

Engerix B Vaccine Analysis Print (VAP)

All UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with the Engerix B vaccine up to and including 27/04/2025

| Reaction MedDRA SOC Name | Reaction MedDRA HLT Name | Reaction MedDRA HLT Name | Reaction MedDRA PT Name | Total | Fatal |
|--|--|--------------------------------|------------------------------------|------------------|-------|
| Blood and lymphatic system disorders | Anaemias nonhaemolytic and marrow depression | Anaemia deficiencies | Iron deficiency anaemia | 1 | 0 |
| | | Anaemias NEC | Anaemia | 4 | 0 |
| | Haemolyses and related conditions | Anaemias haemolytic immune | Autoimmune haemolytic anaemia | 1 | 0 |
| | | | Coombs positive haemolytic anaemia | 1 | 0 |
| | | Anaemias haemolytic NEC | Haemolytic anaemia | 4 | 0 |
| | | Haemolyses NEC | Jaundice acholuric | 1 | 0 |
| | Platelet disorders | Platelet disorders NEC | Platelet disorder | 1 | 0 |
| | | Thrombocytopenias | Immune thrombocytopenia | 4 | 0 |
| | | | Thrombocytopenia | 7 | 0 |
| | Spleen, lymphatic and reticuloendothelial system disorders | Lymphatic system disorders NEC | Hilar lymphadenopathy | 1 | 0 |
| | | | Lymph node pain | 1 | 0 |
| | | | Lymphadenitis | 3 | 0 |
| | | | Lymphadenopathy | 60 | 0 |
| | | | Pseudolymphoma | 1 | 0 |
| | | Spleen disorders | Splenomegaly | 2 | 0 |
| | White blood cell disorders | Eosinophilic disorders | Eosinophilia | 2 | 0 |
| | | Leukocytoses NEC | Leukaemoid reaction | 1 | 0 |
| | | | Lymphocytosis | 1 | 0 |
| | | Leukopenias NEC | Leukopenia | 2 | 0 |
| | | | Lymphopenia | 1 | 0 |
| | | Neutropenias | Agranulocytosis | 1 | 0 |
| | | | Autoimmune neutropenia | 1 | 0 |
| | | | Granulocytopenia | 2 | 0 |
| | | | Neutropenia | 2 | 0 |
| | Cardiac disorders | Cardiac arrhythmias | Cardiac conduction disorders | Long QT syndrome | 1 |
| | | | Wolff-Parkinson-White syndrome | 1 | 0 |
| Rate and rhythm disorders NEC | | | Arrhythmia | 2 | 0 |
| | | | Bradycardia | 5 | 0 |
| | | | Extrasystoles | 4 | 0 |
| | | | Tachycardia | 27 | 0 |
| Supraventricular arrhythmias | | | Atrial fibrillation | 1 | 0 |
| | | | Sinus bradycardia | 1 | 0 |
| | | | Sinus tachycardia | 1 | 0 |
| | | | Supraventricular tachycardia | 1 | 0 |
| Ventricular arrhythmias and cardiac arrest | | | Cardiac arrest | 3 | 1 |
| | | | Ventricular extrasystoles | 1 | 0 |
| Cardiac disorders, signs and symptoms | | Cardiac disorders NEC | Cardiac disorder | 1 | 0 |

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|--|---|---|-----------------------------|----|---|
| | NEC | Cardiac signs and symptoms NEC | Palpitations | 23 | 0 |
| | Coronary artery disorders | Ischaemic coronary artery disorders | Angina pectoris | 1 | 0 |
| | | | Myocardial infarction | 2 | 0 |
| | Heart failures | Left ventricular failures | Left ventricular failure | 1 | 0 |
| | Myocardial disorders | Cardiomyopathies | Cardiomyopathy | 1 | 0 |
| | | | Dilated cardiomyopathy | 1 | 0 |
| | | Noninfectious myocarditis | Myocarditis | 1 | 0 |
| Congenital, familial and genetic disorders | Pericardial disorders | Noninfectious pericarditis | Pericarditis | 1 | 0 |
| | Chromosomal abnormalities, gene alterations and gene variants | Autosomal chromosomal abnormalities | Trisomy 21 | 1 | 0 |
| | Congenital and hereditary disorders NEC | Congenital disorders NEC | Congenital anomaly | 1 | 0 |
| | Ear and labyrinthine disorders congenital | Hearing disorders congenital | Deafness congenital | 1 | 0 |
| | Gastrointestinal tract disorders congenital | Intestinal disorders congenital | Intestinal atresia | 1 | 0 |
| | | Oral cavity disorders congenital NEC | Tethered oral tissue | 2 | 0 |
| | Metabolic and nutritional disorders congenital | Inborn errors of bilirubin metabolism | Gilbert's syndrome | 2 | 0 |
| Ear and labyrinth disorders | Musculoskeletal and connective tissue disorders congenital | Musculoskeletal and connective tissue disorders of limbs congenital | Polydactyly | 1 | 0 |
| | Aural disorders NEC | Ear disorders NEC | Ear discomfort | 2 | 0 |
| | | | Ear pain | 7 | 0 |
| | Hearing disorders | Hearing losses | Deafness | 3 | 0 |
| | | | Deafness neurosensory | 2 | 0 |
| | | | Deafness transitory | 1 | 0 |
| | | | Hypoacusis | 1 | 0 |
| | | | Sudden hearing loss | 1 | 0 |
| | Inner ear and VIIIth cranial nerve disorders | Inner ear disorders NEC | Inner ear disorder | 1 | 0 |
| | | | Vestibular disorder | 1 | 0 |
| | | Inner ear signs and symptoms | Tinnitus | 15 | 0 |
| | | | Vertigo | 27 | 0 |
| Endocrine disorders | Thyroid gland disorders | Acute and chronic thyroiditis | Autoimmune thyroiditis | 1 | 0 |
| | | Thyroid disorders NEC | Thyroid disorder | 3 | 0 |
| | | Thyroid hypofunction disorders | Hypothyroidism | 5 | 0 |
| | | | Myxoedema | 1 | 0 |
| | Anterior eye structural change, deposit and degeneration | Conjunctival structural change, deposit and degeneration | Conjunctival discolouration | 2 | 0 |
| | Eye disorders NEC | Lacrimation disorders | Dry eye | 3 | 0 |
| | | | Lacrimation increased | 1 | 0 |
| | | Ocular disorders NEC | Eye disorder | 3 | 0 |
| | | | Eye oedema | 1 | 0 |
| | | | Eye pain | 20 | 0 |
| | | | Eye swelling | 26 | 0 |
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Eye disorders

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|--|--|---------------------------|----|---|
| | | Eyelid disorder | 1 | 0 |
| | | Periorbital oedema | 10 | 0 |
| | | Periorbital swelling | 3 | 0 |
| Ocular infections, irritations and inflammations | Corneal infections, oedemas and inflammations | Keratitis | 1 | 0 |
| | | | | |
| | Iris and uveal tract infections, irritations and inflammations | Iridocyclitis | 3 | 0 |
| | | Iritis | 2 | 0 |
| | | Uveitis | 3 | 0 |
| | Lid, lash and lacrimal infections, irritations and inflammations | Eyelid oedema | 1 | 0 |
| | | Eyelid rash | 1 | 0 |
| | | Swelling of eyelid | 6 | 0 |
| | Ocular infections, inflammations and associated manifestations | Eye discharge | 1 | 0 |
| | | Eye irritation | 2 | 0 |
| | | Eye pruritus | 5 | 0 |
| | | Ocular hyperaemia | 7 | 0 |
| Ocular neuromuscular disorders | Ocular nerve and muscle disorders | Eye movement disorder | 2 | 0 |
| | Pupil disorders | Miosis | 2 | 0 |
| | | Mydriasis | 3 | 0 |
| Ocular sensory symptoms NEC | Ocular sensation disorders | Abnormal sensation in eye | 2 | 0 |
| | | Photophobia | 17 | 0 |
| Ocular structural change, deposit and degeneration NEC | Choroid and vitreous structural change, deposit and degeneration | Vitreous floaters | 2 | 0 |
| | Optic disc abnormalities NEC | Papilloedema | 1 | 0 |
| | Retinal structural change, deposit and degeneration | Retinal pigmentation | 1 | 0 |
| Retina, choroid and vitreous haemorrhages and vascular disorders | Retinal bleeding and vascular disorders (excl retinopathy) | Retinal haemorrhage | 1 | 0 |
| | | Retinal vein occlusion | 2 | 0 |
| | Retinopathies NEC | Retinopathy | 1 | 0 |
| Vision disorders | Refractive and accommodative disorders | Accommodation disorder | 1 | 0 |
| | | | | |
| | Visual colour distortions | Xanthopsia | 1 | 0 |
| | | | | |
| | Visual disorders NEC | Diplopia | 6 | 0 |
| | | Photopsia | 4 | 0 |
| | | Vision blurred | 29 | 0 |
| | Visual impairment and blindness (excl colour blindness) | Blindness | 3 | 0 |
| | | Blindness transient | 3 | 0 |
| Visual acuity reduced | | 1 | 0 | |
| Visual impairment | | 30 | 0 | |
| Abdominal hernias and other abdominal wall conditions | Diaphragmatic hernias | Hiatus hernia | 2 | 0 |
| Anal and rectal conditions NEC | Anal and rectal signs and symptoms | Rectal tenesmus | 1 | 0 |
| | Dental pain and sensation disorders | Toothache | 1 | 0 |

