	DIRECT		OT			57 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bladder Pain; Erythema Of Eyelid; Micturition Urgency; Photophobia; Pollakiuria; Recalled Product Administered; Renal Disorder; Renal Pain; Swelling Of Eyelid;	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Other Quantity : 1 Drop(S);6 WEEK Frequency : Every 6 Hours;		Ezricare	

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Urinary Tract Infection

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2023	21956998	DIRECT		DS			53 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Anxiety; Drug Ineffective; Eye Discharge; Eyelid Margin Crusting; Headache; Lacrimation Increased; Memory Impairment; Nervousness; Ocular Hyperaemia; Visual Impairment	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium) Lumify Systane Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Frequency : Every 4 Hours;		Ezricare	
				S				Not Reported	
				S				Not Reported	
				S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2023	21957012	DIRECT		OT			67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blepharitis; Conjunctival Haemorrhage; Hypertension; Keratitis	Carboxymethylcellulose Sodium Lisinopril Areds		Y	S	Ophthalmic	Frequency : As Needed;		Delsam Pharm	
			N	C				Not Reported	
			N	C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2023	21957079	DIRECT		DS, OT			46 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Arthralgia; Chest Pain; Chills; Cough; Dyspnoea; Ear Pain; Ear Pruritus; Eye Pain; Eye Pruritus; Fatigue; Headache; Loss Of Personal Independence In Daily Activities; Malaise; Nausea; Pelvic Pain; Pyrexia; Viral Infection;	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	2 Drop(S) As Needed		Global Pharmaceuticals	

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Vision Blurred

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2023	21957980	DIRECT	N					Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		N	S					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Feb-2023	21958512	DIRECT	N	OT			57 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blindness; Corneal Transplant; Endophthalmitis; Ulcerative Keratitis	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S					Ezricare

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2023	21961577	DIRECT		OT			54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctivitis; Eye Infection; Eye Pain; Feeling Abnormal; Product Contamination; Recalled Product Administered	Carboxymethylcellulose Sodium	N		S					Not Reported
	Adderall	N		C					Not Reported
	Duloxetine	N		C					Not Reported
	Vitamin And Mineral Supplements	N		C					Not Reported
	Vitamin B1	N		C					Not Reported
	Nettle Tea	N		C					Not Reported
	Black Walnut And Wormwood Extract	N		C					Not Reported
	Nac	N		C					Not Reported
	Amino Acids	N		C					Not Reported
	R-Alpha Lipoic Acid	N		C					Not Reported
	Berberine	N		C					Not Reported
	Krill Oil	N		C					Not Reported

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		Dim	N	C					Not Reported
		7-Keto	N	C					Not Reported
		Adrenal Glandular & Adaptogens	N	C					Not Reported
		Ptobiotics	N	C					Not Reported
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2023	21961754	DIRECT		RI			63 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Adverse Event; Recalled Product Administered	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Frequency : As Needed;		Ezricare	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2023	21961780	DIRECT		RI			24 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Infection	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Other Quantity : 2 Drop(S); Frequency : As Needed;		Ezricare	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2023	21961796	DIRECT					63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eyelid Margin Crusting; Vision Blurred	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Other Quantity : 2 Drop(S);2 MTH Other Frequency : As Needed;		Ezricare	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Feb-2023	21961797	DIRECT		HO			58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Pneumonia; Recalled	Artificial Tears Lubricant Eye		Y	S	Ophthalmic			Ezricare	

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Product Administered	Drops (Carboxymethylcellulose Sodium)								
	Prozac	N	C						Not Reported
	Albuterol	N	C						Not Reported
	Zetia	N	C						Not Reported
	Cetirizine	N	C						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2023	21962804	DIRECT		OT			50 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Instillation Site Burn; Product Contamination; Recalled Product; Vision Blurred	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Frequency : At Bedtime;	90 DAY	Not Reported
	Armor Throid		N	C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Feb-2023	21962923	DIRECT		OT			51 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Discharge; Eye Irritation; Eye Irritation; Visual Impairment	Carboxymethylcellulose Sodium		Y	S	Ophthalmic	Other Quantity : 1 Drop(S);10 DAY Frequency : As Needed;		Delsam Pharm

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2023	21449961	EXPEDITED (15-DAY)	Y	OT	FR-MYLANLABS-2022M1113538		76 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mouth Ulceration	Atorvastatin		N	S	Oral	40 Milligram, Qd, Once In The Evening		Not Reported
	Bisoprolol		N	S	Oral	5 Milligram, Qd, One Tablet In The Morning		Not Reported
	Paracetamol		N	S	Oral	1 Df, As Necessary (1 G, One Tablet Every 8 H)		Not Reported
	Venlafaxine		N	S	Oral	75 Milligram, Qd, Once In		Not Reported

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Amlodipine	N	S	Oral	The Morning 5 Milligram, Qd, Once In The Morning	Not Reported
Clopidogrel Bisulfate	N	S	Oral	75 Milligram, Qd, Once In The Morning	Not Reported
Lasilix	N	S	Oral	40 Milligram, Qd, One Tablet In The Morning	Not Reported
Levothyrox	N	S	Oral	1 Dosage Form, Qd, Once In The Morning	Not Reported
Istodax	N	S	Intravenous (not otherwise specified)	53.1 Milligram, Monthly	Not Reported
Bronchodual	N	S		1 Dosage Form, Qd, 50 Microg / 20 Microg Per Dose	Not Reported
Hydrocortisone	N	S	Oral	20 Milligram, Qd, Two In The Morning	Not Reported
Januvia	N	S	Oral	100 Milligram, Qd, Once In The Morning	Not Reported
Oracilline	N	S	Oral	2 Dosage Form, Qd, 1 000 000 U.I./10 MI	Not Reported
Diffu K	N	S	Oral	1800 Mg, Qd, Two In The Morning, One At Midday	Not Reported
Vitamine B12	N	S	Oral	2 Df Qw, Two Ampoules Weekly, 1000 Microg / 2 MI	Not Reported
Optive	N	S	Unknown	1-2 Drops Per Day Depending On Discomfort	Not Reported
Glycerin\Mineral Oil\Petrolatum	N	S	Unknown	One Daily Application On The Whole Body	Not Reported
Clarelux	N	C	Unknown	2 Tubes Weekly: One Weekly Application	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2023	21956498	EXPEDITED (15-DAY)	Y	HO, OT	CA-Accord-298352		65 YR	Female	CAN

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Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
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	N		S				Not Reported
Nausea; Oral Candidiasis;	Acetoni							
Pain; Paraesthesia Oral;	Acetylsalicylic Acid	N		S				Not Reported
Procedural Pain; Proctitis;	Acetylsalicylic Acid, Sodium	N		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	N		S		Route: Inhalation		Not Reported
	Calcitriol, Calcium Carbonate,	N		S				Not Reported
	Zinc							
	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

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

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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	N	S			Not Reported
Sucralfate	N	S			Not Reported
Sulfamethoxazole	N	S			Not Reported
W/Trimethoprim					
Triamcinolone Acetonide	N	S			Not Reported
Ubidecarenone	N	S			Not Reported
Vitamin D3	N	S			Not Reported
Xantofyl Palmitate	N	S	Oral		Not Reported
Zeaxanthin	N	S	Oral		Not Reported
Zinc Oxide	N	S			Not Reported
Zopiclone	N	S			Not Reported
Pregabalin	N	S			Not Reported
Cortenema	N	S		Suspension	Not Reported
Empracet	N	S			Not Reported
Fructose	N	S			Not Reported
Nadolol	N	S			Not Reported
Metronidazole	N	S			Not Reported
Hydrochlorothiazide	N	S			Not Reported
Loperamide	N	S			Not Reported
Loperamide	N	S	Oral	4 Every 1 Days	Not Reported
Loperamide	N	S	Oral	1 Every 1 Days	Not Reported
Loperamide	N	S	Oral	1 Every 1 Days	Not Reported
Alprazolam	N	S			Not Reported
Atropine Sulfate	N	S	Oral		Not Reported
W/Diphenoxylate Hy					
Atropine Sulfate	N	S	Oral	1 Every 1 Days	Not Reported
W/Diphenoxylate Hy					
Atropine Sulfate	N	S	Oral		Not Reported
W/Diphenoxylate Hy					
Budesonide	N	S	Oral		Not Reported
Clarithromycin	N	S			Not Reported
Diphenhydramine	N	S	Oral		Not Reported
Ertapenem	N	S	Intramuscular		Not Reported

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Glycerin	N	S	Oral		Not Reported
Azithromycin	N	S			Not Reported
Biaxin XI	N	S		Tablet (Extended-Release)	Not Reported
Mesalazine	N	S			Not Reported
Metronidazole	N	S			Not Reported
Morphine Sulfate	N	S			Not Reported
Refresh Tears	N	S		Eye Drops	Not Reported
Magnesium	N	S			Not Reported
Magnesium	N	S			Not Reported
Magnesium	N	S			Not Reported
Magnesium	N	S			Not Reported
Triamcinolone Acetonide	N	S	Intra-articular		Not Reported
Triamcinolone Acetonide	N	S		Suspension Intra- Articular	Not Reported
Pregabalin	N	S			Not Reported
Magnesium	N	S		50 %, Liquid Intramuscular	Not Reported
Budesonide	N	S			Not Reported
Pantoprazole	N	S			Not Reported
Sulfamethoxazole	N	S			Not Reported
W/Trimethoprim					
Zinc Oxide	N	S			Not Reported
Nicoderm	N	S			Not Reported
Triamcinolone Acetonide	N	S			Not Reported
Hydromorphone Hydrochloride	N	S			Not Reported
Hydromorphone Hydrochloride	N	S		Endocervical	Not Reported
Humira	N	S	Subcutaneous		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2023	21959582	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2302972US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Coeliac Disease; Spinal Cord Injury; Stress	Refresh Optive Advanced Preservative-Free		Y	S		Unk		Allergan	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2023	21966956	DIRECT		RI			36 YR	Female	USA

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blindness; Condition Aggravated; Eye Disorder	Refresh Tears		N	S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2023	21966958	DIRECT		DS, RI, OT			26 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Discharge; Eye Infection Bacterial; Ocular Hyperaemia; Periorbital Swelling; Product Contamination Microbial; Product Quality Issue; Product Quality Issue; Respiratory Tract Congestion; Respiratory Tract Infection; Sinusitis; Skin Discolouration; Suspected Product Tampering	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Frequency : As Needed;		Ezricare	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2023	21966968	DIRECT		OT			43 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Eyelid Function Disorder; Ocular Hyperaemia	Carboxymethylcellulose Sodium		Y	S				Delsam Pharm	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2023	21967394	DIRECT					63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Dermatitis Contact; Documented	Refresh Tears		N	S			3 YR	Allergan	

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

Hypersensitivity To Administered Product;	Refresh Optive Gel Drops	N	S		Not Reported
Drug Ineffective; Eye Infection; Insomnia;	Protonix	N	C		Not Reported
Reading Disorder; Sinusitis	Pepcid	N	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Feb-2023	21969485	DIRECT		OT			51 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Irritation	Carboxymethylcellulose Sodium	Y	S					Delsam Pharm

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2023	21968555	DIRECT		RI, OT			54 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Disorder; Visual Impairment	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)	Y	S		Ophthalmic	Frequency : Twice A Day;		Ezricare

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2023	21968556	DIRECT		RI, OT			42 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dry Skin; Eye Infection Bacterial; Recalled Product Administered	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)	Y	S		Ophthalmic	Frequency : Twice A Day;	4 MTH	Ezricare

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Feb-2023	21968575	DIRECT					66 YR	Female	USA

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

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Hyperaemia	Pravastatin	N	C						Not Reported
	L-Thyroxine	N	C						Not Reported
	One A Day Vitamin	N	C						Not Reported
	Calcium Supplement	N	C						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2023	21937837	EXPEDITED (15-DAY)	N	DS, HO, OT	US-ALLERGAN-2302217US			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Atrial Fibrillation;	Refresh Plus		Y	S	Ophthalmic	Unk, Qd		Not Reported
Blindness Unilateral;	Eliquis		N	C		Unk		Not Reported
Cardiac Ablation; Choroid								
Melanoma; Heart Rate								
Increased; Macular								
Degeneration; Poor								
Quality Product								
Administered; Product								
Quality Issue; Visual								
Impairment								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2023	21968756	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2127468US			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dry Eye; Eyelid Operation;	Refresh Celluvisc Solution		Y	S		Unk		Allergan
Eyelid Ptosis; Poor Quality								
Product Administered								

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2023	21968785	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2303292US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cataract; Dry Eye; Dry	Refresh Relieva		Y	S	Ophthalmic	1-3 Drops In Each Eye At		Not Reported
Eye; Eye Discharge; Eye						Day Time		
Disorder; Eye Infection;	Refresh Tears		N	S	Ophthalmic	1-2 Drops In Each Eye,		Not Reported
Eye Pain; Eye Pain;						Night Time Only		
Foreign Body Sensation In								

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Eyes; Foreign Body Sensation In Eyes	Unspecified Ingredient	N	S	Unk	Not Reported
	Unspecified Ingredient	N	S	Unk	Not Reported
	Atenolol	N	C	Unk	Not Reported
	Gabapentin	N	C	Unk	Not Reported
	Buspirone	N	C	Unk	Not Reported
	Aspirin [Acetylsalicylic Acid]	N	C	Unk	Not Reported
	Ibuprofen	N	C	Unk Unk, Prn	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2023	21972567	DIRECT		OT			43 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Vision Blurred	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)	N	S		Endocervical	Frequency : Twice A Day;		Not Reported	
	Atorvastatin	N	C					Not Reported	
	Multivitamin	N	C					Not Reported	
	Calcium	N	C					Not Reported	
	Vitamin D	N	C					Not Reported	
	Vitamin B12	N	C					Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2023	21974001	DIRECT					54 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Infection; Eye Irritation; Product Quality Issue; Visual Impairment	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)	Y	S		Ophthalmic		30 DAY	Ezricare	
	Crestor	N	C					Not Reported	
	One-A-Day Men'S Vitamin	N	C					Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2023	21974004	DIRECT		OT			65 YR	Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Pain; Periorbital Swelling; Product Quality Issue; Vision Blurred; Visual Impairment	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Other Quantity : 2 Drop(S); Frequency : Twice A Day;		Ezricare	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2023	21974006	DIRECT		DS, RI			39 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blindness; Impaired Driving Ability; Impaired Work Ability; Middle Insomnia; Ocular Hyperaemia; Periorbital Pain; Vision Blurred	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S			60 DAY	Unknown Manufacturer	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2023	21974228	DIRECT		OT			80 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Central Vision Loss; Erythema Of Eyelid; Eye Pruritus; Lacrimation Increased; Ocular Hyperaemia; Therapy Cessation; Vision Blurred	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Frequency : As Needed;		Ezricare	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2023	21974229	DIRECT		DS, RI, OT			32 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Bacterial Infection; Conjunctivitis; Corneal Disorder; Eye Infection Bacterial; Eye	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Frequency : Every 4 Hours;		Ezricare	

FDA Adverse Event Reporting System

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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	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Conjunctivitis	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium) Zyrtec		Y	S				Ezricare	
			N	C				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2023	21974388	DIRECT		OT			64 YR	Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Eye Irritation; Instillation Site Foreign Body Sensation	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium) Latanoprost Saw Palmetto		Y	S	Ophthalmic	Other Quantity : 1 Drop(S); Frequency : As Needed;		Ezricare	
				C				Not Reported	
				C				Not Reported	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2023	21974415	DIRECT		OT				Male	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	
Eye Pruritus; Recalled Product Administered; Vision Blurred	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Frequency : As Needed;		Ezricare	
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
08-Feb-2023	21974424	DIRECT		DS			58 YR	Female	USA
Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr	

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

Eye Pruritus; Product Contamination; Recalled Product Administered; Vision Blurred; Visual Impairment	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)	Y	S	Ophthalmic	Frequency : As Needed;	Global Pharmaceuticals
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2023	21974425	DIRECT		OT			76 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Hordeolum; Recalled Product Administered	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Frequency : As Needed;		Ezricare	
	Gemfibrozil		N	C				Not Reported	
	Losartan Hctz		N	C				Not Reported	
	Pantoprazole		N	C				Not Reported	
	Atrovastatin		N	C				Not Reported	
	Meloxicam		N	C				Not Reported	
	Propranolol		N	C				Not Reported	
	Co Q 10		N	C				Not Reported	
	Refresh Eye Drops For Contacts		N	C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2023	21974454	DIRECT		DS				Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Infection; Recalled Product Administered	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S				Not Reported	
	Multivitamin			C				Not Reported	
	Fish Oil			C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2023	21974629	DIRECT					54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Eye Pruritus; Thermal Burns Of Eye; Vision Blurred	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)	Y	S	Ophthalmic				Ezricare	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2023	21974673	DIRECT	Y	DS, HO, LT, RI			83 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cellulitis Orbital; Corneal Perforation; Endophthalmitis; Open Globe Injury; Pseudomonas Test Positive	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)	Y	S	Ophthalmic				Ezricare	
	Lumigan Eye Drops	N	C					Not Reported	
	Prednisolone Eye Drops	N	C					Not Reported	
	Combigan Eye Drops	N	C					Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2023	21974681	DIRECT		RI			49 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Infection	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)	Y	S	Ophthalmic		Frequency : As Needed;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
08-Feb-2023	21974685	DIRECT		DS			45 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctivitis; Dry Eye; Eye Discharge; Eye Pain; Illness; Liquid Product Physical Issue; Recalled Product Administered; Vision Blurred	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)	Y	S	Ophthalmic		Other Quantity : 30 Drop (S); Frequency : As Needed;		Ezricare	
	Armour Thyroid		C					Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2023	20725230	EXPEDITED (15-DAY)	N	HO, OT	NVSC2022CA089948		71 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Anaemia;	Adalimumab		N	S	Subcutaneous	Unk		Novartis
Chronic Sinusitis; Colitis;	Pregabalin		N	S	Unknown	150 Mg		Not Reported
Colitis Ulcerative;	Pregabalin		N	S	Unknown	Unk		Not Reported
Constipation; Drug	Infliximab		N	S	Intravenous (not	Unk		Not Reported
Ineffective; Dyspepsia;					otherwise specified)			
Erythema; Female Genital								
Tract Fistula; Frequent								
Bowel Movements;	Methotrexate		N	S	Unknown	Unk		Novartis
Haematochezia;	Pantoprazole		N	S	Unknown	Unk		Novartis
Headache; Infusion	Triamcinolone Acetonide		N	S	Intra-articular	Unk		Novartis
Related Reaction; Macular	Triamcinolone Acetonide		N	S	Unknown	Unk		Novartis
Degeneration; Malaise;	Amoxicillin		N	S	Unknown	Unk		Novartis
Nausea; Off Label Use;	Sodium Bicarbonate		N	S	Unknown	Unk		Not Reported
Oral Candidiasis; Pain;	Atorvastatin Calcium		N	S	Unknown	Unk		Novartis
Paraesthesia Oral;	Atorvastatin Calcium		N	S	Unknown	Formulation: Hard		Novartis
Procedural Pain; Proctitis;						Capsule, Unk		
Pyrexia; Radiculopathy;								
Rectal Haemorrhage;								
Therapeutic Product Effect								
Incomplete; Vaginal	Fentanyl		N	S	Intravenous (not	Unk		Not Reported
Discharge; Vaginal					otherwise specified)			
Flatulence; Weight	Fentanyl		N	S	Intravenous (not	Unk		Not Reported
Decreased					otherwise specified)			
	Magnesium Sulfate		N	S	Intramuscular	Unk		Not Reported
	Ciprofloxacin Hydrochloride		N	S	Intravenous (not	Unk		Novartis
					otherwise specified)			
	Ciprofloxacin Hydrochloride		N	S	Unknown	Unk		Novartis
	Hydromorphone Hydrochloride		N	S	Unknown	Unk		Not Reported
	Hydromorphone Hydrochloride		N	S	Endocervical	Unk		Not Reported
	Calcium Carbonate		N	S	Unknown	Unk		Not Reported
	Calcium Carbonate		N	S	Unknown	Unk		Not Reported

