

COVID-19 Brand Unspecified Vaccine Analysis Print

Report Run Date: 25-Aug-2022
Data Lock Date: 24-Aug-2022 18:30:05

All UK spontaneous reports received up to and including 24/08/22 for COVID-19 vaccines where the brand has not been specified.

A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

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| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Blood disorders | | |
| <i>Anaemias NEC</i> | | |
| Anaemia | 3 | 0 |
| <i>Coagulopathies</i> | | |
| Disseminated intravascular coagulation | 1 | 0 |
| <i>Eosinophilic disorders</i> | | |
| Eosinophilia | 1 | 0 |
| <i>Haematological disorders</i> | | |
| Blood disorder | 1 | 1 |
| <i>Leukocytoses NEC</i> | | |
| Hyperleukocytosis | 1 | 0 |
| <i>Lymphatic system disorders NEC</i> | | |
| Lymph node pain | 4 | 0 |
| Lymphadenitis | 1 | 0 |
| Lymphadenopathy | 32 | 0 |
| <i>Marrow depression and hypoplastic anaemias</i> | | |
| Aplastic anaemia | 1 | 0 |
| Myelosuppression | 1 | 0 |
| <i>Neutropenias</i> | | |
| Neutropenia | 1 | 0 |
| <i>Platelet disorders NEC</i> | | |
| Platelet disorder | 1 | 0 |
| <i>Thrombocytopenias</i> | | |
| Immune thrombocytopenia | 5 | 3 |
| Thrombocytopenia | 8 | 0 |
| Thrombosis with thrombocytopenia syndrome | 3 | 0 |
| <i>White blood cell abnormal findings NEC</i> | | |
| White blood cell disorder | 1 | 0 |
| Blood disorders SOC TOTAL | 65 | 4 |

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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Cardiac disorders | | |
| <i>Cardiac conduction disorders</i> | | |
| Atrioventricular block | 1 | 0 |
| Bundle branch block | 1 | 0 |
| <i>Cardiac disorders NEC</i> | | |
| Cardiac disorder | 1 | 0 |
| <i>Cardiac signs and symptoms NEC</i> | | |
| Cardiac discomfort | 2 | 0 |
| Palpitations | 48 | 0 |
| <i>Heart failures NEC</i> | | |
| Cardiac failure | 1 | 0 |
| <i>Ischaemic coronary artery disorders</i> | | |
| Acute myocardial infarction | 2 | 0 |
| Angina pectoris | 6 | 0 |
| Myocardial infarction | 10 | 4 |
| Myocardial ischaemia | 2 | 2 |
| <i>Myocardial disorders NEC</i> | | |
| Cardiomegaly | 2 | 1 |
| Left ventricular dilatation | 1 | 0 |
| Left ventricular dysfunction | 1 | 0 |
| Myocardial injury | 1 | 0 |
| <i>Noninfectious myocarditis</i> | | |
| Immune-mediated myocarditis | 1 | 0 |
| Myocarditis | 3 | 0 |
| <i>Noninfectious pericarditis</i> | | |
| Pericarditis | 5 | 0 |
| <i>Pericardial disorders NEC</i> | | |
| Pericardial effusion | 1 | 0 |
| <i>Rate and rhythm disorders NEC</i> | | |
| Bradycardia | 1 | 0 |
| Cardiac flutter | 3 | 0 |
| Postural orthostatic tachycardia syndrome | 1 | 0 |
| Tachycardia | 12 | 0 |
| <i>Supraventricular arrhythmias</i> | | |
| Atrial fibrillation | 7 | 0 |
| Atrial tachycardia | 1 | 0 |
| Supraventricular tachycardia | 1 | 0 |
| <i>Ventricular arrhythmias and cardiac arrest</i> | | |
| Cardiac arrest | 4 | 1 |
| Cardiac disorders SOC TOTAL | 119 | 8 |

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| Reaction Name | Total | Fatal |
|---|----------|----------|
| Congenital disorders | | |
| <i>Cardiac disorders congenital NEC</i> | | |
| Heart disease congenital | 1 | 0 |
| Congenital disorders SOC TOTAL | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Ear disorders | | |
| <i>Ear disorders NEC</i> | | |
| Ear discomfort | 4 | 0 |
| Ear disorder | 1 | 0 |
| Ear pain | 10 | 0 |
| Ear swelling | 1 | 0 |
| <i>Eustachian tube disorders</i> | | |
| Eustachian tube disorder | 1 | 0 |
| Eustachian tube dysfunction | 1 | 0 |
| <i>External ear disorders NEC</i> | | |
| Excessive cerumen production | 2 | 0 |
| <i>Hearing losses</i> | | |
| Deafness | 6 | 0 |
| Deafness neurosensory | 2 | 0 |
| Deafness unilateral | 1 | 0 |
| Hypoacusis | 6 | 0 |
| <i>Hyperacusia</i> | | |
| Hyperacusis | 1 | 0 |
| <i>Inner ear disorders NEC</i> | | |
| Vestibular disorder | 1 | 0 |
| <i>Inner ear signs and symptoms</i> | | |
| Tinnitus | 32 | 0 |
| Vertigo | 17 | 0 |
| <i>Tympanic membrane disorders (excl infections)</i> | | |
| Tympanic membrane perforation | 1 | 0 |
| Ear disorders SOC TOTAL | 87 | 0 |

