

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
Blood and lymphatic system disorders	Haemolyses and related conditions	Anaemias haemolytic mechanical factor	Haemolytic uraemic syndrome	2	0
	Platelet disorders	Thrombocytopenias	Immune thrombocytopenia	5	0
			Thrombocytopenia	1	0
	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Lymph node pain	3	0
			Lymphadenitis	1	0
			Lymphadenopathy	25	0
Cardiac disorders	Cardiac arrhythmias	Rate and rhythm disorders NEC	Tachycardia	4	0
		Ventricular arrhythmias and cardiac arrest	Cardiac arrest	1	0
	Cardiac disorders, signs and symptoms NEC	Cardiac signs and symptoms NEC	Cardiac discomfort	1	0
			Palpitations	1	0
	Coronary artery disorders	Ischaemic coronary artery disorders	Angina pectoris	4	0
Congenital, familial and genetic disorders	Myocardial disorders	Noninfectious myocarditis	Myocarditis	1	0
	Neurological disorders congenital	Neurological disorders congenital NEC	Tourette's disorder	2	0
Ear and labyrinth disorders	Aural disorders NEC	Ear disorders NEC	Ear congestion	3	0
			Ear discomfort	1	0
			Ear pain	62	0
			Ear pruritus	1	0
			Ear swelling	3	0
			Otorrhoea	2	0
	Hearing disorders	Hearing losses	Hypoacusis	2	0
		Hyperacusia	Hyperacusis	1	0
	Inner ear and VIIIth cranial nerve disorders	Inner ear signs and symptoms	Tinnitus	1	0
			Vertigo	1	0
	Middle ear disorders (excl congenital)	Tympanic membrane disorders (excl infections)	Tympanic membrane perforation	1	0
Endocrine disorders	Adrenal gland disorders	Adrenal cortical hypofunctions	Adrenocortical insufficiency acute	1	0
	Thyroid gland disorders	Thyroid disorders NEC	Thyroid mass	1	0

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Eye disorders	Anterior eye structural change, deposit and degeneration	Lid, lash and lacrimal structural disorders	Lagophthalmos	1	0
	Eye disorders NEC	Lacrimation disorders	Lacrimation increased	31	0
		Ocular disorders NEC	Dark circles under eyes	2	0
			Eye disorder	2	0
			Eye pain	27	0
			Eye swelling	38	0
			Ocular discomfort	1	0
			Periorbital oedema	1	0
			Periorbital swelling	11	0
	Ocular infections, irritations and inflammations	Conjunctival infections, irritations and inflammations	Conjunctival hyperaemia	1	0
		Lid, lash and lacrimal infections, irritations and inflammations	Blepharitis	1	0
			Erythema of eyelid	5	0
			Eyelid oedema	2	0
			Swelling of eyelid	11	0
		Ocular infections, inflammations and associated manifestations	Eye discharge	7	0
			Eye inflammation	1	0
			Eye irritation	2	0
			Eye pruritus	21	0
			Ocular hyperaemia	25	0
		Scleral infections, irritations and inflammations	Episcleritis	1	0
	Ocular neuromuscular disorders	Eyelid movement disorders	Blepharospasm	1	0
			Excessive eye blinking	2	0
		Ocular nerve and muscle disorders	Eye movement disorder	2	0
			Ophthalmoplegia	1	0
			Strabismus	2	0
		Pupil disorders	Mydriasis	3	0
			Pupil fixed	1	0

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	Ocular sensory symptoms NEC	Ocular sensation disorders	Pupillary disorder	1	0
			Abnormal sensation in eye	1	0
			Asthenopia	1	0
			Photophobia	12	0
	Ocular structural change, deposit and degeneration NEC	Optic disc abnormalities NEC	Papilloedema	1	0
		Structural change, deposit and degeneration of eye NEC	Exophthalmos	1	0
	Vision disorders	Amblyopic vision impairment	Amblyopia	1	0
		Visual disorders NEC	Diplopia	1	0
			Photopsia	2	0
			Vision blurred	8	0
		Visual impairment and blindness (excl colour blindness)	Blindness	1	0
			Blindness unilateral	1	0
			Visual impairment	7	0
Gastrointestinal disorders	Dental and gingival conditions	Dental pain and sensation disorders	Toothache	2	0
		Gingival disorders, signs and symptoms NEC	Gingival blister	1	0
			Gingival pain	1	0
			Gingival swelling	1	0
	Gastrointestinal conditions NEC	Gastrointestinal disorders NEC	Appendix disorder	1	0
			Gastrointestinal disorder	3	0
	Gastrointestinal haemorrhages NEC	Non-site specific gastrointestinal haemorrhages	Haematemesis	2	0
			Haematochezia	1	0
	Gastrointestinal inflammatory conditions	Colitis (excl infective)	Colitis	2	0
	Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	187	0
		Gastrointestinal atonic and hypomotility disorders NEC	Constipation	2	0
			Gastrooesophageal reflux disease	1	0
			Infrequent bowel movements	1	0
		Gastrointestinal spastic and hypermotility disorders	Frequent bowel movements	1	0

