U.S. FOOD & DRUG ADMINISTRATION

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

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**:	384			
Total Events*** :	2310			
Total Deaths****:	5			
Number of Pages:	9			

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 followup 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.

*** "Total Events" is the number of coded MedDRA Preferred terms (PT) representing adverse events, medication errors and other information described in cases for the product of interest. The total number of events may be greater than the number of cases because a case may describe more than one event. For example, an individual may report that his son experienced nausea and rash (two events) while taking drug A.

**** "Total Deaths" is the number of cases where the stated "outcome" for the patient was death. Typically, death is recorded as an "outcome" and not an "event", unless "death" is the only information that is reported on a case. For example, a case might only state that "a patient took drug A and died". For this reason, the number "total deaths" is usually greater than the number of coded events of "death".

Total Number of Cases: 384

The percent of cases containing an event is calculated by dividing the count for the event by the total number of cases, multiplied by 100.

Event (MedDRA® Preferred Term)	Event Count	% Of Cases Containing this Event
DRUG INEFFECTIVE	171	44.5
MACULAR DEGENERATION	163	42.4
OFF LABEL USE	64	16.7
THERAPEUTIC PRODUCT EFFECT INCOMPLETE	61	15.9
PYREXIA	60	15.6
PAIN	59	15.4
NAUSEA	59	15.4
MALAISE	58	15.1
DYSPEPSIA	58	15.1
CHRONIC SINUSITIS	58	15.1
WEIGHT DECREASED	57	14.8
PROCEDURAL PAIN	57	14.8
PARAESTHESIA ORAL	57	14.8
INFUSION RELATED REACTION	57	14.8
EYE IRRITATION	48	12.5
CATARACT	43	11.2
EYE PAIN	35	9.1
HEADACHE	34	8.9
VISION BLURRED	31	8.1
OCULAR HYPERAEMIA	30	7.8
ERYTHEMA	27	7.0
ABDOMINAL PAIN	25	6.5
CONSTIPATION	24	6.2
VAGINAL FLATULENCE	23	6.0
VAGINAL DISCHARGE	23	6.0
RECTAL HAEMORRHAGE	23	6.0
RADICULOPATHY	23	6.0
PROCTITIS	23	6.0
ORAL CANDIDIASIS	23	6.0
HAEMATOCHEZIA	23	6.0
FREQUENT BOWEL MOVEMENTS	23	6.0
FEMALE GENITAL TRACT FISTULA	23	6.0
COLITIS ULCERATIVE	23	6.0
VISUAL IMPAIRMENT	22	5.7
COLITIS	22	5.7
ANAEMIA	22	5.7
RECALLED PRODUCT ADMINISTERED	21	5.5
EYE PRURITUS	17	4.4
EYE DISCHARGE	15	3.9
PRODUCT QUALITY ISSUE	14	3.6

Event (MedDRA® Preferred Term)	Event Count	% Of Cases Containing this Event
EYE INFECTION	14	3.6
DRY EYE	14	3.6
CONJUNCTIVITIS	12	3.1
LACRIMATION INCREASED	11	2.9
EYE SWELLING	10	2.6
EYE DISORDER	10	2.6
BLINDNESS	10	2.6
HYPERSENSITIVITY	8	2.1
PSEUDOMONAS INFECTION	7	1.8
PHOTOPHOBIA	7	1.8
EYE INFLAMMATION	7	1.8
SINUSITIS	6	1.6
NEUTROPENIA	6	1.6
LEUKOPENIA	6	1.6
FOREIGN BODY SENSATION IN EYES	6	1.6
ERYTHEMA OF EYELID	6	1.6
CONDITION AGGRAVATED	6	1.6
PERIORBITAL SWELLING	5	1.3
OCULAR DISCOMFORT	5	1.3
MOUTH ULCERATION	5	1.3
LIQUID PRODUCT PHYSICAL ISSUE	5	1.3
EYE INFECTION BACTERIAL	5	1.3
EXPIRED PRODUCT ADMINISTERED	5	1.3
CORNEAL TRANSPLANT	5	1.3
BLINDNESS TRANSIENT	5	1.3
ABNORMAL SENSATION IN EYE	5	1.3
PRODUCT CONTAMINATION	5	1.3
ULCERATIVE KERATITIS	4	1.0
THERAPY CESSATION	4	1.0
SWELLING OF EYELID	4	1.0
RECALLED PRODUCT	4	1.0
PRODUCT USE COMPLAINT	4	1.0
PRODUCT CONTAMINATION MICROBIAL	4	1.0
MULTIPLE USE OF SINGLE-USE PRODUCT	4	1.0
KERATITIS	4	1.0
INAPPROPRIATE SCHEDULE OF PRODUCT ADMINISTRATION	4	1.0
FATIGUE	4	1.0
EYELID MARGIN CRUSTING	4	1.0
BURNING SENSATION	4	1.0
BLINDNESS UNILATERAL	4	1.0
ADVERSE EVENT	4	1.0
DYSGEUSIA	3	0.8
DECREASED APPETITE	3	0.8
DEATH	3	0.8
COUGH	3	0.8

