

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
Blood and lymphatic system disorders	Anaemias nonhaemolytic and marrow depression	Anaemias NEC	Anaemia	1	0
		Marrow depression and hypoplastic anaemias	Myelosuppression	1	0
	Haemolyses and related conditions	Haemolyses NEC	Haemolysis	2	0
	Platelet disorders	Thrombocytopenias	Immune thrombocytopenia	2	0
	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Lymphadenopathy	8	0
	White blood cell disorders	Leukocytoses NEC	Lymphocytic infiltration	1	0
			Neutrophilia	1	0
Cardiac disorders	Cardiac arrhythmias	Rate and rhythm disorders NEC	Bradycardia	10	0
			Bradycardia neonatal	3	0
			Tachycardia	28	0
		Supraventricular arrhythmias	Sinus arrhythmia	1	0
			Supraventricular tachycardia	1	0
		Ventricular arrhythmias and cardiac arrest	Cardiac arrest	5	2
			Cardio-respiratory arrest	5	2
			Ventricular fibrillation	1	0
		Cardiac disorders, signs and symptoms NEC	Cardiac signs and symptoms NEC	Palpitations	3
	Coronary artery disorders	Coronary artery disorders NEC	Coronary artery aneurysm	1	0
	Ear and labyrinth disorders	Aural disorders NEC	Ear disorders NEC	Ear discomfort	1
Ear pain				1	0
Ear swelling				4	0
Hearing disorders		Hearing losses	Deafness	2	0
			Hypoacusis	1	0
Inner ear and VIIIth cranial nerve disorders		Inner ear signs and symptoms	Tinnitus	1	0
			Vertigo	2	0
Middle ear disorders (excl congenital)		Tympanic membrane disorders (excl infections)	Tympanic membrane hyperaemia	1	0

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Eye disorders	Anterior eye structural change, deposit and degeneration	Cataract conditions	Cataract	1	0
	Eye disorders NEC	Lacrimation disorders	Lacrimation increased	2	0
			Tear discolouration	1	0
		Ocular disorders NEC	Dark circles under eyes	1	0
			Eye disorder	1	0
			Eye oedema	1	0
			Eye pain	2	0
			Eye swelling	5	0
			Periorbital swelling	1	0
	Ocular haemorrhages and vascular disorders NEC	Conjunctival and corneal bleeding and vascular disorders	Conjunctival haemorrhage	1	0
	Ocular infections, irritations and inflammations	Iris and uveal tract infections, irritations and inflammations	Iridocyclitis	1	0
		Lid, lash and lacrimal infections, irritations and inflammations	Erythema of eyelid	1	0
			Swelling of eyelid	2	0
		Ocular infections, inflammations and associated manifestations	Ocular hyperaemia	1	0
	Ocular neuromuscular disorders	Eyelid movement disorders	Excessive eye blinking	1	0
			Eyelid function disorder	1	0
		Ocular nerve and muscle disorders	Eye movement disorder	16	0
			Gaze palsy	2	0
			Strabismus	3	0
		Pupil disorders	Anisocoria	1	0
			Miosis	1	0
			Mydriasis	2	0
			Pupillary disorder	1	0
	Ocular sensory symptoms NEC	Ocular sensation disorders	Photophobia	5	0
	Ocular structural change, deposit and degeneration NEC	Optic disc abnormalities NEC	Papilloedema	1	0

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	Vision disorders	Scleral structural change, deposit and degeneration	Scleral discolouration	1	0
		Visual disorders NEC	Vision blurred	4	0
		Visual impairment and blindness (excl colour blindness)	Blindness	1	0
			Blindness transient	1	0
			Cortical visual impairment	1	0
			Visual impairment	4	0
Gastrointestinal disorders	Gastrointestinal conditions NEC	Gastrointestinal disorders NEC	Gastrointestinal disorder	2	0
	Gastrointestinal haemorrhages NEC	Non-site specific gastrointestinal haemorrhages	Haematochezia	6	0
	Gastrointestinal inflammatory conditions	Colitis (excl infective)	Necrotising colitis	1	1
		Gastritis (excl infective)	Reflux gastritis	1	0
	Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	132	0
			Diarrhoea haemorrhagic	1	0
		Gastrointestinal atonic and hypomotility disorders NEC	Constipation	15	0
			Gastrooesophageal reflux disease	10	0
		Gastrointestinal dyskinetic disorders	Change of bowel habit	1	0
			Infant dyschezia	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	3	0
		Dyspeptic signs and symptoms	Dyspepsia	3	0
		Faecal abnormalities NEC	Abnormal faeces	8	0
			Faecaloma	1	0
			Faeces discoloured	11	0
			Faeces pale	2	0
			Faeces soft	1	0
			Mucous stools	8	0
		Flatulence, bloating and distension	Abdominal distension	7	0