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			Irritable bowel syndrome	1	0
	Gastrointestinal signs and symptoms	Dyspeptic signs and symptoms	Dyspepsia	1	0
			Eructation	1	0
		Faecal abnormalities NEC	Abnormal faeces	3	0
			Faecaloma	1	0
			Faeces soft	1	0
			Mucous stools	1	0
		Flatulence, bloating and distension	Abdominal distension	1	0
			Flatulence	4	0
		Gastrointestinal and abdominal pains (excl oral and throat)	Abdominal pain	49	0
			Abdominal pain lower	3	0
			Abdominal pain upper	130	0
		Gastrointestinal signs and symptoms NEC	Abdominal discomfort	21	0
			Anal incontinence	1	0
			Dysphagia	4	0
			Odynophagia	3	0
		Nausea and vomiting symptoms	Cyclic vomiting syndrome	1	0
			Discoloured vomit	1	0
			Nausea	148	0
			Regurgitation	2	0
			Retching	3	0
			Vomiting	427	0
			Vomiting projectile	24	0
	Oral soft tissue conditions	Oral soft tissue disorders NEC	Chapped lips	5	0
			Cheilitis	3	0
			Lip blister	2	0
		Oral soft tissue infections	Angular cheilitis	1	0
		Oral soft tissue signs and symptoms	Lip discolouration	1	0

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			Lip erythema	3	0
			Lip exfoliation	1	0
			Lip pain	6	0
			Oral discomfort	2	0
			Oral mucosal blistering	4	0
			Oral mucosal eruption	1	0
			Oral mucosal erythema	2	0
			Oral pain	8	0
			Paraesthesia oral	1	0
		Oral soft tissue swelling and oedema	Lip swelling	27	0
			Mouth swelling	2	0
		Stomatitis and ulceration	Lip ulceration	1	0
			Mouth ulceration	14	0
			Stomatitis	1	0
	Salivary gland conditions	Oral dryness and saliva altered	Dry mouth	2	0
			Lip dry	4	0
		Salivary gland enlargements	Parotid gland enlargement	1	0
	Tongue conditions	Tongue disorders	Tongue disorder	1	0
			Tongue geographic	2	0
			Tongue ulceration	1	0
		Tongue signs and symptoms	Glossodynia	1	0
			Protrusion tongue	1	0
			Strawberry tongue	1	0
			Swollen tongue	6	0
			Tongue blistering	1	0
			Tongue discolouration	1	0
			Tongue discomfort	1	0
			Tongue dry	1	0

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			Tongue pruritus	1	0
General disorders and administration site conditions	Administration site reactions	Administration site reactions NEC	Administration site rash	1	0
		Application site reactions	Application site rash	1	0
			Application site vesicles	2	0
		Vaccination site reactions	Vaccination site erythema	2	0
			Vaccination site haemorrhage	1	0
			Vaccination site hypersensitivity	1	0
			Vaccination site inflammation	2	0
			Vaccination site mass	1	0
			Vaccination site pain	3	0
			Vaccination site scab	1	0
			Vaccination site swelling	1	0
	Body temperature conditions	Body temperature altered	Temperature regulation disorder	1	0
		Febrile disorders	Hyperpyrexia	1	0
			Pyrexia	950	0
	Fatal outcomes	Death and sudden death	Death	6	6
	General system disorders NEC	Asthenic conditions	Asthenia	83	0
			Chronic fatigue syndrome	3	0
			Decreased activity	1	0
			Fatigue	229	0
			Malaise	276	0
			Sluggishness	1	0
		Feelings and sensations NEC	Chills	95	0
			Feeling abnormal	20	0
			Feeling cold	25	0
			Feeling hot	27	0
			Feeling of body temperature change	7	0
			Hunger	1	0