Gastrointestinal disorders

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|--|---|--------------------------------------|-----|---|
| Dental and gingival conditions | Gingival disorders, signs and symptoms NEC | Gingival blister | 1 | 0 |
| | | Gingival swelling | 1 | 0 |
| | | Gingival haemorrhages | 1 | 0 |
| Exocrine pancreas conditions | Acute and chronic pancreatitis | Gingival bleeding | 1 | 0 |
| | | Pancreatitis | 1 | 0 |
| Gastrointestinal conditions NEC | Gastrointestinal disorders NEC | Functional gastrointestinal disorder | 1 | 0 |
| | | Gastrointestinal disorder | 6 | 0 |
| | | Stomach mass | 1 | 0 |
| Gastrointestinal haemorrhages NEC | Intestinal haemorrhages | Rectal haemorrhage | 1 | 0 |
| | Non-site specific gastrointestinal haemorrhages | Haematochezia | 2 | 0 |
| Gastrointestinal inflammatory conditions | Colitis (excl infective) | Colitis | 1 | 0 |
| | | Colitis ulcerative | 1 | 0 |
| | | Crohn's disease | 2 | 0 |
| | | Inflammatory bowel disease | 1 | 0 |
| | Oesophagitis (excl infective) | Oesophagitis | 1 | 0 |
| Gastrointestinal motility and defaecation conditions | Diarrhoea (excl infective) | Diarrhoea | 153 | 0 |
| | | Diarrhoea haemorrhagic | 3 | 0 |
| | Gastrointestinal atonic and hypomotility disorders NEC | Constipation | 4 | 0 |
| | Gastrointestinal spastic and hypermotility disorders | Defaecation urgency | 1 | 0 |
| | | Irritable bowel syndrome | 1 | 0 |
| | | Oesophageal spasm | 1 | 0 |
| Gastrointestinal signs and symptoms | Abdominal findings abnormal | Gastrointestinal sounds abnormal | 1 | 0 |
| | Dyspeptic signs and symptoms | Dyspepsia | 3 | 0 |
| | Faecal abnormalities NEC | Faeces discoloured | 2 | 0 |
| | | Faeces pale | 1 | 0 |
| | Flatulence, bloating and distension | Abdominal distension | 7 | 0 |
| | | Flatulence | 1 | 0 |
| | Gastrointestinal and abdominal pains (excl oral and throat) | Abdominal pain | 108 | 0 |
| | | Abdominal pain lower | 2 | 0 |
| | | Abdominal pain upper | 42 | 0 |
| | Gastrointestinal signs and symptoms NEC | Abdominal discomfort | 7 | 0 |
| | | Anal incontinence | 1 | 0 |
| | | Dysphagia | 13 | 0 |
| | Nausea and vomiting symptoms | Nausea | 421 | 0 |
| | | Retching | 2 | 0 |
| | | Vomiting | 232 | 0 |
| Gastrointestinal ulceration and perforation | Duodenal ulcers and perforation | Duodenal ulcer | 1 | 0 |
| | Oral soft tissue disorders NEC | Cheilitis | 1 | 0 |
| | | Lip blister | 3 | 0 |
| | | Oral lichen planus | 1 | 0 |

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| | Oral soft tissue conditions | Oral soft tissue haemorrhages | Mouth haemorrhage | 1 | 0 |
| | | Oral soft tissue signs and symptoms | Anaesthesia oral | 1 | 0 |
| | | | Hypoaesthesia oral | 7 | 0 |
| | | | Oral mucosal blistering | 2 | 0 |
| | | | Oral pain | 2 | 0 |
| | | | Paraesthesia oral | 15 | 0 |
| | | Oral soft tissue swelling and oedema | Lip oedema | 1 | 0 |
| | | | Lip swelling | 30 | 0 |
| | | | Mouth swelling | 5 | 0 |
| | | Stomatitis and ulceration | Lip ulceration | 2 | 0 |
| | | | Mouth ulceration | 6 | 0 |
| | | | Stomatitis | 1 | 0 |
| | Salivary gland conditions | Oral dryness and saliva altered | Dry mouth | 13 | 0 |
| | | | Lip dry | 1 | 0 |
| | | Salivary gland disorders NEC | Salivary gland pain | 1 | 0 |
| | | Salivary gland enlargements | Salivary gland enlargement | 2 | 0 |
| | Tongue conditions | Tongue disorders | Tongue disorder | 1 | 0 |
| | | Tongue signs and symptoms | Glossodynia | 2 | 0 |
| | | | Swollen tongue | 17 | 0 |
| | | | Tongue blistering | 1 | 0 |
| | | | Tongue coated | 1 | 0 |
| | | | Tongue discomfort | 1 | 0 |
| | | | Tongue oedema | 1 | 0 |
| | | Administration site reactions NEC | Administration site erythema | 1 | 0 |
| | | | Administration site papule | 1 | 0 |
| | | | Administration site rash | 3 | 0 |
| | | Application and instillation site reactions | Application site reaction | 1 | 0 |
| | | Application site reactions | Application site reaction | 1 | 0 |
| | | Injection site reactions | Injection site atrophy | 2 | 0 |
| | | | Injection site dermatitis | 1 | 0 |
| | | | Injection site discharge | 1 | 0 |
| | | | Injection site erythema | 7 | 0 |
| | | | Injection site exfoliation | 1 | 0 |
| | | | Injection site haematoma | 1 | 0 |
| | | | Injection site haemorrhage | 1 | 0 |
| | | | Injection site hypersensitivity | 1 | 0 |
| | | | Injection site hypoaesthesia | 2 | 0 |
| | | | Injection site induration | 2 | 0 |
| | | | Injection site inflammation | 34 | 0 |
| | | | Injection site mass | 6 | 0 |
| | | | Injection site nodule | 1 | 0 |

