

Prevenar 13 Pneumococcal Vaccine Analysis Print.

All UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with the Prevenar 13 Pneumococcal vaccine up to and including 14/05/2025.

Report run: 15/05/2025

Earliest reaction date: 01/01/2009

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
Blood and lymphatic system disorders	Anaemias nonhaemolytic and marrow depression	Anaemias NEC	Anaemia	3	0
	Haematological disorders NEC	Haematological disorders	Mastocytosis	1	0
	Haemolyses and related conditions	Anaemias haemolytic mechanical factor	Haemolytic uraemic syndrome	7	0
		Haemolyses NEC	Haemolysis	2	0
	Platelet disorders	Thrombocytopenias	Immune thrombocytopenia	1	0
			Thrombocytopenia	4	0
	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Abdominal lymphadenopathy	1	0
			Lymphadenitis	1	0
			Lymphadenopathy	6	0
	White blood cell disorders	Leukocytoses NEC	Lymphocytic infiltration	1	0
		Neutropenias	Febrile neutropenia	1	0
			Neutropenia	1	0
	Total			29	0
Cardiac disorders	Cardiac arrhythmias	Rate and rhythm disorders NEC	Bradycardia	9	0
			Bradycardia neonatal	1	0
			Tachycardia	13	0
		Supraventricular arrhythmias	Supraventricular tachycardia	1	0
		Ventricular arrhythmias and cardiac arrest	Cardiac arrest	11	3
			Cardio-respiratory arrest	4	1
			Ventricular fibrillation	1	0
			Ventricular tachycardia	1	0
	Cardiac disorders, signs and symptoms NEC	Cardiac disorders NEC	Cardiac disorder	1	0
			Cardiovascular disorder	3	0
	Heart failures	Heart failures NEC	Cardiac failure	1	0
	Myocardial disorders	Myocardial disorders NEC	Cardiomegaly	1	0
			Left ventricular dysfunction	1	0
	Pericardial disorders	Pericardial disorders NEC	Pericardial effusion	2	0
			Pericardial haemorrhage	1	0
	Total			51	4
Congenital, familial and genetic disorders	Cardiac and vascular disorders congenital	Cardiac septal defects congenital	Atrial septal defect	1	0

	Musculoskeletal and connective tissue disorders congenital	Connective tissue disorders congenital	Hypermobility syndrome	2	0
	Neurological disorders congenital	Cerebral disorders congenital	Lissencephaly	1	0
	Total			4	0
Ear and labyrinth disorders	Aural disorders NEC	Ear disorders NEC	Ear pain	4	0
			Ear swelling	5	0
	External ear disorders (excl congenital)	External ear disorders NEC	Excessive cerumen production	1	0
	Hearing disorders	Hearing losses	Deafness	4	0
	Inner ear and VIIIth cranial nerve disorders	Inner ear signs and symptoms	Vertigo	1	0
	Middle ear disorders (excl congenital)	Tympanic membrane disorders (excl infections)	Tympanic membrane disorder	1	0
	Total			16	0
Eye disorders	Eye disorders NEC	Lacrimation disorders	Lacrimation increased	1	0
		Ocular disorders NEC	Eye disorder	1	0
			Eye oedema	1	0
			Eye swelling	12	0
	Ocular haemorrhages and vascular disorders NEC	Conjunctival and corneal bleeding and vascular disorders	Conjunctival haemorrhage	1	0
	Ocular infections, irritations and inflammations	Lid, lash and lacrimal infections, irritations and inflammations	Erythema of eyelid	1	0
			Swelling of eyelid	2	0
		Ocular infections, inflammations and associated manifestations	Eye pruritus	1	0
			Ocular hyperaemia	1	0
	Ocular neuromuscular disorders	Eyelid movement disorders	Excessive eye blinking	1	0
			Eyelid ptosis	1	0
		Ocular nerve and muscle disorders	Eye movement disorder	10	0
			Gaze palsy	2	0
			Strabismus	3	0
		Pupil disorders	Anisocoria	2	0
			Miosis	1	0
			Mydriasis	3	0
	Ocular sensory symptoms NEC	Ocular sensation disorders	Pupil fixed	1	0
			Photophobia	1	0
	Vision disorders	Visual disorders NEC	Photopsia	1	0
		Visual impairment and blindness (excl colour blindness)	Blindness	1	0
			Cortical visual impairment	1	0
	Total		Visual impairment	3	0
				52	0
Gastrointestinal disorders	Abdominal hernias and other abdominal wall conditions	Inguinal hernias	Inguinal hernia, obstructive	1	0
	Gastrointestinal conditions NEC	Gastrointestinal disorders NEC	Gastrointestinal disorder	3	0