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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 Trimethoprim	N	S	Unknown	200 Mg	Not Reported
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

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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
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
Inflectra	N	S	Intravenous (not otherwise specified)	10 Mg/Kg, Every 6 Weeks	Not Reported
Inflectra	N	S	Intravenous (not otherwise specified)	10 Mg/Kg, Every 6 Weeks 132 DAY	Not Reported
Bifidobacterium Infantis	N	S	Unknown	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk 7 DAY	Not Reported
Zopiclone	N	S	Unknown	Unk	Not Reported
Zopiclone	N	S	Unknown	Unk	Not Reported
Alprazolam	N	S	Unknown	0.25 Mg	Not Reported
Alprazolam	N	S		Unk	Not Reported
Apo Hydromorphone	N	S	Endocervical	Unk	Not Reported
Sodium Chloride	N	S	Nasal	Unk, (Formulation: Pellet)	Not Reported
Sodium Chloride	N	S	Nasal	Unk	Not Reported
Sodium Chloride	N	S		Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Avamys	N	S	Unknown	Unk(Spray Metered Dose)	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Glycerine	N	S	Unknown	Unk	Not Reported
Acetaminophen	N	S	Unknown	Unk	Not Reported

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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	N	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

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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

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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

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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

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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

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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

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Benzydamine	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Betamethasone Sodium Phosphate	N	S	Unknown	Unk	Not Reported
Betamethasone	N	S	Topical	Unk	Not Reported
Bromhexine Hydrochloride/Sulfa Methoxazole/Trimethoprim	N	S	Unknown	Unk	Not Reported
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 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 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	C	Unknown	Unk	Not Reported
Metoclopramide Hydrochloride	N	C	Oral	Unk	Not Reported
Maxeron	N	C	Unknown	Unk	Not Reported
Benadryl Allergy	N	C	Unknown	Unk	Not Reported
Calcium And Ergocalciferol	N	C	Unknown	Unk	Not Reported
Sodium Stearate	N	C	Unknown	Unk	Not Reported
Benadryl	N	C	Unknown	Unk	Not Reported

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Vitamin D Nos	N	C	Unknown	Unk	Not Reported
Valsartan	N	C	Oral	40 Mg, Qd	Not Reported
Valsartan	N	C	Oral	4 Dosage Form, Qd	Not Reported
Valsartan	N	C	Intracardiac	Unk	Not Reported
Loperamide	N	C	Oral	4 Dosage Form, Qd	Not Reported
Loperamide	N	C	Oral	1 Dosage Form, Q6h	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk	Novartis

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2023	21322996	EXPEDITED (15-DAY)	Y	OT	FR-US-Provell Pharmaceuticals LLC- E2B_90088984		76 YR	Male	FRA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Mouth Ulceration	Levothyrox		N	S	Oral	Once In Morning		Not Reported
	Bisoprolol		N	S	Oral	One Tablet In The Morning		Not Reported
	Vitamine 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
	Venlafaxine		N	S	Oral	Once In The Morning		Not Reported
	Amlodipine		N	S	Oral	Once In The Morning		Not Reported
	Hydrocortisone		N	S	Oral	Two In The Morning		Not Reported
	Oracilline [Phenoxymethylpenicillin]		N	S	Oral	1 000 000 U.I./10 MI, Suspension Buvable		Not Reported
	Lasilix [Furosemide]		N	S	Oral	One Tablet In The Morning		Not Reported
	Atorvastatin		N	S	Oral	Once In The Evening		Not Reported
	Paracetamol		N	S	Oral	(1 G, One Tablet Every 8 H)		Not Reported
Bronchodual		N	S	Respiratory (inhalation)	100 Micrograms /40 Micrograms; 50 Micrograms /20 Micrograms Dose Two		Not Reported	

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Januvia	N	S	Oral	Puffs In Morning And Evening	Not Reported
Istodax	N	S	Intravenous (not otherwise specified)	Once In The Morning	Not Reported
Zymad	N	S	Oral	50000 Ui; 50000 International Unit Oral Drinkable Solution In Ampoule	Not Reported
Clopidogrel Bisulfate	N	S	Oral	Once In The Morning	Not Reported
Optive	N	S	Unknown	Solution Lubricating And Osmoprotective Ocular Solution; 1-2 Drops Per Day Depending On Discomfort	Not Reported
Dexeryl [Glycerol;Paraffin, Liquid;White Soft Paraffin]	N	S		Application On The Whole Body, 2 Tubes Weekly Via Unknown Route	Not Reported
Clarelux	N	C			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2023	21974458	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2302977US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Retinal Oedema; Retinal Tear	Refresh Optive Mega-3		Y	S		Unk		Allergan
	Refresh Optive		N	S		Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2023	21974491	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2303342US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cataract	Refresh Plus		Y	S				Allergan

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2023	21977324	DIRECT					68 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Drug Ineffective; Endophthalmitis	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Other Quantity : 1 Or 2 Drops ; Frequency : As Needed;	2 DAY	Ezricare	
	Metoprolol			C				Not Reported	
	Restasis Eye Drops			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2023	21978271	DIRECT	N	DS, RI, OT			63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Condition Aggravated; Crying; Eye Infection; Lung Disorder; Product Container Issue; Recalled Product Administered; Sinusitis	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Other Quantity : 1 Drop(S) Other Frequency : As Needed		Global Pharmaceuticals	
	Duloxetine			C				Not Reported	
	Lamotrigine			C				Not Reported	
	Memantine			C				Not Reported	
	Montelukast			C				Not Reported	
	Pilocarpine			C				Not Reported	
	Pregabalin			C				Not Reported	
	Famotidine			C				Not Reported	
	Maxalt-Mlt			C				Not Reported	
	Restasis			C				Not Reported	
	Tramadol			C				Not Reported	
	Zyrtec			C				Not Reported	
	Breztri			C				Not Reported	
	Flaxsee Oil Glucosamine			C				Not Reported	
	Chondrotin								
	Magnesium			C				Not Reported	
	Glycinate			C				Not Reported	
	Multivitamin			C				Not Reported	
	Tumeric			C				Not Reported	
	Amino Acid			C				Not Reported	

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Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2023	21978273	DIRECT		DS, HO, LT, RI, OT			76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blindness; Pseudomonas Infection	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		N	S	Ophthalmic	Other Quantity : 0.5 Ounce (S); Frequency : As Needed;	30 DAY	Ezricare	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2023	21978278	DIRECT		OT			78 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Corneal Oedema; Eye Disorder; Eye Irritation; Eye Pain; Lacrimation Increased; Photophobia; Product Container Seal Issue	Carboxymethylcellulose Sodium		Y	S	Ophthalmic	Frequency : At Bedtime;		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2023	21979040	DIRECT		OT			44 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Rash; Vision Blurred	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S				Not Reported	
	Ozypic			C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2023	21979050	DIRECT		RI			63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Hypersensitivity	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose		Y	S			1 WEEK	Ezricare	

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Sodium)		
Valtrex	C	Not Reported
Xanaex	C	Not Reported
Clariten	C	Not Reported
Dyrennium	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2023	21979215	DIRECT	Y	DS			74 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bacterial Infection; Pseudomonas Test Positive; Ulcerative Keratitis	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S				Ezricare

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
09-Feb-2023	21979707	DIRECT		HO			66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chemical Burns Of Eye; Eye Pain; Instillation Site Irritation; Instillation Site Pain	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Intraocular	Other Quantity : 1 Or 2 Drops; Frequency : As Needed;		Ezricare
	Nitric Oxide		N	C				Not Reported
	Aleve		N	C				Not Reported
	Lortab		N	S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2023	21977334	EXPEDITED (15-DAY)	Y	HO, OT	CA-BAYER- 2023A013622		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chronic Sinusitis; Drug Ineffective; Dyspepsia; Infusion Related Reaction; Macular Degeneration; Malaise; Nausea; Off Label Use; Pain;	Restoralax		N	S				Bayer
	Trimethoprim		N	S				Not Reported
	Isoniazid/Pyridoxine		N	S				Not Reported
	Hydrochloride/Sulfamethoxazole /Trimethoprim							
	Acetaminophen		N	S				Not Reported

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Paraesthesia Oral;	Gramicidin	N	S		Not Reported
Procedural Pain; Pyrexia;	Zeaxanthin	N	S		Not Reported
Therapeutic Product Effect	Xantofyl Palmitate	N	S		Not Reported
Incomplete; Weight	Nicomorphine	N	S		Not Reported
Decreased	Budesonide	N	S		Not Reported
	Metronidazole	N	S		Not Reported
	Glyceryl Trinitrate	N	S		Not Reported
	Ak-Spore [Gramicidin;Neomycin Sulfate;Polymyxin B Sulfate]	N	S		Not Reported
	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 Acid;Zinc	N	S		Not Reported
	Gramicidin;Polymyxin B	N	S		Not Reported
	Pantoprazole Sodium	N	S		Not Reported
	[Pantoprazole Sodium Monohydrate]				
	Benzydamine Hydrochloride	N	S		Not Reported
	Valsartan	N	C	Unk	Not Reported
	Amoxicillin	N	C		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 XL	N	S		Not Reported

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Humira	N	S		Not Reported
Pantoprazole Sodium Anhydrous	N	S		Not Reported
Ergocalciferol	N	S		Not Reported
Clotrimazole	N	S		Not Reported
Pantoprazole	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
Ertapenem Sodium	N	S		Not Reported
Vitamin D3	N	S		Not Reported
Zinc Chloride	N	S		Not Reported
Salinex [Sodium Chloride]	N	S		Not Reported
Mentha Arvensis	N	S		Not 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 Hydrochloride;	N	S		Not Reported
Sulfamethoxazole;Trimethoprim				
Infa-3 [Gramicidin;Neomycin Sulfate;Polymyxin B]	N	S		Not Reported
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

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	Hydrochlorothiazide	N	S						Not Reported
	Nicoderm	N	S						Not Reported
	Simvastatin	N	S						Not Reported
	Amoxicillin Trihydrate	N	S						Not Reported
	Zinc Oxide	N	S						Not Reported
	Magnesium Sulfate	N	S						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2023	21979746	DIRECT					66 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Headache; Recalled Product Administered; Vision Blurred	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Other Quantity : 2 Drop(S); Frequency : Twice A Day;		Ezricare
	Atorvastatin	N		C				Not Reported
	Fish Oil	N		C				Not Reported
	Vitamin B	N		C				Not Reported
	Turmeric	N		C				Not Reported
	Vitamin D	N		C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2023	21983779	DIRECT		OT				Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dry Eye; Eye Colour Change; Eye Inflammation; Eye Pain; Haemorrhage; Product Contamination Microbial; Visual Impairment	Theratears Dry Eye Therapy		N	S		Other Quantity : 1 Ounce;		Akorn

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2023	21983780	DIRECT	N	DE, OT			74 YR	Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Bacterial Infection; Cardiac Failure;	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose		N	S		Other Quantity : 15		Ezricare

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Clostridium Difficile Colitis; Sodium)
 Decreased Appetite; Milliliters Bot;
 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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2023	21984292	DIRECT					60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Therapy Cessation; Vision Blurred	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Other Quantity : 2 Drop(S); Frequency : As Needed;		Ezricare	
	Multi Vitamins		N	C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Feb-2023	21984314	DIRECT		DS, RI			32 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Instillation Site Infection	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Other Quantity : 1 Drop(S); Frequency : At Bedtime;		Ezricare	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2023	21983783	DIRECT	N	OT				Unknown	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Instillation Site Pruritus; Recalled Product Administered; Therapeutic Product Effect Incomplete	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		N	S				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2023	21983784	DIRECT		OT				Unknown	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Instillation Site Reaction; Recalled Product	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		N	S				Global Pharmaceuticals	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2023	21985604	DIRECT		RI			54 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Irritation; Ocular Hyperaemia; Product Quality Issue	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Other Quantity : 2 Ounce (S); Frequency : 4 Times A Day;		Unknown Manufacturer	
	Lisinopril		N	C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2023	21985626	DIRECT	N				77 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Pain; Vision Blurred	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	2 Drops As Needed Ophthalmic		Global Pharmaceuticals	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
11-Feb-2023	21985698	DIRECT		RI, OT			39 YR	Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Infection; Loss Of Personal Independence In Daily Activities; Visual Impairment	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S				Ezricare	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2023	21986090	DIRECT		OT			67 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Asthenopia; Headache; Recalled Product Administered; Vision Blurred	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Frequency : As Needed;		Ezricare	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2023	21986098	DIRECT		DS, RI, OT			58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Instillation Site Infection	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Frequency : Twice A Day;		Ezricare	
	Hydroxy Chloroquine		N	C				Not Reported	
	Vitamin D		N	C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
12-Feb-2023	21986109	DIRECT		OT			58 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Lid Sulcus Deepened; Recalled Product; Vision Blurred	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Other Quantity : 30 Drop (S); Other Frequency : 6-7 Times Daily;		Ezricare	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2023	21892436	EXPEDITED (15-DAY)	Y		FR-ALLERGAN-2239708US			Female	FRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Liquid Product Physical Issue; Ocular Discomfort	Optive		Y	S	Ophthalmic	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2023	21982383	EXPEDITED (15-DAY)	Y	HO, OT	CA-GLENMARK PHARMACEUTICALS-2023GMK078810			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
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	Mupirocin		N	S	Unknown	Unk		Glenmark	
	Mupirocin		N	S	Topical	Unk (Formulation: Ointment)		Glenmark	
	Acetaminophen		N	S	Unknown	Unk		Not Reported	
	Acetaminophen		N	S	Unknown	Unk		Not Reported	
	Adalimumab		N	S	Unknown	Unk (Solution Subcutaneous)		Not Reported	
	Alprazolam		N	S	Unknown	Unk		Not Reported	
	Amoxicillin Trihydrate		N	S	Unknown	Unk		Not Reported	
	Atorvastatin		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	
	Atropine Sulfate		N	S	Unknown	Unk		Not Reported	
	Azithromycin Dihydrate		N	S	Unknown	Unk		Not Reported	
	Benzydamine Hydrochloride		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	

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Biaxin XL	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

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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

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Simvastatin	N	S	Unknown	Unk	Not Reported
Sinus Rinse	N	S	Nasal	Unk (Solution Nasal)	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk (Suspension Intra-Articular)	Not Reported
Triamcinolone Acetonide	N	S	Unknown	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
Zeaxanthin	N	S	Oral	Unk	Not Reported
Zinc Chloride	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Amoxicillin	N	C	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	C	Unknown	Unk	Not Reported
Mupirocin Calcium	N	C	Unknown	Unk	Not Reported
Neomycin Sulfate	N	C	Unknown	Unk	Not Reported
Sodium Stearate	N	C	Unknown	Unk	Not Reported
Valsartan	N	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2023	21984367	EXPEDITED (15-DAY)	Y	HO, OT	CA-Allegis Pharmaceuticals, LLC-APL202302-000005		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Anaemia; Chronic Sinusitis; Colitis; Colitis Ulcerative; Constipation; Drug	Nitroglycerin	N	S			Unknown		Espero Pharmaceuticals
	Acetaminophen	N	S			Unknown		Not Reported



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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	Acetaminophen/Dextropropoxyphene	N	S	Unknown	Not Reported
	Acetaminophen/Pseudoephedrine Hydrochloride	N	S	Unknown	Not Reported
	Acetic Acid/Triamcinolone Acetonide	N	S	Unknown	Not Reported
	Acetylsalicylic Acid	N	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-Alprazolam	N	S		Not Reported
	Apo-Pregabalin	N	S		Not Reported
	Atorvastatin Calcium	N	S	Unknown	Not Reported
	Atropine Sulfate/Diphenoxylate Hydrochloride	N	S	Unknown	Not Reported
	Azithromycin	N	S	Unknown	Not Reported
	Benzylamine	N	S	Unknown	Not Reported
	Betamethasone Valerate	N	S	Unknown	Not Reported
	Biaxin XL	N	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
	Cortenema Suspension	N	S	Unknown	Not Reported

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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/Folic Acid/Nicotinamide/Riboflavin/Thiamin	N	S	Unknown	Not Reported
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 otherwise specified)	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
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	Not Reported
Hydrochlorothiazide	N	S	Unknown	Not Reported
Hydrocortisone	N	S	Unknown	Not Reported
Hydromorphone Hydrochloride	N	S	Unknown	Not Reported
Isoniazid/Pyridoxine Hydrochloride/Sulfamethoxazole/Trimethoprim	N	S	Unknown	Not Reported
Loperamide Hydrochloride	N	S	Unknown	Not Reported
Macrogol/Potassium Chloride/Sodium	N	S	Unknown	Not Reported

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Bicarbonate/Sodium Chloride	N	S		Unknown	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
Magnesium Sulfate	N	S		Unknown	Not Reported
Magnesium Sulfate Inj 50%	N	S	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		Unknown	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unknown	Not Reported
Ubidecarenone	N	S		Unknown	Not Reported

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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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2023	21984569	EXPEDITED (15-DAY)	N	OT	ALC2023CA000920			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Atropine	N	S	Unknown	Unk			Not Reported
	Adalimumab	N	S	Subcutaneous	Unk			Not Reported
	Salinex [Sodium Chloride]	N	S	Nasal	Unk			Not Reported
	Atropine	N	S	Oral	Unk			Not Reported
	Morphine Sulfate	N	S	Unknown	Unk			Not Reported
	Amoxicillin	N	S	Unknown	Unk			Not Reported
	Atorvastatin	N	S	Unknown	Unk			Not Reported
	Clarithromycin	N	S	Unknown	Unk			Not Reported
	Magnesium Sulfate	N	S	Unknown	Unk			Not Reported
	Ertapenem Sodium	N	S	Unknown	Unk			Not Reported
	Zinc Oxide	N	S	Unknown	Unk			Not Reported
	Diphenhydramine Hydrochloride	N	S	Unknown	Unk			Not Reported
	Pregabalin	N	S	Unknown	Unk			Not Reported
	Pantoprazole	N	S	Unknown	Unk			Not Reported
	Colecalciferol	N	S	Unknown	Unk			Not Reported
	Prednisone	N	S	Unknown	Unk			Not Reported
	Cetirizine	N	S	Unknown	Unk			Not Reported
	Amoxicillin Trihydrate	N	S	Unknown	80 Mg			Not Reported
	Atorvastatin Calcium	N	S	Unknown	Unk			Not Reported

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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

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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 Acetonide]	N	S	Intra-articular	Unk	Not Reported
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