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| General disorders and administration site conditions | Administration site reactions | Injection site reactions | Injection site pain | 62 | 0 |
| | | | Injection site pruritus | 2 | 0 |
| | | | Injection site rash | 12 | 0 |
| | | | Injection site reaction | 112 | 0 |
| | | | Injection site scar | 1 | 0 |
| | | | Injection site swelling | 9 | 0 |
| | | | Injection site vesicles | 1 | 0 |
| | | | Injection site warmth | 5 | 0 |
| | | Vaccination site reactions | Vaccination site bruising | 4 | 0 |
| | | | Vaccination site discomfort | 1 | 0 |
| | | | Vaccination site erythema | 3 | 0 |
| | | | Vaccination site haemorrhage | 1 | 0 |
| | | | Vaccination site hypoaesthesia | 1 | 0 |
| | | | Vaccination site induration | 1 | 0 |
| | | | Vaccination site joint erythema | 1 | 0 |
| | | | Vaccination site mass | 4 | 0 |
| | | | Vaccination site movement impairment | 1 | 0 |
| | | | Vaccination site pain | 12 | 0 |
| | | | Vaccination site paraesthesia | 1 | 0 |
| | | | Vaccination site pruritus | 1 | 0 |
| | | | Vaccination site rash | 1 | 0 |
| | | | Vaccination site swelling | 5 | 0 |
| | | | Vaccination site vesicles | 1 | 0 |
| | | | Vaccination site warmth | 1 | 0 |
| | Body temperature conditions | Febrile disorders | Pyrexia | 306 | 0 |
| | Fatal outcomes | Death and sudden death | Death | 2 | 2 |
| | | | Sudden infant death syndrome | 1 | 1 |
| | | Asthenic conditions | Asthenia | 60 | 0 |
| | | | Chronic fatigue syndrome | 25 | 0 |
| | | | Fatigue | 227 | 0 |
| | | | Malaise | 363 | 0 |
| | | Feelings and sensations NEC | Chills | 69 | 0 |
| | | | Feeling abnormal | 27 | 0 |
| | | | Feeling cold | 14 | 0 |
| | | | Feeling drunk | 3 | 0 |
| | | | Feeling hot | 39 | 0 |
| | | | Feeling of body temperature change | 17 | 0 |
| | | | Temperature intolerance | 1 | 0 |
| | | | Thirst | 5 | 0 |
| | | Gait disturbances | Gait disturbance | 14 | 0 |
| | | | Gait inability | 1 | 0 |

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|--|--|--|--|---|--|---------------------------------------|-----|---|
| | | | | | | Loss of control of legs | 1 | 0 |
| | | | | | | Condition aggravated | 5 | 0 |
| | | | | | | Crying | 6 | 0 |
| | | | | | | Developmental delay | 1 | 0 |
| | | | | | | General physical health deterioration | 1 | 0 |
| | | | | | | Ill-defined disorder | 3 | 0 |
| | | | | | | Illness | 11 | 0 |
| | | | | | | Induration | 1 | 0 |
| | | | | | | Influenza like illness | 358 | 0 |
| | | | | | | Local reaction | 45 | 0 |
| | | | | | | Nonspecific reaction | 1 | 0 |
| | | | | | | Peripheral swelling | 68 | 0 |
| | | | | | | Swelling | 38 | 0 |
| | | | | | | Swelling face | 42 | 0 |
| | | | | | Inflamations | Inflammation | 14 | 0 |
| | | | | | Oedema NEC | Face oedema | 12 | 0 |
| | | | | | | Generalised oedema | 1 | 0 |
| | | | | | | Gravitational oedema | 2 | 0 |
| | | | | | | Oedema | 9 | 0 |
| | | | | | | Oedema peripheral | 23 | 0 |
| | | | | | Pain and discomfort NEC | Axillary pain | 3 | 0 |
| | | | | | | Chest discomfort | 39 | 0 |
| | | | | | | Chest pain | 58 | 0 |
| | | | | | | Discomfort | 7 | 0 |
| | | | | | | Facial pain | 4 | 0 |
| | | | | | | Non-cardiac chest pain | 1 | 0 |
| | | | | | | Pain | 117 | 0 |
| | | | | | | Tenderness | 4 | 0 |
| | | | | Therapeutic and nontherapeutic effects (excl toxicity) | Interactions | Alcohol interaction | 1 | 0 |
| | | | | | | Drug interaction | 1 | 0 |
| | | | | | Therapeutic and nontherapeutic responses | Adverse drug reaction | 2 | 0 |
| | | | | | | Adverse event | 1 | 0 |
| | | | | | | Drug ineffective | 4 | 0 |
| | | | | | | Therapeutic response decreased | 6 | 0 |
| | | | | | | Therapy non-responder | 11 | 0 |
| | | | | | | Vaccination failure | 4 | 0 |
| | | | | Tissue disorders NEC | Healing abnormal NEC | Impaired healing | 1 | 0 |
| | | | | Bile duct disorders | Bile duct infections and inflammations | Biliary colic | 2 | 0 |
| | | | | Gallbladder disorders | Cholecystitis and cholelithiasis | Cholelithiasis | 1 | 0 |
| | | | | | Cholestasis and jaundice | Cholestasis | 1 | 0 |
| | | | | | | Hepatitis cholestatic | 1 | 0 |

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|-----------------------------|-------------------------------------|---|--------------------------------------|---------------------------|---|---|
| Hepatobiliary disorders | Hepatic and hepatobiliary disorders | Cholestasis and jaundice | Hyperbilirubinaemia | 3 | 0 | |
| | | | Jaundice | 32 | 1 | |
| | | Hepatic and hepatobiliary disorders NEC | Hepatic cyst | 1 | 0 | |
| | | | Liver disorder | 1 | 0 | |
| | | Hepatic enzymes and function abnormalities | Hepatic function abnormal | 6 | 0 | |
| | | Hepatic fibrosis and cirrhosis | Hepatic cirrhosis | 1 | 0 | |
| | | Hepatobiliary signs and symptoms | Hepatic pain | 2 | 0 | |
| | | | Hepatomegaly | 1 | 0 | |
| | | | Liver tenderness | 2 | 0 | |
| | | Hepatocellular damage and hepatitis NEC | Autoimmune hepatitis | 2 | 0 | |
| | | | Hepatitis | 5 | 0 | |
| | | | Hepatitis acute | 2 | 0 | |
| | | | Hepatitis fulminant | 1 | 0 | |
| Immune system disorders | Allergic conditions | Allergic conditions NEC | Allergic oedema | 2 | 0 | |
| | | | Hypersensitivity | 52 | 0 | |
| | | | Serum sickness | 3 | 0 | |
| | | Allergies to foods, food additives, drugs and other chemicals | Allergy to vaccine | 2 | 0 | |
| | | | Drug hypersensitivity | 1 | 0 | |
| | | | Food allergy | 2 | 0 | |
| | | | Reaction to excipient | 1 | 0 | |
| | | Anaphylactic and anaphylactoid responses | Anaphylactic reaction | 53 | 0 | |
| | | | Anaphylactic shock | 4 | 0 | |
| | | | Anaphylactoid reaction | 11 | 0 | |
| | | Autoimmune disorders | Autoimmune disorders NEC | Autoimmune disorder | 1 | 0 |
| | | Immune disorders NEC | Acute and chronic sarcoidosis | Sarcoidosis | 3 | 0 |
| | | | Immune and associated conditions NEC | Immune system disorder | 1 | 0 |
| | Immunodeficiency syndromes | Immunodeficiency disorders NEC | Immunodeficiency | 1 | 0 | |
| | | Bacterial infectious disorders | Bacterial infections NEC | Bronchitis bacterial | 1 | 0 |
| | | | | Cellulitis | 5 | 0 |
| | | | | Folliculitis | 1 | 0 |
| | | | | Injection site cellulitis | 1 | 0 |
| | | | Staphylococcal infections | Furuncle | 2 | 0 |
| Fungal infectious disorders | | Candida infections | Oral candidiasis | 1 | 0 | |
| | | Fungal infections NEC | Fungal infection | 1 | 0 | |
| | | Abdominal and gastrointestinal infections | Diverticulitis | 2 | 0 | |
| | | | Gastroenteritis | 1 | 0 | |
| | | Central nervous system and spinal infections | Encephalitis | 5 | 0 | |
| | | | Encephalomyelitis | 3 | 0 | |
| | | | Meningitis | 4 | 0 | |
| | | | Myelitis | 4 | 0 | |