Gastrointestinal haemorrhages NEC	Non-site specific gastrointestinal haemorrhages	Haematemesis	1	0
		Haematochezia	8	0
Gastrointestinal inflammatory conditions	Colitis (excl infective)	Colitis	1	0
		Necrotising colitis	2	1
	Gastritis (excl infective)	Reflux gastritis	1	0
	Gastrointestinal inflammatory disorders NEC	Necrotising enterocolitis neonatal	1	0
Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	96	0
		Diarrhoea haemorrhagic	2	0
	Gastrointestinal atonic and hypomotility disorders NEC	Constipation	12	0
		Gastroesophageal reflux disease	9	0
		Intestinal dilatation	1	0
	Gastrointestinal spastic and hypermotility disorders	Frequent bowel movements	3	0
		Irritable bowel syndrome	1	0
Gastrointestinal signs and symptoms	Abdominal findings abnormal	Gastrointestinal sounds abnormal	1	0
	Dyspeptic signs and symptoms	Dyspepsia	3	0
	Faecal abnormalities NEC	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
	Flatulence, bloating and distension	Abdominal distension	3	0
		Flatulence	8	0
	Gastrointestinal and abdominal pains (excl oral and throat)	Abdominal pain	10	0
		Abdominal pain upper	15	0
		Abdominal rigidity	1	0
		Gastrointestinal pain	1	0
	Gastrointestinal signs and symptoms NEC	Abdominal discomfort	11	0
		Dysphagia	1	0
		Gastrointestinal wall thickening	1	0
	Nausea and vomiting symptoms	Infantile vomiting	4	0
		Nausea	13	0
		Vomiting	133	0
		Vomiting projectile	12	0
Gastrointestinal stenosis and obstruction	Gastrointestinal stenosis and obstruction NEC	Intussusception	1	0
Oral soft tissue conditions	Oral soft tissue disorders NEC	Lip blister	1	0
	Oral soft tissue signs and symptoms	Oral pain	1	0
	Oral soft tissue swelling and oedema	Lip swelling	6	0

			Mouth swelling	2	0
	Salivary gland conditions	Oral dryness and saliva altered	Salivary hypersecretion	1	0
	Tongue conditions	Tongue disorders	Tongue geographic	1	0
		Tongue signs and symptoms	Protrusion tongue	1	0
			Swollen tongue	2	0
			Tongue movement disturbance	1	0
	Total			401	1
General disorders and administration site conditions	Administration site reactions	Administration site reactions NEC	Administration site erythema	1	0
			Administration site swelling	1	0
		Application site reactions	Application site irritation	1	0
		Injection site reactions	Injected limb mobility decreased	1	0
			Injection site bruising	3	0
			Injection site discolouration	3	0
			Injection site erythema	36	0
			Injection site induration	6	0
			Injection site inflammation	9	0
			Injection site irritation	1	0
			Injection site mass	10	0
			Injection site oedema	1	0
			Injection site pain	9	0
			Injection site rash	9	0
			Injection site reaction	6	0
			Injection site swelling	35	0
			Injection site urticaria	1	0
			Injection site vesicles	1	0
			Injection site warmth	6	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	26	0
		Vaccination site movement impairment	1	0
		Vaccination site pain	23	0
		Vaccination site pruritus	2	0
		Vaccination site rash	12	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
Body temperature conditions	Body temperature altered	Hyperthermia	1	0
		Hypothermia	2	0
	Febrile disorders	Hyperpyrexia	1	0
		Pyrexia	409	0
Fatal outcomes	Death and sudden death	Brain death	1	0
		Death	17	17
		Sudden death	5	5
		Sudden infant death syndrome	7	7
General system disorders NEC	Asthenic conditions	Asthenia	11	0
		Decreased activity	2	0
		Fatigue	22	0
		Malaise	62	0
	Feelings and sensations NEC	Chills	13	0
		Feeling abnormal	12	0
		Feeling cold	2	0
		Feeling drunk	1	0
		Feeling hot	18	0
		Feeling of body temperature change	1	0
		Thirst	4	0
		Thirst decreased	3	0
	Gait disturbances	Gait disturbance	9	0
		Gait inability	9	0
		Loss of control of legs	1	0
	General signs and symptoms NEC	Condition aggravated	9	0
		Crepitations	1	0
		Crying	126	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
			Pneumatosi	1	0
			Screaming	55	0
			Secretion discharge	3	0
			Swelling	31	0
			Swelling face	13	0
		Inflammations	Inflammation	8	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 effects (excl toxicity)	Therapeutic and nontherapeutic responses	Drug ineffective	196	1
			Immediate post-injection reaction	1	0
			Product ineffective	215	0
			Vaccination failure	22	0
	Tissue disorders NEC	Mass conditions NEC	Mass	3	0
		Ulcers NEC	Ulcer	1	0
	Total			1,823	30
Hepatobiliary disorders	Hepatic and hepatobiliary disorders	Cholestasis and jaundice	Jaundice	2	0
			Jaundice cholestatic	1	0
		Hepatobiliary signs and symptoms	Hepatomegaly	1	0
	Total			4	0
Immune system disorders	Allergic conditions	Allergic conditions NEC	Allergy to metals	1	0
			Hypersensitivity	24	0
			Multiple allergies	2	0
		Allergies to foods, food additives, drugs and other chemicals	Allergy to vaccine	1	0
			Drug hypersensitivity	1	0
			Food allergy	3	0
			Milk allergy	4	0
			Reaction to excipient	2	0

