

**Case Series Drug Analysis Print**  
**Name: Prevenar 13 Vaccine Analysis Print**

Report Run Date: 23-Nov-2022

Data Lock Date: 16-Nov-2022 18:30:05

Earliest Reaction Date: 23-Jan-2009

MedDRA Version: MedDRA 25.1

Prevenar 13 Vaccine Analysis Print: All UK spontaneous ADR reports for Prevenar 13 since the start of the Yellow Card system to 11/11/2022

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<b><i>Anaemias NEC</i></b>		
Anaemia	3	0
<b><i>Anaemias haemolytic mechanical factor</i></b>		
Haemolytic uraemic syndrome	5	0
<b><i>Haematological disorders</i></b>		
Mastocytosis	1	0
<b><i>Haemolyses NEC</i></b>		
Haemolysis	1	0
<b><i>Leukocytoses NEC</i></b>		
Lymphocytic infiltration	1	0
<b><i>Lymphatic system disorders NEC</i></b>		
Abdominal lymphadenopathy	1	0
Lymphadenitis	1	0
Lymphadenopathy	5	0
<b><i>Neutropenias</i></b>		
Febrile neutropenia	1	0
Neutropenia	1	0
<b><i>Thrombocytopenias</i></b>		
Immune thrombocytopenia	1	0
Thrombocytopenia	4	0
<b>Blood disorders SOC TOTAL</b>	<b>25</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Cardiac disorders NEC</b></i>		
Cardiac disorder	1	0
Cardiovascular disorder	3	0
<i><b>Heart failures NEC</b></i>		
Cardiac failure	1	0
<i><b>Myocardial disorders NEC</b></i>		
Cardiomegaly	1	0
Left ventricular dysfunction	1	0
<i><b>Pericardial disorders NEC</b></i>		
Pericardial effusion	2	0
Pericardial haemorrhage	1	0
<i><b>Rate and rhythm disorders NEC</b></i>		
Bradycardia	9	0
Bradycardia neonatal	1	0
Tachycardia	13	0
<i><b>Supraventricular arrhythmias</b></i>		
Supraventricular tachycardia	1	0
<i><b>Ventricular arrhythmias and cardiac arrest</b></i>		
Cardiac arrest	11	3
Cardio-respiratory arrest	4	1
Ventricular fibrillation	1	0
Ventricular tachycardia	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>51</b>	<b>4</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Congenital disorders</b>		
<i>Cardiac septal defects congenital</i>		
Atrial septal defect	1	0
<i>Connective tissue disorders congenital</i>		
Hypermobility syndrome	2	0
<b>Congenital disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear pain	4	0
Ear swelling	5	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	1	0
<i>Hearing losses</i>		
Deafness	4	0
<i>Inner ear signs and symptoms</i>		
Vertigo	1	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane disorder	1	0
<b>Ear disorders SOC TOTAL</b>	<b>16</b>	<b>0</b>

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<b>Eye disorders</b>		
<i><b>Conjunctival and corneal bleeding and vascular disorders</b></i>		
Conjunctival haemorrhage	1	0
<i><b>Eyelid movement disorders</b></i>		
Excessive eye blinking	1	0
Eyelid ptosis	1	0
<i><b>Lacrimation disorders</b></i>		
Lacrimation increased	1	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Erythema of eyelid	1	0
Swelling of eyelid	2	0
<i><b>Ocular disorders NEC</b></i>		
Eye disorder	1	0
Eye oedema	1	0
Eye swelling	12	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye pruritus	1	0
Ocular hyperaemia	1	0
<i><b>Ocular nerve and muscle disorders</b></i>		
Eye movement disorder	10	0
Gaze palsy	2	0
Strabismus	3	0
<i><b>Ocular sensation disorders</b></i>		
Photophobia	1	0
<i><b>Pupil disorders</b></i>		
Anisocoria	2	0
Miosis	1	0
Mydriasis	3	0
Pupil fixed	1	0
<i><b>Visual disorders NEC</b></i>		
Photopsia	1	0
<i><b>Visual impairment and blindness (excl colour blindness)</b></i>		
Blindness	1	0
Cortical visual impairment	1	0
Visual impairment	2	0
<b>Eye disorders SOC TOTAL</b>	<b>51</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	1	0
<i>Colitis (excl infective)</i>		
Colitis	1	0
Necrotising colitis	2	1
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	95	0
Diarrhoea haemorrhagic	2	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	3	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	5	0
Faecaloma	1	0
Faeces discoloured	10	0
Faeces hard	1	0
Faeces pale	1	0
Faeces soft	1	0
Mucous stools	6	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	3	0
Flatulence	8	0
<i>Gastritis (excl infective)</i>		
Reflux gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	9	0
Abdominal pain upper	15	0
Gastrointestinal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	11	0
Gastrooesophageal reflux disease	9	0
Intestinal dilatation	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastric disorder	1	0
Gastrointestinal disorder	2	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Necrotising enterocolitis neonatal	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	11	0
Dysphagia	1	0
Gastrointestinal wall thickening	1	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	3	0
Irritable bowel syndrome	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intussusception	1	0
<i>Inguinal hernias</i>		
Inguinal hernia, obstructive	1	0
<i>Nausea and vomiting symptoms</i>		
Infantile vomiting	4	0
Nausea	13	0
Vomiting	131	0
Vomiting projectile	12	0
<i>Non-site specific gastrointestinal haemorrhages</i>		

