

Case Series Drug Analysis Print

Name: Prevenar 13

Report Run Date: 12-Nov-2021
Data Lock Date: 11-Nov-2021 18:30:04
Earliest Reaction Date: 23-Jan-2009
MedDRA Version: MedDRA 24.1

Prevenar 13: Vaccine Analysis Print. All UK spontaneous suspected adverse reaction reports received up to and including the 11/11/2021 for Prevenar 13 vaccination.

This Vaccine Analysis Print (VAP) only contains reports where the brand of vaccine was specifically reported as Prevenar 13.

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Reaction Name	Total	Fatal
Blood disorders		
Anaemias NEC		
Anaemia	3	0
Anaemias haemolytic mechanical factor		
Haemolytic uraemic syndrome	5	0
Haematological disorders		
Mastocytosis	1	0
Haemolyses NEC		
Haemolysis	1	0
Leukocytoses NEC		
Lymphocytic infiltration	1	0
Lymphatic system disorders NEC		
Abdominal lymphadenopathy	1	0
Lymphadenitis	1	0
Lymphadenopathy	3	0
Neutropenias		
Febrile neutropenia	1	0
Neutropenia	1	0
Thrombocytopenias		
Immune thrombocytopenia	1	0
Thrombocytopenia	4	0
Blood disorders SOC TOTAL	23	0

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

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac septal defects congenital</i>		
Atrial septal defect	1	0
Congenital disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	3	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
Ear disorders SOC TOTAL	14	0

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

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<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	92	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	7	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	14	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>		
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	12	0
Vomiting	129	0
Vomiting projectile	12	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Haematochezia	8	0
<i>Oral dryness and saliva altered</i>		
Salivary hypersecretion	1	0
<i>Oral soft tissue signs and symptoms</i>		
Oral pain	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	6	0
Mouth swelling	2	0
<i>Tongue disorders</i>		
Tongue geographic	1	0
<i>Tongue signs and symptoms</i>		
Protrusion tongue	1	0
Swollen tongue	2	0
Tongue movement disturbance	1	0
Gastrointestinal disorders SOC TOTAL	385	1

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Reaction Name	Total	Fatal
General disorders		
<i>Application and instillation site reactions</i>		
Application site irritation	1	0
<i>Asthenic conditions</i>		
Asthenia	11	0
Decreased activity	2	0
Fatigue	20	0
Malaise	58	0
<i>Body temperature altered</i>		
Hyperthermia	1	0
Hypothermia	2	0
<i>Death and sudden death</i>		
Brain death	1	0
Death	17	17
Sudden death	5	5
Sudden infant death syndrome	7	7
<i>Febrile disorders</i>		
Hyperpyrexia	1	0
Pyrexia	394	0
<i>Feelings and sensations NEC</i>		
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
<i>Gait disturbances</i>		
Gait disturbance	9	0
Gait inability	8	0
Loss of control of legs	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	8	0
Crepitations	1	0
Crying	123	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
Screaming	55	0
Secretion discharge	3	0
Swelling	27	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Swelling face	13	0
Inflammations		
Inflammation	7	0
Injection site reactions		
Injection site bruising	2	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
Mass conditions NEC		
Mass	3	0
Oedema NEC		
Localised oedema	1	0
Oedema	1	0
Oedema peripheral	3	0
Pain and discomfort NEC		
Chest discomfort	2	0
Discomfort	11	0
Pain	48	0
Tenderness	5	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	2	0
Drug ineffective	122	0
Immediate post-injection reaction	1	0
Therapeutic product ineffective	194	0
Vaccination failure	12	0
Ulcers NEC		
Ulcer	1	0
Vaccination site reactions		
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	24	0
Vaccination site movement impairment	1	0
Vaccination site pain	23	0
Vaccination site pruritus	2	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site rash	10	0
Vaccination site reaction	3	0
Vaccination site scab	1	0
Vaccination site swelling	36	0
Vaccination site urticaria	1	0
Vaccination site vesicles	2	0
Vaccination site warmth	13	0
General disorders SOC TOTAL	1672	29