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| Reaction Name | Total | Fatal |
|--|--------------|--------------|
| Endocrine disorders | | |
| <i>Acute and chronic thyroiditis</i> | | |
| Thyroiditis | 1 | 0 |
| <i>Adrenal cortical hypofunctions</i> | | |
| Adrenal insufficiency | 1 | 0 |
| <i>Adrenal gland disorders NEC</i> | | |
| Adrenal haemorrhage | 2 | 0 |
| Haemorrhagic adrenal infarction | 1 | 0 |
| <i>Female gonadal function disorders</i> | | |
| Ovulation delayed | 1 | 0 |
| <i>Thyroid hyperfunction disorders</i> | | |
| Thyrotoxic crisis | 1 | 0 |
| Endocrine disorders SOC TOTAL | 7 | 0 |

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| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Eye disorders | | |
| <i>Choroid and vitreous structural change, deposit and degeneration</i> | | |
| Vitreous floaters | 6 | 0 |
| <i>Corneal infections, oedemas and inflammations</i> | | |
| Keratitis | 1 | 0 |
| <i>Eyelid movement disorders</i> | | |
| Blepharospasm | 1 | 0 |
| <i>Iris and uveal tract infections, irritations and inflammations</i> | | |
| Iridocyclitis | 1 | 0 |
| <i>Lacrimation disorders</i> | | |
| Dry eye | 2 | 0 |
| Lacrimation increased | 2 | 0 |
| <i>Lid, lash and lacrimal infections, irritations and inflammations</i> | | |
| Chalazion | 1 | 0 |
| Eyelid cyst | 1 | 0 |
| Eyelid margin crusting | 1 | 0 |
| Swelling of eyelid | 1 | 0 |
| <i>Ocular disorders NEC</i> | | |
| Eye disorder | 4 | 0 |
| Eye pain | 7 | 0 |
| Eye swelling | 9 | 0 |
| Ocular discomfort | 1 | 0 |
| Periorbital swelling | 3 | 0 |
| <i>Ocular infections, inflammations and associated manifestations</i> | | |
| Eye allergy | 1 | 0 |
| Eye discharge | 1 | 0 |
| Eye pruritus | 3 | 0 |
| Ocular hyperaemia | 1 | 0 |
| <i>Ocular nerve and muscle disorders</i> | | |
| Eye movement disorder | 1 | 0 |
| <i>Ocular sensation disorders</i> | | |
| Photophobia | 4 | 0 |
| <i>Pupil disorders</i> | | |
| Anisocoria | 1 | 0 |
| Pupil fixed | 1 | 0 |
| <i>Retinal bleeding and vascular disorders (excl retinopathy)</i> | | |
| Retinal haemorrhage | 1 | 0 |
| Retinal vein occlusion | 3 | 0 |
| <i>Retinal structural change, deposit and degeneration</i> | | |
| Macular degeneration | 1 | 0 |
| Retinal toxicity | 1 | 0 |
| <i>Structural change, deposit and degeneration of eye NEC</i> | | |
| Exophthalmos | 1 | 0 |
| <i>Visual disorders NEC</i> | | |
| Diplopia | 6 | 0 |
| Photopsia | 3 | 0 |
| Vision blurred | 16 | 0 |
| <i>Visual impairment and blindness (excl colour blindness)</i> | | |
| Blindness | 4 | 0 |
| Blindness transient | 1 | 0 |
| Visual impairment | 8 | 0 |
| Eye disorders SOC TOTAL | 99 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Gastrointestinal disorders | | |
| <i>Anal and rectal pains</i> | | |
| Proctalgia | 1 | 0 |
| <i>Colitis (excl infective)</i> | | |
| Colitis | 3 | 0 |
| Colitis ulcerative | 2 | 0 |
| Crohn's disease | 2 | 0 |
| <i>Dental pain and sensation disorders</i> | | |
| Toothache | 4 | 0 |
| <i>Diarrhoea (excl infective)</i> | | |
| Diarrhoea | 59 | 0 |
| <i>Dyspeptic signs and symptoms</i> | | |
| Dyspepsia | 4 | 0 |
| <i>Faecal abnormalities NEC</i> | | |
| Abnormal faeces | 2 | 0 |
| Faeces discoloured | 4 | 0 |
| <i>Flatulence, bloating and distension</i> | | |
| Abdominal distension | 4 | 0 |
| Flatulence | 1 | 0 |
| <i>Gastritis (excl infective)</i> | | |
| Gastritis | 1 | 0 |
| <i>Gastrointestinal and abdominal pains (excl oral and throat)</i> | | |
| Abdominal pain | 14 | 0 |
| Abdominal pain lower | 3 | 0 |
| Abdominal pain upper | 27 | 0 |
| Abdominal tenderness | 1 | 0 |
| Gastrointestinal pain | 3 | 0 |
| <i>Gastrointestinal atonic and hypomotility disorders NEC</i> | | |
| Constipation | 4 | 0 |
| Gastrooesophageal reflux disease | 3 | 0 |
| <i>Gastrointestinal signs and symptoms NEC</i> | | |
| Abdominal discomfort | 16 | 0 |
| Anal incontinence | 1 | 0 |
| Dysphagia | 2 | 0 |
| <i>Gastrointestinal spastic and hypermotility disorders</i> | | |
| Irritable bowel syndrome | 2 | 0 |
| <i>Gastrointestinal stenosis and obstruction NEC</i> | | |
| Ileus | 1 | 0 |
| <i>Gastrointestinal vascular occlusion and infarction</i> | | |
| Mesenteric vein thrombosis | 1 | 0 |
| <i>Gingival disorders, signs and symptoms NEC</i> | | |
| Gingival pain | 3 | 0 |
| <i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i> | | |
| Haemorrhoids | 1 | 0 |
| <i>Intestinal haemorrhages</i> | | |
| Intestinal haemorrhage | 1 | 0 |
| <i>Nausea and vomiting symptoms</i> | | |
| Nausea | 146 | 0 |
| Retching | 4 | 0 |
| Vomiting | 64 | 0 |
| Vomiting projectile | 2 | 0 |
| <i>Non-site specific gastrointestinal haemorrhages</i> | | |
| Gastrointestinal haemorrhage | 1 | 1 |
| Haematemesis | 3 | 0 |