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			Flatulence	8	0
		Gastrointestinal and abdominal pains (excl oral and throat)	Abdominal pain	13	0
			Abdominal pain upper	23	0
		Gastrointestinal signs and symptoms NEC	Abdominal discomfort	13	0
			Dysphagia	3	0
		Nausea and vomiting symptoms	Infantile vomiting	8	0
			Nausea	30	0
			Regurgitation	1	0
			Retching	2	0
			Vomiting	235	0
			Vomiting projectile	27	0
	Gastrointestinal stenosis and obstruction	Gastrointestinal stenosis and obstruction NEC	Intussusception	1	0
	Malabsorption conditions	Malabsorption syndromes	Coeliac disease	2	0
	Oral soft tissue conditions	Oral soft tissue disorders NEC	Chapped lips	1	0
			Lip blister	1	0
			Lip disorder	1	0
		Oral soft tissue signs and symptoms	Lip discolouration	1	0
			Oral discomfort	1	0
			Oral mucosal blistering	1	0
			Oral pain	2	0
		Oral soft tissue swelling and oedema	Lip swelling	6	0
		Stomatitis and ulceration	Aphthous ulcer	1	0
			Mouth ulceration	3	0
	Salivary gland conditions	Oral dryness and saliva altered	Dry mouth	1	0
			Salivary hypersecretion	1	0
		Salivary gland enlargements	Parotid gland enlargement	1	0
			Salivary gland enlargement	1	0
	Tongue conditions	Tongue disorders	Tongue geographic	1	0

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			Tongue ulceration	1	0
		Tongue signs and symptoms	Protrusion tongue	1	0
			Strawberry tongue	1	0
			Swollen tongue	4	0
			Tongue movement disturbance	1	0
General disorders and administration site conditions	Administration site reactions	Administration site reactions NEC	Administration site bruise	2	0
			Administration site erythema	3	0
			Administration site inflammation	1	0
			Administration site swelling	1	0
		Application site reactions	Application site erythema	1	0
			Application site swelling	1	0
		Injection site reactions	Injected limb mobility decreased	2	0
			Injection site bruising	6	0
			Injection site discharge	1	0
			Injection site discolouration	5	0
			Injection site discomfort	2	0
			Injection site erythema	33	0
			Injection site haemorrhage	1	0
			Injection site indentation	1	0
			Injection site induration	7	0
			Injection site inflammation	7	0
			Injection site irritation	1	0
			Injection site joint erythema	1	0
			Injection site joint inflammation	1	0
			Injection site mass	77	0
			Injection site nodule	4	0
			Injection site oedema	1	0
			Injection site pain	31	0

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			Injection site pruritus	10	0
			Injection site rash	4	0
			Injection site reaction	5	0
			Injection site scar	1	0
			Injection site swelling	27	0
			Injection site urticaria	1	0
			Injection site vesicles	6	0
			Injection site warmth	9	0
		Vaccination site reactions	Extensive swelling of vaccinated limb	7	0
			Vaccination site bruising	29	0
			Vaccination site cyst	3	0
			Vaccination site discharge	4	0
			Vaccination site discolouration	12	0
			Vaccination site discomfort	7	0
			Vaccination site eczema	1	0
			Vaccination site erythema	212	0
			Vaccination site granuloma	2	0
			Vaccination site haematoma	4	0
			Vaccination site haemorrhage	3	0
			Vaccination site hypersensitivity	2	0
			Vaccination site induration	80	0
			Vaccination site inflammation	31	0
			Vaccination site injury	1	0
			Vaccination site irritation	3	0
			Vaccination site joint erythema	1	0
			Vaccination site joint movement impairment	2	0
			Vaccination site joint pain	1	0