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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
Hydrochlorothiazide	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	Endosinusal	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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	Loperamide Hydrochloride	N	S	Oral	Unk	Not Reported
	Metronidazole Hydrochloride	N	S	Unknown	Unk	Not Reported
	Nicotine	N	S	Unknown	Unk	Not Reported
	Simvastatin	N	S	Unknown	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
	Atropine	N	S	Oral	Unk	Not Reported
	Zinc Chloride	N	S	Unknown	Unk	Not Reported
	Hyrimoz [Adalimumab]	N	C	Unknown	Unk	Not Reported
	Valsartan	N	C	Unknown	Unk	Not Reported
	Calcium	N	C	Intracardiac	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2023	21987000	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2303414US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Disorder; Eyelid	Refresh Relieva	Y	S					Not Reported
Margin Crusting; Liquid	Refresh Plus	N	S			Unk		Not Reported
Product Physical Issue	Refresh Plus	N	S			Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2023	21987003	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2303508US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Pruritus; Macular Degeneration; Off Label Use; Vitreous Floaters	Refresh Tears	Y	S		Ophthalmic	3 To 4 Per Day		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2023	21987007	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2303696US			Male	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataract; Vision Blurred	Refresh Tears		Y	S	Ophthalmic	Unk		Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2023	21990232	DIRECT		DS, HO, OT			80 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Infection; Pseudomonas Infection	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Other Quantity : 6 6; Frequency : As Needed;		Ezricare	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Feb-2023	21991655	DIRECT		RI			76 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctivitis; Culture Positive; Pathogen Resistance; Pseudomonas Infection	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Other Quantity : Drop; Frequency : As Needed; Duration: Years		Ezricare	
	Nexium		N	C				Not Reported	
	Losartan		N	C				Not Reported	
	Victoza		N	C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2023	21973017	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2303391US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataract	Refresh Relieva Pf Ud		Y	S		In The Morning And At Bedtime		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2023	21990746	NON-EXPEDITED	N		US-SOMERSET-2023-US-000002		73 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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Dry Eye; Erythema; Eyelid Oedema; Photophobia	Latanoprost Ophthalmic Solution, 0.005%	N	S		1 Drop Ou Qd	Somerset
	Refresh Tears Moisture Drops	N	I			Not Reported
	Advil Tablets	N	C	Oral		Not Reported
	Puritan'S Pride Vitamin B-12	N	S	Oral		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2023	21991840	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2303112US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataract; Eye Inflammation; Lacrimation Increased	Refresh Tears		Y	S	Ophthalmic			Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2023	21994131	DIRECT		DE, HO			74 YR	Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</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 Retention; Urine Analysis Abnormal; Urine Odour Abnormal	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		N	S	Intraocular			Global Pharmaceuticals	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
14-Feb-2023	21994602	DIRECT		OT			72 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Headache	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Other Quantity : 1 Ounce (S); Frequency : As Needed;	4 DAY	Ezricare
	Prednisone		N	C				Not Reported
	Sertraline		N	C				Not Reported
	Hydrocodone		N	C				Not Reported
	Xeljanz		N	C				Not Reported
	Losartan		N	C				Not Reported
	Ropinerole		N	C				Not Reported
	Vit A - D		N	C				Not Reported
	Biotin		N	C				Not Reported
	Fish Oil		N	C				Not Reported
	Lutein		N	C				Not Reported
	Cranberry Fiber		N	C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2023	17484674	EXPEDITED (15-DAY)	N	OT	NVSC2020CA058057			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Adalimumab		N	S	Subcutaneous	Unk		Novartis
	Sodium Chloride		N	S	Nasal	Unk		Not Reported
	Atropine Sulfate		N	S	Oral	Unk		Not Reported
	Morphine Sulfate		N	S	Unknown	Unk		Not Reported
	Amoxicillin		N	S	Unknown	Unk		Novartis
	Atorvastatin		N	S	Unknown	Unk (Not Specified)		Novartis
	Clarithromycin		N	S	Unknown	Unk		Novartis
	Magnesium Sulfate		N	S	Unknown	Unk		Not Reported
	Ertapenem Sodium		N	S	Unknown	Unk		Not Reported

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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, Sodium Hydrogen Carbo	N	S	Unknown	Unk	Not Reported
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

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Statex	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	Unknown	Unk (Not Specified)	Not Reported
Diphenoxylate Hydrochloride And Atropine Sulf	N	S	Oral	Unk	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
Hydrochlorothiazide	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 (Suspension Intraarticular)	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	Unknown	Unk (Intra Nasal),	Not Reported

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				Endosinusial	
Vitamin D	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	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Fructose	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	Unk	Not Reported
Metronidazole Hydrochloride	N	S	Unknown	Unk	Not Reported
Nicotine	N	S	Unknown	Unk	Not Reported
Simvastatin	N	S	Unknown	Unk	Not Reported
Sodium Stearate	N	S	Oral	Unk	Not Reported
Triamcinolone	N	S	Intra-articular	Unk (Suspention Intra-Articular)	Not Reported
Trimethoprim	N	S	Unknown	Unk	Not Reported
Zinc Chloride	N	S	Unknown	Unk	Not Reported
Valsartan	N	C	Unknown		Not Reported
Valsartan	N	C	Vaginal	Unk	Not Reported
Calcium	N	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2023	21996646	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2303880US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cataract; Post Procedural Complication	Refresh Tears		Y	S	Ophthalmic	Unk		Allergan
	Restasis		N	S	Ophthalmic	Unk		Allergan

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2023	21996649	EXPEDITED (15-DAY)	N	HO	US-ALLERGAN-2303891US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cardiac Disorder; Dry Eye	Refresh Relieva		Y	S	Ophthalmic	Unk		Allergan	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2023	21996650	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2303997US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Ulcer; Macular Degeneration	Refresh Tears Pataday		Y N	S C				Allergan Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
15-Feb-2023	21999381	DIRECT		RI			76 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctivitis; Product Quality Issue	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Frequency : 4 Times A Day;		Global Pharmaceuticals	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Feb-2023	22004962	DIRECT		DS			72 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Conjunctivitis	Artificial Tears (Carboxymethylcellulose Sodium) Extensive		Y N	S C	Ophthalmic	Frequency : Twice A Day;		Delsam Pharm Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2023	22020027	DIRECT						Female	USA

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Periorbital Swelling; Recalled Product Administered; Suspected Product Contamination; Vision Blurred	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Other Quantity : 2 Drop(S); Frequency : Twice A Day;		Ezricare
	Synthroid		N	C				Not Reported
	Phentermine		N	C				Not Reported
	Multivitamins		N	C				Not Reported
	Vitamin D3		N	C				Not Reported
	Organic Greens With Superfood Blend		N	C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2023	22020031	DIRECT		OT			52 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Ear Discomfort; Ear Infection; Eye Discharge; Eye Swelling; Eyelid Margin Crusting; Pain; Therapy Non-Responder; Tinnitus	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Other Quantity : 2 Ounce (S); Frequency : Twice A Day;		Ezricare
	Lisinopril		N	C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
17-Feb-2023	22020485	DIRECT	N	OT			42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Product Contamination; Vision Blurred	Ezricare Artificial Tears Lubricant Eye Drops		N	S				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2023	22021536	DIRECT					42 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<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;		Ezricare

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Effexor	C	Not Reported
Vyvanse	C	Not Reported
Iron Supplements	C	Not Reported
Hydroxychloroquine	C	Not Reported
Eye Drops	C	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
18-Feb-2023	22021614	DIRECT					78 YR	Prefer not to disclose	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eyelid Infection	Artificial Tears (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Other Quantity : 2 Drops; Frequency : Every 8 Hours;		Delsam Pharm	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2023	22021616	DIRECT		RI			60 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Swelling; Instillation Site Erythema; Keratitis Bacterial; Ocular Hyperaemia; Pseudomonas Infection	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium) Blood Pressure Meds		Y	S				Ezricare	
				C				Not Reported	

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
19-Feb-2023	22021648	DIRECT		OT			65 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Ear Pain; Eye Pain; Instillation Site Pain; Lung Disorder; Oropharyngeal Pain; Product Contamination; Recalled Product Administered	Ezricare Artificial Tears Lubricant Eye Drops Erythromycin Inhaler One A Day Vitamin		Y	S	Ophthalmic	Frequency : Twice A Day;		Ezricare	
			N	C				Not Reported	
			N	C				Not Reported	
			N	C				Not Reported	

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
20-Feb-2023	21932001	EXPEDITED (15-DAY)	Y	HO, OT	CA-JNJFOC-20230149335		65 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Anaemia;	Budesonide		N	S	Unknown			Not Reported	
Chronic Sinusitis; Colitis;	Cetirizine Hydrochloride		N	S	Unknown			Not Reported	
Colitis Ulcerative;	Cetirizine Hydrochloride		N	S	Unknown			Not Reported	
Constipation; Drug	Cetirizine Hydrochloride		N	S	Unknown			Not Reported	
Ineffective; Dyspepsia;	Cetirizine Hydrochloride		N	S	Unknown			Not Reported	
Erythema; Female Genital	Cetirizine Hydrochloride		N	S	Unknown			Not Reported	
Tract Fistula; Frequent	Cetirizine Hydrochloride		N	S	Unknown			Not Reported	
Bowel Movements;	Cetirizine Hydrochloride		N	S	Unknown			Not Reported	
Haematochezia;	Nicotine		N	S	Unknown			Not Reported	
Headache; Infusion	Nicotine		N	S	Unknown			Not Reported	
Related Reaction; Macular	Nicotine		N	S	Unknown			Not Reported	
Degeneration; Malaise;	Nicotine		N	S	Unknown			Not Reported	
Nausea; Off Label Use;	Nicotine		N	S	Unknown			Not Reported	
Oral Candidiasis; Pain;	Nicotine		N	S	Unknown			Not Reported	
Paraesthesia Oral;	Nicoderm		N	S	Unknown			Not Reported	
Procedural Pain; Proctitis;	Nicoderm		N	S	Unknown			Not Reported	
Pyrexia; Radiculopathy;	Nicoderm		N	S	Topical			Not Reported	
Rectal Haemorrhage;	Nicoderm		N	S	Unknown			Not Reported	
Therapeutic Product Effect	Nicoderm		N	S	Unknown			Not Reported	
Incomplete; Vaginal	Diphenhydramine Hydrochloride		N	S	Unknown			Not Reported	
Discharge; Vaginal	Diphenhydramine Hydrochloride		N	S	Unknown			Not Reported	
Flatulence; Weight	Diphenhydramine Hydrochloride		N	S	Unknown			Not Reported	
Decreased	Diphenhydramine Hydrochloride		N	S	Unknown			Not Reported	
	Diphenhydramine 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	
	Loperamide Hydrochloride		N	S	Oral			Not Reported	

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Loperamide Hydrochloride	N	S	Oral	Not Reported
Loperamide Hydrochloride	N	S	Unknown	Not Reported
Paracetamol	N	S	Unknown	Not Reported
Zinc Oxide	N	S	Unknown	Not Reported
Zinc Oxide	N	S	Unknown	Not Reported
Hydrocortisone	N	S	Unknown	Not Reported
Acetaminophen; Dextropropoxyphene	N	S	Unknown	Not Reported
Paracetamol;Pseudoephedrine Hydrochloride	N	S	Unknown	Not Reported
Acetic Acid;Triamcinolone Acetonide	N	S	Unknown	Not Reported
Acetylsalicylic Acid	N	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	N	S	Unknown	Not Reported
Apo Pregabalin	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	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
Azithromycin	N	S	Oral	Not Reported
Benzydamine	N	S	Unknown	Not Reported
Betamethasone Valerate	N	S	Unknown	Not Reported

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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

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Glyceryl Trinitrate	N	S	Unknown		Not Reported
Glyceryl Trinitrate	N	S	Oral		Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown		Not Reported
Habitrol [Nicotine]	N	S	Unknown		Not Reported
Humira	N	S	Unknown	6 YR	Not Reported
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 Hydrochloride/Sulfamethoxazole /Trimethoprim	N	S	Unknown		Not Reported
Macrogol;Potassium Chloride; Sodium Bicarbonate;Sodium Chloride	N	S	Unknown		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
Magnesium Sulfate	N	S	Unknown		Not Reported
Magnesium Sulfate	N	S	Unknown		Not Reported
Magnesium Sulfate	N	S	Unknown		Not Reported

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Mesalazine	N	S	Unknown	Not Reported
Mesalazine	N	S	Unknown	Not Reported
Methylprednisolone Sodium Succinate	N	S	Unknown	Not Reported
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

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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 Glycol;Sodium Chloride]	N	S	Unknown	Not Reported
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

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	Budesonide	N	S	Oral		Not Reported
	Entyvio	N	S	Unknown		Not Reported
	Ertapenem Sodium	N	S			Not Reported
	Ertapenem Sodium	N	S	Intramuscular		Not Reported
	Ertapenem Sodium	N	S	Unknown		Not Reported
	Flovent	N	S	Unknown		Not Reported
	Flovent	N	S	Unknown		Not Reported
	Fluticasone Propionate; Salmeterol Xinafoate	N	S	Unknown		Not Reported
	Pregabalin	N	S	Unknown		Not Reported
	Pregabalin	N	S	Unknown		Not Reported
	Pregabalin	N	S	Unknown		Not Reported
	Simvastatin	N	S	Unknown		Not Reported
	Simvastatin	N	S	Unknown		Not Reported
	Zinc Oxide	N	S	Unknown		Not Reported
	Teva Alprazolam	N	S	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2023	22018055	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2304462US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Corneal Transplant; Surgery	Refresh Plus		Y	S					Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2023	22018067	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2304581US			Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataract; Eye Disorder	Refresh Tears		Y	S	Ophthalmic	Unk			Allergan

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21-Feb-2023	22028837	DIRECT		DS, RI			77 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Eye Infection; Eye Pruritus; Ulcerative Keratitis	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Other Quantity : 1 Drop(S); Frequency : As Needed;		Ezricare	
	Vit B		N	C				Not Reported	
	Biotin		N	C				Not Reported	
	Probiotic		N	C				Not Reported	
	Turmeric		N	C				Not Reported	
	Fish Oil		N	C				Not Reported	
	Magnesium		N	C				Not Reported	
	Iron And Vit C		N	C				Not Reported	
	Milk Thistle		N	C				Not Reported	
	Baby Aspirin		N	C				Not Reported	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
21-Feb-2023	22028872	DIRECT		DS, HO, LT, RI, OT			63 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Blindness Unilateral; Corneal Transplant; Eye Infection Bacterial; Instillation Site Infection; Pseudomonas Infection	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S				Ezricare	
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2023	21211123	EXPEDITED (15-DAY)	Y	HO, OT	CA-MYLANLABS-2022M1085896		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Sinusitis; Drug Ineffective; Dyspepsia; Infusion Related Reaction; Macular Degeneration; Malaise; Nausea; Off	Biaxin XI		N	S	Unknown	Unk		Mylan	
	Acetaminophen		N	S	Unknown	Unk		Not Reported	
	Calcium Carbonate		N	S	Unknown	Unk		Not Reported	

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Label Use; Pain;	Clarithromycin	N	S	Unknown	Unk	Not Reported
Paraesthesia Oral;	Tocopherol	N	S	Unknown	Unk	Not Reported
Procedural Pain; Pyrexia;	Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Therapeutic Product Effect	Mesalazine	N	S	Unknown	Unk	Not Reported
Incomplete; Weight	Sodium Chloride	N	S	Unknown	Unk	Not Reported
Decreased	Zinc Oxide	N	S	Unknown	Unk	Not Reported
	Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
	Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
	Avamys	N	S	Unknown	Unk	Not Reported
	Bactrim	N	S	Unknown	Unk	Not Reported
	Benadryl	N	S	Oral	50 Milligram	Not Reported
	Bisacodyl	N	S	Unknown	Unk	Not Reported
	Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
	Cholecalciferol	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
	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;	N	S	Unknown	Unk	Not Reported
	Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
	Humira	N	S	Subcutaneous	Unk	Not Reported
	Hydromorphone Hydrochloride	N	S	Endocervical	Unk	Not Reported
	Infliximab	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
	Isoniazid;Pyridoxine Hydrochloride;	N	S	Unknown	Unk	Not Reported

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

Sulfamethoxazole;Trimethoprim						
Lomotil	N	S	Oral	Unk		Not Reported
Macrogol;Potassium Chloride;	N	S	Unknown	Unk		Not Reported
Sodium Bicarbonate						
Metronidazole	N	S	Unknown	Unk		Not Reported
Mupirocin	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
Nicotine	N	S	Unknown	Unk		Not Reported
Pantoprazol	N	S	Unknown	Unk		Not Reported
Azithromycin	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
Triamcinolone Acetonide	N	S	Unknown	Unk		Not Reported
Xantofyl Palmitate	N	S	Unknown	Unk		Not Reported
Zeaxanthin	N	S	Unknown	Unk		Not Reported
Calcium Carbonate	N	C	Unknown	Unk		Not Reported
Metoclopramide Hydrochloride	N	C	Oral	Unk		Not Reported
Loperamide	N	C	Oral	4 Dosage Form, Qd		Not Reported
Valsartan	N	C	Oral	4 Dosage Form, Qd		Not Reported
Valsartan	N	C	Unknown	Unk		Not Reported
Ergocalciferol	N	C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2023	21850397	EXPEDITED (15-DAY)	N		US-ALLERGAN-2242708US			Unknown	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Accidental Exposure To Product Packaging; Foreign Body In Eye; Product Primary Packaging Issue	Refresh Optive Advanced	Y	S	Ophthalmic	Allergan
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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2023	22013128	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2304530US			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cataract; Condition Aggravated; Eye Discharge; Eye Disorder; Eye Pain; Eye Pruritus; Eye Swelling; Hypersensitivity; Lacrimation Increased; Ocular Hyperaemia; Vision Blurred	Refresh Plus		Y	S	Ophthalmic	Unk	3 DAY	Not Reported
	Refresh Plus		Y	S	Ophthalmic	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2023	22022359	EXPEDITED (15-DAY)	N	HO, OT	CA-PFIZER INC-202200579945		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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	Alprazolam Mylan		N	S	Unknown	0.25 Milligram		Mylan
	Atorvastatin Calcium		N	S	Unknown	Unk		Mylan
	Pregabalin Mylan		N	S	Unknown	150 Milligram		Mylan
	Biaxin XI		N	S	Unknown	Unk		Mylan
	Pantoprazole		N	S	Unknown	Unk		Not Reported
	Metronidazole		N	S	Unknown	Unk		Not Reported
	Adalimumab		N	S	Subcutaneous	Unk		Not Reported
	Azithromycin		N	S	Unknown	Unk		Not Reported
	Hydromorphone Hydrochloride		N	S	Endocervical	Unk		Not Reported
	Hydromorphone Hydrochloride		N	S	Unknown	Unk		Not Reported

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

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

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

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 Gramicidin	N	S	Unknown		Not Reported
Humira	N	S	Unknown	Unk	Not Reported
Isoniazid;Pyridoxine Hydrochloride;	N	S	Unknown	Unk	Not Reported

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

	Sulfamethoxazole;Trimethoprim Lomotil	N	S	Unknown	Unk			Not Reported
	Macrogol;Potassium Chloride; Sodium Bicarbonate Pentasa	N	S	Unknown	Unk			Not Reported
	Pulmicort	N	S	Unknown	Unk			Not Reported
	Benadryl Allergy	N	C	Unknown	Unk			Not Reported
	Calcium And Ergocalciferol	N	C	Unknown	Unk			Not Reported
	Sodium Bicarbonate	N	S	Unknown	Unk			Not Reported
	Tocopherols Mixed	N	S	Unknown	Unk			Not Reported
	Calcium Gluconate Cox	N	C	Unknown	Unk			Not Reported
	Metoclopramide Hydrochloride	N	C	Unknown	Unk			Not Reported
	Valsartan	N	C	Unknown	Unk			Not Reported
	Valsartan	N	C	Unknown	4 Dosage Form, Qd			Not Reported
	Loperamide Chlorhydrate	N	C	Unknown	Unk			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2023	22022409	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2304817US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Cataract; Product Use Complaint	Refresh Tears		Y	S		Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Feb-2023	22027870	DIRECT		RI			60 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Dry Eye; Eye Infection; Eye Inflammation; Eye Irritation; Eye Pain; Foreign Body Sensation In Eyes; Hypersensitivity; Ocular Hyperaemia;	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Intraocular	Frequency : As Needed;	1 WEEK	Ezricare
	Vitamin D		N	C				Not Reported
	Zinc		N	C				Not Reported
	Elderberry		N	C				Not Reported