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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| <i>Oral dryness and saliva altered</i> | | |
| Dry mouth | 1 | 0 |
| <i>Oral soft tissue disorders NEC</i> | | |
| Enlarged uvula | 1 | 0 |
| Oral papule | 1 | 0 |
| <i>Oral soft tissue haemorrhages</i> | | |
| Oral blood blister | 1 | 0 |
| <i>Oral soft tissue signs and symptoms</i> | | |
| Hypoaesthesia oral | 2 | 0 |
| Lip erythema | 1 | 0 |
| Lip exfoliation | 1 | 0 |
| Oral mucosal eruption | 1 | 0 |
| Oral pain | 1 | 0 |
| Paraesthesia oral | 3 | 0 |
| <i>Oral soft tissue swelling and oedema</i> | | |
| Lip swelling | 7 | 0 |
| Mouth swelling | 2 | 0 |
| <i>Stomatitis and ulceration</i> | | |
| Mouth ulceration | 3 | 0 |
| <i>Tongue disorders</i> | | |
| Glossitis | 1 | 0 |
| <i>Tongue signs and symptoms</i> | | |
| Glossodynia | 2 | 0 |
| Swollen tongue | 2 | 0 |
| Tongue discolouration | 1 | 0 |
| Gastrointestinal disorders SOC TOTAL | 421 | 1 |

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| General disorders | | |
| <i>Administration site reactions NEC</i> | | |
| Administration site erythema | 1 | 0 |
| <i>Application and instillation site reactions</i> | | |
| Application site swelling | 1 | 0 |
| <i>Asthenic conditions</i> | | |
| Asthenia | 49 | 0 |
| Chronic fatigue syndrome | 2 | 0 |
| Fatigue | 235 | 0 |
| Malaise | 95 | 0 |
| <i>Body temperature altered</i> | | |
| Hyperthermia | 1 | 0 |
| Hypothermia | 1 | 0 |
| <i>Death and sudden death</i> | | |
| Death | 14 | 14 |
| Sudden death | 1 | 1 |
| <i>Febrile disorders</i> | | |
| Pyrexia | 185 | 0 |
| <i>Feelings and sensations NEC</i> | | |
| Chills | 109 | 0 |
| Feeling abnormal | 32 | 0 |
| Feeling cold | 25 | 0 |
| Feeling hot | 16 | 0 |
| Feeling of body temperature change | 11 | 0 |
| Sensation of foreign body | 1 | 0 |
| Thirst | 5 | 0 |
| <i>Gait disturbances</i> | | |
| Gait disturbance | 8 | 0 |
| Gait inability | 2 | 0 |
| <i>General signs and symptoms NEC</i> | | |
| Condition aggravated | 17 | 0 |
| Crying | 1 | 0 |
| General physical health deterioration | 3 | 0 |
| Ill-defined disorder | 1 | 0 |
| Illness | 34 | 0 |
| Induration | 4 | 0 |
| Influenza like illness | 41 | 0 |
| Local reaction | 1 | 0 |
| Organ failure | 1 | 0 |
| Peripheral swelling | 44 | 0 |
| Secretion discharge | 1 | 0 |
| Swelling | 37 | 0 |
| Swelling face | 18 | 0 |
| Symptom recurrence | 1 | 0 |
| Unevaluable event | 2 | 0 |
| <i>Implant and catheter site reactions</i> | | |
| Catheter site related reaction | 1 | 0 |
| <i>Inflammations</i> | | |
| Inflammation | 10 | 1 |
| Systemic inflammatory response syndrome | 2 | 0 |
| <i>Injection site reactions</i> | | |
| Injection site discomfort | 3 | 0 |
| Injection site erythema | 3 | 0 |
| Injection site induration | 3 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| Injection site inflammation | 2 | 0 |
| Injection site joint erythema | 1 | 0 |
| Injection site mass | 6 | 0 |
| Injection site nodule | 2 | 0 |
| Injection site pain | 17 | 0 |
| Injection site paraesthesia | 1 | 0 |
| Injection site pruritus | 1 | 0 |
| Injection site reaction | 1 | 0 |
| Injection site swelling | 6 | 0 |
| Injection site warmth | 1 | 0 |
| Interactions | | |
| Device interaction | 5 | 0 |
| Drug interaction | 1 | 0 |
| Drug-device interaction | 15 | 0 |
| Mass conditions NEC | | |
| Cyst | 2 | 0 |
| Mass | 1 | 0 |
| Nodule | 5 | 0 |
| Oedema NEC | | |
| Face oedema | 1 | 0 |
| Oedema | 6 | 0 |
| Oedema peripheral | 1 | 0 |
| Pain and discomfort NEC | | |
| Axillary pain | 12 | 0 |
| Chest discomfort | 10 | 0 |
| Chest pain | 48 | 0 |
| Discomfort | 6 | 0 |
| Facial discomfort | 1 | 0 |
| Facial pain | 4 | 0 |
| Pain | 103 | 0 |
| Tenderness | 3 | 0 |
| Therapeutic and nontherapeutic responses | | |
| Drug ineffective | 34 | 0 |
| Drug intolerance | 1 | 0 |
| No reaction on previous exposure to drug | 1 | 0 |
| Surgical failure | 1 | 0 |
| Therapeutic product effect decreased | 1 | 0 |
| Therapeutic product ineffective | 1 | 0 |
| Therapeutic response decreased | 1 | 0 |
| Therapeutic response unexpected | 1 | 0 |
| Vaccination site reactions | | |
| Shoulder injury related to vaccine administration | 4 | 0 |
| Vaccination site bruising | 2 | 0 |
| Vaccination site erythema | 19 | 0 |
| Vaccination site hypoaesthesia | 1 | 0 |
| Vaccination site induration | 2 | 0 |
| Vaccination site inflammation | 2 | 0 |
| Vaccination site mass | 4 | 0 |
| Vaccination site movement impairment | 4 | 0 |
| Vaccination site pain | 19 | 0 |
| Vaccination site papule | 1 | 0 |
| Vaccination site pruritus | 4 | 0 |
| Vaccination site rash | 2 | 0 |