		Anaphylactic and anaphylactoid responses	Anaphylactic reaction	21	0		
			Anaphylactic shock	1	0		
Immune disorders NEC	Immune and associated conditions NEC		Decreased immune responsiveness	1	0		
			Haemophagocytic lymphohistiocytosis	1	0		
			Immune system disorder	2	0		
Immunodeficiency syndromes	Immunodeficiency disorders NEC		Hypogammaglobulinaemia	1	0		
			Immunodeficiency	3	0		
Total				68	0		
Infections and infestations	Bacterial infectious disorders	Bacterial infections NEC	Arthritis bacterial	4	0		
			Bacterial infection	1	0		
			Bacterial sepsis	9	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		
			Bordetella infections	Pertussis	2	0	
			Haemophilus infections	Haemophilus bacteraemia	1	0	
			Neisseria infections	Meningococcal sepsis	1	0	
			Staphylococcal infections	Staphylococcal infection	1	0	
			Streptococcal infections	Meningitis pneumococcal	44	2	
				Pneumococcal bacteraemia	23	0	
				Pneumococcal infection	283	10	
				Pneumococcal sepsis	38	2	
				Pneumonia pneumococcal	50	1	
				Pneumonia streptococcal	19	0	
				Septic arthritis streptococcal	1	0	
				Streptococcal bacteraemia	1	0	
				Streptococcal sepsis	1	0	
				Tonsillitis streptococcal	1	0	
			Fungal infectious disorders	Candida infections	Candida infection	1	0
					Oral candidiasis	1	0
			Infections - pathogen unspecified	Abdominal and gastrointestinal infections	Appendicitis	1	0
				Bone and joint infections	Intervertebral discitis	1	0

	Cardiac infections	Endocarditis	1	0
	Central nervous system and spinal infections	Encephalitis	3	1
		Meningitis	15	1
		Meningitis aseptic	6	0
		Subdural abscess	1	0
	Dental and oral soft tissue infections	Gingivitis	1	0
	Ear infections	Ear infection	9	0
		Mastoiditis	5	0
		Otitis media	1	0
		Otitis media acute	1	0
		Otitis media chronic	1	0
	Eye and eyelid infections	Conjunctivitis	4	0
		Eye infection	1	0
	Infections NEC	Abscess	2	0
		Abscess limb	1	0
		Empyema	64	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
	Lower respiratory tract and lung infections	Atypical pneumonia	1	0
		Bronchitis	2	0
		Infectious pleural effusion	1	0
		Lower respiratory tract infection	21	0
		Pneumonia	54	1
		Pneumonia necrotising	1	0
	Sepsis, bacteraemia, viraemia and fungaemia NEC	Bacteraemia	23	0
		Sepsis	33	0
		Septic shock	1	0
	Skin structures and soft tissue infections	Eczema infected	1	0
		Skin infection	1	0
	Upper respiratory tract infections	Croup infectious	3	0
		Epiglottitis	1	0
		Nasopharyngitis	11	0
		Rhinitis	5	0
		Tonsillitis	6	0
		Upper respiratory tract infection	8	0
	Urinary tract infections	Kidney infection	1	0
		Urinary tract infection	1	0
Viral infectious disorders	Adenoviral infections	Adenovirus infection	1	0
	Cytomegaloviral infections	Cytomegalovirus infection	1	0
	Enteroviral infections NEC	Hand-foot-and-mouth disease	1	0
		Meningitis enteroviral	1	0

