

Reaction MedDRA SOC Name	Reaction MedDRA HLT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal	
Blood and lymphatic system disorders	Haematological disorders NEC	Haematological disorders	Blood disorder	1	0	
	Platelet disorders	Thrombocytopenias	Thrombocytopenia	2	0	
	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Lymph node pain	2	0	
	White blood cell disorders	Leukocytoses NEC	Lymphadenopathy	25	0	
			Lymphocytosis	3	0	
	Total			33	0	
Cardiac disorders	Cardiac arrhythmias	Rate and rhythm disorders NEC	Bradycardia	1	0	
		Supraventricular arrhythmias	Tachycardia	12	0	
			Atrial fibrillation	4	0	
			Atrial flutter	1	0	
	Cardiac disorders, signs and symptoms NEC	Cardiac signs and symptoms NEC	Palpitations	15	0	
	Myocardial disorders	Noninfectious myocarditis	Myocarditis	1	0	
	Pericardial disorders	Noninfectious pericarditis	Pericarditis	1	0	
		Pericardial disorders NEC	Pericardial effusion	1	0	
	Total			36	0	
Ear and labyrinth disorders	Aural disorders NEC	Ear disorders NEC	Ear disorder	1	0	
			Ear pain	7	0	
	Hearing disorders	Hearing losses	Deafness	2	0	
			Deafness unilateral	1	0	
			Sudden hearing loss	2	0	
	Inner ear and VIIIth cranial nerve disorders	Inner ear signs and symptoms	Tinnitus	7	0	
		Vertigo	9	0		
	Total			29	0	
Eye disorders	Anterior eye structural change, deposit and degeneration	Corneal structural change, deposit and degeneration	Corneal scar	2	0	
	Eye disorders NEC	Lacrimation disorders	Dry eye	3	0	
			Lacrimation increased	2	0	
		Ocular disorders NEC	Eye disorder	1	0	
			Eye pain	9	0	
			Eye swelling	6	0	
			Periorbital pain	1	0	
	Glaucoma and ocular hypertension	Glaucomas (excl congenital)	Glaucoma	1	0	
	Ocular haemorrhages and vascular disorders NEC	Ocular bleeding and vascular disorders NEC	Eye haemorrhage	1	0	
	Ocular infections, irritations and inflammations	Corneal infections, oedemas and inflammations	Keratitis	4	0	
			Ulcerative keratitis	1	0	
			Ocular infections, inflammations and associated manifestations	Eye discharge	1	0
				Eye inflammation	2	0
				Eye irritation	1	0
			Eye pruritus	3	0	
			Ocular hyperaemia	3	0	
	Ocular neuromuscular disorders	Eyelid movement disorders	Blepharospasm	1	0	
	Ocular sensory symptoms NEC	Ocular sensation disorders	Asthenopia	1	0	
			Photophobia	1	0	
	Ocular structural change, deposit and degeneration NEC	Choroid and vitreous structural change, deposit and degeneration	Vitreous floaters	1	0	
		Retinal structural change, deposit and degeneration	Macular cherry-red spots	1	0	
	Vision disorders	Visual disorders NEC	Diplopia	2	0	
			Metamorphopsia	1	0	
			Vision blurred	10	0	
		Visual impairment and blindness (excl colour blindness)	Blindness	1	0	
			Visual impairment	8	0	
	Total			68	0	
Gastrointestinal disorders	Dental and gingival conditions	Dental pain and sensation disorders	Toothache	1	0	
		Gingival disorders, signs and symptoms NEC	Gingival pain	1	0	
	Gastrointestinal conditions NEC	Gastrointestinal disorders NEC	Gastrointestinal disorder	1	0	
	Gastrointestinal haemorrhages NEC	Gastric and oesophageal haemorrhages	Gastric haemorrhage	1	0	
	Gastrointestinal inflammatory conditions	Colitis (excl infective)	Colitis	1	0	
			Colitis ulcerative	1	0	
	Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	96	0	
		Gastrointestinal atonic and hypomotility disorders NEC	Constipation	4	0	