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|-----------------------------|------------------------------------|---|-----------------------------------|----|---|
| Infections and infestations | Infections - pathogen unspecified | Dental and oral soft tissue infections | Parotitis | 3 | 0 |
| | | Ear infections | Labyrinthitis | 4 | 0 |
| | | Eye and eyelid infections | Conjunctivitis | 8 | 0 |
| | | Hepatobiliary and spleen infections | Liver abscess | 1 | 0 |
| | | Infections NEC | Infection | 1 | 0 |
| | | | Pyuria | 1 | 0 |
| | | Lower respiratory tract and lung infections | Bronchitis | 1 | 0 |
| | | | Lower respiratory tract infection | 7 | 0 |
| | | | Pneumonia | 3 | 0 |
| | | Muscle and soft tissue infections | Necrotising fasciitis | 1 | 0 |
| | | Sepsis, bacteraemia, viraemia and fungaemia NEC | Sepsis | 2 | 0 |
| | | | Septic rash | 1 | 0 |
| | | Skin structures and soft tissue infections | Infected dermal cyst | 1 | 0 |
| | | | Pustule | 1 | 0 |
| | | | Rash pustular | 4 | 0 |
| | | | Skin infection | 1 | 0 |
| | | | Subcutaneous abscess | 1 | 0 |
| | | Upper respiratory tract infections | Laryngitis | 6 | 0 |
| | | | Nasopharyngitis | 17 | 0 |
| | | | Pharyngitis | 11 | 0 |
| | | | Rhinitis | 11 | 0 |
| | | | Tonsillitis | 2 | 0 |
| | | | Tracheitis | 1 | 0 |
| | | | Upper respiratory tract infection | 4 | 0 |
| | | Urinary tract infections | Urinary tract infection | 2 | 0 |
| | Mycobacterial infectious disorders | Tuberculous infections | Tuberculosis | 1 | 0 |
| | Viral infectious disorders | Arenaviral infections | Choriomeningitis lymphocytic | 1 | 0 |
| | | Coronavirus infections | COVID-19 | 1 | 0 |
| | | Epstein-Barr viral infections | Infectious mononucleosis | 3 | 0 |
| | | Hepatitis virus infections | Chronic hepatitis B | 1 | 0 |
| | | | Hepatitis A | 1 | 0 |
| | | Herpes viral infections | Herpes simplex | 4 | 0 |
| | | | Herpes zoster | 5 | 0 |
| | | | Oral herpes | 1 | 0 |
| | | Influenza viral infections | Influenza | 5 | 0 |
| | | Rubeola viral infections | Measles | 1 | 0 |
| | | Viral infections NEC | Encephalitis viral | 1 | 1 |
| | | | Hepatitis viral | 1 | 0 |
| | | | Vestibular neuronitis | 3 | 0 |
| | | | Viral infection | 3 | 0 |
| | | | Exposure during pregnancy | 5 | 0 |

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|--|---|---|--|----|---|
| Injury, poisoning and procedural complications | Exposures, chemical injuries and poisoning | Exposures associated with pregnancy, delivery and lactation | Maternal exposure before pregnancy | 1 | 0 |
| | | | Maternal exposure during breast feeding | 1 | 0 |
| | | | Maternal exposure during pregnancy | 1 | 0 |
| | | | Maternal exposure timing unspecified | 1 | 0 |
| | Injuries by physical agents | Radiation injuries | Sunburn | 1 | 0 |
| | Injuries NEC | Abdominal and gastrointestinal injuries NEC | Mouth injury | 1 | 0 |
| | | | Splenic rupture | 1 | 0 |
| | | Non-site specific injuries NEC | Fall | 4 | 0 |
| | | Site specific injuries NEC | Head injury | 4 | 0 |
| | | Skin injuries NEC | Contusion | 15 | 0 |
| | | | Scar | 1 | 0 |
| | | | Skin abrasion | 1 | 0 |
| | | | Skin laceration | 1 | 0 |
| | Medication errors and other product use errors and issues | Product administration errors and issues | Accidental overdose | 1 | 0 |
| | | | Accidental underdose | 1 | 0 |
| | | | Expired product administered | 1 | 0 |
| | | | Extra dose administered | 1 | 0 |
| | | | Inappropriate schedule of product administration | 18 | 0 |
| | | | Incomplete course of vaccination | 6 | 0 |
| | | | Incorrect dose administered | 2 | 0 |
| | | | Incorrect route of product administration | 1 | 0 |
| | | | Lack of vaccination site rotation | 1 | 0 |
| | | | Product administered to patient of inappropriate age | 2 | 0 |
| | | | Product administration error | 1 | 0 |
| | Overdoses and underdoses NEC | Overdoses NEC | Intentional overdose | 1 | 0 |
| | | | Overdose | 1 | 0 |
| | | Underdoses NEC | Underdose | 2 | 0 |
| | Procedural related injuries and complications NEC | Non-site specific procedural complications | Injection related reaction | 1 | 0 |
| | | Vaccination related complications | Adverse event following immunisation | 1 | 0 |
| | | | Immunisation reaction | 3 | 0 |
| | Cardiac and vascular investigations (excl enzyme tests) | ECG investigations | Electrocardiogram PR shortened | 1 | 0 |
| | | | Electrocardiogram QT prolonged | 1 | 0 |
| | | | Electrocardiogram T wave inversion | 1 | 0 |
| | | Heart rate and pulse investigations | Heart rate decreased | 5 | 0 |
| | | | Heart rate increased | 12 | 0 |
| | | | Heart rate irregular | 5 | 0 |
| | | | Pulse abnormal | 5 | 0 |

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|------------------|---|---|---|----|---|
| Investigations | | Vascular tests NEC (incl blood pressure) | Blood pressure abnormal | 1 | 0 |
| | | | Blood pressure decreased | 7 | 0 |
| | | | Blood pressure diastolic decreased | 1 | 0 |
| | | | Blood pressure increased | 9 | 0 |
| | | | Blood pressure systolic normal | 1 | 0 |
| | Enzyme investigations NEC | Skeletal and cardiac muscle analyses | Blood creatine phosphokinase abnormal | 1 | 0 |
| | | | Blood creatine phosphokinase increased | 2 | 0 |
| | | Tissue enzyme analyses NEC | Blood alkaline phosphatase increased | 2 | 0 |
| | Haematology investigations (incl blood groups) | Blood counts NEC | Full blood count abnormal | 1 | 0 |
| | | Coagulation and bleeding analyses | Coagulation time prolonged | 1 | 0 |
| | | Haematological analyses NEC | Blood viscosity increased | 1 | 0 |
| | | | Red blood cell sedimentation rate abnormal | 1 | 0 |
| | | | Red blood cell sedimentation rate increased | 2 | 0 |
| | | | | | |
| | Hepatobiliary investigations | Hepatobiliary function diagnostic procedures | Alanine aminotransferase increased | 4 | 0 |
| | | | Blood bilirubin increased | 1 | 0 |
| | | | Gamma-glutamyltransferase increased | 8 | 0 |
| | | | Hepatic enzyme increased | 1 | 0 |
| | | | Liver function test abnormal | 17 | 0 |
| | | | Liver function test increased | 6 | 0 |
| | Immunology and allergy investigations | Autoimmunity analyses | Antinuclear antibody positive | 2 | 0 |
| | | Immunoglobulin analyses | Immunoglobulins increased | 1 | 0 |
| | | Immunology skin tests NEC | Skin test positive | 1 | 0 |
| | Investigations, imaging and histopathology procedures NEC | Investigations NEC | Laboratory test interference | 1 | 0 |
| | Lipid analyses | Cholesterol analyses | Blood cholesterol increased | 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 decreased | 1 | 0 |
| | | | Blood glucose increased | 1 | 0 |
| | Microbiology and serology investigations | Virus identification and serology | Hepatitis B antibody abnormal | 1 | 0 |
| | | | Hepatitis B antibody negative | 1 | 0 |
| | | | HIV test false positive | 1 | 0 |
| | Physical examination and organ system status topics | Physical examination procedures and organ system status | Body temperature decreased | 1 | 0 |
| | | | Body temperature fluctuation | 1 | 0 |
| | | | Body temperature increased | 18 | 0 |
| | | | Grip strength decreased | 1 | 0 |
| | | | Respiratory rate decreased | 1 | 0 |
| | | | Respiratory rate increased | 1 | 0 |
| Skin temperature | | | 1 | 0 | |