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|---|-------------|-----------|
| General disorders General disorders cont'd | | |
| Vaccination site reaction | 1 | 0 |
| Vaccination site scab | 1 | 0 |
| Vaccination site swelling | 18 | 0 |
| Vaccination site warmth | 7 | 0 |
| General disorders SOC TOTAL | 1416 | 16 |

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|--|-----------|----------|
| Hepatic disorders | | |
| <i>Cholecystitis and cholelithiasis</i> | | |
| Cholecystitis acute | 1 | 0 |
| <i>Cholestasis and jaundice</i> | | |
| Jaundice | 1 | 0 |
| <i>Gallbladder disorders NEC</i> | | |
| Gallbladder enlargement | 1 | 0 |
| <i>Hepatic vascular disorders</i> | | |
| Hepatic infarction | 1 | 0 |
| Hepatic vein thrombosis | 1 | 0 |
| Portal vein thrombosis | 5 | 1 |
| Hepatic disorders SOC TOTAL | 10 | 1 |

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|--|-----------|----------|
| Immune system disorders | | |
| <i>Acute and chronic sarcoidosis</i> | | |
| Sarcoidosis | 1 | 0 |
| <i>Allergic conditions NEC</i> | | |
| Dust allergy | 1 | 0 |
| Hypersensitivity | 11 | 0 |
| <i>Allergies to foods, food additives, drugs and other chemicals</i> | | |
| Allergy to vaccine | 4 | 0 |
| Drug hypersensitivity | 3 | 0 |
| Food allergy | 1 | 0 |
| <i>Anaphylactic and anaphylactoid responses</i> | | |
| Anaphylactic reaction | 3 | 0 |
| Anaphylactic shock | 1 | 0 |
| <i>Atopic disorders</i> | | |
| Seasonal allergy | 2 | 0 |
| <i>Immune and associated conditions NEC</i> | | |
| Immune system disorder | 1 | 0 |
| Immunisation reaction | 14 | 0 |
| <i>Immunodeficiency disorders NEC</i> | | |
| Immunodeficiency | 1 | 0 |
| <i>Transplant rejections</i> | | |
| Corneal graft rejection | 1 | 0 |
| Immune system disorders SOC TOTAL | 44 | 0 |

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|--|-------|-------|
| Infections | | |
| <i>Abdominal and gastrointestinal infections</i> | | |
| Appendicitis | 1 | 0 |
| Diverticulitis | 1 | 0 |
| <i>Bacterial infections NEC</i> | | |
| Arthritis bacterial | 1 | 0 |
| Cellulitis | 5 | 0 |
| <i>Breast infections</i> | | |
| Mastitis | 1 | 0 |
| <i>Caliciviral infections</i> | | |
| Norovirus infection | 1 | 0 |
| <i>Candida infections</i> | | |
| Candida infection | 1 | 0 |
| <i>Cardiac infections</i> | | |
| Endocarditis | 1 | 0 |
| <i>Central nervous system and spinal infections</i> | | |
| Encephalitis | 1 | 0 |
| Meningitis aseptic | 1 | 0 |
| <i>Clostridia infections</i> | | |
| Clostridium difficile infection | 1 | 0 |
| <i>Coronavirus infections</i> | | |
| COVID-19 | 61 | 1 |
| Post-acute COVID-19 syndrome | 4 | 0 |
| Suspected COVID-19 | 11 | 0 |
| <i>Ear infections</i> | | |
| Ear infection | 2 | 0 |
| <i>Eye and eyelid infections</i> | | |
| Conjunctivitis | 2 | 0 |
| Eye infection | 1 | 0 |
| Hordeolum | 1 | 0 |
| Retinitis | 1 | 0 |
| <i>Fungal infections NEC</i> | | |
| Fungal infection | 1 | 0 |
| Fungal skin infection | 1 | 0 |
| <i>Herpes viral infections</i> | | |
| Disseminated varicella zoster vaccine virus infection | 1 | 0 |
| Genital herpes | 2 | 0 |
| Herpes zoster | 19 | 0 |
| Herpes zoster oticus | 1 | 0 |
| Oral herpes | 3 | 0 |
| Varicella | 1 | 0 |
| <i>Infections NEC</i> | | |
| Abscess | 1 | 0 |
| Infection | 9 | 0 |
| Localised infection | 1 | 0 |
| <i>Infectious transmissions</i> | | |
| Vaccine virus shedding | 1 | 0 |
| <i>Influenza viral infections</i> | | |
| Influenza | 22 | 0 |
| <i>Lower respiratory tract and lung infections</i> | | |
| Lower respiratory tract infection | 3 | 1 |
| Pneumonia | 11 | 3 |
| <i>Mumps viral infections</i> | | |
| Mumps | 1 | 0 |

