

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
Blood and lymphatic system disorders	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Lymph node pain	4	0
			Lymphadenitis	1	0
			Lymphadenopathy	39	0
			Mesenteric lymphadenitis	1	0
Cardiac disorders	Cardiac arrhythmias	Rate and rhythm disorders NEC	Arrhythmia	1	0
			Cardiac flutter	3	0
			Extrasystoles	1	0
			Tachycardia	5	0
		Supraventricular arrhythmias	Atrial fibrillation	1	0
		Ventricular arrhythmias and cardiac arrest	Cardiac arrest	5	3
			Ventricular extrasystoles	2	0
	Cardiac disorders, signs and symptoms NEC	Cardiac signs and symptoms NEC	Palpitations	21	0
	Coronary artery disorders	Coronary artery disorders NEC	Arteriosclerosis coronary artery	1	0
		Ischaemic coronary artery disorders	Angina pectoris	1	0
			Myocardial infarction	2	1
	Myocardial disorders	Noninfectious myocarditis	Myocarditis	3	0
	Pericardial disorders	Noninfectious pericarditis	Pericarditis	3	0
		Pericardial disorders NEC	Pericardial effusion	1	1
			Pericardial haemorrhage	1	0
Congenital, familial and genetic disorders	Eye disorders congenital	Ocular disorders congenital NEC	Colour blindness	1	0
Ear and labyrinth disorders	Aural disorders NEC	Ear disorders NEC	Ear discomfort	1	0
			Ear pain	9	0
			Otorrhoea	1	0
	Hearing disorders	Hearing losses	Deafness	2	0
			Deafness neurosensory	1	0
			Deafness transitory	1	0
			Deafness unilateral	2	0

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	Inner ear and VIIIth cranial nerve disorders	Inner ear signs and symptoms	Hypoacusis	3	0
			Tinnitus	8	0
			Vertigo	11	0
			Vertigo positional	1	0
Eye disorders	Eye disorders NEC	Lacrimation disorders	Dry eye	2	0
			Lacrimation increased	3	0
		Ocular disorders NEC	Eye disorder	1	0
			Eye oedema	2	0
			Eye pain	9	0
			Eye swelling	10	0
			Eyelids pruritus	1	0
			Periorbital swelling	1	0
	Ocular infections, irritations and inflammations	Conjunctival infections, irritations and inflammations	Conjunctival hyperaemia	1	0
		Lid, lash and lacrimal infections, irritations and inflammations	Swelling of eyelid	3	0
		Ocular infections, inflammations and associated manifestations	Eye irritation	1	0
			Eye pruritus	5	0
			Ocular hyperaemia	1	0
	Ocular neuromuscular disorders	Eyelid movement disorders	Blepharospasm	1	0
		Pupil disorders	Pupil fixed	1	0
	Ocular sensory symptoms NEC	Ocular sensation disorders	Asthenopia	1	0
			Photophobia	2	0
	Vision disorders	Visual disorders NEC	Diplopia	1	0
			Photopsia	1	0
			Vision blurred	8	0
		Visual impairment and blindness (excl colour blindness)	Blindness transient	1	0
			Visual impairment	4	0
Gastrointestinal disorders	Dental and gingival conditions	Dental pain and sensation disorders	Toothache	1	0

