

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Count	Fatal Count
Blood and lymphatic system disorders	Anaemias nonhaemolytic and marrow depression	Marrow depression and hypoplastic anaemias	Pancytopenia	1	
	Coagulopathies and bleeding diatheses (excl thrombocytopenic)	Coagulopathies	Coagulopathy	1	
	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Lymphadenopathy	4	
Cardiac disorders	Cardiac arrhythmias	Rate and rhythm disorders NEC	Tachycardia	3	
		Supraventricular arrhythmias	Atrial fibrillation	4	
		Ventricular arrhythmias and cardiac arrest	Cardiac arrest	5	2
			Ventricular extrasystoles	1	
			Ventricular fibrillation		
			Ventricular tachycardia	1	
	Cardiac disorders, signs and symptoms NEC	Cardiac disorders NEC	Cardiac disorder	2	
		Cardiac signs and symptoms NEC	Palpitations	5	
	Coronary artery disorders	Coronary artery disorders NEC	Coronary artery disease		
			Coronary artery occlusion		
			Coronary artery thrombosis		
		Ischaemic coronary artery disorders	Acute myocardial infarction		
			Angina pectoris	2	
			Myocardial infarction	3	1
	Heart failures	Heart failures NEC	Myocardial ischaemia		
			Cardiac failure acute		
			Cardiac failure congestive		
			Cardiogenic shock		
		Left ventricular failures	Left ventricular failure		
		Right ventricular failures	Right ventricular failure		
	Myocardial disorders	Cardiomyopathies	Cardiomyopathy	1	
Congenital, familial and genetic disorders	Cardiac and vascular disorders congenital	Cardiovascular disorders congenital NEC	Right-to-left cardiac shunt	1	
Ear and labyrinth disorders	Aural disorders NEC	Ear disorders NEC	Ear pain	1	
	Hearing disorders	Hearing losses	Deafness	3	
			Hypoacusis	1	

Eye disorders	Inner ear and VIIIth cranial nerve disorders	Inner ear signs and symptoms	Tinnitus	5	
			Vertigo	1	
	Anterior eye structural change, deposit and degeneration	Cataract conditions	Cataract	1	
	Eye disorders NEC	Ocular disorders NEC	Eye pain	3	
	Ocular haemorrhages and vascular disorders NEC	Ocular bleeding and vascular disorders NEC	Eye haemorrhage	2	
		Optic nerve bleeding and vascular disorders	Optic ischaemic neuropathy	3	
	Ocular infections, irritations and inflammations	Lid, lash and lacrimal infections, irritations and inflammations	Swelling of eyelid	2	
		Ocular infections, inflammations and associated manifestations	Ocular hyperaemia	4	
	Ocular structural change, deposit and degeneration NEC	Retinal structural change, deposit and degeneration	Neovascular age-related macular degeneration	1	
	Retina, choroid and vitreous haemorrhages and vascular disorders	Retinal bleeding and vascular disorders (excl retinopathy)	Retinal artery occlusion	1	
			Retinal vein occlusion	1	
		Retinopathies NEC	Diabetic retinopathy	1	
	Vision disorders	Visual colour distortions	Cyanopsia	4	
		Visual disorders NEC	Photopsia	3	
			Vision blurred	2	
		Visual impairment and blindness (excl colour	Blindness	1	
			Visual impairment	7	
Gastrointestinal disorders	Dental and gingival conditions	Gingival disorders, signs and symptoms NEC	Gingival pain	1	
		Tooth missing	Tooth loss	1	
	Gastrointestinal haemorrhages NEC	Gastric and oesophageal haemorrhages	Gastric haemorrhage	1	
		Non-site specific gastrointestinal haemorrhages	Haematemesis	1	
	Gastrointestinal inflammatory conditions	Gastritis (excl infective)	Gastritis	1	
		Oesophagitis (excl infective)	Oesophagitis	1	
	Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	13	
		Gastrointestinal atonic and hypomotility disorders NEC	Constipation	2	
			Gastrooesophageal reflux disease	3	