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| Infections Infections cont'd | | |
| <i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i> | | |
| Sepsis | 2 | 0 |
| <i>Skin structures and soft tissue infections</i> | | |
| Rash pustular | 1 | 0 |
| <i>Staphylococcal infections</i> | | |
| Furuncle | 2 | 0 |
| <i>Trypanosomal infections</i> | | |
| African trypanosomiasis | 1 | 0 |
| <i>Tuberculous infections</i> | | |
| Tuberculosis | 1 | 0 |
| <i>Upper respiratory tract infections</i> | | |
| Acute sinusitis | 1 | 0 |
| Laryngitis | 1 | 0 |
| Nasopharyngitis | 11 | 0 |
| Sinusitis | 2 | 0 |
| Tonsillitis | 2 | 0 |
| Upper respiratory tract infection | 1 | 0 |
| <i>Urinary tract infections</i> | | |
| Kidney infection | 2 | 0 |
| Urinary tract infection | 5 | 0 |
| <i>Viral infections NEC</i> | | |
| Gastroenteritis viral | 1 | 0 |
| Post viral fatigue syndrome | 1 | 0 |
| Sweating fever | 1 | 0 |
| Viral infection | 3 | 0 |
| Viral rash | 1 | 0 |
| Infections SOC TOTAL | 215 | 5 |

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| Injuries | | |
| <i>Abdominal and gastrointestinal injuries NEC</i> | | |
| Gallbladder injury | 1 | 0 |
| <i>Bone and joint injuries NEC</i> | | |
| Joint injury | 1 | 0 |
| <i>Cerebral injuries NEC</i> | | |
| Subdural haematoma | 1 | 1 |
| <i>Exposures associated with pregnancy, delivery and lactation</i> | | |
| Exposure via breast milk | 2 | 0 |
| Maternal exposure during breast feeding | 2 | 0 |
| Maternal exposure during pregnancy | 10 | 0 |
| <i>Exposures to agents or circumstances NEC</i> | | |
| Exposure to vaccinated person | 2 | 0 |
| <i>Eye injuries NEC</i> | | |
| Eye contusion | 1 | 0 |
| Eye injury | 3 | 0 |
| Retinal injury | 1 | 0 |
| <i>Intentional product misuses</i> | | |
| Intentional product misuse | 2 | 0 |
| <i>Intentional product use issues</i> | | |
| Intentional dose omission | 2 | 0 |
| <i>Limb fractures and dislocations</i> | | |
| Upper limb fracture | 1 | 0 |
| <i>Medication errors, product use errors and issues NEC</i> | | |
| Medication error | 2 | 0 |
| Prescription drug used without a prescription | 1 | 0 |
| Vaccination error | 1 | 0 |
| Wrong technique in product usage process | 2 | 0 |
| <i>Muscle, tendon and ligament injuries</i> | | |
| Muscle strain | 2 | 0 |
| Tendon rupture | 1 | 0 |
| <i>Nerve injuries NEC</i> | | |
| Nerve injury | 1 | 0 |
| <i>Non-site specific injuries NEC</i> | | |
| Fall | 12 | 0 |
| <i>Non-site specific procedural complications</i> | | |
| Incision site pain | 1 | 0 |
| Injection related reaction | 2 | 0 |
| <i>Off label uses</i> | | |
| Off label use | 3 | 0 |
| <i>Overdoses NEC</i> | | |
| Overdose | 1 | 0 |
| <i>Product administration errors and issues</i> | | |
| Expired product administered | 2 | 0 |
| Inappropriate schedule of product administration | 5 | 0 |
| Incorrect route of product administration | 1 | 0 |
| Product administered at inappropriate site | 4 | 0 |
| Product administration error | 1 | 0 |
| Product dose omission in error | 1 | 0 |
| Product dose omission issue | 4 | 0 |
| Wrong product administered | 1 | 0 |
| <i>Product dispensing errors and issues</i> | | |
| Product dispensing error | 1 | 0 |
| <i>Site specific injuries NEC</i> | | |