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|------------------------------------|---|---|-------------------------------------|------------------------------|---|---|
| | | | Weight decreased | 9 | 0 | |
| | | | Weight increased | 1 | 0 | |
| | Protein and chemistry analyses NEC | Protein analyses NEC | Alpha 1 foetoprotein increased | 1 | 0 | |
| | | | Blood albumin abnormal | 1 | 0 | |
| | | | C-reactive protein abnormal | 1 | 0 | |
| | | | Globulin abnormal | 1 | 0 | |
| | | | Protein total abnormal | 1 | 0 | |
| | Renal and urinary tract investigations and urinalyses | Urinalysis NEC | Blood urine present | 1 | 0 | |
| | | | Urine analysis abnormal | 1 | 0 | |
| | | Urinary tract function analyses NEC | Urine output increased | 1 | 0 | |
| | Water, electrolyte and mineral investigations | Mineral and electrolyte analyses | Blood sodium increased | 1 | 0 | |
| Metabolism and nutrition disorders | Appetite and general nutritional disorders | Appetite disorders | Decreased appetite | 38 | 0 | |
| | | General nutritional disorders NEC | Abnormal loss of weight | 3 | 0 | |
| | | | Feeding disorder | 2 | 0 | |
| | | | Poor feeding infant | 1 | 0 | |
| | Diabetic complications | Diabetic complications NEC | Diabetic ketoacidosis | 1 | 0 | |
| | Electrolyte and fluid balance conditions | Fluid intake increased | Polydipsia | 1 | 0 | |
| | | Potassium imbalance | Hypokalaemia | 1 | 0 | |
| | | Total fluid volume decreased | Dehydration | 2 | 0 | |
| | Food intolerance syndromes | Food malabsorption and intolerance syndromes (excl sugar intolerance) | Alcohol intolerance | 6 | 0 | |
| | Glucose metabolism disorders (incl diabetes mellitus) | Diabetes mellitus (incl subtypes) | Type 1 diabetes mellitus | 1 | 0 | |
| | | Hypoglycaemic conditions NEC | Hypoglycaemia | 2 | 0 | |
| | Bone disorders (excl congenital and fractures) | Bone related signs and symptoms | Bone pain | 2 | 0 | |
| | | | Pain in jaw | 10 | 0 | |
| | | | Spinal pain | 1 | 0 | |
| | | | Metabolic bone disorders | Osteopenia | 1 | 0 |
| | Connective tissue disorders (excl congenital) | Connective tissue disorders NEC | Mixed connective tissue disease | 1 | 0 | |
| | | | Myofascitis | 2 | 0 | |
| | | | Polymyalgia rheumatica | 3 | 0 | |
| | | | Lupus erythematosus (incl subtypes) | Systemic lupus erythematosus | 4 | 0 |
| | Joint disorders | Arthropathies NEC | Arthritis | 34 | 0 | |
| | | | Arthropathy | 13 | 0 | |
| | | | Polyarthritis | 9 | 0 | |
| | | | Seronegative arthritis | 2 | 0 | |
| | | | Joint related disorders NEC | Periarthritis | 4 | 0 |
| | | Joint related signs and symptoms | Arthralgia | 369 | 0 | |
| | | | Joint noise | 1 | 0 | |
| | | | Joint stiffness | 21 | 0 | |
| | Joint swelling | | 41 | 0 | | |
| | Osteoarthropathies | Osteoarthritis | 5 | 0 | | |

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|---|--|---|-------------------------------|-----|---|
| Musculoskeletal and connective tissue disorders | | Rheumatoid arthropathies | Rheumatoid arthritis | 17 | 0 |
| | | Spondyloarthropathies | Arthritis reactive | 8 | 0 |
| | Muscle disorders | Muscle infections and inflammations | Myositis | 3 | 0 |
| | | Muscle pains | Fibromyalgia | 2 | 0 |
| | | | Myalgia | 214 | 0 |
| | | Muscle related signs and symptoms NEC | Muscle atrophy | 1 | 0 |
| | | | Muscle discomfort | 2 | 0 |
| | | | Muscle disorder | 1 | 0 |
| | | | Muscle mass | 1 | 0 |
| | | | Muscle spasms | 22 | 0 |
| | | | Muscle tightness | 6 | 0 |
| | | | Muscle twitching | 4 | 0 |
| | | Muscle tone abnormalities | Muscle rigidity | 2 | 0 |
| | | | Trismus | 1 | 0 |
| | | Muscle weakness conditions | Muscular weakness | 37 | 0 |
| | Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders) | Extremity deformities | Hand deformity | 1 | 0 |
| | Musculoskeletal and connective tissue disorders NEC | Musculoskeletal and connective tissue conditions NEC | Mobility decreased | 5 | 0 |
| | | | Musculoskeletal stiffness | 44 | 0 |
| | | Musculoskeletal and connective tissue pain and discomfort | Back pain | 41 | 0 |
| | | | Limb discomfort | 21 | 0 |
| | | | Musculoskeletal discomfort | 1 | 0 |
| | | | Musculoskeletal pain | 1 | 0 |
| | | | Neck pain | 38 | 0 |
| | | | Pain in extremity | 137 | 0 |
| | | Soft tissue disorders NEC | Groin pain | 2 | 0 |
| | | | Neck mass | 1 | 0 |
| | Tendon, ligament and cartilage disorders | Cartilage disorders | Costochondritis | 1 | 0 |
| | | Tendon disorders | Tendon calcification | 1 | 0 |
| | | | Tendonitis | 1 | 0 |
| | | | Tenosynovitis | 1 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | Breast neoplasms benign (incl nipple) | Breast and nipple neoplasms benign | Benign breast neoplasm | 1 | 0 |
| | Breast neoplasms malignant and unspecified (incl nipple) | Breast and nipple neoplasms malignant | Breast cancer | 1 | 0 |
| | Leukaemias | Leukaemias acute myeloid | Acute promyelocytic leukaemia | 1 | 0 |
| | Lymphomas NEC | Lymphomas unspecified NEC | Lymphoma | 1 | 0 |
| | Reproductive neoplasms female benign | Uterine neoplasms benign | Uterine leiomyoma | 1 | 0 |
| | Skin neoplasms malignant and unspecified | Skin neoplasms malignant and unspecified (excl melanoma) | Neoplasm skin | 1 | 0 |
| | | | Skin cancer | 1 | 0 |
| | Central nervous system infections and | Encephalitis NEC | Noninfective encephalitis | 1 | 0 |

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| inflammations | Myelitis (incl infective) | Myelitis transverse | 2 | 0 |
| Central nervous system vascular disorders | Central nervous system aneurysms and dissections | Intracranial aneurysm | 1 | 0 |
| | Central nervous system haemorrhages and cerebrovascular accidents | Cerebral infarction | 1 | 0 |
| | | Cerebral ischaemia | 1 | 0 |
| | | Cerebrovascular accident | 3 | 1 |
| | Central nervous system vascular disorders NEC | Central nervous system vasculitis | 1 | 0 |
| | Transient cerebrovascular events | Transient ischaemic attack | 3 | 0 |
| Cranial nerve disorders (excl neoplasms) | Cranial nerve disorders NEC | Cranial nerve disorder | 1 | 0 |
| | Facial cranial nerve disorders | Bell's palsy | 13 | 0 |
| | | Facial paralysis | 8 | 0 |
| | | Facial paresis | 3 | 0 |
| | Olfactory nerve disorders | Anosmia | 1 | 0 |
| | | Parosmia | 1 | 0 |
| | Optic nerve disorders NEC | Optic neuritis | 10 | 0 |
| Demyelinating disorders | Trigeminal disorders | Trigeminal neuralgia | 1 | 0 |
| | Demyelinating disorders NEC | Demyelination | 3 | 0 |
| | Multiple sclerosis acute and progressive | Multiple sclerosis | 16 | 0 |
| Encephalopathies | Encephalopathies NEC | Encephalopathy | 1 | 0 |
| Headaches | Headaches NEC | Cluster headache | 1 | 0 |
| | | Headache | 463 | 0 |
| | | Tension headache | 3 | 0 |
| | Migraine headaches | Migraine | 29 | 0 |
| | | Ophthalmic migraine | 1 | 0 |
| | | Typical aura without headache | 1 | 0 |
| Increased intracranial pressure and hydrocephalus | Increased intracranial pressure disorders | Brain oedema | 1 | 0 |
| Mental impairment disorders | Memory loss (excl dementia) | Amnesia | 8 | 0 |
| | | Memory impairment | 4 | 0 |
| | Mental impairment (excl dementia and memory loss) | Cognitive disorder | 2 | 0 |
| | | Disturbance in attention | 12 | 0 |
| Movement disorders (incl parkinsonism) | Dyskinesias and movement disorders NEC | Clumsiness | 1 | 0 |
| | | Dyskinesia | 3 | 0 |
| | | Hyperkinesia | 1 | 0 |
| | | Hypokinesia | 6 | 0 |
| | | Movement disorder | 1 | 0 |
| | Dystonias | Dystonia | 1 | 0 |
| | | Opisthotonus | 1 | 0 |
| | Paralysis and paresis (excl cranial nerve) | Diplegia | 1 | 0 |
| | | Monoplegia | 3 | 0 |