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

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergy to metals	1	0
Hypersensitivity	23	0
Multiple allergies	2	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	1	0
Drug hypersensitivity	1	0
Food allergy	3	0
Milk allergy	4	0
Reaction to excipient	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	21	0
Anaphylactic shock	1	0
<i>Immune and associated conditions NEC</i>		
Decreased immune responsiveness	1	0
Immune system disorder	1	0
Immunisation reaction	1	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	3	0
Immune system disorders SOC TOTAL	65	0

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Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Arthritis bacterial	4	0
Bacterial infection	1	0
Bacterial sepsis	4	0
Cellulitis	21	0
Injection site cellulitis	1	0
Meningitis bacterial	2	0
Skin bacterial infection	3	0
Vaccination site cellulitis	5	0
<i>Bone and joint infections</i>		
Intervertebral discitis	1	0
<i>Bordetella infections</i>		
Pertussis	2	0
<i>Candida infections</i>		
Candida infection	1	0
Oral candidiasis	1	0
<i>Cardiac infections</i>		
Endocarditis	1	0
<i>Central nervous system and spinal infections</i>		
Cavernous sinus thrombosis	1	0
Encephalitis	3	1
Meningitis	13	0
Meningitis aseptic	6	0
Subdural abscess	1	0
<i>Dental and oral soft tissue infections</i>		
Gingivitis	1	0
<i>Ear infections</i>		
Ear infection	7	0
Mastoiditis	3	0
Otitis media	1	0
Otitis media chronic	1	0
<i>Enteroviral infections NEC</i>		
Hand-foot-and-mouth disease	1	0
Meningitis enteroviral	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	3	0
Eye infection	1	0
<i>Haemophilus infections</i>		
Haemophilus bacteraemia	1	0
<i>Herpes viral infections</i>		
Herpes virus infection	1	0
Varicella	1	0
<i>Infections NEC</i>		
Abscess	2	0
Abscess limb	1	0
Empyema	62	0
Febrile infection	1	0
Infection	4	0
Injection site abscess	1	0
Localised infection	1	0
Vaccination site abscess	3	0
Vaccination site infection	3	0
<i>Influenza viral infections</i>		

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Influenza	2	0
Lower respiratory tract and lung infections		
Bronchitis	2	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	20	0
Pneumonia	38	0
Pneumonia necrotising	1	0
Neisseria infections		
Meningococcal sepsis	1	0
Parainfluenzae viral infections		
Parainfluenzae virus infection	1	0
Respiratory syncytial viral infections		
Respiratory syncytial virus bronchiolitis	2	0
Respiratory syncytial virus infection	1	0
Rhinoviral infections		
Rhinovirus infection	1	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Bacteraemia	14	0
Sepsis	29	0
Septic shock	1	0
Skin structures and soft tissue infections		
Eczema infected	1	0
Skin infection	1	0
Staphylococcal infections		
Staphylococcal infection	1	0
Streptococcal infections		
Meningitis pneumococcal	40	2
Pneumococcal bacteraemia	17	0
Pneumococcal infection	269	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
Upper respiratory tract infections		
Croup infectious	3	0
Nasopharyngitis	10	0
Rhinitis	5	0
Tonsillitis	5	0
Upper respiratory tract infection	7	0
Urinary tract infections		
Kidney infection	1	0
Urinary tract infection	1	0
Viral infections NEC		
Bronchiolitis	8	0
Gastroenteritis viral	1	0
Viral infection	2	0
Viral rash	1	0
Viral upper respiratory tract infection	2	0
Infections SOC TOTAL	709	16