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| Reaction Name | Total | Fatal |
|---|------------|----------|
| Injuries Injuries cont'd | | |
| Limb injury | 3 | 0 |
| Spinal column injury | 1 | 0 |
| <i>Skin injuries NEC</i> | | |
| Contusion | 20 | 0 |
| Scar | 1 | 0 |
| <i>Skin procedural complications</i> | | |
| Dermal filler reaction | 2 | 0 |
| <i>Underdoses NEC</i> | | |
| Prescribed underdose | 1 | 0 |
| <i>Vaccination related complications</i> | | |
| Vaccination complication | 1 | 0 |
| Injuries SOC TOTAL | 107 | 1 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations | | |
| <i>Autoimmunity analyses</i> | | |
| Anti-HLA antibody test positive | 1 | 0 |
| <i>Blood gas and acid base analyses</i> | | |
| Oxygen saturation decreased | 1 | 0 |
| <i>Carbohydrate tolerance analyses (incl diabetes)</i> | | |
| Blood glucose increased | 3 | 0 |
| <i>Cardiac auscultatory investigations</i> | | |
| Cardiac murmur | 2 | 0 |
| <i>Cardiac function diagnostic procedures</i> | | |
| Myocardial strain imaging | 1 | 0 |
| <i>Cerebrospinal fluid tests (excl microbiology)</i> | | |
| CSF glucose decreased | 1 | 0 |
| CSF protein increased | 1 | 0 |
| <i>Chemistry analyses NEC</i> | | |
| Inflammatory marker increased | 1 | 0 |
| <i>Cholesterol analyses</i> | | |
| Blood cholesterol increased | 2 | 0 |
| <i>Coagulation and bleeding analyses</i> | | |
| Fibrin D dimer increased | 2 | 0 |
| International normalised ratio increased | 3 | 0 |
| <i>ECG investigations</i> | | |
| Electrocardiogram abnormal | 1 | 0 |
| <i>Heart rate and pulse investigations</i> | | |
| Heart rate | 8 | 0 |
| Heart rate decreased | 2 | 0 |
| Heart rate increased | 10 | 0 |
| Heart rate irregular | 3 | 0 |
| <i>Hepatobiliary function diagnostic procedures</i> | | |
| Liver function test | 1 | 0 |
| <i>Hepatobiliary imaging procedures</i> | | |
| Liver scan | 1 | 0 |
| <i>Immunology skin tests NEC</i> | | |
| Skin test positive | 1 | 0 |
| <i>Investigations NEC</i> | | |
| Blood test | 1 | 0 |
| Blood test abnormal | 1 | 0 |
| Quality of life decreased | 1 | 0 |
| <i>Mineral and electrolyte analyses</i> | | |
| Blood iron decreased | 1 | 0 |
| Blood potassium decreased | 1 | 0 |
| <i>Physical examination procedures and organ system status</i> | | |
| Body temperature | 2 | 0 |
| Body temperature abnormal | 2 | 0 |
| Body temperature decreased | 2 | 0 |
| Body temperature fluctuation | 1 | 0 |
| Body temperature increased | 5 | 0 |
| Grip strength decreased | 1 | 0 |
| Respiratory rate decreased | 1 | 0 |
| Respiratory rate increased | 1 | 0 |
| Weight decreased | 7 | 0 |
| Weight increased | 2 | 0 |
| <i>Platelet analyses</i> | | |
| Platelet count decreased | 1 | 0 |

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| Reaction Name | Total | Fatal |
|---|------------|----------|
| Investigations | | |
| Investigations cont'd | | |
| Platelet count increased | 1 | 0 |
| Red blood cell analyses | | |
| Haemoglobin E | 1 | 0 |
| Haemoglobin decreased | 1 | 0 |
| Red cell distribution width increased | 1 | 0 |
| Respiratory and pulmonary function diagnostic procedures | | |
| Peak expiratory flow rate decreased | 1 | 0 |
| Respiratory tract and thoracic histopathology procedures | | |
| Aspiration pleural cavity | 1 | 0 |
| Skeletal and cardiac muscle analyses | | |
| Blood creatine phosphokinase increased | 1 | 0 |
| Therapeutic drug monitoring analyses | | |
| Anticoagulation drug level below therapeutic | 1 | 0 |
| Triglyceride analyses | | |
| Blood triglycerides | 1 | 0 |
| Blood triglycerides increased | 1 | 0 |
| Vascular tests NEC (incl blood pressure) | | |
| Blood pressure abnormal | 1 | 0 |
| Blood pressure decreased | 1 | 0 |
| Blood pressure increased | 10 | 0 |
| Virus identification and serology | | |
| SARS-CoV-2 test | 1 | 0 |
| SARS-CoV-2 test false negative | 1 | 0 |
| SARS-CoV-2 test negative | 2 | 0 |
| SARS-CoV-2 test positive | 2 | 0 |
| White blood cell analyses | | |
| Lymphocyte count decreased | 1 | 0 |
| Neutrophil count decreased | 3 | 0 |
| Neutrophil count increased | 1 | 0 |
| White blood cell count increased | 1 | 0 |
| Investigations SOC TOTAL | 109 | 0 |