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		Gingival haemorrhages	Gingival bleeding	1	0
	Gastrointestinal inflammatory conditions	Colitis (excl infective)	Colitis ulcerative	1	0
	Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	82	0
		Gastrointestinal atonic and hypomotility disorders NEC	Constipation	1	0
			Gastrooesophageal reflux disease	1	0
		Gastrointestinal spastic and hypermotility disorders	Defaecation urgency	1	0
			Frequent bowel movements	1	0
	Gastrointestinal signs and symptoms	Dyspeptic signs and symptoms	Dyspepsia	2	0
			Eructation	2	0
		Faecal abnormalities NEC	Faeces discoloured	1	0
		Flatulence, bloating and distension	Abdominal distension	3	0
			Flatulence	6	0
		Gastrointestinal and abdominal pains (excl oral and throat)	Abdominal pain	6	0
			Abdominal pain upper	16	0
			Abdominal tenderness	1	0
		Gastrointestinal signs and symptoms NEC	Abdominal discomfort	6	0
			Anal incontinence	1	0
			Dysphagia	5	0
		Nausea and vomiting symptoms	Nausea	107	0
			Retching	2	0
			Vomiting	69	0
			Vomiting projectile	2	0
	Oral soft tissue conditions	Oral soft tissue disorders NEC	Uvulitis	1	0
		Oral soft tissue signs and symptoms	Hypoaesthesia oral	1	0
			Oral discomfort	1	0
			Oral mucosal blistering	1	0
			Oral mucosal eruption	1	0
			Oral pruritus	2	0

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			Paraesthesia oral	10	0
		Oral soft tissue swelling and oedema	Lip swelling	5	0
			Mouth swelling	1	0
		Stomatitis and ulceration	Mouth ulceration	2	0
	Peritoneal and retroperitoneal conditions	Peritoneal and retroperitoneal disorders	Ascites	1	0
	Salivary gland conditions	Oral dryness and saliva altered	Dry mouth	2	0
			Lip dry	1	0
		Salivary gland enlargements	Parotid gland enlargement	1	0
	Tongue conditions	Tongue signs and symptoms	Glossodynia	2	0
			Swollen tongue	6	0
			Tongue discolouration	1	0
			Tongue eruption	1	0
			Tongue oedema	1	0
General disorders and administration site conditions	Administration site reactions	Administration site reactions NEC	Administration site injury	1	0
			Administration site joint movement impairment	2	0
			Administration site pain	4	0
			Administration site swelling	2	0
		Application site reactions	Application site erythema	1	0
			Application site inflammation	1	0
			Application site pain	3	0
			Application site pruritus	2	0
			Application site rash	1	0
			Application site swelling	1	0
		Injection site reactions	Injected limb mobility decreased	4	0
			Injection site bruising	1	0
			Injection site coldness	2	0
			Injection site discharge	1	0

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			Injection site discolouration	1	0
			Injection site discomfort	2	0
			Injection site erythema	8	0
			Injection site haemorrhage	1	0
			Injection site hypertrophy	1	0
			Injection site hypoaesthesia	1	0
			Injection site indentation	1	0
			Injection site inflammation	4	0
			Injection site mass	2	0
			Injection site pain	19	0
			Injection site paraesthesia	1	0
			Injection site pruritus	5	0
			Injection site rash	2	0
			Injection site reaction	1	0
			Injection site swelling	4	0
			Injection site urticaria	1	0
			Injection site warmth	1	0
		Vaccination site reactions	Extensive swelling of vaccinated limb	2	0
			Shoulder injury related to vaccine administration	8	0
			Vaccination site bruising	4	0
			Vaccination site discolouration	1	0
			Vaccination site discomfort	2	0
			Vaccination site erythema	29	0
			Vaccination site haemorrhage	2	0
			Vaccination site hypoaesthesia	1	0
			Vaccination site induration	7	0
			Vaccination site inflammation	5	0

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			Vaccination site irritation	1	0
			Vaccination site joint erythema	1	0
			Vaccination site joint movement impairment	6	0
			Vaccination site joint pain	3	0
			Vaccination site mass	5	0
			Vaccination site movement impairment	11	0
			Vaccination site nodule	1	0
			Vaccination site pain	56	0
			Vaccination site pruritus	4	0
			Vaccination site rash	10	0
			Vaccination site reaction	2	0
			Vaccination site swelling	31	0
			Vaccination site urticaria	1	0
			Vaccination site vesicles	2	0
			Vaccination site warmth	12	0
	Body temperature conditions	Body temperature altered	Temperature regulation disorder	1	0
		Febrile disorders	Pyrexia	80	0
Fatal outcomes		Death and sudden death	Death	11	11
			Sudden death	2	2
General system disorders NEC	Asthenic conditions		Asthenia	25	0
			Fatigue	136	0
			Malaise	55	0
	Feelings and sensations NEC		Chills	78	0
			Feeling abnormal	19	0
			Feeling cold	8	0
			Feeling hot	24	0
			Feeling of body temperature change	7	0