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Reaction Name	Total	Fatal
Injuries		
<i>Cerebral injuries NEC</i>		
Craniocerebral injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure via breast milk	1	0
Maternal exposure during breast feeding	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Wrong technique in product usage process	2	0
<i>Muscle, tendon and ligament injuries</i>		
Muscle injury	1	0
<i>Non-site specific injuries NEC</i>		
Injury	1	0
Wound secretion	1	0
<i>Product administration errors and issues</i>		
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
<i>Product prescribing errors and issues</i>		
Product prescribing error	1	0
Product prescribing issue	1	0
<i>Product storage errors and issues in the product use system</i>		
Product storage error	2	0
<i>Skin injuries NEC</i>		
Contusion	9	0
Scar	1	0
Scratch	1	0
Skin injury	1	0
Skin laceration	1	0
<i>Vaccination related complications</i>		
Post vaccination syndrome	1	0
Injuries SOC TOTAL	46	0

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Investigations		
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Streptococcus test positive	1	0
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	12	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose fluctuation	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	1	0
<i>Central nervous system histopathology procedures</i>		
Biopsy brain abnormal	1	0
<i>Cerebrospinal fluid tests (excl microbiology)</i>		
CSF white blood cell count increased	1	0
<i>Chemistry analyses NEC</i>		
Inflammatory marker increased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate abnormal	3	0
Heart rate decreased	1	0
Heart rate increased	8	0
Pulse abnormal	1	0
<i>Immunology analyses NEC</i>		
Tryptase increased	1	0
<i>Metabolism tests NEC</i>		
Blood ketone body increased	1	0
<i>Mineral and electrolyte analyses</i>		
Blood magnesium decreased	1	0
Blood sodium decreased	1	0
<i>Ophthalmic function diagnostic procedures</i>		
Intraocular pressure increased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature abnormal	3	0
Body temperature decreased	3	0
Body temperature fluctuation	3	0
Body temperature increased	39	0
Breath sounds abnormal	2	0
Respiratory rate increased	3	0
<i>Platelet analyses</i>		
Platelet count increased	2	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	16	0
<i>Red blood cell analyses</i>		
Haemoglobin decreased	3	0
<i>Renal function analyses</i>		
Blood creatinine decreased	1	0
Blood urea decreased	1	0
<i>Urinalysis NEC</i>		
Blood urine present	1	0
White blood cells urine	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output decreased	4	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Capillary nail refill test abnormal	1	0
<i>Virus identification and serology</i>		
Coronavirus test positive	1	0

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Reaction Name	Total	Fatal
Investigations 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
Investigations SOC TOTAL	126	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	2	0
Decreased appetite	66	0
Food refusal	2	0
Hypophagia	4	0
<i>Cell metabolism disorders NEC</i>		
Mitochondrial cytopathy	1	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	2	0
<i>Fluid intake increased</i>		
Polydipsia	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Dairy intolerance	3	0
Food intolerance	3	0
<i>General nutritional disorders NEC</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>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Metabolic acidosis	2	0
<i>Potassium imbalance</i>		
Hyperkalaemia	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	1	0
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	1	0
<i>Total fluid volume decreased</i>		
Dehydration	4	0
Metabolic disorders SOC TOTAL	151	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	1	0
<i>Joint related disorders NEC</i>		
Hypermobility syndrome	2	0
<i>Joint related signs and symptoms</i>		
Arthralgia	12	0
Joint effusion	1	0
Joint range of motion decreased	1	0
Joint swelling	2	0
Joint warmth	1	0
<i>Muscle pains</i>		
Myalgia	5	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	3	0
Muscle tightness	1	0
Muscle twitching	6	0
<i>Muscle tone abnormalities</i>		
Floppy infant	25	0
Muscle rigidity	1	0
Trismus	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	4	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Limb mass	1	0
Musculoskeletal stiffness	12	0
Toe walking	1	0
Weight bearing difficulty	8	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Limb discomfort	4	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	1	0
Neck pain	1	0
Pain in extremity	33	0
<i>Tendon disorders</i>		
Tendonitis	1	0
Muscle & tissue disorders SOC TOTAL	129	0