			Gastrooesophageal reflux disease	1	0	
				Impaired gastric emptying	1	0
				Intestinal dilatation	1	0
			Gastrointestinal dyskinetic disorders	Change of bowel habit	1	0
		Gastrointestinal spastic and hypermotility disorders	Irritable bowel syndrome	1	0	
	Gastrointestinal signs and symptoms	Dyspeptic signs and symptoms	Dyspepsia	3	0	
			Epigastric discomfort	1	0	
		Faecal abnormalities NEC	Faeces discoloured	1	0	
		Flatulence, bloating and distension	Abdominal distension	2	0	
			Flatulence	1	0	
		Gastrointestinal and abdominal pains (excl oral and throat)	Abdominal migraine	1	0	
			Abdominal pain	20	0	
			Abdominal pain lower	1	0	
			Abdominal pain upper	57	0	
			Gastrointestinal pain	5	0	
		Gastrointestinal signs and symptoms NEC	Abdominal discomfort	32	0	
			Anal incontinence	1	0	
			Breath odour	1	0	
			Dysphagia	1	0	
		Nausea and vomiting symptoms	Nausea	205	0	
	Retching		1	0		
	Vomiting		73	0		
	Vomiting projectile		1	0		
	Oral soft tissue conditions	Oral soft tissue disorders NEC	Cheilitis	1	0	
			Lip blister	1	0	
Oral disorder			1	0		
Oral lichen planus			1	0		
Hypoaesthesia oral			2	0		
Oral soft tissue signs and symptoms		Oral discomfort	1	0		
		Oral mucosal blistering	1	0		
		Oral pain	1	0		
		Paraesthesia oral	3	0		
		Oral soft tissue swelling and oedema	Lip swelling	14	0	

	Stomatitis and ulceration	Mouth ulceration	6	0		
		Stomatitis	2	0		
Salivary gland conditions	Oral dryness and saliva altered	Dry mouth	2	0		
	Salivary gland enlargements	Salivary gland enlargement	1	0		
Tongue conditions	Tongue disorders	Tongue disorder	1	0		
	Tongue signs and symptoms	Glossodynia	1	0		
		Swollen tongue	6	0		
Total			563	0		
General disorders and administration site conditions	Administration site reactions	Administration site reactions NEC	Administration site bruise	1	0	
			Administration site swelling	1	0	
		Application site reactions	Application site rash	1	0	
			Infusion site erythema	2	0	
		Injection site reactions	Injected limb mobility decreased	2	0	
			Injection site bruising	2	0	
			Injection site cyst	1	0	
			Injection site discharge	1	0	
			Injection site erythema	53	0	
			Injection site haemorrhage	1	0	
			Injection site induration	4	0	
			Injection site inflammation	6	0	
			Injection site joint movement impairment	1	0	
			Injection site joint pain	1	0	
			Injection site mass	4	0	
			Injection site oedema	2	0	
			Injection site pain	91	0	
			Injection site pruritus	15	0	
			Injection site rash	12	0	
			Injection site reaction	1	0	
			Injection site swelling	33	0	
			Injection site urticaria	3	0	
			Injection site vesicles	1	0	
			Injection site warmth	14	0	
			Vaccination site reactions	Extensive swelling of vaccinated limb	1	0
				Shoulder injury related to vaccine administration	1	0
				Vaccination site bruising	3	0
				Vaccination site discolouration	2	0
				Vaccination site discomfort	1	0
				Vaccination site erythema	29	0
				Vaccination site induration	2	0
				Vaccination site inflammation	5	0
				Vaccination site joint erythema	2	0
				Vaccination site joint movement impairment	1	0
				Vaccination site joint pain	3	0
				Vaccination site mass	3	0
		Vaccination site pain		41	0	
		Vaccination site papule		1	0	
		Vaccination site pruritus		3	0	
		Vaccination site rash		6	0	