Event (MedDRA® Preferred Term)	Event Count	% Of Cases Containing this Event
CATARACT OPERATION	3	0.8
BACTERIAL INFECTION	3	0.8
ASTHENOPIA	3	0.8
SKIN EXFOLIATION	3	0.8
PRODUCT DELIVERY MECHANISM ISSUE	3	0.8
POOR QUALITY PRODUCT ADMINISTERED	3	0.8
OCULAR HYPERTENSION	3	0.8
LOSS OF PERSONAL INDEPENDENCE IN DAILY ACTIVITIES	3	0.8
INSTILLATION SITE INFECTION	3	0.8
INSOMNIA	3	0.8
GLAUCOMA	3	0.8
FEELING ABNORMAL	3	0.8
ENDOPHTHALMITIS	3	0.8
DEHYDRATION	2	0.5
COVID-19	2	0.5
CORNEAL OEDEMA	2	0.5
CLOSTRIDIUM DIFFICILE COLITIS	2	0.5
CHILLS	2	0.5
CEREBROVASCULAR ACCIDENT	2	0.5
CARDIAC FAILURE	2	0.5
BLOOD PRESSURE INCREASED	2	0.5
BLEPHARITIS	2	0.5
ATRIAL FIBRILLATION	2	0.5
ALOPECIA	2	0.5
ACCIDENTAL EXPOSURE TO PRODUCT	2	0.5
VITREOUS FLOATERS	2	0.5
VISUAL ACUITY REDUCED	2	0.5
URINE ODOUR ABNORMAL	2	0.5
URINE ANALYSIS ABNORMAL	2	0.5
URINARY RETENTION	2	0.5
URINARY INCONTINENCE	2	0.5
TREATMENT FAILURE	2	0.5
THERAPY NON-RESPONDER	2	0.5
THERAPY INTERRUPTED	2	0.5
THERAPEUTIC RESPONSE DECREASED	2	0.5
SOMNOLENCE	2	0.5
SKIN CANCER	2	0.5
RESPIRATORY TRACT CONGESTION	2	0.5
RESPIRATORY FAILURE	2	0.5
READING DISORDER	2	0.5
PSEUDOMONAS TEST POSITIVE	2	0.5
PRODUCT PACKAGING QUANTITY ISSUE	2	0.5
PRODUCT PACKAGING ISSUE	2	0.5
PRODUCT CONTAINER ISSUE	2	0.5
PLATELET COUNT DECREASED	2	0.5

Event (MedDRA® Preferred Term)	Event Count	% Of Cases Containing this Event
NEOVASCULAR AGE-RELATED MACULAR DEGENERATION	2	0.5
NEOPLASM MALIGNANT	2	0.5
MYELODYSPLASTIC SYNDROME	2	0.5
LUNG DISORDER	2	0.5
INSTILLATION SITE REACTION	2	0.5
INSTILLATION SITE PRURITUS	2	0.5
INCORRECT DOSE ADMINISTERED	2	0.5
IMPAIRED HEALING	2	0.5
ILLNESS	2	0.5
HYPERTENSION	2	0.5
HORDEOLUM	2	0.5
FOREIGN BODY IN EYE	2	0.5
FLUID INTAKE REDUCED	2	0.5
EYELID PTOSIS	2	0.5
EYELID OPERATION	2	0.5
EYE OEDEMA	2	0.5
EYE INJURY	2	0.5
EAR PAIN	2	0.5
DYSPNOEA	2	0.5
DYSPHAGIA	2	0.5
DRY SKIN	2	0.5
DRUG INTERACTION	2	0.5
DISTRIBUTIVE SHOCK	2	0.5
DERMATITIS CONTACT	2	0.5
WRONG PRODUCT ADMINISTERED	1	0.3
WHEEZING	1	0.3
WEIGHT INCREASED	1	0.3
VOMITING	1	0.3
VIRAL INFECTION	1	0.3
VERTIGO	1	0.3
VASOMOTOR RHINITIS	1	0.3
VASCULAR GRAFT	1	0.3
URINARY TRACT INFECTION	1	0.3
UPPER RESPIRATORY TRACT INFECTION	1	0.3
UMBILICAL ERYTHEMA	1	0.3
TRANSIENT ISCHAEMIC ATTACK	1	0.3
TONGUE DISORDER	1	0.3
TINNITUS	1	0.3
THYROID OPERATION	1	0.3
THYROID MASS	1	0.3
THROMBOCYTOPENIA	1	0.3
THROAT TIGHTNESS	1	0.3
THROAT IRRITATION	1	0.3
THINKING ABNORMAL	1	0.3
THERMAL BURNS OF EYE	1	0.3