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

Product Contamination	Tumeric	N	C						Not Reported
Microbial	Flaxseed Oil	N	C						Not Reported
	Collagen For Joint Health	N	C						Not Reported
	Coq10	N	C						Not Reported
	Garlic Extract	N	C						Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2023	22032769	DIRECT					62 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Erythema Of Eyelid; Eye Irritation; Eye Pain; Ocular Hyperaemia; Periorbital Swelling; Photosensitivity Reaction	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Frequency : Twice A Day; 2 DAY		Global Pharmaceuticals
	Crestor		N	C				Not Reported
	Tylenol		N	C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Feb-2023	22032772	DIRECT		DS			68 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Pain; Lacrimation Increased; Recalled Product Administered	Artificial Tears Lubricant Eye Drops (Carboxymethylcellulose Sodium)		Y	S	Ophthalmic	Other Quantity : 50 Drop (S); Other Frequency : As Needed;		Ezricare
	Cymbalta		N	C				Not Reported
	Prednisone		N	C				Not Reported
	Meloxicam		N	C				Not Reported
	Hydroxychloroquine		N	C				Not Reported
	Valsartan		N	C				Not Reported
	Trazodone		N	C				Not Reported
	Cetirizine Hcl		N	C				Not Reported
	Multivitamin		N	C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2023	21855508	EXPEDITED (15-DAY)	Y	OT	CA-BAXTER-2023BAX009992			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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FDA Adverse Event Reporting System Freedom of Information Act (FOIA) Detailed Report

Drug Ineffective; Macular Degeneration	Sodium Chloride	N	S	Endosinusal	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

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

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

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

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

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

Pentasa	N	S	Unknown	Specified) (Dosage Form: Not Specified)	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Prednisone	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
Pregabalin	N	S	Unknown		Not Reported
Pulmicort	N	S	Unknown	(Dosage Form: Not Specified)	Not Reported
Sinus Rinse	N	S	Endosinusal	Dosage Form: Solution Nasal	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic		Not Reported
Sodium Stearate	N	S	Oral		Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Triamcinolone	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	Unknown		Not Reported
Zinc Chloride	N	S	Unknown		Not Reported
Zinc Oxide	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Acetaminophene	N	S	Unknown		Not Reported
Amoxicillin Trihydrate	N	S	Unknown		Not Reported
Atropine	N	S	Oral	(Dosage Form: Not Specified)	Not Reported
Azithromycin Dihydrate	N	S	Oral	Unk	Not Reported
Biaxin XI	N	S	Unknown	(Dosage Form: Tablet (Extended Release))	Not Reported
Calcium Gluconate	N	S	Unknown		Not Reported

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

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	Endosinusal	(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	C	Intracardiac	Dosage Form: Not Specified	Not Reported
Calcium	N	C	Unknown	(Dosage Form: Not Specified)	Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2023	21921073	EXPEDITED (15-DAY)	Y	HO, OT	CA-JNJFOC-20230146070		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
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	Remicade		N	S	Intravenous drip			Not Reported	
	Cetirizine Hydrochloride		N	S	Unknown			Not Reported	
	Acetaminophen		N	S	Unknown			Not Reported	
	Adalimumab		N	S	Subcutaneous			Not Reported	
	Alprazolam		N	S	Unknown			Not Reported	
	Alprazolam		N	S	Unknown			Not Reported	
	Azithromycin		N	S	Unknown			Not Reported	
	Betamethasone Valerate		N	S	Unknown			Not Reported	
	Budesonide		N	S	Unknown			Not Reported	
	Budesonide		N	S	Unknown			Not Reported	
	Budesonide		N	S	Unknown			Not Reported	
	Calcium Carbonate		N	S	Unknown			Not Reported	
	Diphenhydramine Hydrochloride		N	S	Unknown			Not Reported	
	Loperamide		N	S	Unknown			Not Reported	
	Nicotine Polacrilex		N	S	Unknown			Not Reported	
	Nicotine Polacrilex		N	S	Unknown			Not Reported	
	Zinc Oxide		N	S	Unknown			Not Reported	
	Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate		N	S	Unknown			Not Reported	
	Sodium Chloride		N	S				Not Reported	
	Amoxicillin Trihydrate		N	S	Unknown			Not Reported	
	Atropine Sulfate;Diphenoxylate Hydrochloride		N	S	Oral			Not Reported	
	Atorvastatin Calcium		N	S	Unknown			Not Reported	
	Betamethasone Valerate		N	S	Unknown			Not Reported	
	Calcium Carbonate/Vitamin D3		N	S	Unknown			Not 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
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	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
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 Carboxymethylcellulose	N	S	Unknown	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
Betamethasone Dipropionate	N	S	Unknown	Not Reported
Nicoderm	N	S	Unknown	Not Reported
Lomotil [Atropine Sulfate; Diphenoxylate Hydrochloride]	N	C	Unknown	Not Reported

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Valsartan	N	C	Unknown	Not Reported
Metoclopramide Hydrochloride	N	C	Unknown	Not Reported
Calcium Lactate;Calcium Phosphate;Ergocalciferol	N	C	Unknown	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	N	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Feb-2023	22039937	DIRECT		OT			65 YR	Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Eye Swelling; Hordeolum; Instillation Site Pruritus; Swelling Of Eyelid	Refresh Optive Drops		Y	S	Ophthalmic	Other Quantity : .33 Ounce (S); Frequency : Twice A Day;		Allergan
	Gabapentin			C				Not Reported
	Baclofen			C				Not Reported
	Buspirone			C				Not Reported
	Cetirizine			C				Not Reported
	Naproxen			C				Not Reported
	Scopolamine			C				Not Reported
	Amitriptyln			C				Not Reported
	Ventolin			S				Not Reported
	Gentamycin			C				Not Reported
	Magnesium			C				Not Reported
	B-12			C				Not Reported
	Vitamin D3			C				Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Feb-2023	22013286	EXPEDITED (15-DAY)	N	HO	US-ALLERGAN-2304587US			Female	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Blood Magnesium Decreased; Burning Sensation; Condition Aggravated; Headache; Hypoaesthesia; Illness; Ocular Hyperaemia;	Refresh Tears		Y	S	Ophthalmic	2 Gtt, Qd		Allergan
	Refresh Tears		Y	S		Unk		Allergan
	Losartan		N	C		Unk		Not Reported
	Atorvastatin		N	C		Unk		Not Reported

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Paraesthesia

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Feb-2023	20484734	EXPEDITED (15-DAY)	Y	HO, OT	CA-drreddys-SPO/CAN/22/0146792		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Sinusitis; Drug	Reddy-Atorvastatin		N	S	Unknown			Not Reported	
Ineffective; Dyspepsia;	Reddy-Atorvastatin		N	S	Unknown			Not Reported	
Infusion Related Reaction;	Ertapenem For Injection, 1		N	S				Not Reported	
Macular Degeneration;	G/Vial								
Malaise; Nausea; Off	Acetaminophen		N	S				Not Reported	
Label Use; Pain;	Acetaminophen		N	S				Not Reported	
Paraesthesia Oral;	Amoxicillin Trihydrate		N	S				Not Reported	
Procedural Pain; Pyrexia;	Avamys		N	S				Not Reported	
Therapeutic Product Effect	Bactrim		N	S				Not Reported	
Incomplete; Weight	Benadryl		N	S	Oral			Not Reported	
Decreased									
	Biaxin XI		N	S				Not Reported	
	Bisacodyl		N	S				Not Reported	
	Calcium Carbonate		N	S				Not Reported	
	Cetirizine Hydrochloride		N	S				Not Reported	
	Cholecalciferol		N	S				Not Reported	
	Clarithromycin		N	S				Not Reported	
	Clotrimazole		N	S				Not Reported	
	Cupric Oxide		N	S				Not Reported	
	D-Alpha Tocopherol		N	S				Not Reported	
	Desonide		N	S				Not Reported	
	Dilaudid		N	S				Not Reported	
	Diphenhydramine Hydrochloride		N	S				Not Reported	
	Entocort		N	S	Oral			Not Reported	
	Flovent		N	S				Not Reported	
	Glycerol		N	S	Oral			Not Reported	
	Gramicidin/Neomycin		N	S	Unknown			Not Reported	
	Sulfate/Polymyxin B Sulfate								
	Humira		N	S	Subcutaneous		12 YR	Not Reported	
	Humira		N	S	Unknown		12 YR	Not Reported	
	Humira		N	S			12 YR	Not Reported	

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Hydromorphone Hydrochloride	N	S	Endocervical	Not Reported
Infliximab	N	S	Intravenous (not otherwise specified)	Not Reported
Isoniazid/Pyridoxine Hydrochloride/Sulfa	N	S		Not Reported
Methoxazole/Trimeth Oprim				
Lomotil	N	S	Oral	Not Reported
Macrogol/Potassium/ Sodium Bicarbonate	N	S		Not Reported
Magnesium Sulfate	N	S		Not Reported
Metronidazole	N	S		Not Reported
Mupirocin	N	S	Topical	Not Reported
Mupirocin	N	S	Topical	Not Reported
Nadolol	N	S		Not Reported
Nicoderm	N	S		Not Reported
Nicotine	N	S		Not Reported
Pantoprazole	N	S	Unknown	Not Reported
Pentasa	N	S		Not Reported
Pms-Azithromycin	N	S	Unknown	Not Reported
Prednisone	N	S		Not Reported
Pregabalin	N	S		Not Reported
Pulmicort	N	S	Respiratory (inhalation)	Not Reported
Refresh Tears	N	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	N	S		Not Reported
Adalimumab	N	S	Subcutaneous	Not Reported
Alprazolam	N	S		Not Reported
Alprazolam	N	S	Unknown	Not Reported
Macrogol	N	S	Unknown	Not Reported
Sodium Bicarbonate	N	S	Unknown	Not Reported
Acetaminophen/Dextropropoxyphene	N	S		Not Reported

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Ambroxol/Cetirizine Hydrochloride	N	S		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
Betamethasone	N	S	Unknown	Not Reported
Betamethasone	N	S	Unknown	Not Reported
Calcium Carbonate/Ergocaci Ferol	N	S	Unknown	Not Reported
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 Cellulose	N	S	Ophthalmic	Not Reported
Sulfamethoxazole/Trimethoprim	N	S		Not Reported
Vitamin D3	N	S		Not Reported
Calcium Carbonate With Vitamin D	N	C		Not Reported
Loperamide	N	C	Oral	Not Reported
Metoclopramide Hydrochloride	N	C	Oral	Not Reported
Valsartan	N	C	Oral	Not Reported
Diphenoxylate Hydrochloride	N	C		Not Reported
Lomotil	N	C	Unknown	Not Reported
Benadryl Allergy	N	C	Oral	Not Reported

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

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<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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	Magnesium Sulfate	N		S	Intramuscular	Dosage Form: Not Specified		Baxter
	Potassium Chloride	N		S	Unknown	Dosage Form : Not Specified		Baxter
	Sodium Bicarbonate Concentrate	N		S	Unknown	Dosage Form: Not Specified		Baxter
	Sodium Chloride	N		S		Dosage Form: Not Specified		Baxter
	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

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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

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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	C	Unknown	Dosage Form: Not Specified	Not Reported
Benadryl Allergy	N	C	Oral		Not Reported
Calcium Carbonate And Vitamin D3	N	C	Unknown	Unk	Not Reported
Neomycin Sulfate	N	C	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	C	Unknown	Unk	Not Reported
Sodium Stearate	N	C	Unknown	Unk	Not Reported
Valsartan	N	C	Unknown	Not Specified	Not Reported
Mupirocin Calcium Hydrate	N	C	Unknown	Unk	Not Reported
Lomotil	N	C	Unknown		Not Reported
Metoclopramide Hydrochloride	N	C	Unknown		Not Reported
Calcium Lactate	N	C	Unknown		Not Reported
Calcium Gluconate	N	C	Unknown	Not Specified	Not Reported

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2023	17015451	EXPEDITED (15-DAY)	N	HO, OT	CA-009507513-1911CAN001744		71 YR	Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Anaemia;	Invanz		N	S	Unknown	Unk		Merck	
Chronic Sinusitis; Colitis;	Invanz		N	S	Unknown	Unk		Merck	
Colitis Ulcerative;	Invanz		N	S	Unknown	Unk		Merck	
Constipation; Drug	Invanz		N	S	Unknown	Unk		Merck	
Ineffective; Dyspepsia;	Invanz		N	S	Unknown	Unk		Merck	
Erythema; Female Genital	Invanz		N	S	Nasal	Unk		Merck	
Tract Fistula; Frequent	Remicade		N	S	Intravenous (not otherwise specified)	Unk		Not Reported	
Bowel Movements;	Remicade		N	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported	
Haematochezia;	Remicade		N	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported	
Headache; Infusion	Remicade		N	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported	
Related Reaction; Macular	Remicade		N	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported	
Degeneration; Malaise;	Remicade		N	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported	
Nausea; Off Label Use;	Remicade		N	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported	
Oral Candidiasis; Pain;	Remicade		N	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported	
Paraesthesia Oral;	Remicade		N	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported	
Procedural Pain; Proctitis;	Remicade		N	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported	
Pyrexia; Radiculopathy;	Remicade		N	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported	
Rectal Haemorrhage;	Remicade		N	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported	
Therapeutic Product Effect	Remicade		N	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported	
Incomplete; Vaginal	Remicade		N	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported	
Discharge; Vaginal	Remicade		N	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported	
Flatulence; Weight	Remicade		N	S	Intravenous (not otherwise specified)	5 Milligram/Kilogram		Not Reported	
Decreased	Remicade		N	S	Intravenous (not otherwise specified)	10 Milligram/Kilogram		Not Reported	
	Remicade		N	S	Intravenous (not otherwise specified)	10 Milligram/Kilogram		Not Reported	
	Remicade		N	S	Intravenous (not otherwise specified)	10 Milligram/Kilogram		Not Reported	
	Zocor		N	S	Unknown	Unk		Merck	
	Zocor		N	S	Unknown	Unk		Merck	
	Betamethasone Dipropionate		N	S	Unknown	Unk		Merck	
	Betamethasone Dipropionate		N	S	Unknown	Unk		Merck	

FDA Adverse Event Reporting System

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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: Solution Subcutaneous	5 YR	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	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Dosage Form: Film-Coated Tablet	Not Reported
Atorvastatin Calcium	N	S	Unknown	Dosage Form: Tablet	Not Reported
Atorvastatin Calcium	N	S	Unknown	Dosage Form: Film-Coated Tablet	Not Reported
Atorvastatin Calcium	N	S	Unknown	Dosage Form: Film-Coated Tablet	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
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 Specified	Not Reported
Betaderm Ointment	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Betaderm Ointment	N	S	Unknown	Dosage Form: Ointment	Not Reported
Betaderm Ointment	N	S	Unknown	Dosage Form: Ointment 0.122 Gram	Not Reported
Betaderm Ointment	N	S	Topical	Dosage Form: Ointment	Not Reported
Bisacodyl	N	S	Unknown	Unk, Dosage Form: Not Specified	Not 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

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

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

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Flovent	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Flovent	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
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 Phosphate;Ergocalciferol	N	C	Unknown	Unk	Not Reported
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
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
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
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
Pantoprazole	N	S	Unknown	Unk	Not Reported

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

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	C	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	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
03-Mar-2023	21168433	EXPEDITED (15-DAY)	Y	HO, OT	CA-BAUSCH-BL-2022-018901		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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	Metronidazole	N	S		Unknown			Not Reported
	Budesonide	N	S		Unknown			Santarus
	Mesalazine	N	S		Unknown			Valeant
	Glyceryl Trinitrate	N	S		Unknown			Not Reported
	Amoxicillin	N	S		Unknown			Not Reported
	Atorvastatin Calcium	N	S		Unknown			Not Reported
	Azithromycin Dihydrate	N	S		Oral			Not Reported
	Bisacodyl	N	S		Unknown			Not Reported
	Calcium Carbonate	N	S		Unknown			Not Reported
	Cetirizine Hydrochloride	N	S		Unknown			Not Reported
	Clotrimazole	N	S		Unknown			Not Reported

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

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

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

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 XL	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

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

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 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

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

Calcium 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
Nicotinamide	N	S	Unknown	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Not Reported
Valsartan	N	C	Intracardiac	Not Reported

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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	Calcitriol	N	S		Intra-articular	Unk		Validus
	Ergocalciferol	N	S		Unknown	Unk		Validus
	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
	Alprazolam	N	S		Unknown	0.25 Mg		Not Reported
	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

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

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

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

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

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

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

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

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	N	S	Unknown	Unk	Not Reported
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

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Natural Vitamin E [Tocopherol]	N	S	Unknown	Unk	Not Reported
Potassium Chloride	N	S	Unknown	Unk	Not Reported
Potassium Chloride	N	S	Unknown		Not Reported
Pulmicort	N	S	Other	Unk, Inhalation	Not Reported
Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Vitamin E Nos	N	S	Unknown	Unk	Not Reported
Tocopherols Mixed	N	S	Unknown	Unk	Not Reported
Amoxicillin Trihydrate	N	C	Unknown	Unk	Not Reported
Amoxicillin	N	C	Unknown	Unk	Not Reported
Neomycin Sulfate	N	C	Unknown	Unk	Not Reported
Sodium Stearate	N	C	Unknown	Unk	Not Reported
Calcium Carbonate And Vitamin D3	N	C	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	C	Unknown	Unk	Not Reported
Mupirocin Calcium	N	C	Unknown	Unk	Not Reported
Calcium	N	C	Unknown	Unk	Not Reported
Calcium And Ergocalciferol	N	C	Unknown	Unk	Not Reported
Loperamide	N	C	Oral	4 Df, Qd	Not Reported
Metoclopramide Hydrochloride	N	C	Oral	Unk	Not Reported
Valsartan	N	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Mar-2023	21996600	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2303874US			Male	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Cataract; Visual Impairment	Refresh Plus		Y	S	Ophthalmic	Unk		Allergan	
	Refresh Plus		Y	S	Ophthalmic	2 Gtt, Qd		Allergan	
	Dapsone		N	C		Unk		Not Reported	
	Ozempic		N	C		Unk		Not Reported	

FDA Adverse Event Reporting System

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<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2023	20723601	EXPEDITED (15-DAY)	Y	HO, OT	CA-ICU MEDICAL, INC.- ICU2022CA00018			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Abdominal Pain; Anaemia;	Sodium Chloride Injection		N	S	Unknown			Icu Medical	
Chronic Sinusitis; Colitis;	Acetaminophen		N	S				Not Reported	
Colitis Ulcerative;	Acetylsalicylic Acid		N	S				Not Reported	
Constipation; Drug	Alprazolam		N	S				Not Reported	
Ineffective; Dyspepsia;	Amoxicillin Trihydrate		N	S				Not Reported	
Erythema; Female Genital	Atorvastatin Calcium		N	S				Not Reported	
Tract Fistula; Frequent	Atropine Sulfate		N	S				Not Reported	
Bowel Movements;	W/Diphenoxylate Hydrochlor.								
Haematochezia;	Avamys		N	S				Not Reported	
Headache; Infusion	Azithromycin		N	S				Not Reported	
Related Reaction; Macular	Bactrim		N	S				Not Reported	
Degeneration; Malaise;	Betamethasone		N	S				Not Reported	
Nausea; Off Label Use;	Betamethasone Valerate		N	S				Not Reported	
Oral Candidiasis; Pain;	Biaxin XI		N	S				Not Reported	
Paraesthesia Oral;	Bisacodyl		N	S				Not Reported	
Procedural Pain; Proctitis;	Calcium Carbonate		N	S				Not Reported	
Pyrexia; Radiculopathy;	Calcium Carbonate		N	S				Not Reported	
Rectal Haemorrhage;	W/Colecalciferol								
Therapeutic Product Effect	Calcium Carbonate/Vitamin D3		N	S				Not Reported	
Incomplete; Vaginal	Calcium		N	S				Not Reported	
Discharge; Vaginal	Carbonate\Ergocalciferol								
Flatulence; Weight	Cetirizine Hydrochloride		N	S				Not Reported	
Decreased	Cetirizine Hydrochloride		N	S				Not Reported	
	Cholecalciferol		N	S				Not Reported	
	Clarithromycin		N	S				Not Reported	
	Clotrimazole		N	S				Not Reported	
	Cupric Oxide		N	S				Not Reported	
	D-Alpha Tocopherol		N	S				Not Reported	
	Desonide		N	S				Not Reported	
	Difenoxin Hydrochloride		N	S				Not Reported	
	Dilaudid		N	S				Not Reported	
	Diphenhydramine Hydrochloride		N	S				Not Reported	
	Entocort		N	S				Not Reported	
	Ertapenem Sodium		N	S				Not Reported	
	Flovent		N	S				Not Reported	