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			Vaccination site macule	1	0
			Vaccination site mass	144	0
			Vaccination site movement impairment	9	0
			Vaccination site nodule	12	0
			Vaccination site oedema	3	0
			Vaccination site pain	135	0
			Vaccination site pallor	1	0
			Vaccination site papule	2	0
			Vaccination site pruritus	7	0
			Vaccination site rash	30	0
			Vaccination site reaction	11	0
			Vaccination site scar	7	0
			Vaccination site swelling	182	0
			Vaccination site urticaria	1	0
			Vaccination site vesicles	3	0
			Vaccination site warmth	52	0
Body temperature conditions	Body temperature altered		Hyperthermia	1	0
			Hypothermia	3	0
	Febrile disorders		Fever neonatal	1	0
			Hyperpyrexia	10	0
			Pyrexia	903	0
Fatal outcomes	Death and sudden death		Death	10	10
			Sudden death	6	6
			Sudden infant death syndrome	6	6
General system disorders NEC	Asthenic conditions		Asthenia	13	0
			Decreased activity	1	0
			Fatigue	38	0
			Malaise	122	0

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		Feelings and sensations NEC	Chills	31	0
			Feeling abnormal	17	0
			Feeling cold	9	0
			Feeling drunk	1	0
			Feeling hot	32	0
			Feeling jittery	1	0
			Feeling of body temperature change	2	0
			Thirst	2	0
			Thirst decreased	3	0
		Gait disturbances	Gait disturbance	26	0
			Gait inability	17	0
			Loss of control of legs	1	0
		General signs and symptoms NEC	Condition aggravated	6	0
			Crying	178	0
			Developmental delay	4	0
			Developmental regression	3	0
			Foaming at mouth	1	0
			General physical health deterioration	2	0
			General symptom	1	0
			Glassy eyes	4	0
			High-pitched crying	22	0
			Illness	25	0
			Induration	18	0
			Influenza like illness	6	0
			Irritability postvaccinal	4	0
			Local reaction	12	0
			Moaning	4	0

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			Multiple organ dysfunction syndrome	1	0
			Peripheral swelling	88	0
			Screaming	58	0
			Secretion discharge	4	0
			Swelling	68	0
			Swelling face	15	0
		Inflammations	Inflammation	22	0
			Systemic inflammatory response syndrome	1	0
		Oedema NEC	Oedema	2	0
			Oedema peripheral	3	0
		Pain and discomfort NEC	Chest discomfort	1	0
			Chest pain	3	0
			Discomfort	20	0
			Pain	83	0
			Tenderness	13	0
	Therapeutic and nontherapeutic effects (excl toxicity)	Therapeutic and nontherapeutic responses	Adverse drug reaction	2	0
			Drug ineffective	1	0
			Immediate post-injection reaction	1	0
			Vaccination failure	24	0
	Tissue disorders NEC	Mass conditions NEC	Mass	25	0
		Ulcers NEC	Ulcer	1	0
Hepatobiliary disorders	Hepatic and hepatobiliary disorders	Cholestasis and jaundice	Jaundice cholestatic	1	0
Immune system disorders	Allergic conditions	Allergic conditions NEC	Allergy to metals	1	0
			Hypersensitivity	32	0
			Multiple allergies	3	0
			Type I hypersensitivity	1	0
		Allergies to foods, food additives, drugs and other chemicals	Allergy to vaccine	3	0

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			Food allergy	4	0
			Milk allergy	5	0
			Reaction to excipient	2	0
			Reaction to preservatives	2	0
		Anaphylactic and anaphylactoid responses	Anaphylactic reaction	22	0
			Anaphylactic shock	1	0
		Atopic disorders	Atopy	1	0
	Immune disorders NEC	Immune and associated conditions NEC	Haemophagocytic lymphohistiocytosis	1	1
			Immune system disorder	1	0
	Immunodeficiency syndromes	Immunodeficiency disorders NEC	Immunodeficiency	1	0
Infections and infestations	Bacterial infectious disorders	Bacterial infections NEC	Arthritis bacterial	2	0
			Bacterial infection	1	0
			Bacterial sepsis	1	0
			Cellulitis	38	0
			Injection site cellulitis	2	0
			Meningitis bacterial	1	0
			Periorbital cellulitis	1	0
			Skin bacterial infection	3	0
			Urinary tract infection bacterial	1	0
			Vaccination site cellulitis	21	0
		Bordetella infections	Pertussis	1	0
		Neisseria infections	Meningitis meningococcal	9	0
			Meningococcal carditis	1	0
			Meningococcal infection	4	0
			Meningococcal sepsis	13	0
			Septic arthritis neisserial	1	0
		Staphylococcal infections	Furuncle	1	0
		Streptococcal infections	Cellulitis streptococcal	1	0