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			Thirst	2	0
		Gait disturbances	Gait disturbance	3	0
			Gait inability	1	0
		General signs and symptoms NEC	Condition aggravated	6	0
			Crying	1	0
			Illness	9	0
			Influenza like illness	22	0
			Irritability postvaccinal	1	0
			Peripheral swelling	37	0
			Swelling	23	0
			Swelling face	11	0
		Inflammations	Inflammation	10	0
			Systemic inflammatory response syndrome	1	0
		Oedema NEC	Oedema peripheral	2	0
		Pain and discomfort NEC	Axillary pain	15	0
			Chest discomfort	13	0
			Chest pain	10	0
			Discomfort	4	0
			Facial pain	3	0
			Pain	58	0
			Tenderness	6	0
	Therapeutic and nontherapeutic effects (excl toxicity)	Therapeutic and nontherapeutic responses	Adverse drug reaction	4	0
			Vaccination failure	1	0
	Tissue disorders NEC	Fibrosis NEC	Fibrosis	1	0
		Mass conditions NEC	Mass	2	0
			Nodule	2	0
Hepatobiliary disorders	Hepatic and hepatobiliary disorders	Cholestasis and jaundice	Jaundice	1	0

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		Hepatocellular damage and hepatitis NEC	Autoimmune hepatitis	1	1
			Hepatic necrosis	1	0
			Hepatitis	1	0
Immune system disorders	Allergic conditions	Allergic conditions NEC	Hypersensitivity	24	0
			Multiple allergies	1	0
		Allergies to foods, food additives, drugs and other chemicals	Allergy to vaccine	2	0
		Anaphylactic and anaphylactoid responses	Anaphylactic reaction	21	0
	Autoimmune disorders	Autoimmune disorders NEC	Autoimmune disorder	2	0
	Immune disorders NEC	Immune and associated conditions NEC	Bacille Calmette-Guerin scar reactivation	4	0
			Immune-mediated adverse reaction	1	0
Infections and infestations	Bacterial infectious disorders	Bacterial infections NEC	Administration site cellulitis	1	0
			Cellulitis	8	0
			Vaccination site cellulitis	1	0
		Streptococcal infections	Pneumonia pneumococcal	1	0
	Infections - pathogen unspecified	Bone and joint infections	Vaccination site joint infection	1	0
		Central nervous system and spinal infections	Encephalitis	1	0
		Ear infections	Labyrinthitis	1	0
		Eye and eyelid infections	Conjunctivitis	1	0
		Infections NEC	Infection	2	0
			Injection site abscess	1	0
			Respiratory tract infection	1	0
			Vaccination site infection	1	0
			Vaccine breakthrough infection	1	0
		Lower respiratory tract and lung infections	Lower respiratory tract infection	2	0
			Pneumonia	3	1