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Fluticasone Propionate	N	S	Not Reported
Glycerine	N	S	Not Reported
Glycerinum	N	S	Not Reported
Glycerol	N	S	Not Reported
Gramicidin;Naphazoline; Neomycin;Phenylephrine	N	S	Not Reported
Humira	N	S	Not Reported
Hydromorphone Hydrochloride	N	S	Not Reported
Infliximab	N	S	Not Reported
Isoniazid W/Pyridoxine Hydrochloride	N	S	Not Reported
Loperamide	N	S	Not Reported
Polyethylene Glycol 3350\Potassium\Sodium Chloride\Sodium Sulfate	N	S	Not Reported
Macrogol;Potassium;Sodium Bicarbonate	N	S	Not Reported
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	Not Reported
Nadolol	N	S	Not Reported
Nicoderm	N	S	Not Reported
Nicotine	N	S	Not Reported
Nicotine Polacrilex	N	S	Not Reported
Nitroglycerin	N	S	Not Reported
Pantoprazole	N	S	Not Reported
Pentasa	N	S	Not Reported
Prednisone	N	S	Not Reported
Pregabalin	N	S	Not Reported
Pulmicort	N	S	Not Reported
Refresh Tears	N	S	Not Reported
Sinus Rinse	N	S	Not Reported
Sodium Chloride	N	S	Not Reported
Sulfamethoxazole And Trimethoprim	N	S	Not Reported
Triamcinolone Acetonide	N	S	Not Reported
Valsartan	N	S	Not Reported
Vitamin-E /00110506/ Xantofyl Palmitate	N	S	Not Reported
Zeaxanthin	N	S	Not Reported

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Zinc Oxide	N	S	Not Reported
Adalimumab	N	S	Not Reported
Betaderm /00008501/	N	S	Not Reported
Betamethasone Dipropionate	N	S	Not Reported
Ambroxol Hydrochloride	N	S	Not Reported
Calcium Amino Acid Chelate	N	S	Not Reported
Diflucan	N	S	Not Reported
Infa-3 /06152501/	N	S	Not Reported
Kenalog /00031902/	N	S	Not Reported
Lomotil	N	S	Not Reported
Methylprednisolone Sodium Succinate	N	S	Not Reported
Midazolam	N	S	Not Reported
Pms Azithromycin	N	S	Not Reported
Potassium Chloride	N	S	Not Reported
Sodium Bicarbonate	N	S	Not Reported
Solu-Medrol	N	S	Not Reported
Vitamin D3	N	S	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Mar-2023	21917217	EXPEDITED (15-DAY)	Y	HO, OT	CA-ORGANON- O2301CAN001959		65 YR	Female	CAN

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

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

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

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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; Salmeterol Xinafoate	N	S	Unknown	Unk	Not Reported
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 Hydrochloride/Sulfamethoxazole /Trimethoprim	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	4 Every 1 Days	Not Reported

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

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	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
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

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Sodium Carboxymethylcellulose	N	S	Unknown	Unk	Not Reported
Sucralfate	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole;Trimethoprim	N	S	Unknown	200 Milligram	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	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
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Zopiclone	N	S	Unknown	Unk	Not Reported
Acetaminophen; Dextropropoxyphene	N	S	Unknown	Unk	Not Reported
Acetic Acid;Triamcinolone Acetonide	N	S	Unknown	Unk	Not Reported
Align	N	S	Unknown	Unk	Not Reported
Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
Fructose	N	S	Unknown	Unk	Not Reported
Fentanyl	N	S	Unknown	Unk	Not Reported
Empracet [Paracetamol]	N	S	Unknown	Unk	Not Reported
Cortenema	N	S	Unknown	Unk	Not Reported
Diphenhydramine	N	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
13-Mar-2023	19111704	EXPEDITED (15-DAY)	Y	HO, OT	CA-TAKEDA- 2019TUS063868		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Anaemia; Chronic Sinusitis; Colitis; Colitis Ulcerative; Constipation; Drug Ineffective; Dyspepsia;	Mesalazine/Mesalamine (Pentasa)	N	S	Unknown	Unk			Takeda
	Pentasa	N	S	Unknown	Unk			Takeda
	Mezavant	N	S	Unknown	Unk			Takeda

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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	N	S	Endocervical	Unk	Not Reported
	Acetaminophen; Dextropropoxyphene	N	S	Oral	Unk	Not Reported
	Betamethasone	N	S	Unknown	Unk	Not Reported
	Betamethasone Valerate	N	S	Unknown	Unk	Not Reported

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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

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

Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown	Unk		Not Reported
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; Sodium Bicarbonate	N	S	Unknown	Unk		Not Reported
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

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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 Trimethoprim	N	S	Unknown	Unk	Not Reported
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

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

Xantofyl Palmitate	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Cetirizine Hydrochloride	N	S	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Gramicidin	N	S	Unknown	Unk	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Calcium Carbonate;Calcium Citrate;Calcium Phosphate; Colecalciferol;Mag	N	S	Unknown	Unk	Not Reported
Betaderm	N	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid;Citric Acid; Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Apo-Hydrochlorothiazide	N	S	Endocervical	Unk	Not Reported
Difenoxin Hydrochloride	N	S	Unknown	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Dosage Form, Q6hr	Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Dosage Form	Not Reported
Valsartan	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	S	Unknown	Unk	Not Reported
Azithromycin Dihydrate	N	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
16-Mar-2023	20578742	EXPEDITED (15-DAY)	N	OT	BR-ALLERGAN-2206173US			Female	BRA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</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		Not Reported	

FDA Adverse Event Reporting System

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Detailed Report

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

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

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Atorvastatin	N	S		Unknown			Not Reported
	Atropine Sulfate	N	S		Oral			Not Reported
	Hydrochlorothiazide	N	S		Endocervical			Not Reported
	Simvastatin	N	S					Not Reported
	Pantoprazole	N	S		Unknown			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		Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

				Modified-Release Capsule, Hard	
Calcium Carbonate	N	S	Unknown		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
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

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

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 Iu,	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	N	S			Not Reported
DI-Alpha Tocopheryl Acetate	N	S			Not Reported
Dulcolax	N	S			Not Reported
Gramicidin	N	S			Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Every 6 Hours	Not Reported
Magnesium Sulfate	N	S			Not Reported
Neomycin Sulfate	N	S			Not Reported
Paracetamol	N	S			Not Reported
W/Pseudoephedrine Hcl					
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

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

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

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

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	N	S			Not Reported
Potassium Phosphate Monobasic	N	S			Not Reported
Niacinamide\Pyridoxine Hydrochloride\Riboflavin\Thiamine Hydrochloride	N	S			Not Reported
Fluticasone	N	S			Not Reported
Hydrochlorothiazide	N	C			Not Reported
Valsartan	N	C	Vaginal		Not Reported
Calcium Carbonate W/Vitamin D	N	C			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 W/Diphenoxylate Hy Flovent	N	S	Oral	4 Every 1 Days	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	C	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

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
22-Mar-2023	20430704	EXPEDITED (15-DAY)	Y	HO, OT	CA-JNJFOC-20220162776		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Anaemia;	Remicade		N	S	Intravenous drip			Not Reported
Chronic Sinusitis; Colitis;	Remicade		N	S	Intravenous drip			Not Reported
Colitis Ulcerative;	Imodium		N	S	Unknown			Not Reported
Constipation; Drug	Imodium		N	S	Unknown			Not Reported
Ineffective; Dyspepsia;	Cetirizine Hydrochloride		N	S	Endocervical			Not Reported
Dyspepsia; Erythema;	Cetirizine Hydrochloride		N	S	Unknown			Not Reported
Female Genital Tract	Cetirizine Hydrochloride		N	S	Unknown			Not Reported
Fistula; Frequent Bowel	Cetirizine Hydrochloride		N	S	Unknown			Not Reported
Movements;	Benadryl		N	S	Oral			Not Reported
Haematochezia;	Nicoderm		N	S	Unknown			Not Reported
Headache;	Nicoderm		N	S	Transdermal			Not Reported
Hypersensitivity; Infusion	Nicoderm		N	S	Unknown			Not Reported
Related Reaction; Macular	Nicotine		N	S	Unknown			Not Reported
Degeneration; Malaise;	Paracetamol		N	S	Unknown			Not Reported
Malaise; Nausea; Nausea;	Invanz		N	S	Unknown			Not Reported
Off Label Use; Off Label	Alka Seltzer Heartburn		N	S	Unknown			Not Reported
Use; Oral Candidiasis;	Reliefchews		N	S	Unknown			Not Reported
Pain; Pain; Paraesthesia	Amoxicillin		N	S	Unknown			Not Reported
Oral; Paraesthesia Oral;	Amoxicillin		N	S	Unknown			Not Reported
Procedural Pain;	Amoxicilina [Amoxicillin		N	S	Unknown			Not Reported
Procedural Pain; Proctitis;	Trihydrate]		N	S	Unknown			Not Reported
Pyrexia; Pyrexia;	Apo-Hydro		N	S	Endocervical			Not Reported
Radiculopathy; Rectal	Avamys		N	S	Unknown			Not Reported
Haemorrhage;	Bactrim		N	S	Unknown			Not Reported
Therapeutic Product Effect	Bactrim		N	S	Unknown			Not Reported
Incomplete; Vaginal	Bactrim		N	S	Nasal			Not Reported
Discharge; Vaginal	Betamethasone		N	S	Unknown			Not Reported
Flatulence; Weight								
Decreased								

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

Biacin XI	N	S	Unknown	Not Reported
Biacin 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

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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

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

Azithromycin	N	S	Oral		Not Reported
Azithromycin	N	S	Unknown		Not Reported
Betamethasone Valerate	N	S	Unknown		Not Reported
Betamethasone Valerate	N	S	Unknown		Not Reported
Betamethasone Valerate	N	S	Unknown		Not Reported
Betamethasone Valerate	N	S	Unknown		Not Reported
Bisacodyl	N	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		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		Not Reported

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

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	N	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

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

Pregabalin	N	S	Unknown	Not Reported
Pregabalin	N	S	Topical	Not Reported
Pulmicort	N	S	Unknown	Not Reported
Pulmicort	N	S	Oral	Not Reported
Sodium Chloride	N	S		Not Reported
Sodium Chloride	N	S	Unknown	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	N	S	Unknown	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Not Reported
Betamethasone Dipropionate	N	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

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

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

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

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
DL-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; Miconazole Nitrate	N	S	Unknown	Not Reported
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]	N	S			Not Reported
Salinex [Sodium Chloride]	N	S	Nasal		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

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

Lomotil [Loperamide Hydrochloride]	N	S	Oral	Not Reported
Lomotil [Loperamide Hydrochloride]	N	S	Oral	Not Reported
Lomotil [Loperamide Hydrochloride]	N	S	Oral	Not Reported
Alrex [Alprazolam]	N	S	Unknown	Not Reported
Pantoprazole Sodium Sesquihydrate	N	S	Unknown	Not Reported
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; Zinc	N	S	Unknown	Not Reported
Neomycin Sulfate	N	S	Unknown	Not Reported
Sodium Sulfate	N	S	Unknown	Not Reported
Calcium Carbonate;Calcium Gluconate;Vitamin D Nos	N	S	Unknown	Not Reported
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 Phosphate	N	S	Unknown	Not Reported
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
Glycerin	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; Calcium Carbonate; Colecalciferol;Magnesium	N	S	Unknown	Not Reported
Minerals\Vitamins	N	S	Unknown	Not Reported

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Valsartan	N	S	Unknown		Not Reported
Atropine	N	S	Oral		Not Reported
Betamethasone Dipropionate; Mupirocin	N	S	Topical		Not Reported
Trimethoprim	N	S	Unknown		Not Reported
Trimethoprim	N	S	Unknown		Not Reported
Atropine Sulfate	N	S	Unknown		Not Reported
Mycomb [Gramicidin;Neomycin; Nystatin;Triamcinolone]	N	S	Unknown		Not Reported
Nicomorphine	N	S	Unknown		Not Reported
Ms Ir	N	S	Unknown		Not Reported
Ms Ir	N	S	Unknown		Not Reported
Copper Gluconate;Zinc	N	S	Unknown		Not Reported
Potassium Phosphate Monobasic	N	S	Unknown		Not Reported
Vitamins Nos	N	S	Unknown		Not Reported
Macrogol 4000	N	S	Unknown		Not Reported
Macrogol 4000	N	S	Unknown		Not Reported
Carmellose Sodium	N	S	Ophthalmic		Not Reported
Carmellose Sodium	N	S	Ophthalmic		Not Reported
Glycerol;Ichthammol	N	S	Unknown		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
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

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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	N	S	Unknown		Not Reported
Salix [Salix Alba Extract]	N	S	Intramuscular	Solution (Except Syrup)	Not Reported
Dimethyl Sulfoxide	N	S	Unknown		Not Reported
Cortenema	N	S	Unknown		Not Reported
Empracet [Paracetamol]	N	S	Unknown		Not Reported
Flagyl [Metronidazole Benzoate]	N	S	Unknown		Not Reported
Imovan	N	S	Unknown		Not Reported
Sulcrate	N	S	Unknown		Not Reported
Versed	N	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

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Ciprofloxacin Hydrochloride	N	S		Not Reported
Diflucan	N	S	Unknown	Not Reported
Diflucan	N	S		Not Reported
Entyvio	N	S	Unknown	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	N	S	Unknown	Not Reported
Glycerinum	N	S	Oral	Not Reported
Calcium Carbonate; Colecalciferol;Zinc	N	S	Intra-articular	Not Reported
Sulfamethoxazole	N	S	Unknown	Not Reported
Lutein\Zeaxanthin	N	S	Unknown	Not Reported
Lutein\Zeaxanthin	N	S	Oral	Not Reported
Ascorbic Acid;Macrogol; Potassium Chloride;Sodium	N	S	Unknown	Not Reported
Ascorbate;Sodium Chlo				
Ascorbic Acid;Macrogol; Potassium Chloride;Sodium	N	S	Urethral	Not Reported
Ascorbate;Sodium Chlo				
Sulfamethoxazole, Trimethoprim, Bromhexine	N	S	Unknown	Not Reported
Hydrochloride And Clorprena				
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Not Reported
Sodium Carboxymethylcellulose	N	S	Unknown	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Not Reported

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Dexpanthenol	N	S	Unknown	Not Reported
Sulfatrim [Sulfadiazine; Trimethoprim]	N	S	Unknown	Not Reported
Caltrate + D [Calcium Carbonate;Colecalciferol]	N	S	Unknown	Not Reported
Acetaminophen;Codeine Phosphate	N	S	Unknown	Not Reported
Calcitriol	N	S	Intra-articular	Not Reported
Sodium Bicarbonate	N	S	Unknown	Not Reported
Acetaminophen	N	S	Auricular (otic)	Not Reported
Acetaminophen	N	S	Subcutaneous	Not Reported
Acetaminophen	N	S	Unknown	Not Reported
Acetaminophen	N	S	Unknown	Not Reported
Glyceryl Trinitrate	N	S	Unknown	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Not Reported
Macrogol	N	S	Unknown	Not Reported
Hydrochlorothiazide	N	S	Unknown	Not Reported
Hydrochlorothiazide	N	S	Unknown	Not Reported
Simvastatin	N	S	Unknown	Not Reported
Simvastatin	N	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	N	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

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Zopiclone	N	S	Unknown	Not Reported
Mesalazine	N	S	Unknown	Not Reported
Mesalazine	N	S	Unknown	Not Reported
Fentanyl	N	S	Unknown	Not Reported
Isoniazid	N	S	Unknown	Not Reported
Macrogol 3350	N	S	Unknown	Not Reported
Acetic Acid;Triamcinolone Acetonide	N	S	Unknown	Not Reported
Bifidobacterium Infantis	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
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
Fluocinolone Acetonide; Neomycin Sulfate;Polymyxin B Sulfate	N	S	Unknown	Not Reported
Fluticasone Propionate; Salmeterol Xinafoate	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	Unknown	Not Reported
Polyethylene Glycol 4000	N	S	Oral	Not Reported
Mupirocin Calcium	N	C	Topical	Not Reported

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Valsartan	N	C			Not Reported
Benadryl A	N	C	Oral		Not Reported
Metoclopramide Hydrochloride	N	C	Oral		Not Reported
Metoclopramide Hydrochloride	N	C	Unknown		Not Reported
Calcium Carbonate; Cholecalciferol;Sodium	N	C			Not Reported
Hydrochlorothiazide	N	C			Not Reported
Amoxicillin	N	C			Not Reported
Calcium Ergocalciferol	N	C			Not Reported
Lomotil [Atropine Sulfate; Diphenoxylate Hydrochloride]	N	C	Unknown		Not Reported
Maxeran	N	C	Oral		Not Reported
Calcium Carbonate/Vitamin D3	N	C			Not Reported
Diphenoxylate Hydrochloride	N	C			Not Reported
Neomycin Sulfate	N	C			Not Reported
Sodium Stearate	N	C			Not Reported
Calcium Gluconate	N	C			Not Reported
Ammonium Chloride	N	C			Not Reported
Calcium Lactate;Calcium	N	C			Not Reported
Phosphate;Ergocalciferol					
Sulfamethoxazole\Trimethoprim		S			Not Reported
Naphazoline		S			Not Reported
Promethazine Hydrochloride		S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2023	19454468	EXPEDITED (15-DAY)	Y	HO, OT	CA-PFIZER INC- 2019070530		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Anaemia;	Pantoprazole	N	S		Unknown	Unk		Unknown
Chronic Sinusitis; Colitis;	Inflectra	N	S		Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks		Pfizer
Colitis Ulcerative;	Inflectra	N	S		Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks		Pfizer
Constipation; Drug	Inflectra	N	S		Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks		Pfizer
Ineffective; Dyspepsia;	Inflectra	N	S		Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks		Pfizer
Erythema; Female Genital	Inflectra	N	S		Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks		Pfizer
Tract Fistula; Frequent	Inflectra	N	S		Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks		Pfizer
Bowel Movements;	Inflectra	N	S		Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks		Pfizer
Haematochezia;	Inflectra	N	S		Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks		Pfizer
Headache; Infusion	Inflectra	N	S		Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks		Pfizer
Related Reaction; Macular	Inflectra	N	S		Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks		Pfizer

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

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	Inflectra	N	S	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

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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

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				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

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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 Chloride/Sodium Sulfate	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
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

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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/Macrogl/Potassium Chloride/Sodium Ascorbate/Sodium Chloride/Sodium Sulfate	N	S	Urethral	Unk	Not Reported
Ascorbic Acid/Macrogl/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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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	Endosinusal	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;Cholecalciferol]	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk Unk, Tid	Not Reported

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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

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			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 Trihydrate]	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		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 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

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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

FDA Adverse Event Reporting System

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Detailed Report

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	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				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	N	C		Unk		Not Reported
Calcium And Ergocalciferol	N	C	Unknown	Unk		Not Reported