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	Infections - pathogen unspecified		Scarlet fever	1	0
		Abdominal and gastrointestinal infections	Gastroenteritis	2	0
		Bone and joint infections	Osteomyelitis	1	0
		Central nervous system and spinal infections	Encephalitis	3	0
			Meningitis	8	0
			Meningitis aseptic	9	0
		Ear infections	Ear infection	4	0
			Otitis externa	1	0
		Eye and eyelid infections	Conjunctivitis	3	0
			Eye infection	1	0
		Infections NEC	Abscess	3	0
			Abscess limb	1	0
			Infection	4	0
			Injection site infection	2	0
			Localised infection	3	0
			Lymph gland infection	1	0
			Respiratory tract infection	1	0
			Vaccination site abscess	4	0
			Vaccination site infection	11	0
		Lower respiratory tract and lung infections	Atypical pneumonia	1	0
			Lower respiratory tract infection	3	0
			Pneumonia	4	0
			Pneumonia aspiration	1	0
		Sepsis, bacteraemia, viraemia and fungaemia NEC	Sepsis	19	0
			Sepsis neonatal	1	0
		Skin structures and soft tissue infections	Eczema infected	1	0
			Pustule	1	0
			Skin infection	5	0

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			Subcutaneous abscess	1	0
			Vaccination site pustule	1	0
		Upper respiratory tract infections	Croup infectious	3	0
			Nasopharyngitis	9	0
			Pharyngitis	1	0
			Tonsillitis	3	0
			Upper respiratory tract infection	1	0
		Urinary tract infections	Kidney infection	1	0
			Urinary tract infection	3	0
	Mycobacterial infectious disorders	Tuberculous infections	Erythema induratum	3	0
	Viral infectious disorders	Adenoviral infections	Adenoviral meningitis	1	0
		Enteroviral infections NEC	Meningitis enteroviral	1	0
		Herpes viral infections	Varicella	1	0
		Influenza viral infections	Influenza	1	0
		Rotaviral infections	Rotavirus infection	1	0
		Rubeola viral infections	Measles	1	0
		Viral infections NEC	Bronchiolitis	5	0
			Gastroenteritis viral	2	0
			Meningitis viral	2	0
			Viral infection	1	0
			Viral rash	4	0
			Viral upper respiratory tract infection	1	0
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
		Occupational exposures	Occupational exposure to product	1	0
	Injuries NEC	Cerebral injuries NEC	Craniocerebral injury	1	0

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		Muscle, tendon and ligament injuries	Muscle injury	1	0
		Non-site specific injuries NEC	Fall	3	0
			Wound secretion	1	0
		Skin injuries NEC	Contusion	15	0
			Scar	2	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	Inadequate aseptic technique in use of product	1	0
			Medication error	6	0
			Vaccination error	1	0
			Wrong technique in product usage process	2	0
		Product administration errors and issues	Accidental underdose	2	0
			Expired product administered	2	0
			Extra dose administered	1	0
			Inappropriate schedule of product administration	3	0
			Incomplete course of vaccination	3	0
			Incorrect dose administered	3	0
			Incorrect route of product administration	1	0
			Lack of vaccination site rotation	1	0
			Product administered at inappropriate site	5	0
			Product administered to patient of inappropriate age	7	0
			Product administration error	2	0
		Product monitoring errors and issues	Drug monitoring procedure not performed	1	0
		Product prescribing errors and issues	Product prescribing error	1	0

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	Procedural related injuries and complications NEC	Product storage errors and issues in the product use system	Product storage error	4	0
		Gastrointestinal and hepatobiliary procedural complications	Procedural vomiting	3	0
		Non-site specific procedural complications	Post procedural swelling	1	0
		Vaccination related complications	Immunisation reaction	1	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	24	0
			Pulse abnormal	1	0
		Vascular tests NEC (incl blood pressure)	Blood pressure decreased	1	0
			Capillary nail refill test abnormal	1	0
	Haematology investigations (incl blood groups)	Platelet analyses	Platelet count increased	1	0
		Red blood cell analyses	Haemoglobin decreased	2	0
		White blood cell analyses	Lymphocyte count increased	1	0
			Neutrophil count decreased	1	0
			White blood cell count increased	6	0
	Metabolic, nutritional and blood gas investigations	Blood gas and acid base analyses	Oxygen saturation decreased	12	0
	Microbiology and serology investigations	Virus identification and serology	Enterovirus test positive	1	0
	Neurological, special senses and psychiatric investigations	Cerebrospinal fluid tests (excl microbiology)	CSF white blood cell count increased	1	0
		Neurologic diagnostic procedures	Coma scale abnormal	1	0
	Physical examination and organ system status topics	Physical examination procedures and organ system status	Body temperature	1	0
			Body temperature abnormal	7	0
			Body temperature decreased	6	0
			Body temperature fluctuation	3	0
			Body temperature increased	93	0