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<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Haematemesis	1	0
Haematochezia	8	0
<b><i>Oral dryness and saliva altered</i></b>		
Salivary hypersecretion	1	0
<b><i>Oral soft tissue signs and symptoms</i></b>		
Oral pain	1	0
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip swelling	6	0
Mouth swelling	2	0
<b><i>Tongue disorders</i></b>		
Tongue geographic	1	0
<b><i>Tongue signs and symptoms</i></b>		
Protrusion tongue	1	0
Swollen tongue	2	0
Tongue movement disturbance	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>394</b>	<b>1</b>



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Reaction Name	Total	Fatal
<b>General disorders</b>		
<b><i>Administration site reactions NEC</i></b>		
Administration site erythema	1	0
Administration site swelling	1	0
<b><i>Application and instillation site reactions</i></b>		
Application site irritation	1	0
<b><i>Asthenic conditions</i></b>		
Asthenia	11	0
Decreased activity	2	0
Fatigue	21	0
Malaise	58	0
<b><i>Body temperature altered</i></b>		
Hyperthermia	1	0
Hypothermia	2	0
<b><i>Death and sudden death</i></b>		
Brain death	1	0
Death	17	17
Sudden death	5	5
Sudden infant death syndrome	7	7
<b><i>Febrile disorders</i></b>		
Hyperpyrexia	1	0
Pyrexia	401	0
<b><i>Feelings and sensations NEC</i></b>		
Chills	13	0
Feeling abnormal	11	0
Feeling cold	2	0
Feeling drunk	1	0
Feeling hot	18	0
Thirst	4	0
Thirst decreased	3	0
<b><i>Gait disturbances</i></b>		
Gait disturbance	9	0
Gait inability	9	0
Loss of control of legs	1	0
<b><i>General signs and symptoms NEC</i></b>		
Condition aggravated	9	0
Crepitations	1	0
Crying	125	0
Developmental delay	5	0
Developmental regression	1	0
Effusion	1	0
Foaming at mouth	1	0
General physical health deterioration	2	0
Glassy eyes	5	0
High-pitched crying	11	0
Illness	9	0
Induration	8	0
Influenza like illness	2	0
Irritability postvaccinal	2	0
Local reaction	10	0
Moaning	2	0
Multiple organ dysfunction syndrome	1	0
Peripheral swelling	48	0
Pneumatosis	1	0