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

Lomotil [Atropine Sulfate; Diphenoxylate Hydrochloride] Maxeran	N	C	Oral	Unk Unk, Qid	Not Reported
Benadryl Allergy [Diphenhydramine Hydrochloride]	N	C	Oral	10 Mg, Unk	Not Reported
Metoclopramide Hydrochloride	N	C	Unknown	Unk	Not Reported
Benadryl	N	C	Unknown	Unk	Not Reported
Sodium Stearate	N	C	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D Nos	N	C	Unknown	Unk	Not Reported
Mupirocin Calcium	N	C	Unknown	Unk	Not Reported
Mupirocin Calcium	N	C	Topical	Unk	Not Reported
Hydrocortisone		S			Not Reported
Antipyrine		S			Not Reported
Pseudoephedrine.		S			Not Reported
Tetrahydrozoline		S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2023	20711130	EXPEDITED (15-DAY)	Y	HO, OT	CA-TAKEDA- 2022TUS024666		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<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;	Mesalazine	N	S		Unknown	Unk Unk, Tid		Takeda
	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
	Metronidazole	N	S		Unknown	Unk		Not Reported

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Pyrexia; Radiculopathy;	Flagyl	N	S	Unknown	Unk	Not Reported
Rectal Haemorrhage;	Calcium Carbonate,	N	S	Unknown	Unk	Not Reported
Therapeutic Product Effect	Cholecalciferol					
Incomplete; Vaginal	Amoxicillin Trihydrate	N	S	Unknown	Unk	Not Reported
Discharge; Vaginal	Acetaminophen W/Codeine	N	S	Unknown	Unk	Not Reported
Flatulence; Weight	Phosphate					
Decreased	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
	Clotrimazole	N	S	Unknown	Unk	Not Reported

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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

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Sodium Bicarbonate	N	S	Unknown		Not Reported
Acetaminophen; Dextropropoxyphene	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	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

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Glycerine	N	S	Oral	Unk	Not Reported
Glycerine	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	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; Sulfamethoxazole;Trimethoprim	N	S	Unknown	Unk	Not Reported
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

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
23-Mar-2023	21308741	EXPEDITED (15-DAY)	Y	HO, OT	CA-SANOFI US-2022SA237087		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chronic Sinusitis; Colitis	Alprazolam	N	S			Unk		Not Reported
Ulcerative; Constipation; Erythema; Female Genital Tract Fistula; Frequent Bowel Movements; Haematochezia; Headache; Macular Degeneration; Oral Candidiasis; Proctitis; Radiculopathy; Rectal Haemorrhage;	Alprazolam	N	S			Unk		Not Reported
	Alprazolam	N	S			Unk		Not Reported
	Alprazolam	N	S			Unk		Not Reported
	Alprazolam	N	S			Unk		Not Reported
	Amoxicillin Trihydrate	N	S			Unk		Not Reported
	Amoxicillin Trihydrate	N	S			Unk		Not Reported

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

Therapeutic Product Effect	Amoxicillin Trihydrate	N	S		Unk	Not Reported
Incomplete; Vaginal	Hydrochlorothiazide	N	S		Unk	Not Reported
Discharge; Vaginal	Hydrochlorothiazide	N	S		Unk	Not Reported
Flatulence	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

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

Budesonide	N	S	Oral		Not Reported
Glycerine	N	S	Oral	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Sanofi
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
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	N	S	Oral	Unk	Not Reported
Nadolol	N	S	Oral	Unk	Not Reported
Nicoderm	N	S	Transdermal	Unk	Sanofi
Nicoderm	N	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	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

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

Mesalazine	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S	Unknown	Unk	Not Reported
Mesalazine	N	S			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		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	N	S			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

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Fluocinolone Acetonide/Neomycin Sulfate/Polymyxin B Sulfate	N	S		Unk	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

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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	N	S			Not Reported
Simvastatin	N	S		Unk	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	N	S			Not Reported
Calcium Citrate	N	S		Not Specified	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

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Lomotil [Atropine Sulfate; Diphenoxylate Hydrochloride]	N	S	Unknown	Unk	Not Reported
Moviprep [Ascorbic Acid; Macrogol 4000;Potassium Chloride;Sodium Ascorb Neomycin B Sulfate	N	S	Unknown	Unk	Not Reported
Vitamin E [Vitamin E Nos]	N	S	Unknown	Unk	Not Reported
Furosemide	N	S			Sanofi
Sucralfate	N	S	Unknown	Unk	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	N	S			Not Reported
Cupric Oxide	N	S			Not Reported
Calcium	N	S	Unknown	Unk	Sanofi
Habitrol [Nicotine]	N	S			Not Reported
Polymyxin	N	S			Not Reported
Zeaxanthin	N	S			Not Reported
Triamcinolone	N	S	Unknown	Unk	Not Reported
Azathioprine	N	S	Unknown	Unk	Not Reported
Refresh Tears	N	S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
24-Mar-2023	17965347	EXPEDITED (15-DAY)	N	HO, OT	NVSC2020CA180005		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Chronic Sinusitis; Drug	Amoxicillin Trihydrate	N	S	Unknown	Unk			Novartis
Ineffective; Dyspepsia;	Amoxicillin Trihydrate	N	S	Unknown	Unk (Powder For Oral			Novartis
Infusion Related Reaction;					Suspension)			
Macular Degeneration;	Amoxicillin Trihydrate	N	S	Unknown	Unk (Oral Suspension)			Novartis
Malaise; Nausea; Off	Azithromycin Dihydrate	N	S	Unknown	Unk			Novartis
Label Use; Pain;	Atorvastatin	N	S	Unknown	Unk			Novartis
Paraesthesia Oral;	Valsartan	N	S	Unknown	Unk			Novartis
Procedural Pain; Pyrexia;								
Therapeutic Product Effect								
Incomplete; Weight								

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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
	Dextropropoxyphene	N	S	Unknown	Unk	Not Reported

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Alprazolam	N	S	Unknown	Unk		Not Reported
Alprazolam	N	S	Oral	Unk		Not Reported
Alprazolam	N	S	Oral	Unk		Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk		Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk		Not Reported
Biaxin XI	N	S	Oral	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
Cetirizin	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, Sustained Release)		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 Ophthalmic)	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

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

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	C	Unknown		Not Reported
Calcium Phosphate	N	C	Unknown	Unk	Not Reported
Calcium Citrate	N	C	Unknown	Unk	Not Reported
Colecalciferol	N	C	Unknown	Unk	Not Reported
Cupric Oxide	N	C	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	C	Unknown	Unk	Not Reported
Vitamiin C	N	C	Unknown	Unk	Not Reported
Zinc	N	C	Unknown	Unk	Not Reported
Valsartan	N	C	Unknown	Unk	Not Reported
Apo Hydro	N	C	Endocervical	Unk	Not Reported

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Calcium Carbonate And Vitamin D		N	C	Unknown	Unk	Not Reported			
<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2023	17730751	EXPEDITED (15-DAY)	Y	HO, OT	NVSC2020CA113431		71 YR	Female	USA
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	
Chronic Sinusitis; Drug Ineffective; 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	Adalimumab		N	S	Subcutaneous	Unk		Novartis	
	Amoxicillin Trihydrate		N	S	Unknown	Unk		Novartis	
	Amoxicillin Trihydrate		N	S	Unknown	Unk		Novartis	
	Atropine Sulfate		N	S	Oral	Unk		Not Reported	
	Sodium Bicarbonate		N	S	Unknown	Unk		Not Reported	
	Clarithromycin		N	S	Unknown	Unk (Modified-Release Tablet)		Novartis	
	Clarithromycin		N	S	Unknown	Unk (Modified-Release Tablet)		Novartis	
	Clarithromycin		N	S	Unknown	Unk (Modified-Release Tablet)		Novartis	
	Clarithromycin		N	S	Unknown	Unk		Novartis	
	Clarithromycin		N	S	Unknown	Unk		Novartis	
	Atorvastatin Calcium		N	S	Unknown	Unk		Novartis	
	Atorvastatin Calcium		N	S	Unknown	Unk		Novartis	
	Atorvastatin Calcium		N	S	Unknown	Unk		Novartis	
	Atorvastatin Calcium		N	S	Unknown	Unk		Novartis	
	Ergocalciferol		N	S	Unknown	Unk		Not Reported	
	Pantoprazole		N	S	Unknown	Unk		Novartis	
	Pantoprazole		N	S	Unknown	Unk		Novartis	
	Pantoprazole		N	S	Unknown	Unk		Novartis	
	Pantoprazole		N	S	Unknown	Unk		Novartis	
	Pregabalin		N	S	Unknown	Unk		Not Reported	
	Pregabalin		N	S	Unknown	Unk		Not Reported	

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

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

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

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 Bicarbonate, 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

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

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 Ophthalmic)	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

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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
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

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

Hydrochlorothiazide	N	S	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	S	Unknown	100 Mg	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	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

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

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

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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	N	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

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

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

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

Glycerol	N	S	Unknown	Unk	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Unk	Not Reported
Valsartan	N	S	Vaginal	Unk	Not Reported
Valsartan	N	S	Intracardiac	Unk	Not Reported
Neomycin	N	S	Unknown	Unk	Not Reported
Neomycin	N	S	Unknown	Unk	Not Reported
Vitamin D	N	S	Unknown	Unk	Not Reported
Framycetin Sulfate	N	S	Unknown	Unk	Not Reported
Isoniazid	N	S	Unknown	Unk	Not Reported
Glycerol	N	S	Oral		Not Reported
Loperamide	N	S	Oral	4 Dosage Form, Q24h	Not Reported
Loperamide	N	S	Unknown	Unk	Not Reported
Loperamide	N	S	Unknown	1 Dosage Form	Not Reported
Pyridoxine	N	S	Unknown	Unk	Not Reported
Fluocinolone Acetonide	N	S	Unknown	Unk	Not Reported
Atorvastatin Calcium	N	C	Unknown	Unk	Not Reported
Calcium Carbonate	N	C	Unknown	Unk	Not Reported
Sulfamethoxazole/Trimethoprim		S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2023	20518830	EXPEDITED (15-DAY)	Y	HO, OT	CA-TEVA-2022-CA-2011562		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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	Acetaminophen	N	S		Unknown			Not Reported
	Amoxicillin Trihydrate	N	S		Unknown			Teva
	Atorvastatin Calcium	N	S		Unknown			Teva
	Atorvastatin Calcium	N	S		Unknown			Teva
	Calcium Carbonate	N	S		Unknown			Not Reported
	Clarithromycin	N	S		Unknown			Actavis
	Diphenhydramine Hydrochloride	N	S		Unknown			Not Reported

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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

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Infliximab	N	S	Intravenous (not otherwise specified)		Not Reported
Isoniazid/Pyridoxine Hydrochloride/Sulfa Methoxazole/Trimethoprim Lomotil	N	S	Unknown		Not Reported
Polyethylene Glycol\Potassium Chloride\Sodium Bicarbonate Metronidazole	N	S	Oral		Not Reported
Mupirocin	N	S	Unknown		Not Reported
Mupirocin	N	S	Topical	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

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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 Hydrochloride	N	S	Unknown	Not Reported
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	N	S	Unknown	Not Reported
Vitamin D3	N	S	Unknown	Not Reported
Vitamin D3	N	S	Unknown	Not Reported
Atropine Sulfate	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
Benzydamine Hydrochloride	N	S	Unknown	Not Reported
Calcitriol	N	S	Intra-articular	Not Reported
Cupric Oxide/Folic Acid/Nicotinic Acid/Zinc	N	S	Unknown	Not Reported

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Diphenoxylate Hydrochloride	N	S	Unknown	Not Reported
Ergocalciferol	N	S	Unknown	Not Reported
Glycerol/Sodium Stearate	N	S	Unknown	Not Reported
Glyceryl Trinitrate	N	S	Unknown	Not Reported
Gramicidin	N	S	Unknown	Not Reported
Gramicidin/Polymyxin B	N	S	Unknown	Not Reported
Hydrochlorothiazide	N	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 Cellulose	N	S	Ophthalmic	Not Reported
Sodium Carboxymethyl Cellulose	N	S	Ophthalmic	Not Reported
Sulfamethoxazole	N	S	Unknown	Not Reported
Sulfamethoxazole W/Trimethoprim	N	S	Unknown	Teva
Trimethoprim	N	S	Unknown	Not Reported
Zinc Chloride	N	S	Unknown	Not Reported
Calcium Carbonate/Vitamin D	N	C		Not Reported
Loperamide	N	C	Oral	4 Dosage Forms Daily; Not Reported
Metoclopramide Hydrochloride	N	C	Oral	Not Reported
Metoclopramide Hydrochloride	N	C		Not Reported
Valsartan	N	C	Oral	4 Dosage Forms Daily; Not Reported

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	Benadryl	N	C	Unknown	Not Reported
	Calcium	N	C	Unknown	Not Reported
	Calcium Lactate/Calcium Phosphate/Ergocalciferol	N	C	Unknown	Not Reported
	Lomotil	N	C	Unknown	Not Reported
	Amoxicillin	N	C		Not Reported
	Diphenhydramine Hydrochloride	N	C	Unknown	Not Reported
	Mupirocin Calcium Dihydrate	N	C		Not Reported
	Neomycin Sulfate	N	C		Not Reported
	Sodium Stearate	N	C		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
27-Mar-2023	21279828	EXPEDITED (15-DAY)	N	OT	US-ALLERGAN-2228095US			Male	USA

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Arthritis; Device Difficult To Use; Frustration Tolerance Decreased; Myocardial Infarction; Neoplasm Malignant; Product Quality Issue; Vascular Graft	Refresh Optive Sensitive		Y	S	Ophthalmic	Unk		Allergan

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2023	16259298	EXPEDITED (15-DAY)	Y	HO, OT	CA-CELLTRION INC.-2019CA020672			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Anaemia; Chronic Sinusitis; Colitis; Colitis Ulcerative;	Inflectra		N	S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks		Celltrion
Constipation; Drug Ineffective; Dyspepsia;	Inflectra		N	S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks		Celltrion
Erythema; Female Genital Tract Fistula; Frequent Bowel Movements;	Inflectra		N	S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks		Celltrion
Haematochezia; Headache; Infusion	Inflectra		N	S	Intravenous (not otherwise specified)	5 Mg/Kg, Every 6 Weeks		Celltrion

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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	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

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Adalimumab	N	S	Subcutaneous	Unk Solution (Except Syrup)	Not Reported
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

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				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 Simvastatin	N	S	Unknown	Unk	Not Reported
Acetaminophene	N	S	Unknown	Unk	Not Reported
Calcium Carbonate; Colecalciferol;Zinc Sulfamethoxazole	N	S	Intra-articular	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 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	Endosinusal	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

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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

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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	N	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]	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 Hydrochloride	N	S	Oral	Unk	Not Reported
Loperamide Hydrochloride	N	S	Oral	1 Dosage Form, Q6hr	Not Reported

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

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

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

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	N	S	Unknown		Not Reported
Apo-Alpraz	N	S	Unknown	0.25 Milligram	Not Reported
Empracet	N	S	Unknown		Not Reported
Valsartan	N	C	Unknown	Unk	Not Reported
Valsartan	N	C	Unknown	4 Dosage Form, Qd	Not Reported
Calcium Gluconate Cox	N	C		Unk	Not Reported
Calcium And Ergocalciferol	N	C	Unknown	Unk	Not Reported
Lomotil [Atropine Sulfate; Diphenoxylate Hydrochloride]	N	C	Oral	Unk Unk, Qid	Not Reported
Maxeran	N	C	Oral	10 Mg, Unk	Not Reported
Benadryl Allergy [Diphenhydramine Hydrochloride]	N	C	Unknown	Unk	Not Reported
Metoclopramide Hydrochloride	N	C	Unknown	Unk	Not Reported
Benadryl	N	C	Unknown	Unk	Not Reported
Sodium Stearate	N	C	Unknown	Unk	Not Reported
Calcium Carbonate;Vitamin D Nos	N	C	Unknown	Unk	Not Reported
Mupirocin Calcium	N	C	Unknown	Unk	Not Reported
Mupirocin Calcium	N	C	Topical	Unk	Not Reported

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

Hydrocortisone	S	Not Reported
Antipyrine	S	Not Reported
Pseudoephedrine.	S	Not Reported
Tetrahydrozoline	S	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2023	21238409	EXPEDITED (15-DAY)	Y	HO, OT	CA-VALIDUS PHARMACEUTICALS LLC-CA-VDP-2022- 015611			Unknown	USA

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

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

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

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

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
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

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

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

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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

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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	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	N	S	Ophthalmic	Unk	Not Reported
Vitamin E Nos	N	S	Unknown	Unk	Not Reported
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole	N	S	Unknown		Not Reported
Flovent	N	S	Unknown		Not Reported
Benzydamine Hydrochloride	N	S	Unknown	Unk	Not Reported
Dulcolax [Bisacodyl]	N	S	Unknown	Unk	Not Reported
Calcium Phosphate; Colecalciferol	N	S	Unknown	Unk	Not Reported
Difenoxin Hydrochloride	N	S	Unknown	Unk	Not Reported
Ertapenem	N	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	N	S	Unknown	Unk	Not Reported
Vitamin E [Vitamin E Nos]	N	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

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	Ciprofloxacin	N	S	Unknown	Unk		Not Reported
	Zopiclone	N	S	Unknown	Unk		Not Reported
	Azathioprine	N	S	Unknown	Unk		Not Reported
	Azithromycin Dihydrate	N	S	Unknown	Unk		Not Reported
	Cupric Oxide	N	S	Unknown	Unk		Not Reported
	Calcium	N	S	Unknown	Unk		Not Reported
	Habitrol [Nicotine]	N	S	Unknown	Unk		Not Reported
	Polymyxin	N	S	Unknown	Unk		Not Reported
	Salinex [Sodium Chloride]	N	S	Unknown	Unk (Nasal Drop)		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	Unknown	Unk		Not Reported
	Refresh Tears	N	S	Unknown	Unk		Not Reported
	Valsartan	N	C	Unknown	Unk		Not Reported
	Mesalazine	N	C	Oral	1.2 Gram		Not Reported
	Diphenhydramine Hydrochloride	N	C	Unknown	Unk		Not Reported
	Calcium Carbonate And Vitamin D3	N	C	Unknown	Unk		Not Reported
	Neomycin Sulfate	N	C	Unknown	Unk		Not Reported
	Sodium Stearate	N	C	Unknown	Unk		Not Reported
	Amoxicillin	N	C	Unknown	Unk (Amoxicillin; Calcium Carbonate)		Not Reported
	Calcium Carbonate	N	C	Unknown	Unk		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
28-Mar-2023	21384118	EXPEDITED (15-DAY)	Y	HO, OT	NVSC2022CA215906		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Anaemia; Chronic Sinusitis; Colitis;	Pantoprazole	N	S	Unknown	Unk			Novartis

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Colitis Ulcerative;	Pantoprazole	N	S	Unknown	Unk	Novartis
Constipation; Drug	Adalimumab	N	S	Subcutaneous	Unk	Novartis
Ineffective; Dyspepsia;	Atorvastatin	N	S	Unknown	Unk	Novartis
Erythema; Female Genital	Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Tract Fistula; Frequent	Betamethasone	N	S	Unknown	Unk	Novartis
Bowel Movements;	Clarithromycin	N	S	Unknown	Unk	Novartis
Haematochezia;	Pantoprazole Sodium	N	S	Unknown	Unk	Novartis
Headache; Infusion	Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Related Reaction; Macular	Potassium Chloride	N	S	Unknown	Unk	Not Reported
Degeneration; Malaise;	Pregabalin	N	S	Unknown	150 Mg	Not Reported
Nausea; Off Label Use;	Pregabalin	N	S	Unknown	Unk	Not Reported
Oral Candidiasis; Pain;	Amoxicillin Trihydrate	N	S	Unknown	Unk	Novartis
Paraesthesia Oral;	Amoxicillin Trihydrate	N	S	Unknown	Unk	Novartis
Procedural Pain; Proctitis;	Hydromorphone Hydrochloride	N	S	Endocervical	Unk	Not Reported
Pyrexia; Radiculopathy;	Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
Rectal Haemorrhage;	Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Therapeutic Product Effect	Magnesium Sulfate	N	S	Unknown	Unk	Not Reported
Incomplete; Vaginal	Azithromycin Dihydrate	N	S	Unknown	Unk	Novartis
Discharge; Vaginal	Infliximab	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Flatulence; Weight	Infliximab	N	S	Intravenous (not otherwise specified)	5 Mg/Kg	Not Reported
Decreased	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	Not Reported
	Atropine Sulfate	N	S	Oral	4 Dosage Form	Not Reported