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			Breath sounds abnormal	1	0
			Respiratory rate decreased	1	0
			Respiratory rate increased	15	0
	Protein and chemistry analyses NEC	Chemistry analyses NEC	Inflammatory marker increased	2	0
		Protein analyses NEC	C-reactive protein increased	18	0
	Renal and urinary tract investigations and urinalyses	Urinary tract function analyses NEC	Urine output decreased	4	0
	Respiratory and pulmonary investigations (excl blood gases)	Respiratory and pulmonary function diagnostic procedures	Apnoea test abnormal	1	0
		Respiratory tract and thoracic imaging procedures	Chest X-ray abnormal	1	0
	Water, electrolyte and mineral investigations	Mineral and electrolyte analyses	Blood magnesium decreased	1	0
Metabolism and nutrition disorders	Acid-base disorders	Metabolic acidoses (excl diabetic acidoses)	Lactic acidosis	1	0
			Metabolic acidosis	2	0
	Appetite and general nutritional disorders	Appetite disorders	Appetite disorder	1	0
			Decreased appetite	99	0
			Food refusal	3	0
			Hypophagia	8	0
		General nutritional disorders NEC	Feeding disorder	1	0
			Food aversion	3	0
			Poor feeding infant	78	0
			Weight gain poor	1	0
	Electrolyte and fluid balance conditions	Fluid intake decreased	Fluid intake reduced	5	0
		Potassium imbalance	Hyperkalaemia	1	0
		Sodium imbalance	Hyponatraemia	1	0
		Total fluid volume decreased	Dehydration	4	0
	Food intolerance syndromes	Food malabsorption and intolerance syndromes (excl sugar intolerance)	Dairy intolerance	1	0
			Food intolerance	2	0

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		Sugar intolerance (excl glucose intolerance)	Lactose intolerance	1	0
	Glucose metabolism disorders (incl diabetes mellitus)	Hypoglycaemic conditions NEC	Hypoglycaemia	2	0
Musculoskeletal and connective tissue disorders	Joint disorders	Arthropathies NEC	Arthropathy	1	0
		Joint related signs and symptoms	Arthralgia	19	0
			Joint effusion	1	0
			Joint stiffness	1	0
			Joint swelling	5	0
		Spondyloarthropathies	Arthritis reactive	2	0
	Muscle disorders	Muscle infections and inflammations	Myositis	3	0
		Muscle pains	Myalgia	15	0
		Muscle related signs and symptoms NEC	Muscle spasms	4	0
			Muscle tightness	1	0
			Muscle twitching	8	0
		Muscle tone abnormalities	Floppy infant	41	0
			Muscle rigidity	5	0
		Muscle weakness conditions	Muscular weakness	7	0
	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	Infantile back arching	2	0
			Limb mass	5	0
			Mobility decreased	5	0
			Musculoskeletal stiffness	36	0
			Posture abnormal	2	0
			Toe walking	1	0
			Weight bearing difficulty	20	0
		Musculoskeletal and connective tissue pain and discomfort	Back pain	2	0
			Limb discomfort	12	0

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			Musculoskeletal discomfort	2	0
			Neck pain	5	0
			Pain in extremity	262	0
	Synovial and bursal disorders	Synovial disorders	Synovitis	1	0
Nervous system disorders	Central nervous system vascular disorders	Central nervous system vascular disorders NEC	Brain hypoxia	1	0
	Cranial nerve disorders (excl neoplasms)	Eye movement disorders	Vlth nerve paralysis	1	0
		Facial cranial nerve disorders	Facial spasm	1	0
	Headaches	Headaches NEC	Headache	62	0
			Tension headache	1	0
		Migraine headaches	Migraine	2	0
			Migraine with aura	1	0
	Mental impairment disorders	Intellectual disabilities	Intellectual disability	1	0
		Mental impairment (excl dementia and memory loss)	Disturbance in attention	2	0
			Mental impairment	1	0
	Movement disorders (incl parkinsonism)	Dyskinesias and movement disorders NEC	Dyskinesia	12	0
			Hypokinesia	5	0
			Movement disorder	4	0
		Dystonias	Opisthotonus	2	0
		Paralysis and paresis (excl cranial nerve)	Monoplegia	5	0
			Paralysis	3	0
		Tremor (excl congenital)	Tremor	25	0
	Neurological disorders NEC	Abnormal reflexes	Kernig's sign	1	0
		Coordination and balance disturbances	Ataxia	1	0
			Balance disorder	5	0
			Coordination abnormal	2	0
			Developmental coordination disorder	1	0
			Dysstasia	7	0