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|--------------------------|----------------------------|---------------------------------------|--|-----|---|
| Nervous system disorders | Neurological disorders NEC | | Paralysis | 4 | 0 |
| | | Tremor (excl congenital) | Head titubation | 1 | 0 |
| | | | Tremor | 43 | 0 |
| | | Abnormal reflexes | Extensor plantar response | 1 | 0 |
| | | | Hyporeflexia | 2 | 0 |
| | | Coordination and balance disturbances | Ataxia | 4 | 0 |
| | | | Balance disorder | 19 | 0 |
| | | | Coordination abnormal | 5 | 0 |
| | | | Dysstasia | 3 | 0 |
| | | | Nystagmus | 4 | 0 |
| | | Cortical dysfunction NEC | Aphasia | 3 | 0 |
| | | Disturbances in consciousness NEC | Altered state of consciousness | 3 | 0 |
| | | | Consciousness fluctuating | 2 | 0 |
| | | | Depressed level of consciousness | 1 | 0 |
| | | | Lethargy | 81 | 0 |
| | | | Loss of consciousness | 18 | 0 |
| | | | Somnolence | 38 | 0 |
| | | | Syncope | 108 | 0 |
| | | Nervous system disorders NEC | Cerebral disorder | 1 | 0 |
| | | | Meningeal disorder | 1 | 0 |
| | | | Nervous system disorder | 1 | 0 |
| | | Neurological signs and symptoms NEC | Brain fog | 2 | 0 |
| | | | Clonus | 1 | 0 |
| | | | Dizziness | 351 | 0 |
| | | | Head discomfort | 2 | 0 |
| | | | Meningism | 5 | 0 |
| | | | Neurological symptom | 3 | 0 |
| | | | Persistent postural-perceptual dizziness | 1 | 0 |
| | | | Presyncope | 17 | 0 |
| | | | Slow response to stimuli | 1 | 0 |
| | | | Unresponsive to stimuli | 6 | 0 |
| | | Paraesthesias and dysaesthesias | Burning sensation | 14 | 0 |
| | | | Dysaesthesia | 1 | 0 |
| | | | Hyperaesthesia | 4 | 0 |
| | | | Hypoaesthesia | 71 | 0 |
| | | | Lhermitte's sign | 2 | 0 |
| | | | Paraesthesia | 173 | 0 |
| | | Sensory abnormalities NEC | Dysgeusia | 17 | 0 |
| | | | Neuralgia | 3 | 0 |
| | | | Sensory disturbance | 1 | 0 |
| | | | Sensory loss | 6 | 0 |

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| | | | Taste disorder | 5 | 0 |
| | | Speech and language abnormalities | Dysarthria | 7 | 0 |
| | | | Speech disorder | 7 | 0 |
| | Neurological disorders of the eye | Neurologic visual problems NEC | Hemianopia | 1 | 0 |
| | | | Tunnel vision | 2 | 0 |
| | Neuromuscular disorders | Autonomic nervous system disorders | Horner's syndrome | 1 | 0 |
| | | Motor neurone diseases | Motor neurone disease | 1 | 0 |
| | | Muscle tone abnormal | Drop attacks | 1 | 0 |
| | | | Hypertonia | 5 | 0 |
| | | | Hypotonia | 3 | 0 |
| | | Neuromuscular disorders NEC | Muscle contractions involuntary | 3 | 0 |
| | Peripheral neuropathies | Acute polyneuropathies | Guillain-Barre syndrome | 13 | 0 |
| | | Mononeuropathies | Peroneal nerve palsy | 2 | 0 |
| | | Peripheral neuropathies NEC | Neuralgic amyotrophy | 4 | 0 |
| | | | Neuritis | 2 | 0 |
| | | | Neuropathy peripheral | 4 | 0 |
| | | | Peripheral motor neuropathy | 1 | 0 |
| | | | Peripheral sensorimotor neuropathy | 1 | 0 |
| | | | Peripheral sensory neuropathy | 1 | 0 |
| | | | Polyneuropathy | 1 | 0 |
| | Seizures (incl subtypes) | Absence seizures | Petit mal epilepsy | 1 | 0 |
| | | Generalised tonic-clonic seizures | Generalised tonic-clonic seizure | 13 | 0 |
| | | Seizures and seizure disorders NEC | Epilepsy | 13 | 0 |
| | | | Partial seizures | 1 | 0 |
| | | | Seizure | 41 | 0 |
| | | | Status epilepticus | 1 | 0 |
| | Spinal cord and nerve root disorders | Lumbar spinal cord and nerve root disorders | Sciatica | 1 | 0 |
| | | Spinal cord and nerve root disorders NEC | Radiculitis brachial | 2 | 0 |
| | Structural brain disorders | Structural brain disorders NEC | Brain injury | 1 | 0 |
| Pregnancy, puerperium and perinatal conditions | Abortions and stillbirth | Abortion related conditions and complications | Anembryonic gestation | 1 | 0 |
| | | | Retained products of conception | 1 | 0 |
| | | Abortions not specified as induced or spontaneous | Abortion | 1 | 0 |
| | | | Abortion missed | 1 | 0 |
| | | Abortions spontaneous | Abortion spontaneous | 9 | 0 |
| | Foetal complications | Foetal complications NEC | Foetal cardiac disorder | 1 | 0 |
| | Maternal complications of labour and delivery | Labour onset and length abnormalities | Premature rupture of membranes | 1 | 0 |
| | Maternal complications of pregnancy | Haemorrhagic complications of pregnancy | Haemorrhage in pregnancy | 1 | 0 |

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| | Neonatal and perinatal conditions | Gestational age and weight conditions | Premature baby | 1 | 0 |
| | | Neonatal hepatobiliary disorders | Jaundice neonatal | 2 | 0 |
| | Postpartum and puerperal disorders | Postpartum complications NEC | Postpartum haemorrhage | 1 | 0 |
| | Pregnancy, labour, delivery and postpartum conditions | Normal pregnancy, labour and delivery | Live birth | 2 | 0 |
| Product issues | Device issues | Device physical property and chemical issues | Syringe issue | 1 | 0 |
| | Product quality, supply, distribution, manufacturing and quality system issues | Product quality issues NEC | Product complaint | 2 | 0 |
| | | | Product quality issue | 1 | 0 |
| Psychiatric disorders | Anxiety disorders and symptoms | Anxiety disorders NEC | Generalised anxiety disorder | 1 | 0 |
| | | | Neurosis | 1 | 0 |
| | | Anxiety symptoms | Agitation | 3 | 0 |
| | | | Anxiety | 17 | 0 |
| | | | Nervousness | 5 | 0 |
| | | Fear symptoms and phobic disorders (incl social phobia) | Fear | 1 | 0 |
| | | Panic attacks and disorders | Panic attack | 1 | 0 |
| | | | Panic reaction | 6 | 0 |
| | Deliria (incl confusion) | Confusion and disorientation | Confusional state | 10 | 0 |
| | | | Disorientation | 18 | 0 |
| | | Deliria | Delirium | 1 | 0 |
| | Depressed mood disorders and disturbances | Depressive disorders | Depression | 12 | 0 |
| | | Mood alterations with depressive symptoms | Depressed mood | 1 | 0 |
| | | | Feeling of despair | 1 | 0 |
| | | | Tearfulness | 2 | 0 |
| | Developmental disorders NEC | Pervasive developmental disorders NEC | Autism spectrum disorder | 1 | 0 |
| | Dissociative disorders | Dissociative states | Depersonalisation/derealisation disorder | 1 | 0 |
| | | | Dissociation | 2 | 0 |
| | Disturbances in thinking and perception | Hallucinations (excl sleep-related) | Hallucination | 4 | 0 |
| | | | Hallucination, auditory | 1 | 0 |
| | | Thinking disturbances | Thinking abnormal | 4 | 0 |
| | Manic and bipolar mood disorders and disturbances | Bipolar disorders | Bipolar disorder | 1 | 0 |
| | | Mood alterations with manic symptoms | Hypomania | 1 | 0 |
| | | | Mania | 1 | 0 |
| | Mood disorders and disturbances NEC | Emotional and mood disturbances NEC | Emotional distress | 2 | 0 |
| | | | Irritability | 5 | 0 |
| | | Fluctuating mood symptoms | Mood swings | 2 | 0 |
| | | Mood disorders NEC | Apathy | 1 | 0 |
| | | | Listless | 1 | 0 |
| | Personality disorders and disturbances in behaviour | Behaviour and socialisation disturbances | Paranoia | 1 | 0 |