		Epstein-Barr viral infections	Epstein-Barr virus infection	1	0
	Herpes viral infections		Herpes simplex	1	0
			Herpes virus infection	1	0
			Human herpesvirus 6 infection	1	0
			Varicella	2	0
	Influenza viral infections		Influenza	2	0
			Pneumonia influenzal	1	0
	Mumps viral infections		Mumps	1	0
	Parainfluenzae viral infections		Parainfluenzae virus infection	1	0
	Respiratory syncytial viral infections		Respiratory syncytial virus bronchiolitis	2	0
			Respiratory syncytial virus infection	2	0
	Rhinoviral infections		Rhinovirus infection	1	0
	Rubella viral infections		Rubella	1	0
	Rubeola viral infections		Measles	1	0
	Viral infections NEC		Bronchiolitis	10	0
			Gastroenteritis viral	1	0
			Viral infection	2	0
			Viral rash	1	0
			Viral upper respiratory tract infection	2	0
	Total				862
Injury, poisoning and procedural complications	Exposures, chemical injuries and poisoning	Exposures associated with pregnancy, delivery and lactation	Exposure via breast milk	1	0
			Foetal exposure during pregnancy	1	0
			Maternal exposure during breast feeding	1	0
	Injuries NEC	Cerebral injuries NEC	Craniocerebral injury	1	0
		Muscle, tendon and ligament injuries	Muscle injury	1	0
		Non-site specific injuries NEC	Injury	1	0
			Wound secretion	1	0
		Skin injuries NEC	Contusion	9	0
			Scar	1	0
			Scratch	1	0
			Skin injury	1	0
	Skin laceration		1	0	
	Medication errors and other product use errors and issues	Medication errors, product use errors and issues NEC	Medication error	2	0
			Product use in unapproved indication	3	0
			Wrong technique in product usage process	2	0
		Product administration errors and issues	Booster dose missed	3	0

			Extra dose administered	1	0	
			Inappropriate schedule of product administration	15	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	
		Product prescribing errors and issues	Product prescribing error	1	0	
			Product prescribing issue	1	0	
		Product storage errors and issues in the product use system	Product storage error	2	0	
	Procedural related injuries and complications NEC	Vaccination related complications	Immunisation reaction	2	0	
			Post vaccination syndrome	1	0	
	Total			65	0	
	Investigations	Cardiac and vascular investigations (excl enzyme tests)	Cardiac auscultatory investigations	Cardiac murmur	1	0
			Heart rate and pulse investigations	Heart rate abnormal	3	0
				Heart rate decreased	1	0
				Heart rate increased	10	0
Pulse abnormal				1	0	
Vascular tests NEC (incl blood pressure)		Capillary nail refill test abnormal	1	0		
Haematology investigations (incl blood groups)		Platelet analyses	Platelet count increased	2	0	
		Red blood cell analyses	Haemoglobin decreased	3	0	
		White blood cell analyses	Lymphocyte count increased	1	0	
			Neutrophil count decreased	1	0	
			White blood cell count increased	4	0	
		Immunology and allergy investigations	Immunology analyses NEC	Tryptase increased	1	0