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		Male reproductive tract infections	Orchitis	1	0
		Skin structures and soft tissue infections	Pustule	1	0
		Upper respiratory tract infections	Acute sinusitis	1	0
			Laryngitis	1	0
			Nasopharyngitis	11	0
			Pharyngitis	2	0
			Rhinitis	2	0
			Tonsillitis	1	0
			Upper respiratory tract infection	1	0
	Viral infectious disorders	Coronavirus infections	COVID-19	4	0
			Post-acute COVID-19 syndrome	1	0
		Herpes viral infections	Herpes zoster	1	0
		Influenza viral infections	Influenza	19	0
		Viral infections NEC	Bronchiolitis	1	0
			Gastroenteritis viral	1	0
			Vestibular neuronitis	2	0
Injury, poisoning and procedural complications	Exposures, chemical injuries and poisoning	Exposures associated with pregnancy, delivery and lactation	Exposure during pregnancy	3	0
			Exposure via breast milk	1	0
			Foetal exposure during pregnancy	1	0
			Maternal exposure during breast feeding	2	0
			Maternal exposure during pregnancy	5	0
	Injuries NEC	Muscle, tendon and ligament injuries	Ligament sprain	1	0
			Muscle injury	1	0
			Muscle strain	1	0
		Nerve injuries NEC	Nerve injury	1	0
		Non-site specific injuries NEC	Fall	1	0
			Wound	3	0

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			Wound haemorrhage	1	0
		Site specific injuries NEC	Limb injury	1	0
		Skin injuries NEC	Contusion	14	0
			Skin laceration	3	0
		Spinal cord injuries NEC	Central cord syndrome	1	0
	Medication errors and other product use errors and issues	Accidental exposures to product	Accidental exposure to product	1	0
		Medication errors, product use errors and issues NEC	Medication error	15	0
			Wrong technique in product usage process	2	0
		Product administration errors and issues	Extra dose administered	3	0
			Inappropriate schedule of product administration	1	0
			Incorrect dose administered	1	0
			Incorrect route of product administration	1	0
			Poor quality product administered	1	0
			Product administered at inappropriate site	5	0
			Product administered to patient of inappropriate age	8	0
			Product administration error	7	0
			Wrong product administered	1	0
		Product storage errors and issues in the product use system	Product storage error	3	0
	Off label uses and intentional product misuses/use issues	Off label uses	Off label use	2	0
	Procedural related injuries and complications NEC	Gastrointestinal and hepatobiliary procedural complications	Procedural vomiting	1	0
		Non-site specific procedural complications	Injection related reaction	2	0
Investigations	Cardiac and vascular investigations (excl enzyme tests)	ECG investigations	Electrocardiogram abnormal	1	0
		Heart rate and pulse investigations	Heart rate increased	9	0

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		Vascular tests NEC (incl blood pressure)	Heart rate irregular	2	0
			Blood pressure diastolic decreased	1	0
			Blood pressure increased	3	0
			Blood pressure systolic decreased	1	0
			Blood pressure systolic increased	1	0
	Endocrine investigations (incl sex hormones)	Reproductive hormone analyses	Blood testosterone decreased	1	0
	Enzyme investigations NEC	Skeletal and cardiac muscle analyses	Troponin increased	1	0
	Gastrointestinal investigations	Gastrointestinal function diagnostic procedures	Gastric pH decreased	1	0
	Hepatobiliary investigations	Hepatobiliary function diagnostic procedures	Alanine aminotransferase increased	1	0
	Immunology and allergy investigations	Autoimmunity analyses	Anti-HLA antibody test positive	1	0
	Metabolic, nutritional and blood gas investigations	Blood gas and acid base analyses	Oxygen saturation decreased	2	0
		Carbohydrate tolerance analyses (incl diabetes)	Blood glucose decreased	1	0
			Blood glucose increased	1	0
	Microbiology and serology investigations	Virus identification and serology	HIV test false positive	1	0
			SARS-CoV-2 test	1	0
	Physical examination and organ system status topics	Physical examination procedures and organ system status	Body temperature abnormal	1	0
			Body temperature fluctuation	3	0
			Body temperature increased	4	0
			Palpatory finding abnormal	1	0
			Weight increased	1	0
Metabolism and nutrition disorders	Acid-base disorders	Metabolic acidoses (excl diabetic acidoses)	Metabolic acidosis	1	0
	Appetite and general nutritional disorders	Appetite disorders	Decreased appetite	38	0
			Food refusal	1	0
	Electrolyte and fluid balance conditions	Fluid intake decreased	Fluid intake reduced	1	0