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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

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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	N	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	Unk	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

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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 Chloride\Sodium Sulfate	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 3350\Potassium\Sodium Chloride\Sodium Sulfate	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 3350\Potassium\Sodium Chloride\Sodium Sulfate	N	S	Unknown	Unk	Not Reported
Polyethylene Glycol 3350\Potassium\Sodium Chloride\Sodium Sulfate	N	S	Unknown	Unk	Not Reported

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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	C	Unknown	Unk		Not Reported
Amoxicillin	N	C	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	N	S	Unknown	1 Dosage Form, 2 Every 1 Day	Not Reported
Diflucan	N	S	Unknown	Unk	Not Reported
Solu-Medrol	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
Bactrim	N	S	Unknown	Unk	Not Reported
Glycerinum	N	S	Oral	Unk (Drops Oral)	Not Reported
Bactrim	N	S	Nasal	Unk	Not Reported
Calcium	N	S	Unknown	Unk	Not Reported
Calcium Lactate	N	C	Unknown	Unk	Not Reported
Sodium Stearate	N	C	Unknown	Unk	Not Reported
Calcium Gluconate	N	C	Unknown	Unk	Not Reported
Metoclopramide Hydrochloride	N	C	Unknown	Unk	Not Reported
Benadryl	N	C	Unknown	Unk	Not Reported
Benadryl Allergy	N	C	Oral	Unk	Not Reported
Neomycin Sulfate	N	C	Unknown	Unk	Not Reported
Diphenhydramine Hydrochloride	N	C	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
29-Mar-2023	21985846	EXPEDITED (15-DAY)	Y	HO, OT	NVSC2023CA027221		65 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Anaemia;	Adalimumab	N	S	Subcutaneous	Unk			Novartis
Chronic Sinusitis; Colitis;	Atorvastatin Calcium	N	S	Unknown	Unk			Novartis
Colitis Ulcerative;	Atorvastatin Calcium	N	S	Unknown	Unk (Dosage Form: Not Specified)			Novartis
Constipation; Drug	Azithromycin	N	S	Unknown	Unk			Novartis
Ineffective; Dyspepsia;	Azithromycin	N	S	Oral	Unk			Novartis
Erythema; Female Genital	Ciprofloxacin	N	S	Unknown	Unk			Novartis
Tract Fistula; Frequent	Sodium Bicarbonate	N	S	Unknown	Unk			Not Reported
Bowel Movements;								
Haematochezia;								
Headache; Infusion								
Related Reaction; Macular								
Degeneration; Malaise;								

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Nausea; Off Label Use;	Ciprofloxacin Hydrochloride	N	S	Unknown	Unk	Novartis
Oral Candidiasis; Pain;	Clarithromycin	N	S	Unknown	Unk	Novartis
Paraesthesia Oral;	Clarithromycin	N	S	Unknown	Unk	Novartis
Procedural Pain; Proctitis;	Diphenhydramine	N	S	Unknown	Unk	Not Reported
Pyrexia; Radiculopathy;	Diphenhydramine	N	S	Unknown	Unk	Not Reported
Rectal Haemorrhage;	Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Therapeutic Product Effect	Diphenhydramine Hydrochloride	N	S	Oral	50 Mg	Not Reported
Incomplete; Vaginal	Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Discharge; Vaginal	Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Flatulence; Weight	Diphenhydramine Hydrochloride	N	S	Unknown	Unk	Not Reported
Decreased	Fentanyl	N	S	Unknown	Unk	Not Reported
	Fentanyl Citrate	N	S	Unknown	Unk	Not Reported
	Fluconazole	N	S	Unknown	Unk	Not Reported
	Hydrocortisone	N	S	Unknown	Unk	Novartis
	Magnesium	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
	Hydromorphone Hydrochloride	N	S	Unknown	Unk	Not Reported
	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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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	N	S	Nasal	Unk (Intra-Nasal)	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Zopiclone	N	S	Unknown	Unk	Not Reported
Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Magnesium Carbonate	N	S	Unknown	Unk	Not Reported
Acetylsalicylic Acid	N	S	Unknown	Unk	Not Reported

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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)	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
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

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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

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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

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Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Pentasa	N	S	Unknown	Unk	Not Reported
Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Pulmicort	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Other	Unk	Not Reported
Sodium Chloride	N	S	Unknown	Unk	Not Reported
Sodium Chloride	N	S	Nasal	Unk	Not Reported
Statex	N	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
31-Mar-2023	21260399	EXPEDITED (15-DAY)	Y	HO, OT	CA-BAXTER- 2022BAX017696		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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	Sodium Chloride	N	S		Nasal	Dosage Form: Not Specified, Intranasal Route		Baxter
	Sodium Chloride	N	S		Other	Dosage Form: Not Specified		Baxter
	Sodium Chloride	N	S			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		Endocervical	Dosage Form: Not Specified		Baxter
	Sodium Bicarbonate Concentrate	N	S		Unknown	Dosage Form: Not Specified		Baxter
	Acetaminophen Injection	N	S		Unknown	Dosage Form: Not Specified		Baxter
	Alprazolam	N	S		Unknown	0.25 Milligrams (Mg)		Not Reported
	Alprazolam	N	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	N	S			Not Reported
Azithromycin Monohydrate	N	S	Unknown		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

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

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

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

Diphenhydramine Hydrochloride	N	S				Not Reported
Diphenhydramine	N	S	Unknown	Dosage Form: Not Specified		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 Solution 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	N	S	Unknown	Unk		Not Reported
Glycerol;Sodium Stearate	N	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

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

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

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

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

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

Triamcinolone Acetonide	N	S	Intra-articular	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 Propionate	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

FDA Adverse Event Reporting System

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Detailed Report

Nicotinamide	N	S	Unknown	Specified	Not Reported
Glycerin	N	S	Unknown	Dosage Form: Not Specified	Not Reported
Pantoprazole Sodium Anhydrous	N	S	Unknown		Not Reported
Diphenhydramine Hydrochloride	N	C	Unknown		Not Reported
Calcium Carbonate/Vitamin D3	N	C	Unknown		Not Reported
Valsartan	N	C	Oral	Dosage Form: Not Specified, 4 Dosage Form, One Every One Days	Not Reported
Valsartan	N	C	Unknown	40 Milligrams, One Every One Days	Not Reported
Valsartan	N	C	Unknown	Dosage Form: Not Specified	Not Reported
Sodium Stearate	N	C	Unknown		Not Reported
Calcium Ergocalciferol	N	C	Unknown		Not Reported
Metoclopramide Hydrochloride	N	C	Oral		Not Reported
Metoclopramide Hydrochloride	N	C	Unknown	Unk	Not Reported
Calcium	N	C	Unknown	Dosage Form: Not Specified	Not Reported
Calcium Carbonate; Ergocalciferol	N	C	Unknown		Not Reported
Loperamide	N	C	Oral	4 Dosage Forms, One Every One Days	Not Reported
Benadryl	N	C	Unknown	Dosage Form: Not Specified	Not Reported
Lomotil	N	C	Unknown		Not Reported
Calcium Lactate;Calcium Phosphate;Ergocalciferol	N	C	Unknown		Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
04-Apr-2023	17954704	EXPEDITED (15-DAY)	Y	HO, OT	CA-GLENMARK PHARMACEUTICALS- 2020GMK048306			Unknown	CAN

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

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Abdominal Pain; Anaemia; Chronic Sinusitis; Colitis; Colitis Ulcerative; Constipation; Drug Ineffective; Dyspepsia; Erythema; Female Genital Tract Fistula; Frequent Bowel Movements; Haematochezia; Headache; Hypotension; 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; Weight Decreased	Mupirocin		N	S	Unknown	Unk (Formulation: Unknown)		Glenmark
	Mupirocin		N	S	Unknown	Unk (Formulation: Unknown)		Glenmark
	Mupirocin		N	S	Topical	Unk (Formulation: Unknown)		Glenmark
	Mupirocin		N	S	Unknown	Unk (Formulation: Unknown)		Glenmark
	Mupirocin		N	S	Topical	Unk (Formulation: Unknown)		Glenmark
	Mupirocin		N	S	Topical	Unk (Formulation: Ointment)		Glenmark
	Mupirocin		N	S	Topical	Unk (Formulation: Ointment)		Glenmark
	Mupirocin		N	S	Topical	Unk (Formulation: Ointment)		Glenmark
	Mupirocin		N	S	Unknown	Unk (Formulation: Ointment)		Glenmark
	Amoxicillin Trihydrate		N	S	Unknown	Unk		Not Reported
	Amoxicillin Trihydrate		N	S	Unknown	Unk		Not Reported
	Atropine Sulfate;Diphenoxylate Hydrochloride		N	S	Oral	Unk		Not Reported
	Atropine Sulfate;Diphenoxylate Hydrochloride		N	S	Oral	4 Dosage Form, 1 Every 1 Day		Not Reported
	Atropine Sulfate;Diphenoxylate Hydrochloride		N	S	Oral	4 Dosage Form 1 Every 1 Day		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

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

Diphenhydramine Hydrochloride	N	S	Oral	50 Milligram	Not Reported
Calcium Carbonate; Ergocalciferol	N	S	Unknown	Unk	Not Reported
Calcium Carbonate; Ergocalciferol	N	S	Unknown	Unk	Not Reported
Calcium Carbonate; Ergocalciferol	N	S	Unknown	Unk	Not Reported
Calcium Carbonate; Ergocalciferol	N	S	Unknown	Unk	Not Reported
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	N	S	Unknown	Unk	Not Reported
Gramicidin W/Neomycin Sulfate/Polymycin B	N	S	Unknown	Unk	Not Reported
Gramicidin W/Neomycin Sulfate/Polymycin B	N	S	Unknown	Unk	Not Reported
Macrogol 3350 W/Potassium Chloride//01618701/ Humira	N	S	Unknown	Unk	Not Reported
Humira	N	S	Subcutaneous	Unk (Forulation: Solution Subcutaneous) 2190 DAY	Not Reported
Humira	N	S	Unknown	Unk (Forulation: Solution Subcutaneous) 6 YR	Not Reported
Humira	N	S	Unknown	Unk (Forulation: Solution Subcutaneous)	Not Reported
Humira	N	S	Subcutaneous	Unk	Not Reported
Humira	N	S	Subcutaneous	Unk (Forulation: Solution Subcutaneous) 2190 DAY	Not Reported
Metronidazole	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
Morphine Sulfate	N	S	Unknown	Unk	Not Reported
Morphine Sulfate	N	S	Unknown	Unk	Not 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

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

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 Trimethoprim	N	S	Unknown	200 Milligram	Not Reported
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

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

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	Endosinusal	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
DL-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
Cetirizine	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	N	S	Unknown	Unk		Not Reported
Betamethasone Valerate	N	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

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

Adalimumab	N	S	Subcutaneous	Unk (Formulation: Subcutaneous Solution)	Not Reported
Adalimumab	N	S	Unknown	Unk	Not Reported
Adalimumab	N	S	Unknown	Unk (Formulation: Subcutaneous Solution)	Not Reported
Vitamin D3	N	S	Unknown	Unk	Not Reported
Acetaminophen; Dextropropoxyphene	N	S	Unknown	Unk	Not Reported
Mezavant	N	S	Unknown	Unk	Not Reported
Kenalog /00031902/	N	S	Intra-articular	Unk (Formulation: Suspension Intra-Articular)	Not Reported
Kenalog [Triamcinolone Acetonide]	N	S	Intra-articular	Unk, Suspension Intraarticular	Not Reported
Sodium Carboxymethylcellulose	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
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Calcium Carbonate	N	S	Unknown	Unk	Not Reported
Ertapenem	N	S	Intramuscular	Unk	Not Reported
Flovent	N	S	Unknown	Unk	Not Reported
Flovent	N	S	Unknown	Unk	Not Reported
Gramicidin;Polymyxin B	N	S	Unknown	Unk	Not Reported
Metronidazole	N	S	Unknown	Unk	Not Reported
Multivitamin [Vitamins Nos]	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
Atropine Sulfate;Difenoxin Hydrochloride	N	S	Oral	Unk	Not Reported
Atropine Sulfate;Difenoxin Hydrochloride	N	S	Oral	Unk	Not Reported
Atropine Sulfate;Difenoxin	N	S	Oral	4 Dosage Form 1 Every 1	Not Reported

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

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 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

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

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

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

Sulfamethoxazole And Trimethoprim	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole And Trimethoprim	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	Unknown	Unk	Not Reported
Dulcolax [Bisacodyl]	N	S	Unknown	Unk	Not Reported
Paracetamol And Pseudoephedrine Hydrochloride	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
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

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

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

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

Moviprep [Ascorbic Acid; Macrogol 3350;Potassium Chloride;Sodium Ascorb 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	C	Unknown	Unk	Not Reported
Benadryl [Diphenhydramine Hydrochloride]	N	C	Oral	50 Milligram	Not Reported
Metoclopramide Hydrochloride	N	C	Oral	10 Milligram	Not Reported
Vitamin D3	N	C	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D3	N	C	Unknown	Unk	Not Reported
Calcium Carbonate/Vitamin D3	N	C	Unknown	Unk	Not Reported
Hydrochlorothiazide	N	C	Endocervical	Unk	Not Reported
Clotrimazole	N	C	Unknown	Unk	Not Reported
Valsartan	N	C	Unknown	Unk	Not Reported
Valsartan	N	C	Intracardiac	Unk	Not Reported
Valsartan	N	C	Vaginal	Unk	Not Reported
Valsartan	N	C	Unknown	Unk	Not Reported
Sulfamethoxazole\Trimethoprim		S			Not Reported

FDA Adverse Event Reporting System

Freedom of Information Act (FOIA)

Detailed Report

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2023	19930588	EXPEDITED (15-DAY)	N	HO, OT	CA-PURDUE-USA-2021-0285682		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
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	Dilaudid		N	S	Unknown	Unknown		Rhodes
	Ms Ir		N	S	Unknown	Unknown		Not Reported
	Acetaminophen		N	S	Unknown	Unknown		Not Reported
	Acetaminophen		N	S	Unknown	Unk		Not Reported
	Acetaminophen		N	S	Unknown	Unk		Not Reported
	Acetylsalicylic Acid		N	S	Oral	Unknown		Not Reported
	Acetylsalicylic Acid		N	S	Unknown	Unk		Not Reported
	Alprazolam		N	S	Unknown	Unknown		Not Reported
	Alprazolam		N	S	Unknown	0.25 Milligram		Not Reported
	Amoxicillin Trihydrate		N	S	Unknown	Unknown		Not Reported
	Amoxicillin Trihydrate		N	S	Unknown	Unk		Not Reported
	Amoxicillin Trihydrate		N	S	Unknown	Unk		Not Reported
	Betamethasone Valerate		N	S	Unknown	Unknown		Not Reported
	Betamethasone Valerate		N	S	Topical	Unk		Not Reported
	Betamethasone Valerate		N	S	Unknown	0.122 Gram		Not Reported
	Bisacodyl		N	S	Unknown	Unknown		Not Reported
	Bisacodyl		N	S	Unknown	Unk		Not Reported
	Bisacodyl		N	S	Unknown	Unk		Not Reported
	Budesonide		N	S	Unknown	Unknown		Not Reported
	Budesonide		N	S	Respiratory (inhalation)	Unk		Not Reported
Budesonide		N	S	Oral	Unk		Not Reported	
Budesonide		N	S	Respiratory (inhalation)	Unk		Not Reported	
Budesonide		N	S	Oral	1 Dosage Form		Not Reported	

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

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

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

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	N	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 W/Diphenoxylate Hydrochlor.	N	S	Oral	Unk	Not Reported
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	N	S			Not Reported
Adalimumab	N	S			Not Reported
Amoxicillin	N	S	Unknown	Unk	Not Reported

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

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	N	S			Not Reported
Diphenhydramine	N	S	Unknown	Unk	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

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

Sinus Rinse	N	S	Unknown	Unk	Not Reported
Sinus Rinse	N	S	Nasal	Unk	Not Reported
Sulfamethoxazole W/Trimethoprim	N	S	Endocervical	Unk	Not Reported
Sulfamethoxazole W/Trimethoprim	N	S	Endocervical	Unk	Not Reported
Sulfamethoxazole W/Trimethoprim	N	S	Endocervical	200 Mg, Unk	Not Reported
Sulfamethoxazole W/Trimethoprim	N	S	Oral	1 Df, Unk	Not Reported
Triamcinolone Acetonide	N	S	Intra-articular	Unk	Not Reported
Vitamins Nos	N	S	Unknown	Unk	Not Reported
Azithromycin Dihydrate	N	S	Unknown	Unk	Not Reported
Mupirocin Calcium	N	S	Unknown	Unk	Not Reported
Mupirocin Calcium	N	S	Topical	Unk	Not Reported
Lomotil /00034001/	N	S	Oral	Unk,4 Every 1 Day	Not Reported
Niquitin Mint	N	S	Unknown	Unk	Not Reported
Salinex /00075401/	N	S	Unknown	Unk	Not Reported
Salinex /00075401/	N	S	Nasal	Unk	Not Reported
Statex /00036302/	N	S	Unknown	Unk	Not Reported
Betaderm /00008501/	N	S	Unknown	Unk	Not Reported
Sodium Carboxymethylcellulose	N	S	Ophthalmic	Unk	Not Reported
Calcium Carbonate And Vitamin D	N	S	Unknown	Unk	Not Reported
Apo Hydro	N	S	Unknown	Unk	Not Reported
Apo Hydro	N	S	Unknown	100 Milligram	Not Reported
Bactrim	N	S	Unknown	Unk	Not Reported
Bactrim	N	S	Unknown	200 Milligram	Not Reported
Calcium Carbonate W/Colecalciferol//08220201/	N	S	Unknown	Unk	Not Reported
Calcium Carbonate; Colecalciferol	N	S	Unknown	Unk	Not Reported
Habitrol /01033301/	N	S	Unknown	Unk	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

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

Loperamide	N	S	Oral	1 Dosage Form, Cyclical	Not Reported
Loperamide	N	S	Oral	Unk, Weekly	Not Reported
Loperamide	N	S	Oral	Unk, Monthly	Not Reported
Atropine Sulfate	N	S	Unknown	Unknown	Not Reported
Calcitriol	N	S	Unknown	Unknown	Not Reported
Loperamide	N	C	Oral	4 Dosage Form, Daily	Not Reported
Valsartan	N	C	Intracardiac	Unk	Not Reported
Valsartan	N	C	Unknown	40 Milligram, Daily	Not Reported
Valsartan	N	C	Unknown	4 Dosage Form, Daily	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
05-Apr-2023	20844659	EXPEDITED (15-DAY)	Y	HO, OT	CA- GLAXOSMITHKLINE- CA2019AMR240941			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Anaemia; Chronic Sinusitis; Colitis; Colitis Ulcerative;	Avamys	N	S		Unknown	Unk (Spray, Metered Dose)		Glaxosmithkline
Constipation; Drug	Avamys	N	S		Unknown	Unk		Glaxosmithkline
Ineffective; Dyspepsia;	Flovent	N	S			Unk		Glaxosmithkline
Erythema; Female Genital Tract Fistula; Frequent	Flovent	N	S		Unknown	Unk (Spray Metered Dose)		Glaxosmithkline
Bowel Movements;	Fluticasone Propionate	N	S		Unknown	Unk		Glaxosmithkline
Haematochezia;	Betamethasone Valerate	N	S		Unknown	Unk		Not Reported
Headache; Infusion	Betamethasone Valerate	N	S		Topical	Unk		Not Reported
Related Reaction; Macular Degeneration; Malaise;	Betamethasone Valerate	N	S		Unknown	Unk		Not Reported
Nausea; Off Label Use;	Potassium Chloride	N	S		Unknown	Unk		Not Reported
Oral Candidiasis; Pain;	Fluticasone	N	S		Unknown	Unk		Glaxosmithkline
Paraesthesia Oral;	Propionate+Salmeterol							
Procedural Pain; Proctitis;	Xinafoate							
Pyrexia; Radiculopathy;	Mupirocin	N	S		Unknown	Unk		Glaxosmithkline
Rectal Haemorrhage;	Mupirocin	N	S		Topical	Unk		Glaxosmithkline
Therapeutic Product Effect	Sulfamethoxazole + Trimethoprim	N	S		Unknown	Unk		Not Reported
Incomplete; Vaginal Discharge; Vaginal Flatulence; Weight								

