

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Total	Fatal
Blood and lymphatic system disorders	Anaemias nonhaemolytic and marrow depression	Marrow depression and hypoplastic anaemias	Pure white cell aplasia	2	0
	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Lymph node pain	1	0
			Lymphadenopathy	5	0
Cardiac disorders	Cardiac arrhythmias	Rate and rhythm disorders NEC	Tachycardia	1	0
		Ventricular arrhythmias and cardiac arrest	Cardiac arrest	1	1
	Cardiac disorders, signs and symptoms NEC	Cardiac signs and symptoms NEC	Palpitations	1	0
Ear and labyrinth disorders	Aural disorders NEC	Ear disorders NEC	Ear discomfort	1	0
			Ear inflammation	1	0
	Hearing disorders	Hearing losses	Hypoacusis	1	0
	Inner ear and VIIIth cranial nerve disorders	Inner ear disorders NEC	Meniere's disease	1	0
		Inner ear signs and symptoms	Tinnitus	3	0
			Vertigo	2	0
Eye disorders	Eye disorders NEC	Ocular disorders NEC	Eye pain	1	0
			Eye swelling	1	0
			Eyelid pain	1	0
	Ocular infections, irritations and inflammations	Lid, lash and lacrimal infections, irritations and inflammations	Swelling of eyelid	1	0
		Ocular infections, inflammations and associated manifestations	Eye inflammation	2	0
			Eye irritation	2	0
			Eye pruritus	1	0
Gastrointestinal disorders	Anal and rectal conditions NEC	Anal and rectal signs and symptoms	Rectal tenesmus	1	0
	Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	4	0
	Gastrointestinal signs and symptoms	Flatulence, bloating and distension	Abdominal distension	1	0
		Gastrointestinal and abdominal pains (excl oral and throat)	Abdominal pain upper	2	0
		Nausea and vomiting symptoms	Nausea	9	0
			Vomiting	5	0

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	Oral soft tissue conditions	Oral soft tissue signs and symptoms	Paraesthesia oral	2	0
	Tongue conditions	Tongue signs and symptoms	Swollen tongue	1	0
General disorders and administration site conditions	Administration site reactions	Administration site reactions NEC	Administration site bruise	1	0
			Administration site joint erythema	1	0
		Injection site reactions	Injection site erythema	2	0
			Injection site inflammation	2	0
			Injection site mass	1	0
			Injection site pain	1	0
			Injection site swelling	1	0
		Vaccination site reactions	Shoulder injury related to vaccine administration	1	0
			Vaccination site erythema	4	0
			Vaccination site inflammation	1	0
			Vaccination site irritation	1	0
			Vaccination site nodule	1	0
			Vaccination site pain	10	0
			Vaccination site pruritus	2	0
			Vaccination site reaction	1	0
			Vaccination site swelling	7	0
			Vaccination site urticaria	1	0
			Vaccination site warmth	1	0
	Body temperature conditions	Febrile disorders	Pyrexia	5	0
	Fatal outcomes	Death and sudden death	Brain death	1	1
	General system disorders NEC	Asthenic conditions	Asthenia	3	0
			Fatigue	16	0
			Malaise	14	0
		Feelings and sensations NEC	Chills	1	0
			Feeling abnormal	3	0

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		General signs and symptoms NEC	Influenza like illness	2	0
			Multiple organ dysfunction syndrome	1	0
			Peripheral swelling	6	0
			Secretion discharge	1	0
			Swelling	5	0
			Swelling face	1	0
		Pain and discomfort NEC	Chest discomfort	2	0
			Facial pain	1	0
			Pain	7	0
	Therapeutic and nontherapeutic effects (excl toxicity)	Therapeutic and nontherapeutic responses	Adverse drug reaction	1	0
Immune system disorders	Allergic conditions	Allergic conditions NEC	Hypersensitivity	1	0
		Anaphylactic and anaphylactoid responses	Anaphylactic reaction	2	0
			Anaphylactic shock	3	0
Infections and infestations	Infections - pathogen unspecified	Ear infections	Labyrinthitis	1	0
		Sepsis, bacteraemia, viraemia and fungaemia NEC	Septic shock	1	0
Injury, poisoning and procedural complications	Injuries NEC	Cerebral injuries NEC	Brain herniation	1	0
		Skin injuries NEC	Contusion	4	0
	Medication errors and other product use errors and issues	Medication errors, product use errors and issues NEC	Medication error	1	0
			Product use issue	1	0
		Product administration errors and issues	Product administration error	1	0
Investigations	Physical examination and organ system status topics	Physical examination procedures and organ system status	Body temperature increased	1	0
Metabolism and nutrition disorders	Appetite and general nutritional disorders	Appetite disorders	Decreased appetite	1	0
	Glucose metabolism disorders (incl diabetes mellitus)	Hypoglycaemic conditions NEC	Hypoglycaemia	1	0
Musculoskeletal and connective tissue disorders	Bone disorders (excl congenital and fractures)	Bone related signs and symptoms	Bone pain	1	0