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<b>General disorders</b> General disorders cont'd		
Screaming	55	0
Secretion discharge	3	0
Swelling	28	0
Swelling face	13	0
<b>Inflammations</b>		
Inflammation	8	0
<b>Injection site reactions</b>		
Injected limb mobility decreased	1	0
Injection site bruising	3	0
Injection site discolouration	3	0
Injection site erythema	36	0
Injection site induration	5	0
Injection site inflammation	9	0
Injection site mass	10	0
Injection site oedema	1	0
Injection site pain	9	0
Injection site rash	8	0
Injection site reaction	6	0
Injection site swelling	34	0
Injection site urticaria	1	0
Injection site vesicles	1	0
Injection site warmth	6	0
<b>Mass conditions NEC</b>		
Mass	3	0
<b>Oedema NEC</b>		
Localised oedema	1	0
Oedema	1	0
Oedema peripheral	3	0
<b>Pain and discomfort NEC</b>		
Chest discomfort	2	0
Discomfort	11	0
Pain	48	0
Tenderness	5	0
<b>Therapeutic and nontherapeutic responses</b>		
Drug ineffective	127	0
Immediate post-injection reaction	1	0
Therapeutic product ineffective	194	0
Vaccination failure	19	0
<b>Ulcers NEC</b>		
Ulcer	1	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	1	0
Vaccination site bruising	6	0
Vaccination site discomfort	1	0
Vaccination site erythema	45	0
Vaccination site haematoma	2	0
Vaccination site haemorrhage	1	0
Vaccination site induration	15	0
Vaccination site inflammation	9	0
Vaccination site joint erythema	1	0
Vaccination site joint movement impairment	1	0
Vaccination site joint pain	1	0
Vaccination site mass	25	0

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<b>General disorders</b> General disorders cont'd		
Vaccination site movement impairment	1	0
Vaccination site pain	23	0
Vaccination site pruritus	2	0
Vaccination site rash	10	0
Vaccination site reaction	5	0
Vaccination site scab	1	0
Vaccination site swelling	37	0
Vaccination site urticaria	1	0
Vaccination site vesicles	2	0
Vaccination site warmth	13	0
<b>General disorders SOC TOTAL</b>	<b>1704</b>	<b>29</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Hepatic disorders</b>		
<i>Cholestasis and jaundice</i>		
Jaundice	2	0
Jaundice cholestatic	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatomegaly	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Allergy to metals	1	0
Hypersensitivity	23	0
Multiple allergies	2	0
<i><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Allergy to vaccine	1	0
Drug hypersensitivity	1	0
Food allergy	3	0
Milk allergy	4	0
Reaction to excipient	1	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	21	0
Anaphylactic shock	1	0
<i><b>Immune and associated conditions NEC</b></i>		
Decreased immune responsiveness	1	0
Haemophagocytic lymphohistiocytosis	1	0
Immune system disorder	1	0
Immunisation reaction	1	0
<i><b>Immunodeficiency disorders NEC</b></i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	3	0
<b>Immune system disorders SOC TOTAL</b>	<b>66</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Adenoviral infections</b></i>		
Adenovirus infection	1	0
<i><b>Bacterial infections NEC</b></i>		
Arthritis bacterial	4	0
Bacterial infection	1	0
Bacterial sepsis	4	0
Cellulitis	22	0
Injection site cellulitis	2	0
Meningitis bacterial	2	0
Pneumonia bacterial	1	0
Skin bacterial infection	3	0
Vaccination site cellulitis	5	0
<i><b>Bone and joint infections</b></i>		
Intervertebral discitis	1	0
<i><b>Bordetella infections</b></i>		
Pertussis	2	0
<i><b>Candida infections</b></i>		
Candida infection	1	0
Oral candidiasis	1	0
<i><b>Cardiac infections</b></i>		
Endocarditis	1	0
<i><b>Central nervous system and spinal infections</b></i>		
Cavernous sinus thrombosis	1	0
Encephalitis	3	1
Meningitis	14	0
Meningitis aseptic	6	0
Subdural abscess	1	0
<i><b>Cytomegaloviral infections</b></i>		
Cytomegalovirus infection	1	0
<i><b>Dental and oral soft tissue infections</b></i>		
Gingivitis	1	0
<i><b>Ear infections</b></i>		
Ear infection	8	0
Mastoiditis	3	0
Otitis media	1	0
Otitis media acute	1	0
Otitis media chronic	1	0
<i><b>Enteroviral infections NEC</b></i>		
Hand-foot-and-mouth disease	1	0
Meningitis enteroviral	1	0
<i><b>Epstein-Barr viral infections</b></i>		
Epstein-Barr virus infection	1	0
<i><b>Eye and eyelid infections</b></i>		
Conjunctivitis	4	0
Eye infection	1	0
<i><b>Haemophilus infections</b></i>		
Haemophilus bacteraemia	1	0
<i><b>Herpes viral infections</b></i>		
Herpes simplex	1	0
Herpes virus infection	1	0
Human herpesvirus 6 infection	1	0
Varicella	1	0
<i><b>Infections NEC</b></i>		