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|-----------------------------|---|--|-------------------------|---|---|
| | Psychiatric and behavioural symptoms NEC | Abnormal behaviour NEC | Staring | 1 | 0 |
| | Psychiatric disorders NEC | Mental disorders NEC | Mental disorder | 1 | 0 |
| | | Substance related and addictive disorders | Drug dependence | 1 | 0 |
| | Schizophrenia and other psychotic disorders | Psychotic disorder NEC | Psychotic disorder | 1 | 0 |
| | | Schizophrenia NEC | Schizophrenia | 1 | 0 |
| | Sleep disorders and disturbances | Disturbances in initiating and maintaining sleep | Insomnia | 9 | 0 |
| | | | Middle insomnia | 1 | 0 |
| | | | Terminal insomnia | 1 | 0 |
| | | Dyssomnias | Poor quality sleep | 1 | 0 |
| | | Parasomnias | Nightmare | 2 | 0 |
| | | Sleep disorders NEC | Sleep disorder | 6 | 0 |
| | Somatic symptom and related disorders | Factitious disorders | Factitious disorder | 1 | 0 |
| | | Somatic symptom disorders | Conversion disorder | 1 | 0 |
| | Suicidal and self-injurious behaviours NEC | Suicidal and self-injurious behaviour | Suicidal ideation | 1 | 0 |
| Renal and urinary disorders | Nephropathies | Glomerulonephritis and nephrotic syndrome | Nephrotic syndrome | 3 | 0 |
| | Renal disorders (excl nephropathies) | Renal disorders NEC | Renal disorder | 2 | 0 |
| | | Renal failure and impairment | Acute kidney injury | 1 | 0 |
| | | | Renal failure | 1 | 0 |
| | | | Renal impairment | 1 | 0 |
| | | Renal neoplasms | Renal cyst | 1 | 0 |
| | | Renal vascular and ischaemic conditions | Renal necrosis | 1 | 0 |
| | Urinary tract signs and symptoms | Bladder and urethral symptoms | Incontinence | 2 | 0 |
| | | | Micturition disorder | 1 | 0 |
| | | | Micturition urgency | 1 | 0 |
| | | | Pollakiuria | 3 | 0 |
| | | | Urinary incontinence | 5 | 0 |
| | | | Urinary retention | 1 | 0 |
| | | Urinary abnormalities | Chromaturia | 1 | 0 |
| | | | Glycosuria | 2 | 0 |
| | | | Haematuria | 9 | 0 |
| | | | Proteinuria | 5 | 0 |
| | | Urinary tract signs and symptoms NEC | Nocturia | 1 | 0 |
| | | | Polyuria | 2 | 0 |
| | | | Renal pain | 8 | 0 |
| | Breast disorders | Breast signs and symptoms | Breast pain | 4 | 0 |
| | | | Breast tenderness | 1 | 0 |
| | | | Intermenstrual bleeding | 2 | 0 |

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|---|--|---|-------------------------------|----|---|
| Reproductive system and breast disorders | Menstrual cycle and uterine bleeding disorders | Menstruation and uterine bleeding NEC | Menstrual disorder | 3 | 0 |
| | | | Menstruation irregular | 2 | 0 |
| | | Menstruation with decreased bleeding | Amenorrhoea | 1 | 0 |
| | | | Menstruation delayed | 2 | 0 |
| | | Menstruation with increased bleeding | Heavy menstrual bleeding | 4 | 0 |
| | | | Polymenorrhoea | 1 | 0 |
| | Ovarian and fallopian tube disorders | Ovarian and fallopian tube cysts and neoplasms | Ovarian cyst | 1 | 0 |
| | Reproductive tract disorders NEC | Reproductive tract signs and symptoms NEC | Genital rash | 1 | 0 |
| Respiratory, thoracic and mediastinal disorders | Bronchial disorders (excl neoplasms) | Bronchospasm and obstruction | Asthma | 19 | 0 |
| | | | Bronchospasm | 21 | 0 |
| | | | Obstructive airways disorder | 1 | 0 |
| | | | Wheezing | 15 | 0 |
| | Lower respiratory tract disorders (excl obstruction and infection) | Lower respiratory tract inflammatory and immunologic conditions | Pulmonary vasculitis | 1 | 0 |
| | | Pulmonary oedemas | Pulmonary oedema | 2 | 0 |
| | Neonatal respiratory disorders | Neonatal hypoxic conditions | Neonatal asphyxia | 1 | 0 |
| | Respiratory disorders NEC | Breathing abnormalities | Dyspnoea | 75 | 0 |
| | | | Dyspnoea exertional | 1 | 0 |
| | | | Hyperventilation | 8 | 0 |
| | | | Hypopnoea | 3 | 0 |
| | | | Orthopnoea | 1 | 0 |
| | | | Respiration abnormal | 1 | 0 |
| | | | Respiratory distress | 2 | 0 |
| | | Coughing and associated symptoms | Cough | 27 | 0 |
| | | | Haemoptysis | 1 | 0 |
| | | | Productive cough | 4 | 0 |
| | | Respiratory failures (excl neonatal) | Acute respiratory failure | 1 | 0 |
| | | Respiratory tract disorders NEC | Respiratory tract congestion | 4 | 0 |
| | | | Respiratory tract oedema | 1 | 0 |
| | Respiratory tract signs and symptoms | Lower respiratory tract signs and symptoms | Increased bronchial secretion | 1 | 0 |
| | | Upper respiratory tract signs and symptoms | Aphonia | 2 | 0 |
| | | | Catarrh | 1 | 0 |
| | | | Dry throat | 9 | 0 |
| | | | Dysphonia | 3 | 0 |
| | | | Laryngeal pain | 1 | 0 |
| | | | Nasal discomfort | 2 | 0 |

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|--|---|---|-------------------------|----|---|
| | | Upper respiratory tract signs and symptoms | Oropharyngeal pain | 60 | 0 |
| | | | Rhinorrhoea | 5 | 0 |
| | | | Sneezing | 2 | 0 |
| | | | Throat irritation | 7 | 0 |
| | | | Throat tightness | 24 | 0 |
| | | | Yawning | 1 | 0 |
| | Upper respiratory tract disorders (excl infections) | Laryngeal spasm, oedema and obstruction | Laryngospasm | 1 | 0 |
| | | Nasal congestion and inflammations | Nasal congestion | 2 | 0 |
| | | Nasal disorders NEC | Epistaxis | 7 | 0 |
| | | Paranasal sinus disorders (excl infections and neoplasms) | Sinus congestion | 1 | 0 |
| | | Pharyngeal disorders (excl infections and neoplasms) | Pharyngeal oedema | 1 | 0 |
| | | | Pharyngeal paraesthesia | 1 | 0 |
| | | | Pharyngeal swelling | 20 | 0 |
| | | | Tonsillar hypertrophy | 1 | 0 |