	Gastrointestinal signs and symptoms	Dyspeptic signs and symptoms	Dyspepsia	10	
		Faecal abnormalities NEC	Faeces discoloured	1	
			Mucous stools	1	
		Flatulence, bloating and distension	Abdominal distension	1	
			Flatulence	1	
		Gastrointestinal and abdominal pains (excl oral and throat)	Abdominal pain lower	1	
			Abdominal pain upper	5	
		Gastrointestinal signs and symptoms NEC	Anal incontinence	1	
			Dysphagia	2	
		Nausea and vomiting symptoms	Nausea	16	
			Retching	1	
			Vomiting	8	
	Gastrointestinal ulceration and perforation	Anal and rectal ulcers and perforation	Anal ulcer	1	
General disorders and administration site conditions	Oral soft tissue conditions	Oral soft tissue swelling and oedema	Lip swelling	1	
	Salivary gland conditions	Oral dryness and saliva altered	Salivary hypersecretion	1	
	Tongue conditions	Tongue signs and symptoms	Swollen tongue	1	
	Administration site reactions	Administration site reactions NEC	Administration site swelling	1	
		Injection site reactions	Injection site pain	1	
	Body temperature conditions	Febrile disorders	Pyrexia	6	
	Fatal outcomes	Death and sudden death	Death	18	9
			Sudden death		
	General system disorders NEC	Adverse effect absent	No adverse event	1	
		Asthenic conditions	Asthenia	3	
			Fatigue	8	
			Malaise	12	
		Feelings and sensations NEC	Chills	2	
			Feeling abnormal	7	
			Feeling cold	4	
			Sensation of blood flow	1	
		General signs and symptoms NEC	Condition aggravated	3	
			Disease progression	2	
			Disease recurrence	1	
			Illness	2	
			Swelling	3	

		Mucosal findings abnormal	Polyp	1	
		Oedema NEC	Oedema peripheral	3	
		Pain and discomfort NEC	Chest pain	4	
			Discomfort	2	
			Facial pain	1	
			Pain	5	
	Therapeutic and nontherapeutic effects (excl toxicity)	Interactions	Drug interaction	9	
		Therapeutic and nontherapeutic responses	Adverse drug reaction	6	
			Adverse event	1	
			Adverse reaction	4	
			Drug effective for unapproved indication	1	
			Drug ineffective	29	
			Drug ineffective for unapproved indication	4	
			Drug intolerance	2	
			Product intolerance	2	
			Therapeutic product effect incomplete	1	
			Therapeutic response unexpected	3	
	Tissue disorders NEC	Ulcers NEC	Ulcer	1	
Hepatobiliary disorders	Hepatic and hepatobiliary disorders	Cholestasis and jaundice	Jaundice	1	
		Hepatic enzymes and function abnormalities	Hypertransaminasaemia	1	
		Hepatic failure and associated disorders	Acute hepatic failure	1	
		Hepatic fibrosis and cirrhosis	Hepatic cirrhosis		
		Hepatocellular damage and hepatitis NEC	Hepatic necrosis	1	
Immune system disorders	Allergic conditions	Allergic conditions NEC	Hypersensitivity	1	
Infections and infestations	Chlamydial infectious disorders	Chlamydial infections	Chlamydial infection	1	
	Fungal infectious disorders	Aspergillus infections	Bronchopulmonary aspergillosis		
		Pneumocystis infections	Pneumocystis jirovecii pneumonia	2	
	Infections - pathogen unspecified	Abdominal and gastrointestinal infections	Appendicitis	1	
		Infections NEC	Infection	3	

		Lower respiratory tract and lung infections	Lower respiratory tract infection	2	
			Pneumonia	3	
			Pneumonia aspiration		
		Sepsis, bacteraemia, viraemia and fungaemia NEC	Sepsis	2	
			Cystitis	1	
			Kidney infection	2	
		Urinary tract infections	Urinary tract infection	1	
			COVID-19	1	
			Herpes simplex reactivation	1	
		Viral infectious disorders	Influenza	1	
Injury, poisoning and procedural complications	Exposures, chemical injuries and poisoning	Exposures associated with pregnancy, delivery and lactation	Exposure during pregnancy	2	
			Foetal exposure during pregnancy	1	
			Maternal exposure during pregnancy	3	
		Poisoning and toxicity	Alcohol poisoning		
	Injuries NEC	Chest and respiratory tract injuries NEC	Foreign body in throat	2	
			Nerve injury	1	
			Fall	2	
		Reproductive system and breast injuries	Fracture of penis	1	
			Genital injury	1	
			Penis injury	2	
		Skin injuries NEC	Skin wound	1	
	Medication errors and other product use errors and issues	Medication errors, product use errors and issues NEC	Medication error	10	
			Product use in unapproved indication	2	
			Product use issue	1	
			Wrong technique in product usage process	2	
		Product administration errors and issues	Contraindicated product administered	1	
			Expired product administered	1	
			Extra dose administered	2	
			Inappropriate schedule of product administration	1	