Metabolic, nutritional and blood gas investigations	Blood gas and acid base analyses	Oxygen saturation decreased	12	0	
	Carbohydrate tolerance analyses (incl diabetes)	Blood glucose fluctuation	1	0	
	Metabolism tests NEC	Blood ketone body increased	1	0	
Microbiology and serology investigations	Bacteria identification and serology (excl mycobacteria)	Streptococcus test positive	1	0	
	Virus identification and serology	Coronavirus test positive	1	0	
Neurological, special senses and psychiatric investigations	Central nervous system histopathology procedures	Biopsy brain abnormal	1	0	
	Cerebrospinal fluid tests (excl microbiology)	CSF white blood cell count increased	1	0	
	Ophthalmic function diagnostic procedures	Intraocular pressure increased	1	0	
Physical examination and organ system status topics	Physical examination procedures and organ system status	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	
Protein and chemistry analyses NEC	Chemistry analyses NEC	Inflammatory marker increased	1	0	
	Protein analyses NEC	C-reactive protein increased	16	0	
Renal and urinary tract investigations and urinalyses	Renal function analyses	Blood creatinine decreased	1	0	
		Blood urea decreased	1	0	
	Urinalysis NEC	Blood urine present	1	0	
		White blood cells urine	1	0	
	Urinary tract function analyses NEC	Urine output decreased	4	0	
Water, electrolyte and mineral investigations	Mineral and electrolyte analyses	Blood magnesium decreased	1	0	
		Blood sodium decreased	1	0	
Total			129	0	
Metabolism and nutrition disorders	Acid-base disorders	Metabolic acidoses (excl diabetic acidoses)	Metabolic acidosis	2	0
	Appetite and general nutritional disorders	Appetite disorders	Appetite disorder	2	0

Musculoskeletal and connective tissue disorders			Decreased appetite	73	0
			Food refusal	2	0
			Hypophagia	4	0
			Increased appetite	1	0
		General nutritional disorders NEC	Abnormal loss of weight	1	0
			Feeding disorder	2	0
			Food aversion	3	0
			Poor feeding infant	48	0
			Weight gain poor	3	0
	Electrolyte and fluid balance conditions	Fluid intake decreased	Fluid intake reduced	2	0
		Fluid intake increased	Polydipsia	1	0
		Potassium imbalance	Hyperkalaemia	1	0
		Sodium imbalance	Hyponatraemia	2	0
		Total fluid volume decreased	Dehydration	4	0
	Food intolerance syndromes	Food malabsorption and intolerance syndromes (excl sugar intolerance)	Dairy intolerance	3	0
			Food intolerance	3	0
		Sugar intolerance (excl glucose intolerance)	Lactose intolerance	1	0
	Glucose metabolism disorders (incl diabetes mellitus)	Hypoglycaemic conditions NEC	Hypoglycaemia	1	0
	Metabolism disorders NEC	Cell metabolism disorders NEC	Mitochondrial cytopathy	1	0
	Total			160	0
	Joint disorders	Arthropathies NEC	Arthritis	1	0
			Joint related signs and symptoms	14	0
			Joint effusion	1	0
			Joint range of motion decreased	1	0
			Joint stiffness	1	0
			Joint swelling	2	0
			Joint warmth	1	0
		Muscle infections and inflammations	Myositis	1	0
			Muscle pains	6	0
		Muscle related signs and symptoms NEC	Muscle spasms	3	0
			Muscle tightness	1	0
			Muscle twitching	7	0
			Muscle tone abnormalities	25	0
			Muscle rigidity	1	0
			Trismus	1	0
		Muscle weakness conditions	Muscular weakness	4	0

Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)	Extremity deformities	Foot deformity	1	0
	Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue conditions NEC	Limb mass	1	0
			Musculoskeletal stiffness	12	0
			Toe walking	1	0
			Weight bearing difficulty	8	0
		Musculoskeletal and connective tissue pain and discomfort	Back pain	1	0
			Limb discomfort	4	0
			Musculoskeletal discomfort	1	0
			Neck pain	1	0
			Pain in extremity	35	0
	Tendon, ligament and cartilage disorders	Tendon disorders	Tendonitis	1	0
	Total			136	0
	Leukaemias	Leukaemias acute lymphocytic	Acute lymphocytic leukaemia	2	0
	Nervous system neoplasms malignant and unspecified NEC	Nervous system neoplasms unspecified malignancy NEC	Astrocytoma	1	0
	Skin neoplasms malignant and unspecified	Skin neoplasms malignant and unspecified (excl melanoma)	Neoplasm skin	1	0
	Soft tissue neoplasms malignant and unspecified	Rhabdomyosarcomas	Rhabdomyosarcoma	1	0
	Total			5	0
Nervous system disorders	Central nervous system vascular disorders	Central nervous system haemorrhages and cerebrovascular accidents	Cerebral haemorrhage	1	0
			Cerebral infarction	1	0
			Ruptured cerebral aneurysm	1	0
		Central nervous system vascular disorders NEC	Brain hypoxia	1	0
			Cerebrovascular venous and sinus thrombosis	1	0
		Cerebrovascular venous and sinus thrombosis	Superior sagittal sinus thrombosis	1	0
	Encephalopathies	Encephalopathies NEC	Hypoxic-ischaemic encephalopathy	1	0
	Headaches	Headaches NEC	Headache	5	0
	Increased intracranial pressure and hydrocephalus	Hydrocephalic conditions	Tension headache	1	0
			Hydrocephalus	2	0
		Increased intracranial pressure disorders	Brain oedema	3	0