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

Decreased	Sulfamethoxazole + Trimethoprim	N	S		Unk	Not Reported
	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	N	S	Transplacental	Unk	Not Reported
	Bisacodyl	N	S	Unknown	Unk	Not Reported
	Cetirizine	N	S	Unknown	Unk	Not Reported
	Clotrimazole	Y	S	Unknown	Unk	Glaxosmithkline
	Clotrimazole	Y	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	N	S	Unknown	Unk	Not Reported
	Magnesium Hydroxide	N	S	Unknown	Unk	Not Reported
	Metoclopramide Hydrochloride	N	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 + Trimethoprim	N	S	Unknown	Unk	Not Reported
	Sulfamethoxazole +	N	S	Unknown	Unk	Not Reported

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

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 Glycol + Sodium Chloride)	N	S	Nasal	Unk		Not Reported
Nicotinamide	N	S	Unknown	Unk		Not Reported
Nicotinamide	N	S	Unknown	Unk		Not Reported
Magnesium Sulfate Injection	N	S	Unknown	Unk		Not Reported
Acetaminophen + Pseudoephedrine	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
Niquitin	N	S	Unknown	4 Mg		Not Reported
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

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

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	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

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

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 + Nicotinamide + Zinc	N	S	Unknown	Unk	Not Reported
Jackson'S Mineral Salts Sodium Chloride	N	S	Unknown	Unk (Pellet)	Not Reported
Alka-Seltzer (Acetylsalicylic Acid + Citric Acid + Sodium Bicarbonate)	N	S	Unknown	Unk	Not Reported
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 + Zinc	N	S	Unknown	Unk	Not Reported
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

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Ambroxol/Cetirizine	N	S	Unknown	Unk	Not Reported
Isoniazid	N	S	Unknown	Unk	Not Reported
Magnesium Aspartate	N	S	Unknown	Unk	Not Reported
Zinc Chloride	N	S	Unknown	Unk	Not Reported
Valsartan	N	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2023	21836804	EXPEDITED (15-DAY)	Y	OT	CA-GLENMARK PHARMACEUTICALS- 2023GMK077650			Unknown	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Mupirocin	N	S		Topical	Unk (Formulation: Ointment Topical)		Glenmark
	Acetaminophen	N	S		Unknown	Unk		Not Reported
	Acetylsalicylic Acid	N	S		Oral	Unk		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	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 Sulfate	N	S		Oral	Unk		Not Reported
	Atropine Sulfate	N	S		Unknown	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 Valerate	N	S		Unknown	Unk		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

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

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

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Sodium Chloride	N	S	Unknown	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
Zeaxanthin	N	S	Unknown	Unk	Not Reported
Zinc Chloride	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk	Not Reported
Valsartan	N	S	Intracardiac	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Oral	Unk	Not Reported
Calcium Carbonate/Vitamin D3	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
06-Apr-2023	21948537	EXPEDITED (15-DAY)	Y	OT	CA-ORGANON- O2301CAN002057			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Diprosone	N	S		Unknown	Unk, Dosage Form: Not Specified		Organon
	Zocor	N	S		Unknown	Unk		Organon
	Acetaminophen	N	S		Unknown	Unk, Dosage Form: Not Specified		Not Reported
	Acetaminophen	N	S		Unknown	Unk		Not Reported
	Acetylsalicylic Acid	N	S		Unknown	Unk, Dosage Form: Not Specified		Not Reported
	Acetylsalicylic Acid	N	S		Oral	Unk, Dosage Form: Not Specified		Not Reported
	Adalimumab	N	S		Subcutaneous	Unk, Formulation: Solution		Not Reported

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				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

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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 Vitamin D3	N	S	Unknown	Unk	Not Reported
Calcium Carbonate And Vitamin D3	N	S	Intra-articular	Unk	Not Reported
Calcium Carbonate And Vitamin D3	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	Not Reported
Fluticasone Furoate	N	S	Ophthalmic	Unk	Not Reported
Fluticasone Furoate	N	S	Unknown	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

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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

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

Mupirocin	N	S	Topical	Unk	Not Reported
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 [Pantoprazole Sodium Monohydrate]	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Pantoprazole Sodium [Pantoprazole Sodium Monohydrate]	N	S	Unknown	Unk, Dosage Form: Not Specified	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 Specified	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	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
Lutein\Zeaxanthin	N	S	Unknown	Unk	Not Reported
Zinc Oxide	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Fructose;Glycerol;Sodium Chloride	N	S	Oral	Unk	Not Reported
Fructose;Glycerol;Sodium Chloride	N	S	Oral	Unk	Not Reported
Fructose;Glycerol;Sodium Chloride	N	S	Unknown	Unk	Not Reported
Gramicidin;Neomycin Sulfate; Polymyxin B Sulfate	N	S	Unknown	Unk	Not Reported
Acetaminophen; Dextropropoxyphene	N	S	Unknown	Unk	Not Reported
Bactroban [Mupirocin]	N	S	Unknown	Unk	Not Reported
Minerals\Vitamins	N	S	Unknown	Unk	Not Reported
Betamethasone;Mupirocin	N	S	Unknown	Unk	Not Reported
Betamethasone;Mupirocin	N	S	Topical	Unk	Not Reported
1,3-Butandiol;Dexpanthenol; Dimethyl Sulfoxide;Glycerol	N	S	Oral	Unk	Not Reported
1,3-Butandiol;Dexpanthenol; Dimethyl Sulfoxide;Glycerol	N	S	Unknown	Unk	Not Reported
Isoniazid/Pyridoxine Hydrochloride/Sulfamethoxazole /Trimethoprim	N	S	Unknown	Unk	Not Reported
Betamethasone Sodium Phosphate	N	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
07-Apr-2023	20561561	EXPEDITED (15-DAY)	Y	OT	CA-ORGANON-O2203CAN000535			Female	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	

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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 Adminstration : 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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Vitamins Nos	N	S	Unknown	Unk	Not Reported
Valsartan	N	C	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Metronidazole	N	C	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Sulfamethoxazole\Trimethoprim		S			Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2023	17200194	EXPEDITED (15-DAY)	Y	OT	CA-dreddys-USA/CAN/19/0117732			Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Drug Ineffective; Macular Degeneration	Atorvastatin	N	S		Unknown			Not Reported
	Atorvastatin	N	S		Unknown			Not Reported
	Ertapenem For Injection, 1 G/Vial	N	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	N	S		Unknown			Not Reported
	Apo Hydro	N	S		Oral			Not Reported
	Apo Hydro	N	S		Endocervical			Not Reported
	Apo Hydro	N	S		Unknown			Not Reported
	Avamys	N	S		Ophthalmic			Not Reported
	Avamys	N	S		Unknown			Not Reported
	Azithromycin Dihydrate	N	S		Unknown			Not Reported
	Bactroban	N	S		Unknown			Not Reported
	Betaderm	N	S		Unknown			Not Reported

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

Betamethasone Dipropionate	N	S	Unknown		Not Reported
Biaxin XI	N	S	Oral		Not Reported
Biaxin XI	N	S	Unknown		Not Reported
Bisacodyl	N	S	Unknown		Not Reported
Bisacodyl	N	S	Transplacental		Not Reported
Cetirizine	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
Dilaudid	N	S	Unknown		Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown		Not Reported
Diphenhydramine Hydrochloride	N	S	Unknown		Not Reported
Entocort	N	S	Oral		Not Reported
Entocort	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
Gramicidin/Neomycin Sulfate/Polymyxin B Sulfate	N	S	Unknown		Not Reported
Gramicidin/Neomycin Sulfate/Polymyxin B Sulfate	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
Kenalog	N	S	Intra-articular		Not Reported
Lomotil	N	S	Oral		Not Reported
Metronidazole	N	S	Unknown		Not Reported

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

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	N	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	N	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

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

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	N	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

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

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	N	S		Not Reported
Budesonide	N	S		Not Reported
Budesonide	N	S	Oral	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	N	S		Not Reported
Hydrochlorothiazide	N	S	Subcutaneous	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

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

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	N	S			Not Reported
Vitamin E Cap 400unit	N	S	Unknown	400unit	Not Reported
Atropine Sulfate/ Difenoxin/ Hydrochloride	N	S	Oral		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

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

Sinus Rinse	N	S	Other	Not Reported
Sinus Rinse	N	S		Not Reported
Ambroxol/Cetirizine Hydrochloride	N	S	Unknown	Not Reported
Mupirocin Calcium Dihydrate	N	S	Topical	Not Reported
Mupirocin Calcium Dihydrate	N	S	Unknown	Not Reported
Betamethasone Dipropionate	N	S	Unknown	Not Reported
Magnesium Oxide	N	S	Unknown	Not Reported
Calcium Carbonate	N	S	Unknown	Not Reported
Ertapenem	N	S	Unknown	Not Reported
Pseudoephedrine	N	S	Unknown	Not Reported
Pseudoephedrine	N	S	Unknown	Not Reported
Mezavant	N	S	Unknown	Not Reported
Clarithromycin	N	S	Unknown	Not Reported
Calcium Carbonate/Ergocalciferol	N	S		Not Reported
Glycerol/Sodium Stearate	N	S		Not Reported
Mesalamine	N	S	Unknown	Not Reported
Metronidazole Benzoate	N	S	Unknown	Not Reported
Pantoprazole Sodium	N	S	Unknown	Not Reported
Diphenhydramine	N	S	Unknown	Not Reported
Betamethasone	N	S	Unknown	Not Reported
Betamethasone	N	S	Unknown	Not Reported
Gramicidin	N	S	Unknown	Not Reported
Fluticasone Propionate	N	S	Unknown	Not Reported
Benzydamine Hydrochloride	N	S	Unknown	Not Reported
Dulcolax	N	S	Unknown	Not Reported
Pms-Azithromycin	N	S	Unknown	Not Reported
Sulfamethoxazole	N	S	Unknown	Not Reported
Zinc	N	S	Unknown	Not Reported
Vitamins Nos	N	S	Unknown	Not Reported

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

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

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

Valsartan	N	C	Vaginal	Not Reported
Valsartan	N	C	Unknown	Not Reported
Calcium Carbonate/Colecalciferol	N	C	Unknown	Not Reported
Hydrochlorothiazide	N	C	Unknown	Not Reported
Clotrimazole	N	C	Unknown	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2023	20222515	EXPEDITED (15-DAY)	Y	HO, OT	CA-ORGANON-1911CAN001744		71 YR	Female	CAN

<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>
Abdominal Pain; Anaemia;	Diprolene	N	S	Unknown	Unk			Organon
Chronic Sinusitis; Colitis;	Diprolene	N	S	Unknown	Unk			Organon
Colitis Ulcerative;	Diprolene	N	S	Unknown	Unk			Organon
Constipation; Drug	Diprolene	N	S	Unknown	Unk			Organon
Ineffective; Dyspepsia;	Diprolene	N	S	Unknown	Unk			Organon
Erythema; Female Genital	Diprolene	N	S	Unknown	Unk			Organon
Tract Fistula; Frequent	Diprolene	N	S	Unknown	Unk			Organon
Bowel Movements;	Zocor	N	S	Unknown	Unk			Organon
Haematochezia;	Zocor	N	S	Unknown	Unk			Organon
Headache; Infusion	Zocor	N	S	Unknown	Unk			Organon
Related Reaction; Macular	Zocor	N	S	Unknown	Unk			Organon
Degeneration; Malaise;	Zocor	N	S	Unknown	Unk			Organon
Nausea; Off Label Use;	Betamethasone Dipropionate	N	S	Unknown	Unk			Not Reported
Oral Candidiasis; Pain;	Betamethasone	N	S	Unknown	Unk			Not Reported
Paraesthesia Oral;	Betamethasone	N	S	Unknown	Unk			Not Reported
Procedural Pain; Proctitis;	Betamethasone	N	S	Unknown	Unk			Not Reported
Pyrexia; Radiculopathy;	Betaderm Ointment	N	S	Unknown	Unk, Dosage Form: Not Specified			Not Reported
Rectal Haemorrhage;	Betaderm Ointment	N	S	Unknown	0.122 Gram			Not Reported
Therapeutic Product Effect	Invanz	N	S	Unknown	Unk			Not Reported
Incomplete; Vaginal	Invanz	N	S	Unknown	Unk			Not Reported
Discharge; Vaginal	Invanz	N	S	Unknown	Unk			Not Reported
Flatulence; Weight	Invanz	N	S	Unknown	Unk			Not Reported
Decreased	Invanz	N	S	Unknown	Unk			Not Reported

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

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

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

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

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

Glycerol	N	S	Oral	Unk		Not Reported
Glycerine	N	S	Unknown	Unk		Not Reported
Glycerine	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	Unknown	Unk	5 YR	Not Reported
Apo-Hydrochlorothiazide	N	S	Unknown	100 Milligram		Not Reported
Apo-Hydrochlorothiazide	N	S	Endocervical	Unk		Not Reported
Apo-Hydrochlorothiazide	N	S	Endocervical	Unk		Not Reported
Mesalazine	N	S	Unknown	Unk		Not Reported
Mesalazine	N	S	Unknown	Unk		Not Reported
Metronidazole	N	S	Unknown	Unk, Dosage Form: Not Specified		Not Reported
Metronidazole	N	S	Unknown	Unk, Dosage Form: Not Specified		Not Reported
Mupirocin Calcium	N	S	Topical	Unk, Dosage Form: Ointment Topical		Not Reported
Nadolol	N	S	Unknown	Unk		Not Reported
Nadolol	N	S	Unknown	40 Milligram		Not Reported
Nadolol	N	S	Unknown	Unk		Not Reported
Nicotine	N	S	Unknown	Unk		Not Reported
Nicotine	N	S	Unknown	Unk		Not Reported
Niquitin Mint	N	S	Unknown	Unk		Not Reported
Pentasa	N	S	Unknown	Unk, Dosage Form: Not Specified		Not Reported
Pentasa	N	S	Unknown	Unk, Dosage Form: Not Specified		Not Reported
Prednisone Acetate	N	S	Unknown	Dosage Form: Not Specified		Not Reported
Prednisone Acetate	N	S	Unknown	Dosage Form: Not		Not Reported

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

				Specified	
Pregabalin	N	S	Unknown	Unk	Not Reported
Pregabalin	N	S	Topical	Unk	Not Reported
Pregabalin	N	S	Unknown	150 Milligram	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk, Dosage Form: Drops Ophthalmic	Not Reported
Refresh Tears	N	S	Ophthalmic	Unk, Dosage Form: Drops Ophthalmic	Not Reported
Sulfamethoxazole;Trimethoprim	N	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	N	S	Intra-articular	Unk	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
Vitamine D	N	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

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

Bactroban [Mupirocin]	N	S	Unknown	Unk	Not Reported
Bactroban [Mupirocin]	N	S	Topical	Unk	Not Reported
Betaderm [Iodine;Povidone-Iodine]	N	S	Unknown	Unk, Dosage Form: Not Specified	Not Reported
Betaderm [Iodine;Povidone-Iodine]	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]	N	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 Hydrochloride	N	S	Oral	1 Tablet, Q6h	Not Reported
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

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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	N	S	Unknown	Unk	Not Reported
Tocopheryl Acetate;Zi 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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Riva-Pantoprazole	N	S	Unknown	Unk	Not Reported
Isoniazid;Pyridoxine Hydrochloride;	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole;Trimethoprim Isoniazid;Pyridoxine Hydrochloride;	N	S	Unknown	Unk	Not Reported
Sulfamethoxazole;Trimethoprim Polyethylene Glycol;Potassium Chloride;Sodium Bicarbonate	N	S	Unknown	Unk	Not Reported
Tocopherol	N	S	Unknown	Unk	Not Reported
Acetaminophen;	N	S	Unknown	Unk	Not Reported
Dextropropoxyphene	N	S	Unknown	Unk	Not Reported
Acetaminophen;	N	S	Unknown	Unk	Not Reported
Dextropropoxyphene	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
D-Alpha Tocopherol	N	S	Unknown	Unk	Not Reported
Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Magnesium Oxide	N	S	Unknown	Unk	Not Reported
Imodium	N	S	Unknown	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	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	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Nicotine Polacrilex	N	S	Unknown	Unk	Not Reported
Alrex [Loteprednol Etabonate]	N	S	Unknown	Unk	Not Reported
Atropine Sulfate;Diphenoxylate Hydrochloride	N	S	Unknown	Unk	Not Reported

<u>FDA Received Date</u>	<u>Case #</u>	<u>Case Type</u>	<u>Health Prof</u>	<u>Outcomes</u>	<u>Mfr Control #</u>	<u>503B Facility</u>	<u>Age</u>	<u>Sex</u>	<u>Country</u>
10-Apr-2023	21436605	EXPEDITED (15-DAY)	Y	HO, OT	CA-GLAXOSMITHKLINE-CACH2022AMR037200			Unknown	CAN
<u>Preferred Term</u>	<u>Product</u>	<u>Comp.</u>	<u>OTC</u>	<u>Role</u>	<u>Route</u>	<u>Dosage Text</u>	<u>Duration</u>	<u>Mfr</u>	



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Abdominal Pain; Anaemia; Chronic Sinusitis; Colitis; Colitis Ulcerative;	Calcium Carbonate, Cholecalciferol	N	S		Unk	Glaxosmithkline
Constipation; Drug Ineffective; Dyspepsia;	Nicotine	N	S		Unk	Glaxosmithkline
Erythema; Female Genital Tract Fistula; Frequent Bowel Movements;	Nicoderm	N	S		Unk	Glaxosmithkline
Haematochezia;	Nicotine Polacrilex	N	S		Unk	Glaxosmithkline
Headache; Infusion Related Reaction; Macular Degeneration; Malaise;	Pantoprazole	N	S		Unk	Not Reported
Nausea; Off Label Use;	Zinc Oxide	Y	S		Unk	Glaxosmithkline
Oral Candidiasis; Pain; Paraesthesia Oral;	Acetaminophen + Pseudoephedrine	N	S		Unk	Not Reported
Procedural Pain; Proctitis; Pyrexia; Radiculopathy; Rectal Haemorrhage;	Sodium Chloride	N	S		Unk	Not Reported
Therapeutic Product Effect Incomplete; Vaginal Discharge; Vaginal Flatulence; Weight Decreased	Magnesium Sulfate	N	S	Intravenous (not otherwise specified)	Unk	Not Reported
	D-Alpha Tocopherol	N	S		Unk	Glaxosmithkline
	Magnesium Oxide	N	S		Unk	Not Reported
	Cetirizine Hydrochloride	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
	Acetaminophen	Y	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
	Alprazolam	N	S		0.25 Mg	Not Reported
	Mesalazine	N	S		Unk, Tid	Not Reported
	Biaxin XI	N	S		Unk	Not Reported
	Clarithromycin	N	S		Unk	Not Reported

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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

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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	N	S		Not Reported
Citric Acid	N	S	Unk	Not Reported