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<b>Infections</b>		
Infections cont'd		
Abscess	2	0
Abscess limb	1	0
Empyema	62	0
Febrile infection	1	0
Infection	5	0
Injection site abscess	1	0
Localised infection	1	0
Vaccination site abscess	3	0
Vaccination site infection	3	0
<b><i>Influenza viral infections</i></b>		
Influenza	2	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Bronchitis	2	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	20	0
Pneumonia	47	0
Pneumonia necrotising	1	0
<b><i>Mumps viral infections</i></b>		
Mumps	1	0
<b><i>Neisseria infections</i></b>		
Meningococcal sepsis	1	0
<b><i>Parainfluenzae viral infections</i></b>		
Parainfluenzae virus infection	1	0
<b><i>Respiratory syncytial viral infections</i></b>		
Respiratory syncytial virus bronchiolitis	2	0
Respiratory syncytial virus infection	2	0
<b><i>Rhinoviral infections</i></b>		
Rhinovirus infection	1	0
<b><i>Rubella viral infections</i></b>		
Rubella	1	0
<b><i>Rubeola viral infections</i></b>		
Measles	1	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Bacteraemia	21	0
Sepsis	29	0
Septic shock	1	0
<b><i>Skin structures and soft tissue infections</i></b>		
Eczema infected	1	0
Skin infection	1	0
<b><i>Staphylococcal infections</i></b>		
Staphylococcal infection	1	0
<b><i>Streptococcal infections</i></b>		
Meningitis pneumococcal	40	2
Pneumococcal bacteraemia	17	0
Pneumococcal infection	271	10
Pneumococcal sepsis	20	2
Pneumonia pneumococcal	22	1
Pneumonia streptococcal	3	0
Septic arthritis streptococcal	1	0
Streptococcal bacteraemia	1	0
Streptococcal sepsis	1	0
Tonsillitis streptococcal	1	0
<b><i>Upper respiratory tract infections</i></b>		

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<b>Infections</b>		
Infections cont'd		
Croup infectious	3	0
Epiglottitis	1	0
Nasopharyngitis	11	0
Rhinitis	5	0
Tonsillitis	6	0
Upper respiratory tract infection	7	0
<b>Urinary tract infections</b>		
Kidney infection	1	0
Urinary tract infection	1	0
<b>Viral infections NEC</b>		
Bronchiolitis	8	0
Gastroenteritis viral	1	0
Viral infection	2	0
Viral rash	1	0
Viral upper respiratory tract infection	2	0
<b>Infections SOC TOTAL</b>	<b>747</b>	<b>16</b>



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Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Cerebral injuries NEC</i></b>		
Craniocerebral injury	1	0
<b><i>Exposures associated with pregnancy, delivery and lactation</i></b>		
Exposure via breast milk	1	0
Maternal exposure during breast feeding	1	0
<b><i>Medication errors, product use errors and issues NEC</i></b>		
Medication error	2	0
Wrong technique in product usage process	2	0
<b><i>Muscle, tendon and ligament injuries</i></b>		
Muscle injury	1	0
<b><i>Non-site specific injuries NEC</i></b>		
Injury	1	0
Wound secretion	1	0
<b><i>Product administration errors and issues</i></b>		
Extra dose administered	1	0
Inappropriate schedule of product administration	7	0
Incomplete course of vaccination	1	0
Incorrect dose administered	1	0
Incorrect route of product administration	1	0
Product administered at inappropriate site	1	0
Product administered to patient of inappropriate age	5	0
Product administration error	2	0
Wrong product administered	1	0
<b><i>Product prescribing errors and issues</i></b>		
Product prescribing error	1	0
Product prescribing issue	1	0
<b><i>Product storage errors and issues in the product use system</i></b>		
Product storage error	2	0
<b><i>Skin injuries NEC</i></b>		
Contusion	9	0
Scar	1	0
Scratch	1	0
Skin injury	1	0
Skin laceration	1	0
<b><i>Vaccination related complications</i></b>		
Post vaccination syndrome	1	0
<b>Injuries SOC TOTAL</b>	<b>48</b>	<b>0</b>