Mental impairment disorders	Intellectual disabilities	Intellectual disability	1	0
	Mental impairment (excl dementia and memory loss)	Cognitive disorder	1	0
		Disturbance in attention	3	0
Movement disorders (incl parkinsonism)	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
	Paralysis and paresis (excl cranial nerve)	Monoplegia	2	0
		Paralysis	2	0
	Tremor (excl congenital)	Tremor	18	0
Neurological disorders NEC	Coordination and balance disturbances	Balance disorder	5	0
		Coordination abnormal	2	0
		Developmental coordination disorder	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	3	0
	Disturbances in consciousness NEC	Depressed level of consciousness	5	0
		Lethargy	41	0
		Loss of consciousness	10	0
		Somnolence	57	0
		Syncope	6	0
	Nervous system disorders NEC	Brain stem syndrome	1	0
		Nervous system disorder	4	0
		Subdural effusion	3	0
	Neurological signs and symptoms NEC	Cerebrospinal fluid leakage	2	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	51	0	
		Paraesthesias and dysaesthesias	Hyperaesthesia Paraesthesia	1 2	0 0	
		Sensory abnormalities NEC	Sensory disturbance	1	0	
		Speech and language abnormalities	Speech disorder Speech disorder developmental	3 2	0 0	
	Neuromuscular disorders	Muscle tone abnormal	Hypertonia Hypotonia	1 33	0 0	
		Neuromuscular disorders NEC	Hypotonic-hyporesponsive episode Muscle spasticity	6 1	0 0	
	Seizures (incl subtypes)	Absence seizures	Petit mal epilepsy	8	0	
		Generalised tonic-clonic seizures	Generalised tonic-clonic seizure	11	0	
		Seizures and seizure disorders NEC	Epilepsy Epileptic encephalopathy Febrile convulsion Infantile spasms Partial seizures Seizure Seizure anoxic Seizure cluster Seizure like phenomena Status epilepticus	6 1 33 1 7 57 1 2 1 2	0 0 0 0 0 0 0 0 0 0	
	Sleep disturbances (incl subtypes)	Narcolepsy and hypersomnia	Hypersomnia	7	0	
		Sleep disturbances NEC	Sleep deficit	1	0	
		Total		489	0	
	Pregnancy, puerperium and perinatal conditions	Foetal complications	Foetal growth complications	Foetal growth restriction	1	0
		Neonatal and perinatal conditions	Newborn complications NEC	Neonatal disorder	1	0
		Total		2	0	
Product issues	Device issues	Device physical property and chemical issues	Needle issue	2	0	
	Product quality, supply, distribution, manufacturing and quality system issues	Product quality issues NEC	Product quality issue	4	0	
	Total		6	0		
Psychiatric disorders	Anxiety disorders and symptoms	Anxiety disorders NEC Anxiety symptoms Fear symptoms and phobic disorders (incl social phobia)	Separation anxiety disorder Agitation Anxiety Stress Fear of eating Social fear	1 8 4 1 1 1	0 0 0 0 0 0	