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		Total fluid volume decreased	Dehydration	1	0
	Metabolism disorders NEC	Metabolic disorders NEC	Hypermetabolism	1	0
			Metabolic disorder	1	0
	Vitamin related disorders	Fat soluble vitamin deficiencies and disorders	Vitamin D deficiency	1	0
Musculoskeletal and connective tissue disorders	Bone disorders (excl congenital and fractures)	Bone related signs and symptoms	Pain in jaw	2	0
	Connective tissue disorders (excl congenital)	Connective tissue disorders NEC	Polymyalgia rheumatica	3	0
			Sjogren's syndrome	1	0
	Joint disorders	Arthropathies NEC	Arthritis	5	0
		Joint related disorders NEC	Periarthritis	5	0
			Rotator cuff syndrome	1	0
		Joint related signs and symptoms	Arthralgia	77	0
			Joint stiffness	2	0
			Joint swelling	3	0
		Osteoarthropathies	Osteoarthritis	1	0
		Spondyloarthropathies	Arthritis reactive	1	0
	Muscle disorders	Muscle infections and inflammations	Myositis	2	0
		Muscle pains	Fibromyalgia	1	0
			Myalgia	85	0
		Muscle related signs and symptoms NEC	Muscle fatigue	4	0
			Muscle spasms	9	0
			Muscle tightness	2	0
			Muscle twitching	3	0
		Muscle weakness conditions	Muscular weakness	16	0
		Myopathies	Necrotising myositis	1	0
			Rhabdomyolysis	1	0
	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)	Intervertebral disc disorders NEC	Intervertebral disc annular tear	1	0
			Intervertebral disc protrusion	1	0

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		Spine and neck deformities	Spinal stenosis	1	0
	Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue conditions NEC	Mobility decreased	3	0
			Musculoskeletal stiffness	20	0
		Musculoskeletal and connective tissue pain and discomfort	Back pain	19	0
			Limb discomfort	13	0
			Musculoskeletal chest pain	1	0
			Musculoskeletal discomfort	1	0
			Neck pain	15	0
			Pain in extremity	94	0
		Soft tissue disorders NEC	Axillary mass	1	0
			Neck mass	1	0
	Synovial and bursal disorders	Bursal disorders	Bursitis	1	0
	Tendon, ligament and cartilage disorders	Tendon disorders	Tendonitis	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Miscellaneous and site unspecified neoplasms malignant and unspecified	Neoplasms malignant site unspecified NEC	Neoplasm malignant	1	0
	Neoplasm related morbidities	Paraneoplastic syndromes NEC	Paraneoplastic syndrome	1	0
Nervous system disorders	Central nervous system infections and inflammations	Myelitis (incl infective)	Myelitis transverse	1	0
	Central nervous system vascular disorders	Central nervous system aneurysms and dissections	Intracranial aneurysm	1	0
		Central nervous system haemorrhages and cerebrovascular accidents	Cerebrovascular accident	2	1
			Lacunar stroke	1	0
		Transient cerebrovascular events	Transient ischaemic attack	2	0
	Cranial nerve disorders (excl neoplasms)	Eye movement disorders	Vlth nerve disorder	1	0
		Facial cranial nerve disorders	Bell's palsy	2	0
	Headaches	Headaches NEC	Cluster headache	2	0
			Headache	142	0
			Sinus headache	1	0
			Tension headache	5	0