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			Nystagmus	1	0
		Cortical dysfunction NEC	Aphasia	2	0
			Sensory processing disorder	1	0
		Disturbances in consciousness NEC	Consciousness fluctuating	2	0
			Depressed level of consciousness	3	0
			Lethargy	71	0
			Loss of consciousness	15	0
			Postictal state	1	0
			Somnolence	90	0
			Syncope	58	0
		Nervous system disorders NEC	Meningeal disorder	1	0
			Meningocele acquired	1	0
			Nervous system disorder	1	0
		Neurological signs and symptoms NEC	Agitation neonatal	1	0
			Decerebrate posture	1	0
			Dizziness	30	0
			Drooling	2	0
			Exaggerated startle response	2	0
			Fontanelle bulging	7	0
			Hyporesponsive to stimuli	4	0
			Inability to crawl	1	0
			Infant irritability	3	0
			Meningism	3	0
			Myoclonus	2	0
			Neurological decompensation	1	0
			Neurological symptom	1	0
			Pleocytosis	6	0
			Presyncope	8	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Slow response to stimuli	1	0
			Unresponsive to stimuli	69	0
		Paraesthesias and dysaesthesias	Hypoaesthesia	4	0
			Paraesthesia	2	0
		Sensory abnormalities NEC	Aura	2	0
			Sensory disturbance	2	0
			Taste disorder	1	0
		Speech and language abnormalities	Dysarthria	1	0
			Speech disorder	3	0
			Speech disorder developmental	1	0
	Neuromuscular disorders	Muscle tone abnormal	Hypertonia	2	0
			Hypotonia	44	0
		Neuromuscular disorders NEC	Hypotonic-hyporesponsive episode	11	0
			Muscle spasticity	1	0
Seizures (incl subtypes)		Absence seizures	Petit mal epilepsy	10	0
		Generalised tonic-clonic seizures	Generalised tonic-clonic seizure	17	0
		Seizures and seizure disorders NEC	Epilepsy	5	0
			Epileptic encephalopathy	1	0
			Febrile convulsion	51	0
			Infantile spasms	2	0
			Partial seizures	8	0
			Seizure	57	0
			Seizure anoxic	2	0
			Seizure like phenomena	2	0
			Status epilepticus	2	0
			Tonic clonic movements	1	0
			Tonic convulsion	1	0
	Sleep disturbances (incl subtypes)	Narcolepsy and hypersomnia	Hypersomnia	8	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
		Sleep disturbances NEC	Sudden onset of sleep	1	0
Pregnancy, puerperium and perinatal conditions	Foetal complications	Foetal growth complications	Foetal growth restriction	1	0
	Neonatal and perinatal conditions	Neonatal metabolic and endocrine disorders	Hypothermia neonatal	1	0
Product issues	Device issues	Device issues NEC	Device issue	1	0
		Device physical property and chemical issues	Syringe issue	1	0
	Product quality, supply, distribution, manufacturing and quality system issues	Product label issues	Product lot number issue	2	0
		Product quality issues NEC	Product complaint	1	0
			Product quality issue	6	0
Psychiatric disorders	Anxiety disorders and symptoms	Anxiety disorders NEC	Separation anxiety disorder	1	0
		Anxiety symptoms	Agitation	14	0
			Anxiety	2	0
			Stress	1	0
		Fear symptoms and phobic disorders (incl social phobia)	Phonophobia	1	0
		Panic attacks and disorders	Panic reaction	2	0
	Changes in physical activity	Decreased physical activity levels	Catatonia	1	0
		Increased physical activity levels	Restlessness	36	0
		Stereotypies and automatisms	Bruxism	1	0
		Tic disorders	Tic	2	0
	Communication disorders and disturbances	Communications disorders	Communication disorder	1	0
			Mutism	1	0
	Deliria (incl confusion)	Confusion and disorientation	Confusional state	4	0
		Deliria	Delirium	3	0
	Depressed mood disorders and disturbances	Mood alterations with depressive symptoms	Decreased interest	2	0
			Depressed mood	4	0
			Tearfulness	4	0
	Developmental disorders NEC	Pervasive developmental disorders NEC	Autism spectrum disorder	4	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