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<b>Investigations</b>		
<i><b>Bacteria identification and serology (excl mycobacteria)</b></i>		
Streptococcus test positive	1	0
<i><b>Blood gas and acid base analyses</b></i>		
Oxygen saturation decreased	12	0
<i><b>Carbohydrate tolerance analyses (incl diabetes)</b></i>		
Blood glucose fluctuation	1	0
<i><b>Cardiac auscultatory investigations</b></i>		
Cardiac murmur	1	0
<i><b>Central nervous system histopathology procedures</b></i>		
Biopsy brain abnormal	1	0
<i><b>Cerebrospinal fluid tests (excl microbiology)</b></i>		
CSF white blood cell count increased	1	0
<i><b>Chemistry analyses NEC</b></i>		
Inflammatory marker increased	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate abnormal	3	0
Heart rate decreased	1	0
Heart rate increased	9	0
Pulse abnormal	1	0
<i><b>Immunology analyses NEC</b></i>		
Tryptase increased	1	0
<i><b>Metabolism tests NEC</b></i>		
Blood ketone body increased	1	0
<i><b>Mineral and electrolyte analyses</b></i>		
Blood magnesium decreased	1	0
Blood sodium decreased	1	0
<i><b>Ophthalmic function diagnostic procedures</b></i>		
Intraocular pressure increased	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature abnormal	3	0
Body temperature decreased	3	0
Body temperature fluctuation	3	0
Body temperature increased	40	0
Breath sounds abnormal	2	0
Respiratory rate increased	3	0
<i><b>Platelet analyses</b></i>		
Platelet count increased	2	0
<i><b>Protein analyses NEC</b></i>		
C-reactive protein increased	16	0
<i><b>Red blood cell analyses</b></i>		
Haemoglobin decreased	3	0
<i><b>Renal function analyses</b></i>		
Blood creatinine decreased	1	0
Blood urea decreased	1	0
<i><b>Urinalysis NEC</b></i>		
Blood urine present	1	0
White blood cells urine	1	0
<i><b>Urinary tract function analyses NEC</b></i>		
Urine output decreased	4	0
<i><b>Vascular tests NEC (incl blood pressure)</b></i>		
Capillary nail refill test abnormal	1	0
<i><b>Virus identification and serology</b></i>		
Coronavirus test positive	1	0

# Case Series Drug Analysis Print

## Name: Prevenar 13 Vaccine Analysis Print

Report Run Date: 23-Nov-2022

Data Lock Date: 16-Nov-2022 18:30:05

Earliest Reaction Date: 23-Jan-2009

MedDRA Version: MedDRA 25.1

<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Investigations</b> Investigations cont'd		
<i>White blood cell analyses</i>		
Lymphocyte count increased	1	0
Neutrophil count decreased	1	0
White blood cell count increased	4	0
<b>Investigations SOC TOTAL</b>	<b>128</b>	<b>0</b>

## Case Series Drug Analysis Print

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Report Run Date: 23-Nov-2022  
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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Appetite disorder	2	0
Decreased appetite	68	0
Food refusal	2	0
Hypophagia	4	0
Increased appetite	1	0
<i><b>Cell metabolism disorders NEC</b></i>		
Mitochondrial cytopathy	1	0
<i><b>Fluid intake decreased</b></i>		
Fluid intake reduced	2	0
<i><b>Fluid intake increased</b></i>		
Polydipsia	1	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Dairy intolerance	3	0
Food intolerance	3	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	1	0
Feeding disorder	2	0
Food aversion	3	0
Poor feeding infant	48	0
Weight gain poor	3	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	1	0
<i><b>Metabolic acidoses (excl diabetic acidoses)</b></i>		
Metabolic acidosis	2	0
<i><b>Potassium imbalance</b></i>		
Hyperkalaemia	1	0
<i><b>Sodium imbalance</b></i>		
Hyponatraemia	1	0
<i><b>Sugar intolerance (excl glucose intolerance)</b></i>		
Lactose intolerance	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	4	0
<b>Metabolic disorders SOC TOTAL</b>	<b>154</b>	<b>0</b>