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	Joint disorders	Joint related signs and symptoms	Arthralgia	3	0
			Joint swelling	1	0
	Muscle disorders	Muscle pains	Myalgia	6	0
	Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue conditions NEC	Musculoskeletal stiffness	1	0
		Musculoskeletal and connective tissue pain and discomfort	Limb discomfort	1	0
			Musculoskeletal discomfort	1	0
			Neck pain	2	0
			Pain in extremity	3	0
Nervous system disorders	Central nervous system vascular disorders	Central nervous system haemorrhages and cerebrovascular accidents	Ischaemic stroke	1	0
	Cranial nerve disorders (excl neoplasms)	Trigeminal disorders	Trigeminal neuralgia	1	0
	Headaches	Headaches NEC	Headache	16	0
		Migraine headaches	Migraine	1	0
	Movement disorders (incl parkinsonism)	Paralysis and paresis (excl cranial nerve)	Paralysis	1	0
	Neurological disorders NEC	Coordination and balance disturbances	Balance disorder	3	0
		Disturbances in consciousness NEC	Lethargy	1	0
			Syncope	3	0
		Neurological signs and symptoms NEC	Dizziness	8	0
			Head discomfort	2	0
			Presyncope	2	0
		Paraesthesias and dysaesthesias	Hypoaesthesia	1	0
			Paraesthesia	4	0
		Sensory abnormalities NEC	Dysgeusia	1	0
			Neuralgia	1	0
			Taste disorder	1	0
	Seizures (incl subtypes)	Absence seizures	Petit mal epilepsy	1	0

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		Seizures and seizure disorders NEC	Epilepsy	1	0
Psychiatric disorders	Sleep disorders and disturbances	Disturbances in initiating and maintaining sleep	Insomnia	1	0
Renal and urinary disorders	Urinary tract signs and symptoms	Urinary tract signs and symptoms NEC	Renal pain	1	0
Reproductive system and breast disorders	Breast disorders	Breast signs and symptoms	Breast swelling	1	0
Respiratory, thoracic and mediastinal disorders	Bronchial disorders (excl neoplasms)	Bronchospasm and obstruction	Wheezing	3	0
	Respiratory disorders NEC	Breathing abnormalities	Dyspnoea	2	0
	Respiratory tract signs and symptoms	Upper respiratory tract signs and symptoms	Oropharyngeal pain	2	0
	Upper respiratory tract disorders (excl infections)	Pharyngeal disorders (excl infections and neoplasms)	Pharyngeal hypoaesthesia	1	0
Skin and subcutaneous tissue disorders	Angioedema and urticaria	Urticarias	Urticaria	1	0
	Epidermal and dermal conditions	Dermal and epidermal conditions NEC	Skin reaction	2	0
			Skin warm	2	0
		Dermatitis and eczema	Dermatitis allergic	1	0
		Erythemas	Erythema	6	0
		Pruritus NEC	Pruritus	9	0
		Rashes, eruptions and exanthems NEC	Rash	9	0
			Rash erythematous	1	0
			Rash papular	1	0
	Skin and subcutaneous tissue disorders NEC	Skin and subcutaneous conditions NEC	Skin mass	1	0
	Skin appendage conditions	Apocrine and eccrine gland disorders	Cold sweat	1	0
			Hyperhidrosis	1	0
Vascular disorders	Decreased and nonspecific blood pressure disorders and shock	Vascular hypotensive disorders	Hypotension	2	0
	Vascular disorders NEC	Peripheral vascular disorders NEC	Flushing	1	0
			Hot flush	2	0
		Site specific vascular disorders NEC	Pallor	2	0

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Total				114	2