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			Sensation of foreign body	2	0
			Thirst	4	0
			Thirst decreased	1	0
		Gait disturbances	Gait disturbance	2	0
			Gait inability	6	0
			Loss of control of legs	2	0
		General signs and symptoms NEC	Condition aggravated	5	0
			Crying	12	0
			General physical health deterioration	1	0
			Glassy eyes	2	0
			Illness	96	0
			Induration	2	0
			Influenza like illness	141	0
			Irritability postvaccinal	1	0
			Local reaction	1	0
			Moaning	1	0
			Peripheral swelling	17	0
			Secretion discharge	3	0
			Swelling	19	0
			Swelling face	54	0
		Inflammations	Inflammation	6	0
		Oedema NEC	Face oedema	5	0
			Oedema	1	0
		Pain and discomfort NEC	Axillary pain	1	0
			Chest discomfort	12	0
			Chest pain	18	0
			Discomfort	4	0
			Facial pain	2	0

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			Non-cardiac chest pain	1	0
			Pain	104	0
			Tenderness	1	0
	Therapeutic and nontherapeutic effects (excl toxicity)	Interactions	Drug interaction	1	0
		Therapeutic and nontherapeutic responses	Adverse drug reaction	30	0
			Drug ineffective	3	0
			No reaction on previous exposure to drug	1	0
			Vaccination failure	3	0
	Tissue disorders NEC	Mass conditions NEC	Mass	1	0
Hepatobiliary disorders	Hepatic and hepatobiliary disorders	Cholestasis and jaundice	Ocular icterus	1	0
		Hepatocellular damage and hepatitis NEC	Autoimmune hepatitis	1	0
Immune system disorders	Allergic conditions	Allergic conditions NEC	Hypersensitivity	47	0
			Type I hypersensitivity	1	0
		Allergies to foods, food additives, drugs and other chemicals	Allergic reaction to excipient	1	0
			Food allergy	7	0
			Reaction to excipient	1	0
		Anaphylactic and anaphylactoid responses	Anaphylactic reaction	19	0
			Anaphylactic shock	2	0
			Anaphylactoid reaction	1	0
		Atopic disorders	Seasonal allergy	1	0
	Immune disorders NEC	Immune and associated conditions NEC	Immune system disorder	1	0
			Multisystem inflammatory syndrome in children	1	0
	Immunodeficiency syndromes	Immunodeficiency disorders NEC	Immunodeficiency	1	0
Infections and infestations	Ancillary infectious topics	Infectious transmissions	Infection via vaccinee	125	0
			Secondary transmission	1	0
			Vaccine virus shedding	19	0
	Bacterial infectious disorders	Bacterial infections NEC	Bacterial infection	1	0

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			Cellulitis	4	0
			Ear infection bacterial	2	0
			Tonsillitis bacterial	1	0
		Bordetella infections	Pertussis	1	0
		Staphylococcal infections	Furuncle	1	0
			Staphylococcal sepsis	1	0
		Streptococcal infections	Pneumococcal sepsis	2	1
			Pneumonia pneumococcal	2	0
			Scarlet fever	5	0
			Streptococcal infection	1	0
	Infections - pathogen unspecified	Abdominal and gastrointestinal infections	Appendicitis	1	0
			Gastric infection	1	0
			Gastroenteritis	1	0
		Central nervous system and spinal infections	Encephalitis	1	0
			Myelitis	1	0
		Ear infections	Ear infection	14	0
			Labyrinthitis	1	0
			Otitis media	2	0
			Otitis media chronic	1	0
		Eye and eyelid infections	Conjunctivitis	13	0
			Dacryocystitis	1	0
		Female reproductive tract infections	Pelvic inflammatory disease	1	0
		Infections NEC	Abscess limb	1	0
			Infection	5	0
			Localised infection	1	0
			Purulence	1	0
			Respiratory tract infection	1	0
			Vaccination site infection	1	0

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		Lower respiratory tract and lung infections	Bronchitis	3	0
			Lower respiratory tract infection	20	0
			Pneumonia aspiration	1	0
		Sepsis, bacteraemia, viraemia and fungaemia NEC	Bacteraemia	2	0
			Sepsis	1	0
		Skin structures and soft tissue infections	Blister infected	2	0
			Impetigo	4	0
			Rash pustular	1	0
		Upper respiratory tract infections	Croup infectious	21	0
			Laryngitis	2	0
			Nasopharyngitis	97	0
			Peritonsillar abscess	1	0
			Rhinitis	11	0
			Sinusitis	4	0
			Tonsillitis	16	0
			Upper respiratory tract infection	9	0
		Urinary tract infections	Urinary tract infection	1	0
	Rickettsial infectious disorders	Coxiella infections	Q fever	1	0
	Viral infectious disorders	Adenoviral infections	Adenoviral upper respiratory infection	1	0
		Coronavirus infections	COVID-19	2	0
		Herpes viral infections	Herpes zoster	1	0
			Oral herpes	1	0
			Varicella	2	0
		Influenza viral infections	H1N1 influenza	1	0
			Influenza	80	0
		Viral infections NEC	Bronchiolitis	1	0
			Conjunctivitis viral	1	0
			Meningitis viral	1	0