	Disturbances in thinking and perception	Hallucinations (excl sleep-related)	Hallucination	3	0
			Hallucination, visual	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	Anger	2	0
			Emotional disorder	3	0
			Emotional distress	23	0
			Irritability	187	0
			Mood altered	7	0
		Mood disorders NEC	Listless	10	0
	Personality disorders and disturbances in behaviour	Behaviour and socialisation disturbances	Aggression	2	0
			Personality change	5	0
			Social avoidant behaviour	6	0
	Psychiatric and behavioural symptoms NEC	Abnormal behaviour NEC	Abnormal behaviour	21	0
			Behaviour disorder	2	0
			Breath holding	8	0
			Regressive behaviour	1	0
			Staring	7	0
		Psychiatric symptoms NEC	Decreased eye contact	1	0
	Psychiatric disorders NEC	Mental disorders NEC	Mental disorder	1	0
	Sleep disorders and disturbances	Disturbances in initiating and maintaining sleep	Insomnia	24	0
			Middle insomnia	2	0
		Dyssomnias	Poor quality sleep	8	0
		Parasomnias	Abnormal dreams	2	0
			Nightmare	4	0
			Sleep terror	7	0
		Sleep disorders NEC	Sleep disorder	16	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
	Somatic symptom and related disorders	Somatic symptom disorders	Conversion disorder	1	0
Renal and urinary disorders	Nephropathies	Glomerulonephritis and nephrotic syndrome	Nephrotic syndrome	1	0
	Renal disorders (excl nephropathies)	Renal failure and impairment	Acute kidney injury	1	0
			Anuria	1	0
		Renal structural abnormalities and trauma	Kidney enlargement	1	0
	Urinary tract signs and symptoms	Bladder and urethral symptoms	Dysuria	1	0
			Pollakiuria	1	0
			Urinary incontinence	2	0
		Urinary abnormalities	Chromaturia	1	0
			Urine odour abnormal	1	0
Reproductive system and breast disorders	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
			Genital rash	1	0
		Reproductive tract signs and symptoms NEC	Genital swelling	1	0
Respiratory, thoracic and mediastinal disorders	Bronchial disorders (excl neoplasms)	Bronchospasm and obstruction	Wheezing	10	0
	Neonatal respiratory disorders	Neonatal hypoxic conditions	Infantile apnoea	7	0
			Neonatal hypoxia	6	0
	Pleural disorders	Pneumothorax and pleural effusions NEC	Pleural effusion	1	0
	Respiratory disorders NEC	Breathing abnormalities	Apnoea	31	0
			Apnoeic attack	2	0
			Dyspnoea	51	0
			Grunting	3	0
			Hyperventilation	1	0
			Hypopnoea	11	0
			Hypoventilation	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Irregular breathing	2	0
			Respiration abnormal	2	0
			Respiratory arrest	15	1
			Respiratory depression	1	0
			Respiratory distress	3	0
			Tachypnoea	10	0
		Conditions associated with abnormal gas exchange	Cyanosis central	1	0
			Respiratory acidosis	2	0
		Coughing and associated symptoms	Cough	22	0
			Haemoptysis	1	0
			Productive cough	1	0
			Sputum discoloured	1	0
		Respiratory failures (excl neonatal)	Acute respiratory failure	1	0
		Respiratory tract disorders NEC	Respiratory disorder	4	0
	Respiratory tract signs and symptoms	Lower respiratory tract signs and symptoms	Hiccups	1	0
			Rales	1	0
		Respiratory signs and symptoms NEC	Use of accessory respiratory muscles	1	0
		Upper respiratory tract signs and symptoms	Choking	3	0
			Dysphonia	2	0
			Increased viscosity of upper respiratory secretion	1	0
			Nasal obstruction	1	0
			Oropharyngeal blistering	1	0
			Oropharyngeal pain	11	0
			Rhinorrhoea	12	0
			Sneezing	1	0
			Throat tightness	1	0
	Upper respiratory tract disorders (excl infections)	Laryngeal spasm, oedema and obstruction	Stridor	2	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
		Nasal congestion and inflammations	Nasal congestion	4	0
		Nasal disorders NEC	Epistaxis	8	0