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Reaction Name	Total	Fatal
Neoplasms		
<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
Neoplasms SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Absence seizures		
Petit mal epilepsy	8	0
Central nervous system haemorrhages and cerebrovascular accidents		
Cerebral infarction	1	0
Ruptured cerebral aneurysm	1	0
Central nervous system vascular disorders NEC		
Brain hypoxia	1	0
Cerebrovascular venous and sinus thrombosis		
Superior sagittal sinus thrombosis	1	0
Coordination and balance disturbances		
Balance disorder	3	0
Coordination abnormal	1	0
Dysstasia	1	0
Hand-eye coordination impaired	1	0
Nystagmus	1	0
Cortical dysfunction NEC		
Aphasia	2	0
Dyspraxia	2	0
Sensory processing disorder	2	0
Disturbances in consciousness NEC		
Depressed level of consciousness	4	0
Lethargy	39	0
Loss of consciousness	10	0
Somnolence	53	0
Syncope	6	0
Dyskinesias and movement disorders NEC		
Dyskinesia	17	0
Fine motor delay	1	0
Hypokinesia	3	0
Movement disorder	2	0
Psychomotor hyperactivity	1	0
Dystonias		
Opisthotonus	2	0
Encephalopathies NEC		
Hypoxic-ischaemic encephalopathy	1	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	10	0
Headaches NEC		
Headache	5	0
Tension headache	1	0
Hydrocephalic conditions		
Hydrocephalus	2	0
Increased intracranial pressure disorders		
Brain oedema	3	0
Intellectual disabilities		
Intellectual disability	1	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	1	0
Disturbance in attention	3	0
Muscle tone abnormal		
Hypertonia	1	0
Hypotonia	31	0
Narcolepsy and hypersomnia		

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Hypersomnia	7	0
<i>Nervous system disorders NEC</i>		
Brain stem syndrome	1	0
Nervous system disorder	4	0
Subdural effusion	3	0
<i>Neurological signs and symptoms NEC</i>		
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	48	0
<i>Neuromuscular disorders NEC</i>		
Hypotonic-hyporesponsive episode	6	0
Muscle spasticity	1	0
<i>Paraesthesias and dysaesthesias</i>		
Hyperaesthesia	1	0
Paraesthesia	2	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Paralysis	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	5	0
Epileptic encephalopathy	1	0
Febrile convulsion	32	0
Infantile spasms	1	0
Partial seizures	7	0
Seizure	53	0
Seizure anoxic	1	0
Seizure cluster	2	0
Seizure like phenomena	1	0
Status epilepticus	2	0
<i>Sensory abnormalities NEC</i>		
Sensory disturbance	1	0
<i>Sleep disturbances NEC</i>		
Sleep deficit	1	0
<i>Speech and language abnormalities</i>		
Speech disorder	3	0
Speech disorder developmental	2	0
<i>Tremor (excl congenital)</i>		
Tremor	17	0
Nervous system disorders SOC TOTAL	458	0

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

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

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

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Parasomnias</i>		
Sleep terror	3	0
<i>Personality disorders with anxious behaviour (Cluster C)</i>		
Dependent personality disorder	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	9	0
<i>Psychiatric elimination disorders</i>		
Enuresis	1	0
<i>Psychiatric symptoms NEC</i>		
Decreased eye contact	2	0
<i>Sleep disorders NEC</i>		
Sleep disorder	14	0
<i>Speech articulation and rhythm disturbances</i>		
Lack of spontaneous speech	1	0
<i>Stereotypies and automatisms</i>		
Head banging	1	0
<i>Suicidal and self-injurious behaviour</i>		
Self-injurious ideation	1	0
Psychiatric disorders SOC TOTAL	288	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Glomerulonephritis and nephrotic syndrome</i>		
Nephrotic syndrome	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	3	0
Anuria	1	0
<i>Renal structural abnormalities and trauma</i>		
Kidney enlargement	1	0
<i>Urinary abnormalities</i>		
Haematuria	1	0
Urine abnormality	1	0
Renal & urinary disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<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
Reproductive & breast disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	25	0
Apnoeic attack	4	0
Dyspnoea	30	0
Grunting	3	0
Hyperventilation	1	0
Hypopnoea	5	0
Hypoventilation	2	0
Respiration abnormal	2	0
Respiratory arrest	8	1
Respiratory distress	6	0
Tachypnoea	7	0
<i>Bronchospasm and obstruction</i>		
Wheezing	14	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	1	0
Cyanosis central	1	0
Hypoxia	2	1
Respiratory acidosis	1	0
<i>Coughing and associated symptoms</i>		
Cough	28	0
Haemoptysis	1	0
Productive cough	3	0
Sputum discoloured	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	2	0
<i>Lower respiratory tract signs and symptoms</i>		
Pulmonary haemorrhage	3	1
Rales	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	4	0
<i>Nasal disorders NEC</i>		
Epistaxis	2	0
<i>Neonatal hypoxic conditions</i>		
Infantile apnoea	4	0
Neonatal hypoxia	3	0
<i>Parenchymal lung disorders NEC</i>		
Lung consolidation	3	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	3	0
Pharyngeal swelling	1	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	15	0
Pneumothorax	3	0
<i>Pulmonary oedemas</i>		
Pulmonary congestion	1	0
<i>Respiratory failures (excl neonatal)</i>		
Respiratory failure	1	0
<i>Respiratory tract disorders NEC</i>		
Respiratory disorder	3	0
<i>Upper respiratory tract signs and symptoms</i>		
Choking	4	0
Dysphonia	2	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Oropharyngeal pain	10	0
Rhinorrhoea	14	0
Sneezing	1	0
Respiratory disorders SOC TOTAL	225	3