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| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Metabolic disorders | | |
| <i>Appetite disorders</i> | | |
| Decreased appetite | 37 | 0 |
| Hypophagia | 2 | 0 |
| Increased appetite | 1 | 0 |
| <i>Diabetes mellitus (incl subtypes)</i> | | |
| Diabetes mellitus | 2 | 0 |
| Diabetes mellitus inadequate control | 1 | 0 |
| Type 1 diabetes mellitus | 1 | 0 |
| <i>Disorders of purine metabolism</i> | | |
| Gout | 4 | 0 |
| <i>Electrolyte imbalance NEC</i> | | |
| Electrolyte imbalance | 1 | 0 |
| <i>General nutritional disorders NEC</i> | | |
| Abnormal weight gain | 1 | 0 |
| Feeding disorder | 1 | 0 |
| <i>Hyperglycaemic conditions NEC</i> | | |
| Glucose tolerance impaired | 1 | 0 |
| Hyperglycaemia | 3 | 0 |
| <i>Hypoglycaemic conditions NEC</i> | | |
| Hypoglycaemia | 1 | 0 |
| <i>Iron excess</i> | | |
| Haemochromatosis | 1 | 0 |
| <i>Phosphorus metabolism disorders</i> | | |
| Hypophosphataemia | 1 | 0 |
| <i>Sodium imbalance</i> | | |
| Hyponatraemia | 1 | 0 |
| <i>Total fluid volume decreased</i> | | |
| Dehydration | 4 | 0 |
| <i>Water soluble vitamin deficiencies</i> | | |
| Folate deficiency | 1 | 0 |
| Metabolic disorders SOC TOTAL | 64 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Muscle & tissue disorders | | |
| <i>Arthropathies NEC</i> | | |
| Arthritis | 14 | 0 |
| Arthropathy | 2 | 0 |
| Polyarthritis | 1 | 0 |
| <i>Bone disorders NEC</i> | | |
| Osteitis | 1 | 0 |
| <i>Bone related signs and symptoms</i> | | |
| Bone pain | 6 | 0 |
| Pain in jaw | 1 | 0 |
| Spinal pain | 1 | 0 |
| <i>Bursal disorders</i> | | |
| Bursitis | 3 | 0 |
| <i>Cartilage disorders</i> | | |
| Costochondritis | 5 | 1 |
| <i>Connective tissue disorders NEC</i> | | |
| Polymyalgia rheumatica | 6 | 0 |
| <i>Joint related disorders NEC</i> | | |
| Hypermobility syndrome | 1 | 0 |
| Joint lock | 2 | 0 |
| Periarthritis | 5 | 0 |
| Rotator cuff syndrome | 1 | 0 |
| <i>Joint related signs and symptoms</i> | | |
| Arthralgia | 112 | 0 |
| Joint stiffness | 4 | 0 |
| Joint swelling | 13 | 0 |
| <i>Lupus erythematosus (incl subtypes)</i> | | |
| Systemic lupus erythematosus | 2 | 0 |
| <i>Muscle pains</i> | | |
| Fibromyalgia | 3 | 0 |
| Myalgia | 92 | 0 |
| <i>Muscle related signs and symptoms NEC</i> | | |
| Muscle disorder | 2 | 0 |
| Muscle fatigue | 4 | 0 |
| Muscle spasms | 18 | 0 |
| Muscle tightness | 1 | 0 |
| Muscle twitching | 5 | 0 |
| <i>Muscle tone abnormalities</i> | | |
| Muscle rigidity | 5 | 0 |
| <i>Muscle weakness conditions</i> | | |
| Muscular weakness | 21 | 0 |
| <i>Musculoskeletal and connective tissue conditions NEC</i> | | |
| Back disorder | 1 | 0 |
| Mandibular mass | 1 | 0 |
| Mobility decreased | 16 | 0 |
| Musculoskeletal disorder | 1 | 0 |
| Musculoskeletal stiffness | 17 | 0 |
| <i>Musculoskeletal and connective tissue pain and discomfort</i> | | |
| Back pain | 39 | 0 |
| Limb discomfort | 16 | 0 |
| Musculoskeletal chest pain | 2 | 0 |
| Musculoskeletal discomfort | 1 | 0 |
| Musculoskeletal pain | 2 | 0 |
| Neck pain | 17 | 0 |

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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Muscle & tissue disorders | | |
| Muscle & tissue disorders cont'd | | |
| Pain in extremity | 146 | 0 |
| Rheumatic disorder | 1 | 0 |
| <i>Osteoarthropathies</i> | | |
| Osteoarthritis | 1 | 0 |
| Spinal osteoarthritis | 1 | 0 |
| <i>Psoriatic arthropathies</i> | | |
| Psoriatic arthropathy | 1 | 0 |
| <i>Rheumatoid arthropathies</i> | | |
| Rheumatoid arthritis | 7 | 0 |
| <i>Soft tissue disorders NEC</i> | | |
| Axillary mass | 2 | 0 |
| Groin pain | 2 | 0 |
| Neck mass | 2 | 0 |
| <i>Spondyloarthropathies</i> | | |
| Arthritis reactive | 1 | 0 |
| Spondyloarthropathy | 1 | 0 |
| <i>Tendon disorders</i> | | |
| Tendon pain | 1 | 0 |
| Tendonitis | 1 | 0 |
| Trigger finger | 1 | 0 |
| Muscle & tissue disorders SOC TOTAL | 612 | 1 |