	Obsessive-compulsive disorders and symptoms	Obsessive-compulsive symptom	1	0
Changes in physical activity	Decreased physical activity levels	Catatonia	2	0
	Increased physical activity levels	Restlessness	20	0
	Stereotypies and automatisms	Head banging	1	0
Communication disorders and disturbances	Communications disorders	Mutism	1	0
	Speech articulation and rhythm disturbances	Lack of spontaneous speech	1	0
Deliria (incl confusion)	Confusion and disorientation	Confusional state	2	0
		Disorientation	2	0
Depressed mood disorders and disturbances	Mood alterations with depressive symptoms	Depressed mood	4	0
		Tearfulness	1	0
Developmental disorders NEC	Pervasive developmental disorders NEC	Autism spectrum disorder	13	0
Disturbances in thinking and perception	Hallucinations (excl sleep-related)	Hallucination, auditory	1	0
		Hallucinations, mixed	1	0
Eating disorders and disturbances	Eating disorders NEC	Eating disorder	2	0
Mood disorders and disturbances NEC	Affect alterations NEC	Flat affect	1	0
	Emotional and mood disturbances NEC	Emotional distress	19	0
		Emotional poverty	1	0
		Irritability	109	0
		Mood altered	3	0
	Mood disorders NEC	Apathy	1	0
Personality disorders and disturbances in behaviour	Behaviour and socialisation disturbances	Listless	5	0
		Aggression	4	0
		Disturbance in social behaviour	1	0
		Personality change	2	0
	Personality disorders with anxious behaviour (Cluster C)	Social avoidant behaviour	1	0
		Dependent personality disorder	1	0
Psychiatric and behavioural symptoms NEC	Abnormal behaviour NEC	Abnormal behaviour	20	0
		Breath holding	7	0
		Regressive behaviour	1	0
		Staring	5	0
	Psychiatric symptoms NEC	Decreased eye contact	2	0
Psychiatric disorders NEC	Mental disorders NEC	Mental disorder	3	0
	Psychiatric elimination disorders	Enuresis	1	0
Sleep disorders and disturbances	Disturbances in initiating and maintaining sleep	Insomnia	19	0

Renal and urinary disorders			Middle insomnia	3	0
		Dyssomnias	Poor quality sleep	5	0
		Parasomnias	Sleep terror	3	0
		Sleep disorders NEC	Sleep disorder	15	0
	Suicidal and self-injurious behaviours NEC	Suicidal and self-injurious behaviour	Self-injurious ideation	1	0
	Total			301	0
	Nephropathies	Glomerulonephritis and nephrotic syndrome	Nephrotic syndrome	1	0
	Renal disorders (excl nephropathies)	Renal disorders NEC	Renal disorder	1	0
		Renal failure and impairment	Acute kidney injury	3	0
			Anuria	1	0
			Oliguria	1	0
		Renal structural abnormalities and trauma	Kidney enlargement	1	0
Reproductive system and breast disorders	Urinary tract signs and symptoms	Urinary abnormalities	Haematuria	1	0
			Urine abnormality	1	0
		Urinary tract signs and symptoms NEC	Renal pain	1	0
	Total			11	0
	Penile and scrotal disorders (excl infections and inflammations)	Scrotal disorders NEC	Scrotal swelling	1	0
	Reproductive tract disorders NEC	Reproductive tract disorders NEC (excl neoplasms)	Genital blister	1	0
		Reproductive tract signs and symptoms NEC	Genital rash	1	0
			Genital swelling	1	0
	Testicular and epididymal disorders	Testicular and epididymal disorders NEC	Testicular pain	1	0
	Total			5	0
Respiratory, thoracic and mediastinal disorders	Bronchial disorders (excl neoplasms)	Bronchospasm and obstruction	Wheezing	14	0
	Lower respiratory tract disorders (excl obstruction and infection)	Lower respiratory tract inflammatory and immunologic conditions	Pneumonitis	1	0
		Parenchymal lung disorders NEC	Lung consolidation	3	0
		Pulmonary oedemas	Acute respiratory distress syndrome	1	0
			Pulmonary congestion	1	0
	Neonatal respiratory disorders	Neonatal hypoxic conditions	Brief resolved unexplained event	1	0
			Infantile apnoea	4	0