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			Metapneumovirus infection	1	0
			Pneumonia viral	1	0
			Viral infection	12	0
			Viral myositis	1	0
			Viral pharyngitis	1	0
			Viral rash	5	0
			Viral upper respiratory tract infection	2	0
Injury, poisoning and procedural complications	Exposures, chemical injuries and poisoning	Exposures associated with pregnancy, delivery and lactation	Exposure during pregnancy	1	0
			Foetal exposure during pregnancy	1	0
			Maternal exposure during pregnancy	1	0
		Exposures to agents or circumstances NEC	Exposure to vaccinated person	2	0
		Occupational exposures	Occupational exposure to product	18	0
		Poisoning and toxicity	Metal poisoning	2	0
	Injuries NEC	Eye injuries NEC	Eye contusion	1	0
		Non-site specific injuries NEC	Fall	4	0
			Wound	1	0
			Wound secretion	1	0
		Site specific injuries NEC	Head injury	1	0
			Nasal injury	2	0
		Skin injuries NEC	Contusion	6	0
			Scratch	1	0
	Medication errors and other product use errors and issues	Accidental exposures to product	Accidental exposure to product	9	0
			Accidental exposure to product by child	2	0
		Medication errors, product use errors and issues NEC	Medication error	6	0
			Product use in unapproved indication	1	0

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			Product use issue	1	0
			Vaccination error	1	0
		Product administration errors and issues	Accidental overdose	2	0
			Contraindicated product administered	2	0
			Expired product administered	2	0
			Extra dose administered	1	0
			Inappropriate schedule of product administration	2	0
			Incorrect route of product administration	1	0
			Product administered to patient of inappropriate age	5	0
			Product administration error	2	0
			Wrong product administered	1	0
	Off label uses and intentional product misuses/use issues	Off label uses	Off label use	4	0
	Overdoses and underdoses NEC	Overdoses NEC	Overdose	1	0
	Procedural related injuries and complications NEC	Vaccination related complications	Immunisation reaction	2	0
Investigations	Cardiac and vascular investigations (excl enzyme tests)	Heart rate and pulse investigations	Heart rate decreased	1	0
			Heart rate increased	7	0
			Heart rate irregular	1	0
			Pulse abnormal	3	0
		Vascular tests NEC (incl blood pressure)	Blood pressure decreased	1	0
	Haematology investigations (incl blood groups)	Platelet analyses	Platelet count decreased	2	0
	Investigations, imaging and histopathology procedures NEC	Imaging procedures NEC	Magnetic resonance imaging abnormal	1	0
	Metabolic, nutritional and blood gas investigations	Blood gas and acid base analyses	Oxygen saturation decreased	6	0

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		Carbohydrate tolerance analyses (incl diabetes)	Blood glucose decreased	1	0
	Microbiology and serology investigations	Virus identification and serology	SARS-CoV-2 test positive	1	0
	Neurological, special senses and psychiatric investigations	Neurologic diagnostic procedures	Sensory level abnormal	1	0
	Physical examination and organ system status topics	Physical examination procedures and organ system status	Body temperature	3	0
			Body temperature abnormal	10	0
			Body temperature decreased	2	0
			Body temperature fluctuation	7	0
			Body temperature increased	69	0
			Body temperature normal	1	0
			Breath sounds abnormal	1	0
			Respiratory rate increased	1	0
			Skin temperature	1	0
			Temperature difference of extremities	1	0
	Protein and chemistry analyses NEC	Protein analyses NEC	C-reactive protein abnormal	1	0
	Renal and urinary tract investigations and urinalyses	Urinalysis NEC	Blood urine present	1	0
			Urinary sediment present	1	0
	Water, electrolyte and mineral investigations	Mineral and electrolyte analyses	Blood sodium increased	1	0
Metabolism and nutrition disorders	Appetite and general nutritional disorders	Appetite disorders	Decreased appetite	279	0
			Hypophagia	5	0
			Increased appetite	2	0
		General nutritional disorders NEC	Abnormal loss of weight	1	0
			Feeding disorder	7	0
			Food aversion	4	0
	Electrolyte and fluid balance conditions	Fluid intake decreased	Fluid intake reduced	3	0
		Total fluid volume decreased	Dehydration	4	0