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Reaction Name	Total	Fatal
Skin disorders		
Angioedemas		
Angioedema	1	0
Apocrine and eccrine gland disorders		
Cold sweat	8	0
Hyperhidrosis	12	0
Bullous conditions		
Blister	9	0
Dermatitis bullous	1	0
Erythema multiforme	4	0
Pemphigoid	2	0
Dermal and epidermal conditions NEC		
Dry skin	4	0
Macule	1	0
Pain of skin	2	0
Papule	6	0
Scab	1	0
Skin burning sensation	2	0
Skin discolouration	30	0
Skin disorder	1	0
Skin induration	2	0
Skin lesion	4	0
Skin plaque	1	0
Skin reaction	2	0
Skin warm	26	0
Dermatitis and eczema		
Dermatitis	1	0
Dermatitis allergic	12	0
Dermatitis atopic	2	0
Dermatitis diaper	5	0
Eczema	17	0
Eczema weeping	1	0
Dermatitis ascribed to specific agent		
Drug eruption	1	0
Palmar-plantar erythrodysesthesia syndrome	1	0
Erythemas		
Erythema	96	0
Pilar disorders NEC		
Hair growth abnormal	1	0
Pruritus NEC		
Pruritus	16	0
Purpura and related conditions		
Henoch-Schonlein purpura	1	0
Petechiae	22	0
Purpura	8	0
Rashes, eruptions and exanthems NEC		
Rash	142	0
Rash erythematous	22	0
Rash macular	36	0
Rash maculo-papular	9	0
Rash morbilliform	12	0
Rash papular	8	0
Rash pruritic	2	0
Rash rubelliform	2	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rash vesicular	2	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	4	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	15	0
<i>Urticarias</i>		
Urticaria	49	0
Urticaria pigmentosa	1	0
Urticaria pressure	1	0
Skin disorders SOC TOTAL	608	0

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

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Aneurysms and dissections non-site specific</i>		
Aneurysm	1	0
<i>Arterial infections and inflammations</i>		
Kawasaki's disease	1	1
<i>Circulatory collapse and shock</i>		
Circulatory collapse	7	0
Hypoperfusion	1	0
Shock	2	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
<i>Lymphoedemas</i>		
Lymphoedema	1	0
<i>Non-site specific embolism and thrombosis</i>		
Venous thrombosis	1	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Fibromuscular dysplasia	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	20	0
Flushing	3	0
Hot flush	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	5	0
Poor peripheral circulation	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	74	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
Vascular disorders SOC TOTAL	121	1
TOTAL REACTIONS FOR DRUG	5154	54
TOTAL REPORTS	1602	
TOTAL FATAL OUTCOME REPORTS		54