		Pharyngeal disorders (excl infections and neoplasms)	Pharyngeal erythema	2	0
			Pharyngeal swelling	1	0
			Tonsillar hypertrophy	2	0
Skin and subcutaneous tissue disorders	Angioedema and urticaria	Angioedemas	Angioedema	1	0
		Urticarias	Urticaria	60	0
			Urticaria pressure	1	0
	Cornification and dystrophic skin disorders	Skin dystrophies	Skin wrinkling	4	0
	Cutaneous neoplasms benign	Skin cysts and polyps	Dermal cyst	1	0
	Epidermal and dermal conditions	Bullous conditions	Blister	17	0
			Dermatitis bullous	1	0
			Erythema multiforme	2	0
			Pemphigoid	1	0
		Dermal and epidermal conditions NEC	Dry skin	5	0
			Macule	1	0
			Pain of skin	4	0
			Papule	10	0
			Scab	1	0
			Sensitive skin	2	0
			Skin burning sensation	1	0
			Skin discolouration	51	0
			Skin disorder	1	0
			Skin indentation	1	0
			Skin induration	11	0
			Skin lesion	2	0
			Skin odour abnormal	1	0
			Skin plaque	2	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Skin reaction	10	0
			Skin tightness	2	0
			Skin warm	41	0
			Skin weeping	1	0
		Dermatitis and eczema	Dermatitis	1	0
			Dermatitis allergic	16	0
			Dermatitis atopic	2	0
			Dermatitis diaper	4	0
			Eczema	15	0
			Eczema asteatotic	1	0
			Eczema infantile	1	0
		Dermatitis ascribed to specific agent	Drug eruption	1	0
			Palmar-plantar erythrodysesthesia syndrome	1	0
		Erythemas	Erythema	185	0
		Exfoliative conditions	Skin exfoliation	4	0
		Pruritus NEC	Pruritus	22	0
		Pustular conditions	Acute generalised exanthematous pustulosis	1	0
			Rash follicular	1	0
		Rashes, eruptions and exanthems NEC	Rash	216	0
			Rash erythematous	26	0
			Rash macular	48	0
			Rash maculo-papular	5	0
			Rash morbilliform	13	0
			Rash papular	18	0
			Rash pruritic	6	0
			Rash vesicular	3	0
		Skin injuries and mechanical dermatoses	Needle track marks	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
	Skin and subcutaneous tissue disorders NEC	Skin and subcutaneous conditions NEC	Skin mass	9	0
		Skin and subcutaneous tissue ulcerations	Skin erosion	1	0
	Skin appendage conditions	Apocrine and eccrine gland disorders	Cold sweat	13	0
			Hyperhidrosis	20	0
			Hypohidrosis	1	0
			Miliaria	2	0
		Pilar disorders NEC	Hair growth abnormal	2	0
	Skin vascular abnormalities	Purpura and related conditions	Henoch-Schonlein purpura	3	0
			Petechiae	32	0
			Purpura	10	0
		Skin vasomotor conditions	Livedo reticularis	29	0
Social circumstances	Lifestyle issues	Disability issues	Bedridden	1	0
			Immobile	2	0
Surgical and medical procedures	Gastrointestinal therapeutic procedures	Gastrointestinal therapeutic procedures NEC	Antidiarrhoeal supportive care	1	0
Vascular disorders	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	13	0
			Poor peripheral circulation	1	0
	Decreased and nonspecific blood pressure disorders and shock	Circulatory collapse and shock	Circulatory collapse	9	0
			Hypoperfusion	1	0
			Neurogenic shock	1	0
			Peripheral circulatory failure	1	0
			Shock	4	0
		Vascular hypotensive disorders	Hypotension	3	0
	Embolism and thrombosis	Peripheral embolism and thrombosis	Deep vein thrombosis	1	0
	Lymphatic vessel disorders	Lymphoedemas	Lymphoedema	1	0
	Vascular disorders NEC	Peripheral vascular disorders NEC	Cyanosis	28	0

Reaction MedDRA SOC Name	Reaction MedDRA HLT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Flushing	8	0
			Hot flush	2	0
		Site specific vascular disorders NEC	Pallor	147	0
	Vascular haemorrhagic disorders	Haemorrhages NEC	Haematoma	1	0
	Vascular hypertensive disorders	Vascular hypertensive disorders NEC	Hypertension	1	0
			Orthostatic hypertension	1	0
	Vascular infections and inflammations	Arterial infections and inflammations	Kawasaki's disease	6	1
Total				3,013	30