			Incorrect dose administered	2	
			Poor quality product administered	1	
			Product dispensing errors and issues	1	
	Off label uses and intentional product misuses/use issues	Intentional product misuses	Intentional product misuse	1	
		Intentional product use issues	Intentional product use issue	3	
		Off label uses	Off label use	13	
	Overdoses and underdoses NEC	Overdoses NEC	Intentional overdose	1	
			Overdose	1	
	Investigations	Cardiac and vascular investigations (excl enzyme tests)	Cardiac function diagnostic procedures	Cardiac monitoring	1
			Heart rate and pulse investigations	Heart rate abnormal	1
				Heart rate increased	2
				Pulse absent	1
		Vascular tests NEC (incl blood pressure)	Blood pressure abnormal	1	
			Blood pressure decreased	4	
			Blood pressure increased	1	
			Blood pressure measurement	1	
		Cytogenetic investigations and genetic analyses	Cell marker analyses	Prostatic specific antigen decreased	1
		Hepatobiliary investigations	Hepatobiliary function diagnostic procedures	Liver function test abnormal	1
		Lipid analyses	Cholesterol analyses	Blood cholesterol increased	1
		Metabolic, nutritional and blood gas investigations	Blood gas and acid base analyses	Oxygen saturation decreased	2
		Physical examination and organ system status topics	Physical examination procedures and organ system status	Body temperature increased	3
		Renal and urinary tract investigations and urinalyses	Renal function analyses	Renal function test abnormal	1
			Urinalysis NEC	Blood urine present	4
			Urinary tract function analyses NEC	Urine output	1
Metabolism and nutrition disorders	Electrolyte and fluid balance conditions	Total fluid volume increased	Fluid retention	4	
			Hypervolaemia	1	

	Glucose metabolism disorders (incl diabetes mellitus)	Hypoglycaemic conditions NEC	Hypoglycaemia	1	
	Vitamin related disorders	Water soluble vitamin deficiencies	Vitamin B12 deficiency	1	
Musculoskeletal and connective tissue disorders	Bone disorders (excl congenital and fractures)	Bone related signs and symptoms	Pain in jaw	1	
			Spinal pain	1	
		Metabolic bone disorders	Osteoporosis	1	
	Connective tissue disorders (excl congenital)	Connective tissue disorders NEC	Scleroderma	2	
	Joint disorders	Arthropathies NEC	Arthritis	2	
		Joint related signs and symptoms	Arthralgia	6	
			Joint swelling	1	
	Muscle disorders	Muscle pains	Myalgia	2	
		Muscle related signs and symptoms NEC	Muscle spasms	2	
		Muscle tone abnormalities	Muscle rigidity	1	
	Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue conditions NEC	Musculoskeletal stiffness	3	
		Musculoskeletal and connective tissue pain and discomfort	Back pain	1	
			Neck pain	1	
			Pain in extremity	9	
		Soft tissue disorders NEC	Neck mass	1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Leukaemias	Leukaemias chronic NEC	Chronic leukaemia	1	
Nervous system disorders	Central nervous system vascular disorders	Central nervous system haemorrhages and cerebrovascular accidents	Basal ganglia stroke	1	
			Basilar artery thrombosis		
			Cerebellar stroke	1	
			Cerebral haemorrhage	1	
			Cerebral infarction		
			Cerebrovascular accident	1	
			Haemorrhage intracranial	2	
			Ruptured cerebral aneurysm	1	1
			Subarachnoid haemorrhage		
			Transient cerebrovascular events	2	
	Headaches	Headaches NEC	Headache	68	