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		Migraine headaches	Atypical migraine	1	0
			Migraine	12	0
			Migraine with aura	1	0
	Mental impairment disorders	Memory loss (excl dementia)	Memory impairment	1	0
			Transient global amnesia	1	0
		Mental impairment (excl dementia and memory loss)	Disturbance in attention	5	0
	Movement disorders (incl parkinsonism)	Dyskinesias and movement disorders NEC	Bradykinesia	1	0
			Dyskinesia	3	0
			Hypokinesia	4	0
		Paralysis and paresis (excl cranial nerve)	Monoplegia	1	0
			Paralysis	1	0
		Tremor (excl congenital)	Tremor	12	0
	Neurological disorders NEC	Coordination and balance disturbances	Balance disorder	1	0
			Dysstasia	2	0
			Nystagmus	1	0
		Cortical dysfunction NEC	Aphasia	1	0
		Disturbances in consciousness NEC	Depressed level of consciousness	1	0
			Lethargy	5	0
			Loss of consciousness	4	0
			Somnolence	6	0
			Syncope	28	0
		Nervous system disorders NEC	Nervous system disorder	1	0
		Neurological signs and symptoms NEC	Brain fog	4	0
			Dizziness	83	0
			Dizziness postural	4	0
			Head discomfort	2	0
			Neurological symptom	1	0
			Presyncope	11	0

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			Unresponsive to stimuli	2	0
		Paraesthesias and dysaesthesias	Burning sensation	5	0
			Hypoaesthesia	35	0
			Paraesthesia	45	0
		Sensory abnormalities NEC	Ageusia	4	0
			Dysgeusia	5	0
			Electric shock sensation	1	0
			Hypogeusia	1	0
			Neuralgia	9	0
			Sensory disturbance	5	0
			Sensory loss	2	0
			Taste disorder	1	0
		Speech and language abnormalities	Dysarthria	2	0
	Peripheral neuropathies	Acute polyneuropathies	Guillain-Barre syndrome	3	0
		Chronic polyneuropathies	Acrodynia	1	0
		Mononeuropathies	Nerve compression	3	0
		Peripheral neuropathies NEC	Neuralgic amyotrophy	1	0
			Neuropathy peripheral	1	0
			Peripheral sensory neuropathy	1	0
	Seizures (incl subtypes)	Absence seizures	Petit mal epilepsy	2	0
		Seizures and seizure disorders NEC	Epilepsy	2	0
			Seizure	7	0
	Sleep disturbances (incl subtypes)	Narcolepsy and hypersomnia	Hypersomnia	4	0
	Spinal cord and nerve root disorders	Spinal cord and nerve root disorders NEC	Radiculitis brachial	2	0
Pregnancy, puerperium and perinatal conditions	Maternal complications of labour and delivery	Labour onset and length abnormalities	Prolonged pregnancy	1	0
		Maternal complications of delivery NEC	Traumatic delivery	1	0

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		Maternal complications of labour NEC	Intrapartum haemorrhage	1	0
	Neonatal and perinatal conditions	Gestational age and weight conditions	Large for dates baby	1	0
Product issues	Device issues	Device physical property and chemical issues	Needle issue	1	0
			Syringe issue	7	0
	Product quality, supply, distribution, manufacturing and quality system issues	Product physical issues	Product physical issue	1	0
		Product quality issues NEC	Product delivery mechanism issue	1	0
Psychiatric disorders	Anxiety disorders and symptoms	Anxiety symptoms	Agitation	1	0
			Anxiety	3	0
			Nervousness	3	0
			Tension	2	0
		Panic attacks and disorders	Panic attack	1	0
	Changes in physical activity	Tic disorders	Tic	1	0
	Deliria (incl confusion)	Confusion and disorientation	Confusional state	7	0
			Disorientation	1	0
		Deliria	Delirium	2	0
	Depressed mood disorders and disturbances	Depressive disorders	Depression	1	0
		Mood alterations with depressive symptoms	Depressed mood	1	0
	Dissociative disorders	Dissociative states	Depersonalisation/derealisation disorder	1	0
			Dissociation	2	0
	Disturbances in thinking and perception	Hallucinations (excl sleep-related)	Hallucination	1	0
		Thinking disturbances	Tachyphrenia	1	0
			Thinking abnormal	1	0
	Eating disorders and disturbances	Eating disorders NEC	Eating disorder	1	0
	Mood disorders and disturbances NEC	Emotional and mood disturbances NEC	Anger	1	0
			Irritability	5	0