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	Glucose metabolism disorders (incl diabetes mellitus)	Diabetes mellitus (incl subtypes)	Type 1 diabetes mellitus	3	0
		Hyperglycaemic conditions NEC	Hyperglycaemia	1	0
Musculoskeletal and connective tissue disorders	Bone disorders (excl congenital and fractures)	Bone related signs and symptoms	Bone pain	4	0
	Joint disorders	Arthropathies NEC	Arthritis	1	0
		Joint related signs and symptoms	Arthralgia	27	0
			Joint swelling	10	0
	Muscle disorders	Muscle infections and inflammations	Myositis	3	0
		Muscle pains	Myalgia	94	0
		Muscle related signs and symptoms NEC	Muscle discomfort	2	0
			Muscle fatigue	1	0
			Muscle spasms	5	0
			Muscle tightness	1	0
			Muscle twitching	4	0
		Muscle tone abnormalities	Trismus	2	0
		Muscle weakness conditions	Muscular weakness	12	0
	Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue conditions NEC	Mobility decreased	1	0
			Musculoskeletal stiffness	16	0
			Weight bearing difficulty	3	0
		Musculoskeletal and connective tissue pain and discomfort	Back pain	9	0
			Limb discomfort	1	0
			Musculoskeletal chest pain	1	0
			Musculoskeletal pain	1	0
			Neck pain	20	0
			Pain in extremity	56	0
	Synovial and bursal disorders	Synovial disorders	Synovitis	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Leukaemias	Leukaemias acute lymphocytic	Acute lymphocytic leukaemia	1	0
	Skeletal neoplasms malignant and unspecified	Bone sarcomas	Ewing's sarcoma	1	0

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Nervous system disorders	Central nervous system infections and inflammations	Encephalitis NEC	Encephalitis autoimmune	1	0
			Noninfective encephalitis	2	0
	Cranial nerve disorders (excl neoplasms)	Cranial nerve disorders NEC	Cranial nerve palsies multiple	1	0
		Facial cranial nerve disorders	Bell's palsy	3	0
			Facial paralysis	1	0
			Facial paresis	1	0
		Mixed cranial nerve disorders	Palatal palsy	1	0
		Olfactory nerve disorders	Parosmia	2	0
		Optic nerve disorders NEC	Optic neuritis	1	0
	Demyelinating disorders	Demyelinating disorders NEC	Acute disseminated encephalomyelitis	3	0
			Autoimmune demyelinating disease	1	0
	Encephalopathies	Encephalopathies NEC	Encephalopathy	1	0
	Headaches	Headaches NEC	Cluster headache	1	0
			Cold-stimulus headache	1	0
			Headache	554	0
			Tension headache	2	0
		Migraine headaches	Migraine	6	0
			Migraine with aura	1	0
	Increased intracranial pressure and hydrocephalus	Increased intracranial pressure disorders	Brain oedema	1	0
	Mental impairment disorders	Mental impairment (excl dementia and memory loss)	Cognitive disorder	1	0
			Disturbance in attention	2	0
			Mental impairment	2	0
	Movement disorders (incl parkinsonism)	Choreiform movements	Chorea	1	0
		Dyskinesias and movement disorders NEC	Dyskinesia	1	0
			Hypokinesia	1	0
			Motor dysfunction	2	0
			Movement disorder	3	0

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			Psychomotor hyperactivity	2	0
		Dystonias	Dystonia	1	0
			Opisthotonus	1	0
		Paralysis and paresis (excl cranial nerve)	Paralysis	1	0
		Tremor (excl congenital)	Head titubation	1	0
			Tremor	15	0
	Neurological disorders NEC	Abnormal reflexes	Areflexia	1	0
			Hyporeflexia	1	0
		Coordination and balance disturbances	Balance disorder	8	0
			Cerebellar ataxia	1	0
			Dysstasia	3	0
		Cortical dysfunction NEC	Aphasia	2	0
		Disturbances in consciousness NEC	Depressed level of consciousness	3	0
			Lethargy	145	0
			Loss of consciousness	12	0
			Somnolence	54	0
			Syncope	67	0
		Nervous system disorders NEC	Nervous system disorder	1	0
		Neurological signs and symptoms NEC	Brain fog	4	0
			Dizziness	106	0
			Dizziness postural	1	0
			Head discomfort	5	0
			Hyporesponsive to stimuli	2	0
			Presyncope	10	0
			Unresponsive to stimuli	13	0
		Paraesthesias and dysaesthesias	Hyperaesthesia	2	0
			Hypoaesthesia	3	0
			Paraesthesia	12	0