			Sinus headache	2	
			Tension headache	1	
		Migraine headaches	Migraine	4	
			Migraine with aura	1	
	Increased intracranial pressure and hydrocephalus	Increased intracranial pressure disorders	Brain oedema	1	1
Mental impairment disorders		Dementia (excl Alzheimer's type)	Dementia	1	
			Amnesia	1	
			Memory impairment	2	
Movement disorders (incl parkinsonism)		Paralysis and paresis (excl cranial nerve)	Monoplegia	1	
			Tremor	3	
Neurological disorders NEC		Coordination and balance disturbances	Balance disorder	1	
			Lethargy	2	
			Loss of consciousness	4	
			Somnolence	2	
		Disturbances in consciousness NEC	Syncope	12	
			Brain fog	1	
			Dizziness	24	
			Dizziness postural	1	
		Neurological signs and symptoms NEC	Drooling	1	
			Head discomfort	1	
			Myoclonus	1	
			Burning sensation	1	
		Paraesthesias and dysaesthesias	Paraesthesia	1	
			Restless legs syndrome	1	
		Sensory abnormalities NEC	Taste disorder	1	
			Dysarthria	1	
		Speech and language abnormalities	Slow speech	2	
			Seizure	1	
Seizures (incl subtypes)		Seizures and seizure disorders NEC			
Sleep disturbances (incl subtypes)		Narcolepsy and hypersomnia	Hypersomnia	1	
Pregnancy, puerperium and perinatal conditions	Maternal complications of labour and delivery	Labour onset and length abnormalities	Premature delivery	2	
	Neonatal and perinatal conditions	Gestational age and weight conditions	Premature baby	1	

Product issues	Product quality, supply, distribution, manufacturing and quality system issues	Counterfeit, falsified and substandard products Product quality issues NEC	Suspected counterfeit product	1	
			Product complaint	3	
			Product substitution issue	5	
			Suspected product quality issue	1	
Psychiatric disorders	Anxiety disorders and symptoms	Anxiety symptoms	Agitation	1	
			Anxiety	1	
			Nervousness	2	
			Stress	1	
	Deliria (incl confusion)	Confusion and disorientation	Confusional state	4	
			Disorientation	1	
	Personality disorders and disturbances in behaviour	Behaviour and socialisation disturbances	Aggression	1	
	Psychiatric and behavioural symptoms NEC	Abnormal behaviour NEC	Abnormal behaviour	1	
	Sexual dysfunctions, disturbances and gender identity disorders	Orgasmic disorders and disturbances	Male orgasmic disorder	2	
	Sleep disorders and disturbances	Disturbances in initiating and maintaining sleep Dyssomnias	Insomnia	4	
			Poor quality sleep	1	
	Suicidal and self-injurious behaviours NEC	Suicidal and self-injurious behaviour	Completed suicide		
			Suicidal ideation	1	
Renal and urinary disorders	Renal disorders (excl nephropathies)	Renal failure and impairment	Acute kidney injury	2	
	Urinary tract signs and symptoms	Bladder and urethral symptoms	Bladder pain	1	
			Dysuria	1	
			Pollakiuria	2	
			Urinary incontinence	1	
		Urinary abnormalities	Chromaturia	1	
		Urinary tract signs and symptoms NEC	Haemorrhage urinary tract	1	
Reproductive system and breast disorders	Breast disorders	Breast signs and symptoms	Breast swelling	1	
			Breast tenderness	1	
	Menstrual cycle and uterine bleeding disorders	Menstruation and uterine bleeding NEC	Dysmenorrhoea	1	
			Intermenstrual bleeding	1	
			Menstruation irregular	3	
		Menstruation with decreased bleeding	Menstruation delayed	2	

		Menstruation with increased bleeding	Heavy menstrual bleeding	3	
	Penile and scrotal disorders (excl infections and inflammations)	Penile disorders NEC (excl erection and ejaculation)	Penile curvature	1	
			Penile pain	1	
			Penile swelling	2	
			Penile vein thrombosis	1	
			Penis disorder	1	
	Prostatic disorders (excl infections and inflammations)	Prostatic signs, symptoms and disorders NEC	Prostatomegaly	1	
	Reproductive tract disorders NEC	Reproductive tract disorders NEC (excl neoplasms)	Genital hypoaesthesia	1	
	Sexual function and fertility disorders	Erection and ejaculation conditions and disorders	Ejaculation failure	1	
			Erectile dysfunction	5	
			Erection increased	7	
			Painful erection	3	
			Priapism	2	
		Sexual function and fertility disorders NEC	Male sexual dysfunction	4	
		Spermatogenesis and semen disorders	Haemospermia	2	
	Vulvovaginal disorders (excl infections and inflammations)	Vulvovaginal signs and symptoms	Coital bleeding	1	
Respiratory, thoracic and mediastinal disorders	Bronchial disorders (excl neoplasms)	Bronchospasm and obstruction	Chronic obstructive pulmonary disease	2	
			Wheezing	1	
	Lower respiratory tract disorders (excl obstruction and infection)	Parenchymal lung disorders NEC	Interstitial lung disease		
			Lung infiltration	1	
			Pulmonary fibrosis		
		Pulmonary oedemas	Pulmonary oedema	2	
	Pulmonary vascular disorders	Pulmonary hypertension	Pulmonary arterial hypertension	1	
			Pulmonary hypertension		
	Respiratory disorders NEC	Breathing abnormalities	Dyspnoea	15	
			Mouth breathing	1	
			Respiration abnormal	1	
			Respiratory arrest	1	
		Conditions associated with abnormal gas exchange	Hypoxia	1	
		Coughing and associated symptoms	Cough	6	
			Haemoptysis	4	

