

| Reaction MedDRA SOC Name | Reaction MedDRA HLGHT 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 | Lymphadenopathy | 2 | 0 |
| Ear and labyrinth disorders | Aural disorders NEC | Ear disorders NEC | Ear pain | 1 | 0 |
| | | | Ear swelling | 1 | 0 |
| Eye disorders | Eye disorders NEC | Lacrimation disorders | Lacrimation increased | 1 | 0 |
| | | Ocular disorders NEC | Eye pain | 2 | 0 |
| | Eye swelling | | 1 | 0 | |
| | Ocular infections, irritations and inflammations | Lid, lash and lacrimal infections, irritations and inflammations | Erythema of eyelid | 1 | 0 |
| | | | Eyelid oedema | 1 | 0 |
| | | Ocular infections, inflammations and associated manifestations | Eye pruritus | 2 | 0 |
| | Ocular hyperaemia | | 2 | 0 | |
| | Ocular neuromuscular disorders | Eyelid movement disorders | Excessive eye blinking | 1 | 0 |
| Vision disorders | Visual impairment and blindness (excl colour blindness) | Visual impairment | 1 | 0 | |
| Gastrointestinal disorders | Gastrointestinal motility and defaecation conditions | Diarrhoea (excl infective) | Diarrhoea | 5 | 0 |
| | Gastrointestinal signs and symptoms | Dyspeptic signs and symptoms | Eructation | 1 | 0 |
| | | Flatulence, bloating and distension | Flatulence | 1 | 0 |
| | | Gastrointestinal and abdominal pains (excl oral and throat) | Abdominal pain | 2 | 0 |
| | | | Abdominal pain upper | 6 | 0 |
| | | Gastrointestinal signs and symptoms NEC | Abdominal discomfort | 4 | 0 |
| | Nausea and vomiting symptoms | Nausea | 8 | 0 | |
| | | Vomiting | 17 | 0 | |
| Tongue conditions | Tongue signs and symptoms | Protrusion tongue | 1 | 0 | |
| General disorders and administration site conditions | Body temperature conditions | Febrile disorders | Pyrexia | 26 | 0 |
| | Fatal outcomes | Death and sudden death | Death | 1 | 1 |
| | General system disorders NEC | Asthenic conditions | Asthenia | 6 | 0 |
| | | | Fatigue | 8 | 0 |
| | | | Malaise | 14 | 0 |

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|--|--|--|------------------------------------|-------|-------|
| | | Feelings and sensations NEC | Chills | 4 | 0 |
| | | | Feeling abnormal | 2 | 0 |
| | | | Feeling cold | 1 | 0 |
| | | | Feeling hot | 1 | 0 |
| | | | Feeling of body temperature change | 1 | 0 |
| | | General signs and symptoms NEC | Glassy eyes | 1 | 0 |
| | | | Influenza like illness | 3 | 0 |
| | | | Secretion discharge | 1 | 0 |
| | | Pain and discomfort NEC | Chest discomfort | 1 | 0 |
| | | | Chest pain | 2 | 0 |
| | | | Pain | 4 | 0 |
| Therapeutic and nontherapeutic effects (excl toxicity) | Therapeutic and nontherapeutic responses | Adverse drug reaction | 3 | 0 | |
| Immune system disorders | Allergic conditions | Allergic conditions NEC | Hypersensitivity | 2 | 0 |
| | | | Reaction to excipient | 1 | 0 |
| | | Anaphylactic and anaphylactoid responses | Anaphylactic reaction | 1 | 0 |
| | | | Anaphylactic shock | 1 | 0 |
| Infections and infestations | Ancillary infectious topics | Infectious transmissions | Infection via vaccinee | 1 | 0 |
| | Bacterial infectious disorders | Streptococcal infections | Scarlet fever | 1 | 0 |
| | Infections - pathogen unspecified | Central nervous system and spinal infections | Myelitis | 1 | 0 |
| | | | Conjunctivitis | 1 | 0 |
| | | Lower respiratory tract and lung infections | Lower respiratory tract infection | 1 | 0 |
| | | | Pneumonia | 1 | 0 |
| | | Upper respiratory tract infections | Nasopharyngitis | 1 | 0 |
| | Rhinitis | | 1 | 0 | |
| | Viral infectious disorders | Herpes viral infections | Oral herpes | 1 | 0 |