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			Paraesthesia mucosal	1	0
		Sensory abnormalities NEC	Aura	1	0
			Dysgeusia	2	0
			Loss of proprioception	1	0
			Neuralgia	1	0
			Sensory disturbance	3	0
			Sensory loss	1	0
			Taste disorder	1	0
		Speech and language abnormalities	Dysarthria	2	0
			Incoherent	1	0
			Speech disorder	4	0
	Neuromuscular disorders	Muscle tone abnormal	Hypotonia	9	0
	Peripheral neuropathies	Acute polyneuropathies	Guillain-Barre syndrome	3	0
		Mononeuropathies	Ulnar nerve palsy	1	0
	Seizures (incl subtypes)	Absence seizures	Petit mal epilepsy	6	0
		Generalised tonic-clonic seizures	Generalised tonic-clonic seizure	1	0
		Partial simple seizures NEC	Simple partial seizures	1	0
		Seizures and seizure disorders NEC	Epilepsy	7	0
			Febrile convulsion	11	0
			Partial seizures	3	0
			Seizure	25	0
			Seizure like phenomena	2	0
			Status epilepticus	3	0
			Tonic clonic movements	1	0
	Sleep disturbances (incl subtypes)	Narcolepsy and hypersomnia	Cataplexy	17	0
			Hypersomnia	13	0
			Narcolepsy	21	0
		Sleep disturbances NEC	Sudden onset of sleep	1	0