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			Mood altered	1	0
		Mood disorders NEC	Apathy	1	0
	Sleep disorders and disturbances	Disturbances in initiating and maintaining sleep	Initial insomnia	1	0
			Insomnia	12	0
		Dyssomnias	Poor quality sleep	2	0
		Parasomnias	Abnormal dreams	2	0
			Rapid eye movements sleep abnormal	1	0
			Sleep terror	1	0
		Sleep disorders NEC	Sleep disorder	6	0
Renal and urinary disorders	Renal disorders (excl nephropathies)	Renal failure and impairment	Acute kidney injury	1	0
			Chronic kidney disease	1	0
		Renal vascular and ischaemic conditions	Renal tubular necrosis	1	0
	Urinary tract signs and symptoms	Bladder and urethral symptoms	Dysuria	1	0
			Micturition urgency	1	0
			Urinary retention	2	0
		Urinary abnormalities	Paroxysmal nocturnal haemoglobinuria	1	0
		Urinary tract signs and symptoms NEC	Renal pain	1	0
Reproductive system and breast disorders	Menstrual cycle and uterine bleeding disorders	Menstruation and uterine bleeding NEC	Dysmenorrhoea	2	0
			Intermenstrual bleeding	1	0
			Menstruation irregular	1	0
		Menstruation with decreased bleeding	Amenorrhoea	1	0
		Menstruation with increased bleeding	Heavy menstrual bleeding	1	0
	Reproductive tract disorders NEC	Reproductive tract signs and symptoms NEC	Pelvic pain	1	0
	Testicular and epididymal disorders	Testicular and epididymal disorders NEC	Testicular pain	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Testicular swelling	1	0
Respiratory, thoracic and mediastinal disorders	Bronchial disorders (excl neoplasms)	Bronchial conditions NEC	Bronchial secretion retention	1	0
		Bronchospasm and obstruction	Asthma	3	0
			Bronchospasm	1	0
			Chronic obstructive pulmonary disease	2	1
			Wheezing	6	0
	Lower respiratory tract disorders (excl obstruction and infection)	Parenchymal lung disorders NEC	Atelectasis	1	0
		Pulmonary oedemas	Pulmonary congestion	2	0
	Pleural disorders	Pneumothorax and pleural effusions NEC	Pleural effusion	1	0
			Pneumothorax	1	0
	Pulmonary vascular disorders	Pulmonary thrombotic and embolic conditions	Pulmonary embolism	5	2
	Respiratory disorders NEC	Breathing abnormalities	Dyspnoea	28	0
			Dyspnoea exertional	1	0
			Hypopnoea	1	0
			Respiration abnormal	2	0
			Tachypnoea	1	0
		Conditions associated with abnormal gas exchange	Hypoxia	1	0
		Coughing and associated symptoms	Allergic cough	1	0
			Cough	28	0
			Productive cough	3	0
			Sputum discoloured	1	0
		Respiratory failures (excl neonatal)	Respiratory failure	2	1
		Respiratory tract disorders NEC	Respiratory tract inflammation	1	0
	Respiratory tract signs and symptoms	Lower respiratory tract signs and symptoms	Pulmonary pain	1	0
		Upper respiratory tract signs and symptoms	Aphonia	3	0
			Catarrh	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Dry throat	1	0
			Increased viscosity of upper respiratory secretion	1	0
			Oropharyngeal discomfort	1	0
			Oropharyngeal pain	29	0
			Paranasal sinus discomfort	2	0
			Rhinalgia	1	0
			Rhinorrhoea	19	0
			Sinus pain	4	0
			Sneezing	8	0
			Throat irritation	3	0
			Throat tightness	2	0
			Upper-airway cough syndrome	1	0
	Upper respiratory tract disorders (excl infections)	Nasal congestion and inflammations	Nasal congestion	7	0
		Nasal disorders NEC	Epistaxis	4	0
		Paranasal sinus disorders (excl infections and neoplasms)	Sinus congestion	1	0