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| Injury, poisoning and procedural complications | Injuries NEC | Non-site specific injuries NEC | Fall | 1 | 0 |
| | Medication errors and other product use errors and issues | Medication errors, product use errors and issues NEC | Medication error | 2 | 0 |
| Investigations | Physical examination and organ system status topics | Physical examination procedures and organ system status | Body temperature abnormal | 1 | 0 |
| | | | Body temperature increased | 2 | 0 |
| Metabolism and nutrition disorders | Appetite and general nutritional disorders | Appetite disorders | Decreased appetite | 9 | 0 |
| Musculoskeletal and connective tissue disorders | Bone disorders (excl congenital and fractures) | Bone related signs and symptoms | Bone pain | 1 | 0 |
| | Joint disorders | Joint related signs and symptoms | Arthralgia | 1 | 0 |
| | Muscle disorders | Muscle pains | Myalgia | 8 | 0 |
| | | Muscle related signs and symptoms NEC | Muscle twitching | 2 | 0 |
| | | Muscle weakness conditions | Muscular weakness | 2 | 0 |
| | Musculoskeletal and connective tissue disorders NEC | Musculoskeletal and connective tissue conditions NEC | Musculoskeletal stiffness | 1 | 0 |
| Musculoskeletal and connective tissue pain and discomfort | | Pain in extremity | 2 | 0 | |
| Nervous system disorders | Cranial nerve disorders (excl neoplasms) | Facial cranial nerve disorders | Bell's palsy | 1 | 0 |
| | Demyelinating disorders | Demyelinating disorders NEC | Acute disseminated encephalomyelitis | 1 | 0 |
| | Headaches | Headaches NEC | Headache | 26 | 0 |
| | | | Sinus headache | 1 | 0 |
| | Movement disorders (incl parkinsonism) | Dystonias | Opisthotonus | 1 | 0 |
| | Neurological disorders NEC | Disturbances in consciousness NEC | Lethargy | 4 | 0 |
| | | | Somnolence | 4 | 0 |
| | | | Syncope | 7 | 0 |
| Neurological signs and symptoms NEC | | Dizziness | 13 | 0 | |
| | | Unresponsive to stimuli | 2 | 0 | |
| Paraesthesias and dysaesthesias | Paraesthesia | 1 | 0 | | |
| Sensory abnormalities NEC | Dysgeusia | 1 | 0 | | |

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| | | | Sensory disturbance | 1 | 0 |
| | Peripheral neuropathies | Acute polyneuropathies | Guillain-Barre syndrome | 1 | 0 |
| | | Mononeuropathies | Ulnar nerve palsy | 1 | 0 |
| | Seizures (incl subtypes) | Seizures and seizure disorders NEC | Febrile convulsion | 3 | 0 |
| | | | Partial seizures | 2 | 0 |
| | | | Seizure | 2 | 0 |
| Psychiatric disorders | Anxiety disorders and symptoms | Anxiety symptoms | Anxiety | 1 | 0 |
| | Changes in physical activity | Tic disorders | Tic | 1 | 0 |
| | Depressed mood disorders and disturbances | Mood alterations with depressive symptoms | Tearfulness | 1 | 0 |
| | Disturbances in thinking and perception | Thinking disturbances | Thinking abnormal | 1 | 0 |
| | Mood disorders and disturbances NEC | Emotional and mood disturbances NEC | Irritability | 1 | 0 |
| | Personality disorders and disturbances in behaviour | Behaviour and socialisation disturbances | Aggression | 1 | 0 |
| | Psychiatric and behavioural symptoms NEC | Abnormal behaviour NEC | Abnormal behaviour | 1 | 0 |
| | | | Behaviour disorder | 1 | 0 |
| | Psychiatric disorders NEC | Psychiatric elimination disorders | Enuresis | 1 | 0 |
| | Sleep disorders and disturbances | Disturbances in initiating and maintaining sleep | Insomnia | 1 | 0 |
| Parasomnias | | | Sleep terror | 1 | 0 |
| Sleep disorders NEC | | | Sleep disorder | 1 | 0 |
| Respiratory, thoracic and mediastinal disorders | Bronchial disorders (excl neoplasms) | Bronchospasm and obstruction | Wheezing | 2 | 0 |
| | Respiratory disorders NEC | Coughing and associated symptoms | Cough | 8 | 0 |
| | Respiratory tract signs and symptoms | Upper respiratory tract signs and symptoms | Dysphonia | 1 | 0 |
| | | | Oropharyngeal pain | 10 | 0 |
| | | | Rhinorrhoea | 15 | 0 |
| | | | Sneezing | 2 | 0 |
| | Upper respiratory tract disorders (excl infections) | Nasal congestion and inflammations | Nasal congestion | 5 | 0 |
| Nasal disorders NEC | | Epistaxis | 16 | 0 | |

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| Skin and subcutaneous tissue disorders | Angioedema and urticaria | Angioedemas | Angioedema | 1 | 0 | |
| | | Urticarias | Urticaria | 5 | 0 | |
| | Epidermal and dermal conditions | Bullous conditions | Blister | 1 | 0 | |
| | | Dermatitis and eczema | Eczema | 1 | 0 | |
| | | Erythemas | Erythema | 7 | 0 | |
| | | Pruritus NEC | Pruritus | 3 | 0 | |
| | | Rashes, eruptions and exanthems NEC | Rash | Rash | 12 | 0 |
| | | | Rash erythematous | Rash erythematous | 1 | 0 |
| | | | Rash macular | Rash macular | 3 | 0 |
| | Rash pruritic | | Rash pruritic | 3 | 0 | |
| | Skin appendage conditions | Alopecias | Alopecia areata | 1 | 0 | |
| | | Apocrine and eccrine gland disorders | Cold sweat | Cold sweat | 2 | 0 |
| | | | Hyperhidrosis | Hyperhidrosis | 2 | 0 |
| | Skin vascular abnormalities | Purpura and related conditions | Henoch-Schonlein purpura | 1 | 0 | |
| Purpura | | | 1 | 0 | | |
| Surgical and medical procedures | Therapeutic procedures and supportive care NEC | Therapeutic procedures NEC | Hospitalisation | 2 | 0 | |
| Vascular disorders | Vascular disorders NEC | Peripheral vascular disorders NEC | Flushing | 6 | 0 | |
| | | | Hot flush | 1 | 0 | |
| | | Site specific vascular disorders NEC | Pallor | 8 | 0 | |
| Total | | | | 141 | 1 | |