Event (MedDRA® Preferred Term)	Event Count	% Of Cases Containing this Event
THERAPEUTIC PRODUCT EFFECT DECREASED	1	0.3
THALASSAEMIA ALPHA	1	0.3
TASTE DISORDER	1	0.3
SYNCOPE	1	0.3
SWELLING FACE	1	0.3
SUSPECTED PRODUCT TAMPERING	1	0.3
SUSPECTED PRODUCT QUALITY ISSUE	1	0.3
SUSPECTED PRODUCT CONTAMINATION	1	0.3
SURGERY	1	0.3
STRESS	1	0.3
STRABISMUS	1	0.3
STOMATITIS	1	0.3
SPINAL CORD INJURY	1	0.3
SPEECH DISORDER	1	0.3
SNEEZING	1	0.3
SKIN DISCOLOURATION	1	0.3
SINUS DISORDER	1	0.3
SEPSIS	1	0.3
SEBORRHOEA	1	0.3
SCHIZOAFFECTIVE DISORDER	1	0.3
RETINAL TEAR	1	0.3
RETINAL SCAR	1	0.3
RETINAL OEDEMA	1	0.3
RETINAL HAEMORRHAGE	1	0.3
RETCHING	1	0.3
RESPIRATORY TRACT INFECTION	1	0.3
RENAL SURGERY	1	0.3
RENAL STONE REMOVAL	1	0.3
RENAL PAIN	1	0.3
RENAL DISORDER	1	0.3
RENAL CYST	1	0.3
REACTION TO PRESERVATIVES	1	0.3
RASH	1	0.3
PULMONARY OEDEMA	1	0.3
PTERYGIUM	1	0.3
PRURITUS	1	0.3
PRODUCT PRIMARY PACKAGING ISSUE	1	0.3
PRODUCT ODOUR ABNORMAL	1	0.3
PRODUCT LOT NUMBER ISSUE	1	0.3
PRODUCT LABEL ISSUE	1	0.3
PRODUCT IMPURITY	1	0.3
PRODUCT FORMULATION ISSUE	1	0.3
PRODUCT DOSE OMISSION ISSUE	1	0.3
PRODUCT CONTAINER SEAL ISSUE	1	0.3
PRODUCT COMPLAINT	1	0.3

Event (MedDRA® Preferred Term)	Event Count	% Of Cases Containing this Event
PRODUCT COMMINGLING	1	0.3
PRODUCT COLOUR ISSUE	1	0.3
PRODUCT AVAILABILITY ISSUE	1	0.3
PRODUCT ADMINISTRATION ERROR	1	0.3
POST PROCEDURAL COMPLICATION	1	0.3
POLLAKIURIA	1	0.3
PNEUMONIA	1	0.3
PLEURAL EFFUSION	1	0.3
PHOTOSENSITIVITY REACTION	1	0.3
PERIPHERAL SWELLING	1	0.3
PERIORBITAL PAIN	1	0.3
PELVIC PAIN	1	0.3
PATHOGEN RESISTANCE	1	0.3
PARAESTHESIA	1	0.3
PALPITATIONS	1	0.3
OVARIAN CYSTECTOMY	1	0.3
OTOSCLEROSIS	1	0.3
OSTEOARTHRITIS	1	0.3
OROPHARYNGEAL PAIN	1	0.3
OROPHARYNGEAL DISCOMFORT	1	0.3
OPTIC ISCHAEMIC NEUROPATHY	1	0.3
OPHTHALMIC HERPES ZOSTER	1	0.3
OPEN GLOBE INJURY	1	0.3
NIGHT BLINDNESS	1	0.3
NERVOUSNESS	1	0.3
NASAL DISCOMFORT	1	0.3
MYOCARDIAL INFARCTION	1	0.3
MUSCULOSKELETAL CHEST PAIN	1	0.3
MUSCLE TWITCHING	1	0.3
MUSCLE ATROPHY	1	0.3
MULTIPLE-DRUG RESISTANCE	1	0.3
MULTIPLE ALLERGIES	1	0.3
MIDDLE INSOMNIA	1	0.3
MICTURITION URGENCY	1	0.3
MEMORY IMPAIRMENT	1	0.3
MEDICAL DEVICE IMPLANTATION	1	0.3
MASTICATION DISORDER	1	0.3
MANUFACTURING PRODUCT SHIPPING ISSUE	1	0.3
MALOCCLUSION	1	0.3
LOWER RESPIRATORY TRACT CONGESTION	1	0.3
LOSS OF CONSCIOUSNESS	1	0.3
LISTLESS	1	0.3
LID SULCUS DEEPENED	1	0.3
KNEE ARTHROPLASTY	1	0.3
KERATOPATHY	1	0.3