		Vaccination site swelling		28	0	
		Vaccination site warmth		15	0	
	Body temperature conditions	Febrile disorders	Pyrexia	316	0	
	Fatal outcomes	Death and sudden death	Death	4	4	
	General system disorders NEC	Asthenic conditions	Asthenia	49	0	
			Fatigue	281	0	
			Malaise	177	0	
			Sluggishness	1	0	
		Feelings and sensations NEC	Chills	212	0	
			Feeling abnormal	14	0	
			Feeling cold	25	0	
			Feeling drunk	2	0	
			Feeling hot	26	0	
			Feeling of body temperature change	8	0	
Sensation of foreign body			1	0		
Thirst			3	0		
Gait disturbances			Gait disturbance	6	0	
		Gait inability	5	0		
		Loss of control of legs	1	0		
General signs and symptoms NEC		Condition aggravated	4	0		
		Crying	1	0		
		Exercise tolerance decreased	1	0		
		General symptom	2	0		
		Illness	31	0		
		Induration	2	0		
		Influenza like illness	77	0		
		Local reaction	15	0		
		Peripheral swelling	141	0		
		Secretion discharge	1	0		
		Swelling	79	0		
		Swelling face	17	0		
		Inflammations	Inflammation	18	0	
			Systemic inflammatory response syndrome	1	0	
Oedema NEC		Localised oedema	1	0		
		Oedema peripheral	3	0		
Pain and discomfort NEC		Axillary pain	10	0		
		Chest discomfort	8	0		
		Chest pain	19	0		
		Discomfort	6	0		
		Facial pain	5	0		
		Pain	158	0		

			Tenderness	7	0		
Therapeutic and nontherapeutic effects (excl toxicity)	Interactions	Therapeutic and nontherapeutic responses	Drug interaction	1	0		
			Adverse drug reaction	13	0		
			Drug ineffective	1	0		
			Therapeutic response unexpected	1	0		
			Vaccination failure	45	0		
Tissue disorders NEC	Mass conditions NEC	Mass	2	0			
Total			2,201	4			
Immune system disorders	Allergic conditions	Allergic conditions NEC	Hypersensitivity	9	0		
			Anaphylactic and anaphylactoid responses	Anaphylactic reaction	3	0	
				Anaphylactic shock	2	0	
	Immune disorders NEC	Immune and associated conditions NEC	Immune system disorder	2	0		
	Immunodeficiency syndromes	Immunodeficiency disorders NEC	Immunodeficiency	1	0		
			Immunosuppression	1	0		
Total			18	0			
Infections and infestations	Bacterial infectious disorders	Bacterial infections NEC	Administration site cellulitis	1	0		
			Bacterial infection	1	0		
			Cellulitis	20	0		
			Injection site cellulitis	1	0		
			Lymphadenitis bacterial	1	0		
			Bordetella infections	Pertussis	1	0	
			Staphylococcal infections	Furuncle	1	0	
	Fungal infectious disorders	Candida infections	Oral candidiasis	1	0		
			Breast infections	Mastitis	1	0	
	Infections - pathogen unspecified	Central nervous system and spinal infections		Encephalitis	2	0	
				Meningitis	1	0	
		Dental and oral soft tissue infections		Gingival abscess	1	0	
				Pulpitis dental	1	0	
		Eye and eyelid infections		Conjunctivitis	1	0	
				Infections NEC	Infection	4	0
					Injection site infection	2	0
					Vaccination site abscess	2	0
		Lower respiratory tract and lung infections		Infective exacerbation of bronchiectasis	1	0	
				Lower respiratory tract infection	4	0	
				Pneumonia	1	0	
				Skin structures and soft tissue infections	Pustule	1	0
					Skin infection	2	0
		Upper respiratory tract infections		Nasopharyngitis	12	0	
	Rhinitis			1	0		
	Sinusitis			1	0		
	Upper respiratory tract infection			2	0		
	Urinary tract infections			Urinary tract infection	2	0	
	Viral infectious disorders	Coronavirus infections		COVID-19	1	0	