		Neonatal hypoxia	3	0
Pleural disorders	Pneumothorax and pleural effusions NEC	Pleural effusion	15	0
		Pneumothorax	3	0
Respiratory disorders NEC	Breathing abnormalities	Apnoea	26	0
		Apnoeic attack	4	0
		Dyspnoea	34	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
	Conditions associated with abnormal gas exchange	Asphyxia	1	0
		Cyanosis central	1	0
		Hypoxia	2	1
		Respiratory acidosis	1	0
	Coughing and associated symptoms	Cough	29	0
		Haemoptysis	1	0
		Productive cough	3	0
		Sputum discoloured	1	0
	Respiratory failures (excl neonatal)	Respiratory failure	2	1
	Respiratory tract disorders NEC	Respiratory disorder	3	0
		Respiratory tract oedema	1	0
Respiratory tract signs and symptoms	Lower respiratory tract signs and symptoms	Pulmonary haemorrhage	3	1
		Rales	1	0
	Upper respiratory tract signs and symptoms	Choking	5	0
		Dysphonia	2	0
		Oropharyngeal pain	10	0
		Rhinorrhoea	15	0
		Sneezing	1	0
	Upper respiratory tract disorders (excl infections)	Stridor	3	0
		Nasal congestion and inflammations	4	0
		Nasal disorders NEC	2	0
		Pharyngeal disorders (excl infections and neoplasms)	4	0
		Pharyngeal erythema	1	0
		Pharyngeal inflammation	1	0
		Pharyngeal swelling	1	0
		Pharyngeal ulceration	1	0
			243	4
Skin and subcutaneous tissue disorders	Angioedema and urticaria	Angioedemas	2	0
	Urticarias	Urticaria	53	0
		Urticaria pigmentosa	1	0
		Urticaria pressure	1	0
	Epidermal and dermal conditions	Bullous conditions	11	0
		Dermatitis bullous	1	0

			Erythema multiforme	4	0	
			Pemphigoid	2	0	
	Dermal and epidermal conditions NEC		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	
		Dermatitis and eczema		Dermatitis	1	0
				Dermatitis allergic	13	0
			Dermatitis atopic	2	0	
			Dermatitis diaper	5	0	
			Eczema	18	0	
			Eczema weeping	1	0	
	Dermatitis ascribed to specific agent			Drug eruption	1	0
			Palmar-plantar erythrodysesthesia syndrome	1	0	
			Erythemas	98	0	
			Pruritus NEC	17	0	
	Rashes, eruptions and exanthems NEC		Rash	155	0	
			Rash erythematous	26	0	
			Rash macular	38	0	
			Rash maculopapular	9	0	
			Rash morbilliform	13	0	
			Rash papular	9	0	
			Rash pruritic	3	0	
			Rash rubelliform	2	0	
			Rash vesicular	2	0	
	Skin and subcutaneous tissue disorders NEC	Skin and subcutaneous conditions NEC	Cellulite	1	0	
			Skin mass	4	0	
	Skin appendage conditions	Apocrine and eccrine gland disorders	Cold sweat	8	0	
				Hyperhidrosis	12	0
				Miliaria	1	0
			Pilar disorders NEC	Hair growth abnormal	1	0
	Skin vascular abnormalities	Purpura and related conditions	Henoch-Schonlein purpura	1	0	
				Petechiae	22	0
				Purpura	8	0
			Skin vasomotor conditions	Livedo reticularis	15	0
	Total			649	0	
Social circumstances	Lifestyle issues	Disability issues	Immobile	2	0	
	Total			2	0	
Vascular disorders	Aneurysms and artery dissections	Aneurysms and dissections non-site specific	Aneurysm	1	0	

Arteriosclerosis, stenosis, vascular insufficiency and necrosis	Non-site specific necrosis and vascular insufficiency NEC	Fibromuscular dysplasia	1	0
	Peripheral vasoconstriction, necrosis and vascular insufficiency	Peripheral coldness	5	0
		Poor peripheral circulation	1	0
Decreased and nonspecific blood pressure disorders and shock	Circulatory collapse and shock	Circulatory collapse	7	0
		Hypoperfusion	1	0
		Shock	3	0
Embolism and thrombosis	Non-site specific embolism and thrombosis	Venous thrombosis	1	0
Lymphatic vessel disorders	Lymphoedemas	Lymphoedema	1	0
Vascular disorders NEC	Peripheral vascular disorders NEC	Cyanosis	21	0
		Flushing	3	0
		Hot flush	1	0
	Site specific vascular disorders NEC	Pallor	75	0
Vascular haemorrhagic disorders	Haemorrhages NEC	Haematoma	1	0
Vascular hypertensive disorders	Vascular hypertensive disorders NEC	Hypertension	1	0
Vascular infections and inflammations	Arterial infections and inflammations	Kawasaki's disease	1	1
Total			124	1

Total Reaction Count		
Total Report Count	5,637	
Total Fatal Report Count	1,779	58