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Pregnancy, puerperium and perinatal conditions	Abortions and stillbirth	Abortions spontaneous	Abortion spontaneous	1	0
	Maternal complications of labour and delivery	Labour onset and length abnormalities	Premature labour	1	0
	Maternal complications of pregnancy	Hypertension associated disorders of pregnancy	Pre-eclampsia	1	0
Psychiatric disorders	Anxiety disorders and symptoms	Anxiety symptoms	Agitation	4	0
			Anxiety	8	0
			Nervousness	1	0
		Fear symptoms and phobic disorders (incl social phobia)	Fear	1	0
		Obsessive-compulsive disorders and symptoms	Obsessive thoughts	1	0
			Obsessive-compulsive disorder	3	0
		Panic attacks and disorders	Panic attack	1	0
			Panic reaction	2	0
	Changes in physical activity	Increased physical activity levels	Restlessness	3	0
		Tic disorders	Tic	8	0
	Communication disorders and disturbances	Communications disorders	Communication disorder	1	0
			Mutism	1	0
		Speech articulation and rhythm disturbances	Dysphemia	4	0
	Deliria (incl confusion)	Confusion and disorientation	Confusional state	8	0
			Disorientation	8	0
		Deliria	Delirium	6	0
			Delirium febrile	1	0
	Depressed mood disorders and disturbances	Depressive disorders	Depression	1	0
		Mood alterations with depressive symptoms	Decreased interest	1	0
			Depressed mood	7	0
	Developmental disorders NEC	Pervasive developmental disorders NEC	Autism spectrum disorder	2	0
	Disturbances in thinking and perception	Hallucinations (excl sleep-related)	Hallucination	17	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Hallucination, auditory	1	0
			Hallucination, visual	3	0
			Hallucinations, mixed	1	0
		Thinking disturbances	Thinking abnormal	1	0
	Eating disorders and disturbances	Eating disorders NEC	Eating disorder	1	0
	Impulse control disorders NEC	Impulse control disorders	Impulsive behaviour	1	0
	Mood disorders and disturbances NEC	Affect alterations NEC	Inappropriate affect	1	0
		Emotional and mood disturbances NEC	Anger	2	0
			Emotional disorder	1	0
			Emotional distress	8	0
			Irritability	19	0
			Mood altered	2	0
		Fluctuating mood symptoms	Mood swings	1	0
		Mood disorders NEC	Apathy	1	0
			Listless	8	0
	Personality disorders and disturbances in behaviour	Behaviour and socialisation disturbances	Aggression	3	0
			Paranoia	1	0
			Personality change	1	0
			Social avoidant behaviour	2	0
		Personality disorders NEC	Personality disorder	1	0
	Psychiatric and behavioural symptoms NEC	Abnormal behaviour NEC	Abnormal behaviour	10	0
			Behaviour disorder	1	0
			Staring	2	0
	Psychiatric disorders NEC	Infancy, childhood and adolescence psychiatric disorders NEC	School refusal	1	0
		Mental disorders due to a general medical condition NEC	Neuropsychiatric syndrome	1	0
		Mental disorders NEC	Mental disorder	2	0
		Psychiatric elimination disorders	Enuresis	3	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
	Sleep disorders and disturbances	Disturbances in initiating and maintaining sleep	Insomnia	14	0
		Dyssomnias	Poor quality sleep	5	0
		Narcolepsy and associated conditions	Hypnagogic hallucination	1	0
		Parasomnias	Abnormal dreams	1	0
			Nightmare	5	0
			Sleep talking	2	0
			Sleep terror	7	0
			Somnambulism	2	0
		Sleep disorders NEC	Sleep disorder	11	0
Renal and urinary disorders	Nephropathies	Glomerulonephritis and nephrotic syndrome	Nephrotic syndrome	3	0
	Renal disorders (excl nephropathies)	Renal failure and impairment	Acute kidney injury	1	0
	Urinary tract signs and symptoms	Bladder and urethral symptoms	Incontinence	1	0
			Stress urinary incontinence	1	0
			Urinary incontinence	1	0
		Urinary abnormalities	Chromaturia	1	0
			Haematuria	2	0
		Urinary tract signs and symptoms NEC	Renal pain	1	0
Reproductive system and breast disorders	Reproductive tract disorders NEC	Reproductive tract infections and inflammations NEC	Genital tract inflammation	1	0
Respiratory, thoracic and mediastinal disorders	Bronchial disorders (excl neoplasms)	Bronchospasm and obstruction	Asthma	44	0
			Bronchospasm	4	0
			Wheezing	93	0
	Lower respiratory tract disorders (excl obstruction and infection)	Lower respiratory tract inflammatory and immunologic conditions	Pneumonitis	1	0
	Respiratory disorders NEC	Breathing abnormalities	Apnoea	2	0
			Dyspnoea	57	0
			Grunting	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Hyperventilation	1	0
			Mouth breathing	1	0
			Respiration abnormal	5	0
			Respiratory arrest	2	0
			Respiratory distress	3	0
			Sleep apnoea syndrome	1	0
			Tachypnoea	3	0
		Conditions associated with abnormal gas exchange	Hypoxia	1	0
		Coughing and associated symptoms	Cough	388	0
			Productive cough	26	0
			Sputum discoloured	3	0
			Sputum increased	1	0
		Respiratory tract disorders NEC	Respiratory disorder	3	1
			Respiratory tract congestion	3	0
			Respiratory tract irritation	1	0