				Herpes viral infections	Genital herpes	1	0
					Herpes simplex	3	0
					Herpes zoster	140	0
					Herpes zoster cutaneous disseminated	1	0
					Ophthalmic herpes zoster	5	0
					Oral herpes	18	0
					Varicella	5	0
					Varicella meningitis	1	0
		Influenza viral infections	Influenza	45	0		
		Parapox viral infections	Orf	1	0		
		Viral infections NEC		Encephalitis viral	1	0	
				Gastroenteritis viral	1	0	
				Sweating fever	4	0	
				Vestibular neuronitis	1	0	
	Viral infection			1	0		
				Viral rash	1	0	
	Total			299	0		
	Injury, poisoning and procedural complications	Bone and joint injuries	Limb fractures and dislocations	Hip fracture	1	0	
				Upper limb fracture	1	0	
Spinal fractures and dislocations				Spinal fracture	1	0	
Injuries by physical agents		Heat injuries (excl thermal burns)	Heat stroke	1	0		
			Injuries NEC	Eye injuries NEC	1	0	
				Nerve injuries NEC	3	0	
				Non-site specific injuries NEC	2	0	
				Site specific injuries NEC	4	0	
				Skin injuries NEC	17	0	
				Scar	1	0	
Medication errors and other product use errors and issues		Medication errors, product use errors and issues NEC		Medication error	31	0	
				Wrong technique in product usage process	1	0	
		Product administration errors and issues		Inappropriate schedule of product administration	2	0	
				Incomplete course of vaccination	4	0	
				Product administered at inappropriate site	1	0	
				Product administered to patient of inappropriate age	2	0	
				Product administration error	1	0	
Procedural related injuries and complications NEC	Non-site specific procedural complications		Injection related reaction	10	0		
			Vaccination related complications	Immunisation reaction	3	0	
Total			87	0			
Investigations	Cardiac and vascular investigations (excl enzyme tests)	Heart rate and pulse investigations	Heart rate	7	0		
			Heart rate decreased	1	0		
			Heart rate increased	9	0		
			Heart rate irregular	1	0		
			Vascular tests NEC (incl blood pressure)	Blood pressure abnormal	1	0	
		Blood pressure decreased	2	0			
		Blood pressure increased	2	0			
	Endocrine investigations (incl sex hormones)	Gastrointestinal, pancreatic and APUD hormone analyses	Blood insulin increased	1	0		

	Haematology investigations (incl blood groups)	Platelet analyses	Platelet count decreased	1	0			
		Red blood cell analyses	Haemoglobin decreased	1	0			
	Hepatobiliary investigations	Hepatobiliary function diagnostic procedures		Liver function test abnormal	1	0		
		Metabolic, nutritional and blood gas investigations	Blood gas and acid base analyses	Oxygen saturation decreased	1	0		
	Carbohydrate tolerance analyses (incl diabetes)		Blood glucose increased	1	0			
	Microbiology and serology investigations	Virus identification and serology		Herpes simplex test	1	0		
				Varicella virus test positive	1	0		
	Physical examination and organ system status topics	Physical examination procedures and organ system status		Body temperature	2	0		
				Body temperature abnormal	2	0		
				Body temperature decreased	1	0		
				Body temperature fluctuation	2	0		
				Body temperature increased	12	0		
				Grip strength	1	0		
				Respiratory rate increased	1	0		
				Skin temperature	3	0		
				Temperature difference of extremities	1	0		
				Weight decreased	1	0		
				Protein and chemistry analyses NEC	Chemistry analyses NEC	Inflammatory marker increased	1	0