		Pharyngeal disorders (excl infections and neoplasms)	Pharyngeal paraesthesia	2	0
			Pharyngeal swelling	2	0
			Pharyngeal ulceration	1	0
Skin and subcutaneous tissue disorders	Angioedema and urticaria	Angioedemas	Angioedema	4	0
		Urticarias	Cold urticaria	1	0
			Urticaria	38	0
	Epidermal and dermal conditions	Bullous conditions	Blister	4	0
			Blister rupture	1	0
		Dermal and epidermal conditions NEC	Pain of skin	2	0
			Papule	1	0
			Scar pain	1	0
			Skin burning sensation	3	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Skin discolouration	1	0
			Skin disorder	1	0
			Skin induration	2	0
			Skin lesion	1	0
			Skin reaction	7	0
			Skin swelling	3	0
			Skin texture abnormal	2	0
			Skin warm	6	0
			Skin weeping	2	0
		Dermatitis and eczema	Dermatitis	2	0
			Dermatitis allergic	6	0
			Eczema	1	0
			Neurodermatitis	2	0
			Skin irritation	3	0
		Dermatitis ascribed to specific agent	Drug eruption	1	0
		Erythemas	Erythema	59	0
		Exfoliative conditions	Skin exfoliation	1	0
		Papulosquamous conditions	Lichen planus	1	0
			Pityriasis rosea	1	0
		Photosensitivity and photodermatosis conditions	Photosensitivity reaction	2	0
		Pruritus NEC	Pruritus	65	0
		Psoriatic conditions	Palmoplantar pustulosis	1	0
			Psoriasis	1	0
		Rashes, eruptions and exanthems NEC	Rash	51	0
			Rash erythematous	12	0
			Rash macular	6	0
			Rash maculo-papular	2	0
			Rash papular	9	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
			Rash pruritic	5	0
			Rash vesicular	1	0
	Skin and subcutaneous tissue disorders NEC	Skin and subcutaneous conditions NEC	Skin mass	1	0
		Skin and subcutaneous tissue ulcerations	Skin erosion	1	0
	Skin appendage conditions	Apocrine and eccrine gland disorders	Cold sweat	8	0
			Hyperhidrosis	16	0
			Miliaria	2	0
			Night sweats	6	0
		Nail and nail bed conditions (excl infections and infestations)	Onychalgia	1	0
	Skin vascular abnormalities	Purpura and related conditions	Petechiae	1	0
Social circumstances	Lifestyle issues	Disability issues	Bedridden	1	0
			Immobile	3	0
			Impaired work ability	3	0
			Loss of personal independence in daily activities	2	0
Surgical and medical procedures	Obstetric and gynaecological therapeutic procedures	Obstetric therapeutic procedures	Caesarean section	1	0
	Therapeutic procedures and supportive care NEC	Immunisations	Immunisation	1	0
		Therapeutic procedures NEC	Interchange of vaccine products	2	0
Vascular disorders	Arteriosclerosis, stenosis, vascular insufficiency and necrosis	Peripheral vasoconstriction, necrosis and vascular insufficiency	Jugular vein occlusion	1	0
			Peripheral coldness	4	0
			Vasoconstriction	1	0
	Decreased and nonspecific blood pressure disorders and shock	Circulatory collapse and shock	Circulatory collapse	5	0
			Shock	1	0
		Vascular hypotensive disorders	Hypotension	5	0
			Orthostatic hypotension	2	0
	Embolism and thrombosis	Non-site specific embolism and thrombosis	Thrombosis	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGHT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
	Vascular disorders NEC	Peripheral vascular disorders NEC	Cyanosis	1	0
			Flushing	3	0
			Hot flush	7	0
		Site specific vascular disorders NEC	Pallor	9	0
	Vascular hypertensive disorders	Vascular hypertensive disorders NEC	Hypertension	6	0
Total				1,200	25