## Case Series Drug Analysis Print

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Report Run Date: 23-Nov-2022  
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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	1	0
<i><b>Extremity deformities</b></i>		
Foot deformity	1	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	13	0
Joint effusion	1	0
Joint range of motion decreased	1	0
Joint swelling	2	0
Joint warmth	1	0
<i><b>Muscle pains</b></i>		
Myalgia	6	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle spasms	3	0
Muscle tightness	1	0
Muscle twitching	7	0
<i><b>Muscle tone abnormalities</b></i>		
Floppy infant	25	0
Muscle rigidity	1	0
Trismus	1	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	4	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Limb mass	1	0
Musculoskeletal stiffness	12	0
Toe walking	1	0
Weight bearing difficulty	8	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Limb discomfort	4	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	1	0
Neck pain	1	0
Pain in extremity	35	0
<i><b>Tendon disorders</b></i>		
Tendonitis	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>133</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Leukaemias acute lymphocytic</i>		
Acute lymphocytic leukaemia	2	0
<i>Nervous system neoplasms unspecified malignancy NEC</i>		
Astrocytoma	1	0
<i>Rhabdomyosarcomas</i>		
Rhabdomyosarcoma	1	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Neoplasm skin	1	0
<b>Neoplasms SOC TOTAL</b>	<b>5</b>	<b>0</b>

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<b><i>Absence seizures</i></b>		
Petit mal epilepsy	8	0
<b><i>Central nervous system haemorrhages and cerebrovascular accidents</i></b>		
Cerebral infarction	1	0
Ruptured cerebral aneurysm	1	0
<b><i>Central nervous system vascular disorders NEC</i></b>		
Brain hypoxia	1	0
<b><i>Cerebrovascular venous and sinus thrombosis</i></b>		
Superior sagittal sinus thrombosis	1	0
<b><i>Coordination and balance disturbances</i></b>		
Balance disorder	3	0
Coordination abnormal	1	0
Dysstasia	1	0
Hand-eye coordination impaired	1	0
Nystagmus	1	0
<b><i>Cortical dysfunction NEC</i></b>		
Aphasia	2	0
Dyspraxia	2	0
Sensory processing disorder	2	0
<b><i>Disturbances in consciousness NEC</i></b>		
Depressed level of consciousness	4	0
Lethargy	40	0
Loss of consciousness	10	0
Somnolence	55	0
Syncope	6	0
<b><i>Dyskinesias and movement disorders NEC</i></b>		
Dyskinesia	17	0
Fine motor delay	1	0
Hypokinesia	3	0
Movement disorder	2	0
Psychomotor hyperactivity	1	0
<b><i>Dystonias</i></b>		
Opisthotonus	2	0
<b><i>Encephalopathies NEC</i></b>		
Hypoxic-ischaemic encephalopathy	1	0
<b><i>Generalised tonic-clonic seizures</i></b>		
Generalised tonic-clonic seizure	11	0
<b><i>Headaches NEC</i></b>		
Headache	5	0
Tension headache	1	0
<b><i>Hydrocephalic conditions</i></b>		
Hydrocephalus	2	0
<b><i>Increased intracranial pressure disorders</i></b>		
Brain oedema	3	0
<b><i>Intellectual disabilities</i></b>		
Intellectual disability	1	0
<b><i>Mental impairment (excl dementia and memory loss)</i></b>		
Cognitive disorder	1	0
Disturbance in attention	3	0
<b><i>Muscle tone abnormal</i></b>		
Hypertonia	1	0
Hypotonia	31	0
<b><i>Narcolepsy and hypersomnia</i></b>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Hypersomnia	7	0
<b><i>Nervous system disorders NEC</i></b>		
Brain stem syndrome	1	0
Nervous system disorder	4	0
Subdural effusion	3	0
<b><i>Neurological signs and symptoms NEC</i></b>		
Cerebrospinal fluid leakage	1	0
Dizziness	6	0
Dizziness postural	1	0
Drooling	2	0
Exaggerated startle response	2	0
Fontanelle bulging	5	0
Hyporesponsive to stimuli	5	0
Inability to crawl	1	0
Infant irritability	2	0
Meningism	1	0
Neurological decompensation	1	0
Neurological symptom	1	0
Pleocytosis	2	0
Presyncope	3	0
Unresponsive to stimuli	49	0
<b><i>Neuromuscular disorders NEC</i></b>		
Hypotonic-hyporesponsive episode	6	0
Muscle spasticity	1	0
<b><i>Paraesthesias and dysaesthesias</i></b>		
Hyperaesthesia	1	0
Paraesthesia	2	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Monoplegia	1	0
Paralysis	2	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Epilepsy	6	0
Epileptic encephalopathy	1	0
Febrile convulsion	32	0
Infantile spasms	1	0
Partial seizures	7	0
Seizure	54	0
Seizure anoxic	1	0
Seizure cluster	2	0
Seizure like phenomena	1	0
Status epilepticus	2	0
<b><i>Sensory abnormalities NEC</i></b>		
Sensory disturbance	1	0
<b><i>Sleep disturbances NEC</i></b>		
Sleep deficit	1	0
<b><i>Speech and language abnormalities</i></b>		
Speech disorder	3	0
Speech disorder developmental	2	0
<b><i>Tremor (excl congenital)</i></b>		
Tremor	18	0
<b>Nervous system disorders SOC TOTAL</b>	<b>468</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Newborn complications NEC</i>		
Neonatal disorder	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>1</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<i>Device physical property and chemical issues</i>		
Needle issue	2	0
<i>Product quality issues NEC</i>		
Product quality issue	4	0
<b>null SOC TOTAL</b>	<b>6</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	18	0
Breath holding	7	0
Regressive behaviour	1	0
Staring	5	0
<b><i>Affect alterations NEC</i></b>		
Flat affect	1	0
<b><i>Anxiety disorders NEC</i></b>		
Separation anxiety disorder	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	8	0
Anxiety	4	0
Stress	1	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	3	0
Disturbance in social behaviour	1	0
Personality change	2	0
Social avoidant behaviour	1	0
<b><i>Communications disorders</i></b>		
Mutism	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	1	0
Disorientation	2	0
<b><i>Decreased physical activity levels</i></b>		
Catatonia	2	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	18	0
Middle insomnia	3	0
<b><i>Dyssomnias</i></b>		
Poor quality sleep	5	0
<b><i>Eating disorders NEC</i></b>		
Eating disorder	2	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Emotional distress	19	0
Emotional poverty	1	0
Irritability	109	0
Mood altered	2	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Fear of eating	1	0
Social fear	1	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination, auditory	1	0
Hallucinations, mixed	1	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	20	0
<b><i>Mental disorders NEC</i></b>		
Mental disorder	3	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Depressed mood	4	0
Tearfulness	1	0
<b><i>Mood disorders NEC</i></b>		
Apathy	1	0
Listless	5	0