	Respiratory tract signs and symptoms	Lower respiratory tract signs and symptoms	Increased bronchial secretion	1	0
		Respiratory signs and symptoms NEC	Painful respiration	1	0
			Respiratory symptom	4	0
			Use of accessory respiratory muscles	2	0
		Upper respiratory tract signs and symptoms	Aphonia	1	0
			Catarrh	1	0
			Dry throat	2	0
			Dysphonia	10	0
			Increased viscosity of upper respiratory secretion	2	0
			Nasal discharge discolouration	1	0
			Nasal discomfort	9	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Nasal obstruction	1	0
			Oropharyngeal blistering	1	0
			Oropharyngeal discomfort	1	0
			Oropharyngeal pain	231	0
			Paranasal sinus discomfort	1	0
			Rhinalgia	25	0
			Rhinorrhoea	373	0
			Sinus pain	7	0
			Sneezing	53	0
			Snoring	2	0
			Throat clearing	2	0
			Throat irritation	14	0
			Throat tightness	8	0
			Upper respiratory tract congestion	1	0
			Upper respiratory tract irritation	1	0
			Upper-airway cough syndrome	2	0
	Upper respiratory tract disorders (excl infections)	Laryngeal spasm, oedema and obstruction	Stridor	3	0
		Nasal congestion and inflammations	Nasal congestion	150	0
			Nasal inflammation	2	0
		Nasal disorders NEC	Epistaxis	296	0
			Nasal crusting	2	0
			Nasal disorder	1	0
			Nasal dryness	1	0
			Nasal mucosal discolouration	3	0
			Nasal mucosal erosion	1	0
			Nasal mucosal ulcer	2	0
			Nasal odour	1	0
			Nasal oedema	2	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Nasal pruritus	7	0
		Paranasal sinus disorders (excl infections and neoplasms)	Sinonasal obstruction	5	0
			Sinus congestion	4	0
			Sinus disorder	6	0
		Pharyngeal disorders (excl infections and neoplasms)	Pharyngeal erythema	1	0
			Pharyngeal swelling	5	0
			Pharyngeal ulceration	1	0
			Tonsillar disorder	1	0
			Tonsillar hypertrophy	6	0
			Tonsillar inflammation	1	0
			Velopharyngeal incompetence	1	0
Skin and subcutaneous tissue disorders	Angioedema and urticaria	Angioedemas	Angioedema	4	0
		Urticarias	Cold urticaria	1	0
			Idiopathic urticaria	1	0
			Mechanical urticaria	1	0
			Urticaria	166	0
	Cornification and dystrophic skin disorders	Skin dystrophies	Skin wrinkling	1	0
	Epidermal and dermal conditions	Bullous conditions	Blister	12	0
			Dermatitis bullous	1	0
			Erythema multiforme	5	0
			Stevens-Johnson syndrome	2	0
		Dermal and epidermal conditions NEC	Dry skin	6	0
			Pain of skin	4	0
			Papule	11	0
			Scab	4	0
			Sensitive skin	1	0
			Skin discolouration	9	0
			Skin fissures	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Skin lesion	1	0
			Skin reaction	6	0
			Skin swelling	3	0
			Skin tightness	1	0
			Skin warm	12	0
		Dermatitis and eczema	Dermatitis	1	0
			Dermatitis allergic	23	0
			Eczema	9	0
			Perioral dermatitis	1	0
			Skin irritation	6	0
		Erythemas	Erythema	87	0
		Exfoliative conditions	Skin exfoliation	5	0
		Photosensitivity and photodermatosis conditions	Photosensitivity reaction	1	0
		Pruritus NEC	Pruritus	93	0
		Psoriatic conditions	Psoriasis	2	0
		Rashes, eruptions and exanthems NEC	Rash	247	0
			Rash erythematous	47	0
			Rash macular	37	0
			Rash maculo-papular	7	0
			Rash morbilliform	1	0
			Rash papular	28	0
			Rash pruritic	31	0
			Rash vesicular	3	0
	Pigmentation disorders	Hypopigmentation disorders	Skin depigmentation	1	0
	Skin and subcutaneous tissue disorders NEC	Skin and subcutaneous tissue ulcerations	Skin ulcer	1	0
	Skin appendage conditions	Acnes	Dermatitis acneiform	2	0
		Alopecias	Alopecia	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
		Apocrine and eccrine gland disorders	Cold sweat	29	0
			Hyperhidrosis	28	0
			Night sweats	3	0
		Nail and nail bed conditions (excl infections and infestations)	Nail discolouration	1	0
		Pilar disorders NEC	Piloerection	1	0
	Skin vascular abnormalities	Purpura and related conditions	Henoch-Schonlein purpura	8	0
			Petechiae	5	0
			Purpura	5	0
		Skin vasomotor conditions	Livedo reticularis	2	0
Social circumstances	Family issues	Dependents	Sick relative	1	0
	Lifestyle issues	Disability issues	Bedridden	1	0
			Disability	1	0
		Social issues NEC	Contraindication to vaccination	3	0
Surgical and medical procedures	Therapeutic procedures and supportive care NEC	Therapeutic procedures NEC	Hospitalisation	2	0
Vascular disorders	Arteriosclerosis, stenosis, vascular insufficiency and necrosis	Peripheral vasoconstriction, necrosis and vascular insufficiency	Peripheral coldness	4	0
	Decreased and nonspecific blood pressure disorders and shock	Circulatory collapse and shock	Peripheral circulatory failure	2	0
			Shock	1	0
		Vascular hypotensive disorders	Hypotension	4	0
	Embolism and thrombosis	Non-site specific embolism and thrombosis	Thrombosis	1	0
	Vascular disorders NEC	Peripheral vascular disorders NEC	Cyanosis	10	0
			Flushing	36	0
			Hot flush	2	0
		Site specific vascular disorders NEC	Pallor	82	0
	Vascular infections and inflammations	Arterial infections and inflammations	Kawasaki's disease	1	0
Total				3,270	8