Skin and subcutaneous tissue disorders	Respiratory tract signs and symptoms	Respiratory tract disorders NEC	Productive cough	1	
			Sputum discoloured	1	
		Respiratory tract disorders NEC	Lung disorder		
			Respiratory disorder	1	
		Lower respiratory tract signs and symptoms	Hiccups	1	
			Pulmonary haemorrhage		
			Dry throat	1	
			Dysphonia	1	
			Nasal discomfort	1	
			Oropharyngeal pain	1	
	Upper respiratory tract disorders (excl infections)	Laryngeal spasm, oedema and obstruction	Laryngospasm	1	
			Nasal congestion	11	
		Nasal disorders NEC	Epistaxis	6	
		Paranasal sinus disorders (excl infections and neoplasms)	Sinonasal obstruction	1	
			Pharyngeal swelling		
	Angioedema and urticaria	Urticarias	Urticaria	1	
			Urticaria chronic	1	
	Epidermal and dermal conditions	Bullous conditions	Blister	2	
			Sensitive skin	1	
		Dermal and epidermal conditions NEC	Skin burning sensation	1	
			Erythema	1	
		Photosensitivity and photodermatosis conditions	Photosensitivity reaction	1	
			Pruritus	3	
		Pruritus NEC	Psoriasis	1	
			Rash	4	
		Rashes, eruptions and exanthems NEC	Rash erythematous	1	
			Skin ulcer	1	
	Skin and subcutaneous tissue disorders NEC	Skin and subcutaneous tissue ulcerations			
	Skin appendage conditions	Alopecias	Alopecia	1	
			Cold sweat	1	
		Apocrine and eccrine gland disorders	Hyperhidrosis	2	
			Hair growth abnormal	1	
	Skin vascular abnormalities	Purpura and related conditions	Petechiae	1	

Social circumstances	Economic and housing issues	Employment issues	Sick leave	1	
	Family issues	Family and partner issues	Pregnancy of partner	1	
	Lifestyle issues	Disability issues	Impaired driving ability	1	
			Loss of personal independence in daily activities	1	
		Social issues NEC	Substance use	1	
Surgical and medical procedures	Bone and joint therapeutic procedures	Joint therapeutic procedures	Bunion operation	1	
		Limb therapeutic procedures	Leg amputation	2	
	Therapeutic procedures and supportive care NEC	Therapeutic procedures NEC	Hospitalisation	8	
			Surgery	1	
Vascular disorders	Aneurysms and artery dissections	Aortic aneurysms and dissections	Aortic aneurysm rupture		
	Arteriosclerosis, stenosis, vascular insufficiency and necrosis	Peripheral vasoconstriction, necrosis and vascular insufficiency	Raynaud's phenomenon	1	
	Decreased and nonspecific blood pressure disorders and shock	Circulatory collapse and shock	Circulatory collapse	5	
		Vascular hypotensive disorders	Hypotension	5	
			Neonatal hypotension	1	
			Orthostatic hypotension	3	
	Embolism and thrombosis	Non-site specific embolism and thrombosis	Thrombosis	2	
	Vascular disorders NEC	Non-site specific vascular disorders NEC	Reperfusion injury	1	
		Peripheral vascular disorders NEC	Flushing	13	
			Hot flush	5	
		Site specific vascular disorders NEC	Pallor	1	
	Vascular haemorrhagic disorders	Haemorrhages NEC	Haemorrhage	3	
	Vascular hypertensive disorders	Accelerated and malignant hypertension	Hypertensive crisis	1	
		Vascular hypertensive disorders NEC	Hypertension	1	
	Vascular infections and inflammations	Vasculitides NEC	Vasculitis	1	
Total Number of Reports				477	
Total Number of Reactions				851	
Total Number of Fatal Outcome Reports					14