Event (MedDRA® Preferred Term)	Event Count	% Of Cases Containing this Event
KERATITIS BACTERIAL	1	0.3
JOINT EFFUSION	1	0.3
JAW DISORDER	1	0.3
JAW CLICKING	1	0.3
IRRITABLE BOWEL SYNDROME	1	0.3
INSTILLATION SITE PAIN	1	0.3
INSTILLATION SITE IRRITATION	1	0.3
INSTILLATION SITE FOREIGN BODY SENSATION	1	0.3
INSTILLATION SITE ERYTHEMA	1	0.3
INSTILLATION SITE BURN	1	0.3
INJURY CORNEAL	1	0.3
INCORRECT ROUTE OF PRODUCT ADMINISTRATION	1	0.3
IMPAIRED WORK ABILITY	1	0.3
IMPAIRED DRIVING ABILITY	1	0.3
HYPOTENSION	1	0.3
HYPOAESTHESIA	1	0.3
HYPOACUSIS	1	0.3
HOSPITALISATION	1	0.3
HIATUS HERNIA	1	0.3
HEPATIC PAIN	1	0.3
HEART RATE INCREASED	1	0.3
HAEMORRHAGE	1	0.3
GAIT INABILITY	1	0.3
FRUSTRATION TOLERANCE DECREASED	1	0.3
FIBROMYALGIA	1	0.3
FACIAL PARESIS	1	0.3
EYELIDS PRURITUS	1	0.3
EYELID OEDEMA	1	0.3
EYELID INFECTION	1	0.3
EYELID FUNCTION DISORDER	1	0.3
EYE ULCER	1	0.3
EYE OPACITY	1	0.3
EYE CONTUSION	1	0.3
EYE COLOUR CHANGE	1	0.3
EPIRETINAL MEMBRANE	1	0.3
ENDOCRINE OPHTHALMOPATHY	1	0.3
EMOTIONAL DISORDER	1	0.3
ELECTROCARDIOGRAM QT PROLONGED	1	0.3
EAR PRURITUS	1	0.3
EAR INFECTION	1	0.3
EAR DISCOMFORT	1	0.3
DYSPHONIA	1	0.3
DYSARTHRIA	1	0.3
DRY THROAT	1	0.3
DRUG-DEVICE INTERACTION	1	0.3

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DRUG LEVEL INCREASED	1	0.3
DRUG HYPERSENSITIVITY	1	0.3
DOCUMENTED HYPERSENSITIVITY TO ADMINISTERED PRODUCT	1	0.3
DIVERTICULUM	1	0.3
DISEASE RECURRENCE	1	0.3
DISABILITY	1	0.3
DIARRHOEA	1	0.3
DEVICE DIFFICULT TO USE	1	0.3
DEVICE DELIVERY SYSTEM ISSUE	1	0.3
DEVICE ALLERGY	1	0.3
CULTURE POSITIVE	1	0.3
CRYING	1	0.3
CORNEAL PERFORATION	1	0.3
CORNEAL DISORDER	1	0.3
CORNEAL DEGENERATION	1	0.3
CONJUNCTIVITIS ALLERGIC	1	0.3
CONJUNCTIVAL HAEMORRHAGE	1	0.3
COLOUR BLINDNESS	1	0.3
COELIAC DISEASE	1	0.3
CHOROID MELANOMA	1	0.3
CHEST PAIN	1	0.3
CHEMICAL BURNS OF EYE	1	0.3
CENTRAL VISION LOSS	1	0.3
CELLULITIS ORBITAL	1	0.3
CELLULITIS	1	0.3
CARDIAC DISORDER	1	0.3
CARDIAC ABLATION	1	0.3
BLOOD POTASSIUM DECREASED	1	0.3
BLOOD MAGNESIUM DECREASED	1	0.3
BLEPHAROSPASM	1	0.3
BLADDER PAIN	1	0.3
BACK PAIN	1	0.3
ARTHRITIS	1	0.3
ARTHRALGIA	1	0.3
ANXIETY	1	0.3
ANGIOEDEMA	1	0.3
AMNESIA	1	0.3
ALLERGY TO CHEMICALS	1	0.3
ACCIDENTAL EXPOSURE TO PRODUCT PACKAGING	1	0.3
ABDOMINAL PAIN UPPER	1	0.3