					Protein analyses NEC	C-reactive protein increased	1	0
	Total			59	0			
Metabolism and nutrition disorders	Appetite and general nutritional disorders	Appetite disorders	Decreased appetite	41	0			
			Hypophagia	1	0			
		General nutritional disorders NEC	Feeding disorder	4	0			
			Food aversion	2	0			
	Electrolyte and fluid balance conditions	Total fluid volume decreased	Dehydration	2	0			
	Glucose metabolism disorders (incl diabetes mellitus)	Hypoglycaemic conditions NEC	Hypoglycaemia	3	0			
Purine and pyrimidine metabolism disorders	Disorders of purine metabolism	Gout	5	0				
Total			58	0				
Musculoskeletal and connective tissue disorders	Bone disorders (excl congenital and fractures)	Bone related signs and symptoms		Bone pain	12	0		
				Pain in jaw	8	0		
	Connective tissue disorders (excl congenital)	Connective tissue disorders NEC		Polymyalgia rheumatica	1	0		
				Joint disorders	Arthropathies NEC	Arthritis	8	0
	Joint related disorders NEC	Periarthritis	1		0			
		Vertebral foraminal stenosis	1		0			
	Joint related signs and symptoms	Arthralgia	171		0			
		Joint range of motion decreased	1		0			
		Joint stiffness	4		0			
		Joint swelling	8		0			
	Osteoarthropathies	Osteoarthritis	1		0			
	Psoriatic arthropathies	Psoriatic arthropathy	1		0			
	Rheumatoid arthropathies	Rheumatoid arthritis	4		0			
	Spondyloarthropathies	Arthritis reactive	2	0				
	Spondyloarthropathy	Spondyloarthropathy	1	0				
	Muscle disorders	Muscle infections and inflammations		Myositis	1	0		
				Muscle pains		Fibromyalgia	3	0
		Myalgia	266			0		
		Muscle related signs and symptoms NEC		Muscle discomfort	1	0		
				Muscle fatigue	10	0		
				Muscle spasms	10	0		
				Muscle tightness	4	0		
				Muscle twitching	2	0		
				Muscle tone abnormalities	Muscle rigidity	2	0	
		Muscle weakness conditions	Muscular weakness	21	0			
	Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue conditions NEC		Limb mass	2	0		
				Mobility decreased	8	0		
				Musculoskeletal stiffness	14	0		
				Musculoskeletal and connective tissue pain and discomfort	Back pain	40	0	
		Limb discomfort	10		0			
		Musculoskeletal chest pain	2		0			
		Musculoskeletal pain	2		0			
		Neck pain	28		0			
Pain in extremity		204	0					
Soft tissue disorders NEC		Axillary mass	1	0				
		Groin pain	2	0				
Soft tissue disorder		1	0					
Synovial and bursal disorders	Bursal disorders	Bursitis	2	0				
	Synovial disorders	Synovitis	3	0				
Tendon, ligament and cartilage disorders	Cartilage disorders	Slipping rib syndrome	1	0				
	Ligament disorders	Ligament pain	1	0				
	Tendon disorders	Tendon pain	1	0				
		Tendonitis	1	0				
		Tenosynovitis	1	0				
Total			868	0				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haematopoietic neoplasms (excl leukaemias and lymphomas)	Myeloproliferative disorders (excl leukaemias)	Myelofibrosis	1	0			
	Miscellaneous and site unspecified neoplasms malignant and unspecified	Neoplasms malignant site unspecified NEC	Neoplasm malignant	1	0			
	Plasma cell neoplasms	Plasma cell neoplasms NEC	Hypergammaglobulinaemia benign monoclonal	2	0			
	Soft tissue neoplasms benign	Soft tissue neoplasms benign NEC	Lipoma	1	0			
	Total			5	0			
Nervous system disorders	Central nervous system infections and inflammations	Encephalitis NEC	Noninfective encephalitis	1	0			