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
<b><i>Obsessive-compulsive disorders and symptoms</i></b>		
Obsessive-compulsive symptom	1	0
<b><i>Parasomnias</i></b>		
Sleep terror	3	0
<b><i>Personality disorders with anxious behaviour (Cluster C)</i></b>		
Dependent personality disorder	1	0
<b><i>Pervasive developmental disorders NEC</i></b>		
Autism spectrum disorder	9	0
<b><i>Psychiatric elimination disorders</i></b>		
Enuresis	1	0
<b><i>Psychiatric symptoms NEC</i></b>		
Decreased eye contact	2	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	15	0
<b><i>Speech articulation and rhythm disturbances</i></b>		
Lack of spontaneous speech	1	0
<b><i>Stereotypies and automatisms</i></b>		
Head banging	1	0
<b><i>Suicidal and self-injurious behaviour</i></b>		
Self-injurious ideation	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>291</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Renal &amp; urinary disorders</b>		
<i>Glomerulonephritis and nephrotic syndrome</i>		
Nephrotic syndrome	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	3	0
Anuria	1	0
Oliguria	1	0
<i>Renal structural abnormalities and trauma</i>		
Kidney enlargement	1	0
<i>Urinary abnormalities</i>		
Haematuria	1	0
Urine abnormality	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>9</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital blister	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital rash	1	0
Genital swelling	1	0
<i>Scrotal disorders NEC</i>		
Scrotal swelling	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	26	0
Apnoeic attack	4	0
Dyspnoea	32	0
Grunting	3	0
Hyperventilation	1	0
Hypopnoea	5	0
Hypoventilation	2	0
Respiration abnormal	2	0
Respiratory arrest	8	1
Respiratory distress	7	0
Tachypnoea	7	0
<i><b>Bronchospasm and obstruction</b></i>		
Wheezing	14	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Asphyxia	1	0
Cyanosis central	1	0
Hypoxia	2	1
Respiratory acidosis	1	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	29	0
Haemoptysis	1	0
Productive cough	3	0
Sputum discoloured	1	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Stridor	3	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		
Pneumonitis	1	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Pulmonary haemorrhage	3	1
Rales	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	4	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	2	0
<i><b>Neonatal hypoxic conditions</b></i>		
Infantile apnoea	4	0
Neonatal hypoxia	3	0
<i><b>Parenchymal lung disorders NEC</b></i>		
Lung consolidation	3	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal erythema	4	0
Pharyngeal inflammation	1	0
Pharyngeal swelling	1	0
Pharyngeal ulceration	1	0
<i><b>Pneumothorax and pleural effusions NEC</b></i>		
Pleural effusion	15	0
Pneumothorax	3	0
<i><b>Pulmonary oedemas</b></i>		
Acute respiratory distress syndrome	1	0
Pulmonary congestion	1	0
<i><b>Respiratory failures (excl neonatal)</b></i>		
Respiratory failure	2	1