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|----------------|---|-------------------------------------|---------------------------------------|-----|---|
| | Angioedema and urticaria | Angioedemas | Angioedema | 19 | 0 |
| | | Urticarias | Mechanical urticaria | 1 | 0 |
| | | | Urticaria | 207 | 0 |
| | | | Urticarial vasculitis | 1 | 0 |
| | Cornification and dystrophic skin disorders | Hyperkeratoses | Lichenoid keratosis | 3 | 0 |
| | | Bullous conditions | Blister | 10 | 0 |
| | | | Blood blister | 4 | 0 |
| | | | Dermatitis bullous | 2 | 0 |
| | | | Erythema multiforme | 19 | 0 |
| | | | Stevens-Johnson syndrome | 4 | 0 |
| | | Connective tissue disorders | Chronic cutaneous lupus erythematosus | 1 | 0 |
| | | Dermal and epidermal conditions NEC | Dry skin | 8 | 0 |
| | | | Pain of skin | 1 | 0 |
| | | | Papule | 4 | 0 |
| | | | Sensitive skin | 3 | 0 |
| | | | Skin burning sensation | 3 | 0 |
| | | | Skin discolouration | 8 | 0 |
| | | | Skin disorder | 5 | 0 |
| | | | Skin induration | 4 | 0 |
| | | | Skin necrosis | 3 | 0 |
| Skin reaction | | | 4 | 0 | |
| Skin tightness | 2 | | 0 | | |
| Skin warm | 3 | 0 | | | |
| Yellow skin | 2 | 0 | | | |

Skin and subcutaneous tissue disorders

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|--|---|-----------------------------------|-----|---|
| Epidermal and dermal conditions | Dermatitis and eczema | Dermatitis | 2 | 0 |
| | | Dermatitis allergic | 7 | 0 |
| | | Dermatitis contact | 1 | 0 |
| | | Dyshidrotic eczema | 2 | 0 |
| | | Eczema | 18 | 0 |
| | | Eczema nummular | 1 | 0 |
| | | Hand dermatitis | 1 | 0 |
| | | Skin irritation | 6 | 0 |
| | Dermatitis ascribed to specific agent | Drug eruption | 1 | 0 |
| | | Toxic skin eruption | 1 | 0 |
| | Erythemas | Erythema | 53 | 0 |
| | Exfoliative conditions | Dermatitis exfoliative | 1 | 0 |
| | | Skin exfoliation | 3 | 0 |
| | Papulosquamous conditions | Lichen planus | 2 | 0 |
| | | Lichen sclerosus | 1 | 0 |
| | | Lichenification | 1 | 0 |
| | | Pityriasis rosea | 3 | 0 |
| | Photosensitivity and photodermatosis conditions | Photosensitivity reaction | 7 | 0 |
| | | Solar dermatitis | 1 | 0 |
| | Pruritus NEC | Pruritus | 137 | 0 |
| | Psoriatic conditions | Psoriasis | 11 | 0 |
| | Rashes, eruptions and exanthems NEC | Rash | 247 | 0 |
| | | Rash erythematous | 52 | 0 |
| | | Rash macular | 32 | 0 |
| | | Rash maculo-papular | 36 | 0 |
| | | Rash morbilliform | 4 | 0 |
| | | Rash papular | 16 | 0 |
| | | Rash pruritic | 45 | 0 |
| | | Rash rubelliform | 2 | 0 |
| | | Rash vesicular | 7 | 0 |
| | | Systemic lupus erythematosus rash | 2 | 0 |
| Pigmentation disorders | Hyperpigmentation disorders | Ephelides | 1 | 0 |
| | | Skin hyperpigmentation | 1 | 0 |
| | Hypopigmentation disorders | Skin hypopigmentation | 1 | 0 |
| | Pigmentation changes NEC | Pigmentation disorder | 1 | 0 |
| Skin and subcutaneous tissue disorders NEC | Panniculitides | Erythema nodosum | 23 | 0 |
| | | Panniculitis | 2 | 0 |
| | | Panniculitis lobular | 1 | 0 |
| | Skin and subcutaneous conditions NEC | Skin mass | 2 | 0 |
| | Skin and subcutaneous tissue ulcerations | Skin ulcer | 2 | 0 |

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| | Skin appendage conditions | Acnes | Acne | 1 | 0 |
| | | Alopecias | Alopecia | 6 | 0 |
| | | | Alopecia areata | 2 | 0 |
| | | Apocrine and eccrine gland disorders | Cold sweat | 19 | 0 |
| | | | Hyperhidrosis | 92 | 0 |
| | | | Miliaria | 1 | 0 |
| | | | Night sweats | 8 | 0 |
| | | Nail and nail bed conditions (excl infections and infestations) | Nail discolouration | 1 | 0 |
| | Rosaceas | Rosacea | 1 | 0 | |
| | Skin vascular abnormalities | Purpura and related conditions | Henoch-Schonlein purpura | 2 | 0 |
| | | | Petechiae | 4 | 0 |
| | | | Purpura | 16 | 0 |
| | | Skin vasculitides | Capillaritis | 2 | 0 |
| | | | Cutaneous vasculitis | 2 | 0 |
| | | | Palpable purpura | 1 | 0 |
| | | | Vasculitic rash | 3 | 0 |
| Skin vasomotor conditions | | Livedo reticularis | 2 | 0 | |
| Social circumstances | Lifestyle issues | Disability issues | Bedridden | 1 | 0 |
| | | | Disability | 1 | 0 |
| | | | Immobile | 1 | 0 |
| | | | Impaired driving ability | 1 | 0 |
| | | | Impaired work ability | 1 | 0 |
| | | | Loss of personal independence in daily activities | 1 | 0 |
| Surgical and medical procedures | Obstetric and gynaecological therapeutic procedures | Induced abortions | Abortion induced | 1 | 0 |
| | Skin and subcutaneous tissue therapeutic procedures | Skin lesion excisions | Sebaceous cyst excision | 1 | 0 |
| Vascular disorders | Arteriosclerosis, stenosis, vascular insufficiency and necrosis | Peripheral vasoconstriction, necrosis and vascular insufficiency | Peripheral coldness | 7 | 0 |
| | | | Peripheral ischaemia | 1 | 0 |
| | | | Raynaud's phenomenon | 2 | 0 |
| | Decreased and nonspecific blood pressure disorders and shock | Blood pressure disorders NEC | Labile blood pressure | 1 | 0 |
| | | | Circulatory collapse | 19 | 0 |
| | | Circulatory collapse and shock | Peripheral circulatory failure | 1 | 0 |
| | | | Vascular hypotensive disorders | Hypotension | 19 |
| | | Orthostatic hypotension | | 2 | 0 |
| | Embolism and thrombosis | Peripheral embolism and thrombosis | Deep vein thrombosis | 1 | 0 |
| | Vascular disorders NEC | Non-site specific vascular disorders NEC | Angiopathy | 1 | 0 |
| | | | Vasodilatation | 1 | 0 |
| | | Peripheral vascular disorders NEC | Cyanosis | 9 | 0 |
| | | | Flushing | 32 | 0 |

| | | | | | |
|-----------------------------|---------------------------------------|--------------------------------------|----------------------|-------|---|
| | | | Hot flush | 10 | 0 |
| | | Site specific vascular disorders NEC | Pallor | 39 | 0 |
| | Vascular haemorrhagic disorders | Haemorrhages NEC | Extravasation blood | 1 | 0 |
| | | | Haemorrhage | 3 | 0 |
| | Vascular hypertensive disorders | Vascular hypertensive disorders NEC | Hypertension | 14 | 0 |
| | Vascular infections and inflammations | Vasculitides NEC | Polyarteritis nodosa | 1 | 0 |
| | | | Vasculitis | 6 | 0 |
| | Venous varices | Varicose veins NEC | Varicose vein | 1 | 0 |
| Total Reports | | | | 3,524 | |
| Total Fatal Outcome Reports | | | | 7 | |
| Total Number of Reactions | | | | 9,574 | |