		Myelitis (incl infective)	Myelitis transverse	2	0			
	Central nervous system vascular disorders	Central nervous system haemorrhages and cerebrovascular accidents		Cerebral haemorrhage	1	0		
				Cerebrovascular accident	1	0		
		Cerebrovascular venous and sinus thrombosis		Cerebral venous sinus thrombosis	1	0		
				Transient cerebrovascular events	Transient ischaemic attack	1	0	
	Cranial nerve disorders (excl neoplasms)	Eye movement disorders		Vlth nerve disorder	1	0		
				Facial cranial nerve disorders	Bell's palsy	3	0	
		Olfactory nerve disorders		Facial paralysis	4	0		
				Anosmia	1	0		
		Trigeminal disorders	Trigeminal neuralgia	3	0			

Demyelinating disorders	Multiple sclerosis acute and progressive	Multiple sclerosis	1	0		
		Multiple sclerosis relapse	1	0		
Headaches	Headaches NEC	Cluster headache	2	0		
		Headache	442	0		
		Occipital neuralgia	1	0		
		Sinus headache	3	0		
		Tension headache	6	0		
		Vascular headache	1	0		
		Migraine headaches	Migraine	16	0	
Mental impairment disorders	Memory loss (excl dementia)	Migraine with aura	1	0		
		Amnesia	4	0		
	Mental impairment (excl dementia and memory loss)	Transient global amnesia	1	0		
Movement disorders (incl parkinsonism)	Dyskinesias and movement disorders NEC	Disturbance in attention	1	0		
		Mental impairment	1	0		
	Paralysis and paresis (excl cranial nerve)	Hypokinesia	1	0		
		Hemiparesis	1	0		
		Monoplegia	2	0		
	Parkinson's disease and parkinsonism	Paralysis	4	0		
		Freezing phenomenon	2	0		
Tremor (excl congenital)	Tremor	30	0			
Neurological disorders NEC	Abnormal reflexes	Areflexia	1	0		
		Coordination and balance disturbances	Balance disorder	14	0	
	Disturbances in consciousness NEC	Coordination abnormal	3	0		
		Dysstasia	2	0		
		Depressed level of consciousness	1	0		
		Lethargy	26	0		
	Nervous system disorders NEC	Loss of consciousness	8	0		
		Somnolence	20	0		
		Syncope	24	0		
	Neurological signs and symptoms NEC	Cerebral disorder	2	0		
		Nervous system disorder	4	0		
	Paraesthesias and dysaesthesias	Sensory abnormalities NEC	Brain fog	5	0	
			Dizziness	84	0	
		Dizziness exertional	2	0		
		Dizziness postural	11	0		
		Head discomfort	4	0		
		Presyncope	9	0		
		Burning sensation	9	0		
		Hypoaesthesia	12	0		
		Paraesthesia	38	0		
		Speech and language abnormalities	Ageusia	1	0	
	Dysgeusia		3	0		
	Electric shock sensation		3	0		
	Neuralgia		28	0		
	Post herpetic neuralgia		5	0		
	Neuromuscular disorders	Autonomic nervous system disorders	Sensory loss	1	0	
			Taste disorder	2	0	
	Peripheral neuropathies	Acute polyneuropathies	Dysarthria	4	0	
			Incoherent	1	0	
		Slow speech	1	0		
	Seizures (incl subtypes)	Seizures and seizure disorders NEC	Autonomic nervous system imbalance	1	0	
			Hypotonia	1	0	
			Guillain-Barre syndrome	12	0	
	Sleep disturbances (incl subtypes)	Narcolepsy and hypersomnia	Miller Fisher syndrome	1	0	
			Nerve compression	1	0	
	Spinal cord and nerve root disorders	Lumbar spinal cord and nerve root disorders	Neuropathy peripheral	6	0	
			Peripheral sensory neuropathy	1	0	
	Total	Total	Clonic convulsion	1	0	
			Epilepsy	3	0	
	Psychiatric disorders	Anxiety disorders and symptoms	Seizure	5	0	
			Hypersomnia	1	0	
		Changes in physical activity	Increased physical activity levels	Sciatica	1	0
				Total	902	0