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
<b><i>Respiratory tract disorders NEC</i></b>		
Respiratory disorder	3	0
Respiratory tract oedema	1	0
<b><i>Upper respiratory tract signs and symptoms</i></b>		
Choking	4	0
Dysphonia	2	0
Oropharyngeal pain	10	0
Rhinorrhoea	14	0
Sneezing	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>238</b>	<b>4</b>



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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i>Angioedemas</i>		
Angioedema	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	8	0
Hyperhidrosis	12	0
Miliaria	1	0
<i>Bullous conditions</i>		
Blister	10	0
Dermatitis bullous	1	0
Erythema multiforme	4	0
Pemphigoid	2	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	4	0
Macule	2	0
Pain of skin	2	0
Papule	7	0
Scab	2	0
Skin burning sensation	2	0
Skin discolouration	31	0
Skin disorder	1	0
Skin induration	2	0
Skin lesion	5	0
Skin plaque	1	0
Skin reaction	2	0
Skin warm	26	0
<i>Dermatitis and eczema</i>		
Dermatitis	1	0
Dermatitis allergic	13	0
Dermatitis atopic	2	0
Dermatitis diaper	5	0
Eczema	17	0
Eczema weeping	1	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	1	0
Palmar-plantar erythrodysesthesia syndrome	1	0
<i>Erythemas</i>		
Erythema	97	0
<i>Pilar disorders NEC</i>		
Hair growth abnormal	1	0
<i>Pruritus NEC</i>		
Pruritus	16	0
<i>Purpura and related conditions</i>		
Henoch-Schonlein purpura	1	0
Petechiae	22	0
Purpura	8	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	150	0
Rash erythematous	24	0
Rash macular	37	0
Rash maculo-papular	9	0
Rash morbilliform	12	0
Rash papular	9	0
Rash pruritic	2	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Rash rubelliform	2	0
Rash vesicular	2	0
<b><i>Skin and subcutaneous conditions NEC</i></b>		
Cellulite	1	0
Skin mass	4	0
<b><i>Skin vasomotor conditions</i></b>		
Livedo reticularis	15	0
<b><i>Urticarias</i></b>		
Urticaria	50	0
Urticaria pigmentosa	1	0
Urticaria pressure	1	0
<b>Skin disorders SOC TOTAL</b>	<b>631</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Disability issues</i>		
Immobile	2	0
<b>Social circumstances SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i><b>Aneurysms and dissections non-site specific</b></i>		
Aneurysm	1	0
<i><b>Arterial infections and inflammations</b></i>		
Kawasaki's disease	1	1
<i><b>Circulatory collapse and shock</b></i>		
Circulatory collapse	7	0
Hypoperfusion	1	0
Shock	3	0
<i><b>Haemorrhages NEC</b></i>		
Haematoma	1	0
<i><b>Lymphoedemas</b></i>		
Lymphoedema	1	0
<i><b>Non-site specific embolism and thrombosis</b></i>		
Venous thrombosis	1	0
<i><b>Non-site specific necrosis and vascular insufficiency NEC</b></i>		
Fibromuscular dysplasia	1	0
<i><b>Peripheral vascular disorders NEC</b></i>		
Cyanosis	21	0
Flushing	3	0
Hot flush	1	0
<i><b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b></i>		
Peripheral coldness	5	0
Poor peripheral circulation	1	0
<i><b>Site specific vascular disorders NEC</b></i>		
Pallor	75	0
<i><b>Vascular hypertensive disorders NEC</b></i>		
Hypertension	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>124</b>	<b>1</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>5304</b>	<b>55</b>
<b>TOTAL REPORTS</b>	<b>1644</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>55</b>