		Cognitive and attention disorders and disturbances	Cognitive and attention disorders and disturbances NEC	Anxiety	1	0
				Nervousness	4	0
		Deliria (incl confusion)	Confusion and disorientation	Stress	2	0
				Fear	1	0
Depressed mood disorders and disturbances		Mood alterations with depressive symptoms	Fear symptoms and phobic disorders (incl social phobia)	1	0	
			Restlessness	1	0	
Disturbances in thinking and perception		Hallucinations (excl sleep-related)	Daydreaming	1	0	
			Mental fatigue	1	0	
			Confusional state	6	0	
Mood disorders and disturbances NEC		Affect alterations NEC	Disorientation	9	0	
			Emotional and mood disturbances NEC	5	0	
			Delirium	5	0	
Sleep disorders and disturbances		Disturbances in initiating and maintaining sleep	Depressed mood	1	0	
	Hallucination		8	0		
	Hallucination, visual		1	0		
	Near death experience		1	0		
Renal and urinary disorders	Renal disorders (excl nephropathies)	Thinking disturbances	1	0		
		Bradyphrenia	1	0		
		Flat affect	1	0		
Urinary tract signs and symptoms	Bladder and urethral symptoms	Anger	1	0		
		Apathy	1	0		
Total	Total	Listless	1	0		
		Insomnia	27	0		
		Poor quality sleep	6	0		
		Nightmare	2	0		
Total	Total	Sleep disorders NEC	2	0		
		Total	84	0		
Renal disorders (excl nephropathies)	Renal disorders NEC	Renal disorder	2	0		
		Renal impairment	1	0		
Urinary tract signs and symptoms	Bladder and urethral symptoms	Renal injury	1	0		
		Pollakiuria	2	0		
Total	Total	Urinary incontinence	2	0		
		Total	2	0		

		Urinary retention	1	0	
		Urinary abnormalities	3	0	
		Chromaturia	3	0	
		Haematuria	3	0	
		Urinary tract signs and symptoms NEC	6	0	
		Renal pain	6	0	
	Total		21	0	
Reproductive system and breast disorders	Breast disorders	Breast signs and symptoms	Breast pain	4	0
			Breast swelling	1	0
	Reproductive tract disorders NEC	Reproductive tract signs and symptoms NEC	Pelvic pain	1	0
	Total		6	0	
Respiratory, thoracic and mediastinal disorders	Bronchial disorders (excl neoplasms)	Bronchospasm and obstruction	Asthma	6	0
			Chronic obstructive pulmonary disease	1	1
			Obstructive airways disorder	1	0
			Wheezing	3	0
	Lower respiratory tract disorders (excl obstruction and infection)	Parenchymal lung disorders NEC	Organising pneumonia	1	0
	Respiratory disorders NEC	Breathing abnormalities	Apnoea	1	0
			Dyspnoea	31	0
			Hypopnoea	2	0
			Respiratory arrest	1	0
		Coughing and associated symptoms	Cough	17	0
			Sputum discoloured	1	0
		Respiratory tract disorders NEC	Dependence on respirator	1	0
	Respiratory tract signs and symptoms	Respiratory signs and symptoms NEC	Respiratory symptom	1	0
		Upper respiratory tract signs and symptoms	Catarrh	1	0
			Choking	1	0
			Choking sensation	1	0
			Dry throat	2	0
			Oropharyngeal discomfort	1	0
			Oropharyngeal pain	11	0
			Rhinorrhoea	5	0
			Sinus pain	1	0
			Sneezing	2	0
			Throat clearing	1	0
			Throat tightness	1	0
	Upper respiratory tract disorders (excl infections)	Nasal congestion and inflammations	Nasal congestion	1	0
		Nasal disorders NEC	Epistaxis	2	0
			Nasal oedema	1	0
		Pharyngeal disorders (excl infections and neoplasms)	Pharyngeal paraesthesia	1	0
			Pharyngeal swelling	6	0
	Total		105	1	
Skin and subcutaneous tissue disorders	Angioedema and urticaria	Angioedemas	Angioedema	3	0
		Urticarias	Urticaria	26	0
	Epidermal and dermal conditions	Bullous conditions	Blister	15	0
		Dermal and epidermal conditions NEC	Dry skin	4	0
			Pain of skin	10	0
			Scab	3	0
			Sensitive skin	3	0
			Skin burning sensation	6	0
			Skin disorder	2	0
			Skin reaction	8	0
			Skin swelling	1	0
			Skin warm	14	0
			Yellow skin	1	0
		Dermatitis and eczema	Dermatitis	4	0
			Dermatitis allergic	3	0
			Eczema	1	0
			Skin irritation	5	0
		Dermatitis ascribed to specific agent	Drug eruption	4	0
		Erythemas	Erythema	165	0
		Exfoliative conditions	Exfoliative rash	1	0
			Skin exfoliation	2	0
		Papulosquamous conditions	Lichen planus	2	0
		Photosensitivity and photodermatitis conditions	Photosensitivity reaction	1	0
		Pruritus NEC	Pruritus	99	0
		Psoriatic conditions	Psoriasis	3	0
		Pustular conditions	Acute generalised exanthematous pustulosis	1	0
		Rashes, eruptions and exanthems NEC	Nodular rash	1	0
			Rash	165	0
			Rash erythematous	84	0
			Rash macular	13	0
			Rash maculo-papular	1	0
			Rash morbilliform	4	0
			Rash papular	15	0
			Rash pruritic	25	0
			Rash vesicular	10	0
	Pigmentation disorders	Hyperpigmentation disorders	Skin hyperpigmentation	1	0
		Pigmentation changes NEC	Pigmentation disorder	1	0
	Skin appendage conditions	Alopecias	Alopecia	3	0
		Apocrine and eccrine gland disorders	Cold sweat	8	0
			Hyperhidrosis	24	0
			Miliaria	1	0
			Night sweats	8	0
	Skin vascular abnormalities	Purpura and related conditions	Petechiae	1	0
		Skin vasculitides	Cutaneous vasculitis	1	0
			Vasculitic rash	2	0
		Skin vasomotor conditions	Livedo reticularis	1	0
	Total		756	0	
Social circumstances	Lifestyle issues	Disability issues	Bedridden	7	0
			Disability	1	0
			Loss of personal independence in daily activities	7	0
			Walking disability	1	0

	Total			16	0	
Surgical and medical procedures	Nervous system, skull and spine therapeutic procedures	Cerebrospinal fluid therapeutic procedures	Lumboperitoneal shunt	1	0	
	Therapeutic procedures and supportive care NEC	Immunisations	Immunisation	1	0	
		Therapeutic procedures NEC	Injection	Injection	1	0
			Rest regimen	Rest regimen	1	0
			Surgery	Surgery	1	0
	Total			5	0	
Vascular disorders	Arteriosclerosis, stenosis, vascular insufficiency and necrosis	Peripheral vasoconstriction, necrosis and vascular insufficiency	Peripheral coldness	1	0	
	Decreased and nonspecific blood pressure disorders and shock	Blood pressure disorders NEC	Blood pressure fluctuation	1	0	
		Circulatory collapse and shock	Circulatory collapse	1	0	
		Vascular hypotensive disorders	Hypotension	12	0	
	Embolism and thrombosis	Non-site specific embolism and thrombosis	Thrombosis	2	0	
		Peripheral embolism and thrombosis	Deep vein thrombosis	2	0	
	Lymphatic vessel disorders	Lymphoedemas	Lymphoedema	1	0	
	Vascular disorders NEC	Peripheral vascular disorders NEC	Cyanosis	Cyanosis	2	0
			Flushing	Flushing	3	0
			Hot flush	Hot flush	3	0
			Site specific vascular disorders NEC	Pallor	4	0
	Vascular haemorrhagic disorders	Haemorrhages NEC	Haematoma	1	0	
	Vascular hypertensive disorders	Vascular hypertensive disorders NEC	Hypertension	4	0	
	Vascular infections and inflammations	Arterial infections and inflammations	Giant cell arteritis	Giant cell arteritis	2	0
			Phlebitis NEC	Phlebitis	2	0
	Total			41	0	
Total Reaction Count				6,260		
Total Fatal Report Count					5	
Total Report Count				2,352		