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| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Neoplasms | | |
| <i>Breast and nipple neoplasms malignant</i> | | |
| Breast cancer | 1 | 0 |
| Breast cancer female | 3 | 0 |
| <i>Glial tumours malignant</i> | | |
| Astrocytoma malignant | 1 | 0 |
| <i>Haematologic neoplasms NEC</i> | | |
| Benign lymph node neoplasm | 1 | 0 |
| <i>Leukaemias acute myeloid</i> | | |
| Acute myeloid leukaemia | 1 | 1 |
| <i>Lymphomas unspecified NEC</i> | | |
| Lymphoma | 1 | 0 |
| <i>Neoplasms malignant site unspecified NEC</i> | | |
| Malignant neoplasm progression | 1 | 0 |
| Neoplasm malignant | 3 | 0 |
| <i>Nervous system neoplasms unspecified malignancy NEC</i> | | |
| Brain neoplasm | 1 | 0 |
| <i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i> | | |
| Lung neoplasm malignant | 1 | 1 |
| Throat cancer | 1 | 0 |
| <i>Skin neoplasms benign</i> | | |
| Acrochordon | 1 | 0 |
| Skin papilloma | 1 | 0 |
| <i>Uterine neoplasms benign</i> | | |
| Uterine leiomyoma | 1 | 0 |
| Neoplasms SOC TOTAL | 18 | 2 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders | | |
| <i>Acute polyneuropathies</i> | | |
| Guillain-Barre syndrome | 7 | 0 |
| <i>Autonomic nervous system disorders</i> | | |
| Orthostatic intolerance | 1 | 0 |
| <i>Central nervous system haemorrhages and cerebrovascular accidents</i> | | |
| Basilar artery thrombosis | 1 | 1 |
| Carotid artery occlusion | 1 | 0 |
| Cerebral artery embolism | 1 | 0 |
| Cerebral infarction | 1 | 0 |
| Cerebral thrombosis | 1 | 0 |
| Cerebrovascular accident | 12 | 1 |
| Haemorrhage intracranial | 2 | 0 |
| Ischaemic stroke | 1 | 0 |
| Thalamic infarction | 1 | 0 |
| <i>Cerebrovascular venous and sinus thrombosis</i> | | |
| Cerebral venous sinus thrombosis | 2 | 1 |
| <i>Coma states</i> | | |
| Coma | 1 | 0 |
| <i>Coordination and balance disturbances</i> | | |
| Balance disorder | 14 | 0 |
| Coordination abnormal | 2 | 0 |
| Dysstasia | 3 | 0 |
| <i>Cortical dysfunction NEC</i> | | |
| Aphasia | 4 | 0 |
| <i>Dementia (excl Alzheimer's type)</i> | | |
| Dementia | 1 | 0 |
| <i>Disturbances in consciousness NEC</i> | | |
| Depressed level of consciousness | 2 | 0 |
| Lethargy | 31 | 0 |
| Loss of consciousness | 14 | 0 |
| Somnolence | 16 | 0 |
| Syncope | 20 | 0 |
| <i>Dyskinesias and movement disorders NEC</i> | | |
| Bradykinesia | 1 | 0 |
| Hypokinesia | 1 | 0 |
| Movement disorder | 2 | 0 |
| <i>Encephalopathies NEC</i> | | |
| Autoimmune encephalopathy | 1 | 0 |
| <i>Eye movement disorders</i> | | |
| VIth nerve paralysis | 1 | 0 |
| <i>Facial cranial nerve disorders</i> | | |
| Bell's palsy | 3 | 0 |
| Facial paralysis | 6 | 0 |
| Facial paresis | 1 | 0 |
| Facial spasm | 1 | 0 |
| <i>Generalised tonic-clonic seizures</i> | | |
| Generalised tonic-clonic seizure | 2 | 0 |
| <i>Headaches NEC</i> | | |
| Cluster headache | 1 | 0 |
| Headache | 309 | 0 |
| Sinus headache | 2 | 0 |
| Tension headache | 6 | 0 |
| <i>Increased intracranial pressure disorders</i> | | |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders <small>Nervous system disorders cont'd</small> | | |
| Brain oedema | 1 | 0 |
| Lumbar spinal cord and nerve root disorders | | |
| Sciatica | 1 | 0 |
| Memory loss (excl dementia) | | |
| Amnesia | 8 | 0 |
| Memory impairment | 4 | 0 |
| Meningitis NEC | | |
| Meningitis noninfective | 1 | 0 |
| Mental impairment (excl dementia and memory loss) | | |
| Cognitive disorder | 2 | 0 |
| Disturbance in attention | 5 | 0 |
| Mental impairment | 1 | 0 |
| Migraine headaches | | |
| Migraine | 38 | 0 |
| Retinal migraine | 1 | 0 |
| Mononeuropathies | | |
| Carpal tunnel syndrome | 2 | 0 |
| Peroneal nerve palsy | 1 | 0 |
| Motor neurone diseases | | |
| Motor neurone disease | 1 | 0 |
| Multiple sclerosis acute and progressive | | |
| Multiple sclerosis | 2 | 0 |
| Muscle tone abnormal | | |
| Hypotonia | 1 | 0 |
| Myelitis (incl infective) | | |
| Myelitis transverse | 1 | 0 |
| Narcolepsy and hypersomnia | | |
| Hypersomnia | 2 | 0 |
| Nervous system disorders NEC | | |
| Nervous system disorder | 2 | 0 |
| Neurological signs and symptoms NEC | | |
| Dizziness | 117 | 0 |
| Dizziness exertional | 1 | 0 |
| Dizziness postural | 7 | 0 |
| Head discomfort | 2 | 0 |
| Meningism | 1 | 0 |
| Myoclonus | 1 | 0 |
| Neurological symptom | 2 | 0 |
| Presyncope | 4 | 0 |
| Unresponsive to stimuli | 3 | 0 |
| Neuromuscular junction dysfunction | | |
| Myasthenia gravis | 1 | 0 |
| Olfactory nerve disorders | | |
| Anosmia | 3 | 0 |
| Parosmia | 4 | 0 |
| Paraesthesias and dysaesthesias | | |
| Burning sensation | 16 | 0 |
| Formication | 1 | 0 |
| Hypoaesthesia | 41 | 0 |
| Paraesthesia | 57 | 0 |
| Paralysis and paresis (excl cranial nerve) | | |
| Hemiparesis | 2 | 0 |
| Hemiplegia | 2 | 0 |

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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Monoparesis | 1 | 0 |
| Monoplegia | 2 | 0 |
| Paralysis | 3 | 0 |
| Paraparesis | 1 | 0 |
| <i>Parkinson's disease and parkinsonism</i> | | |
| Freezing phenomenon | 2 | 0 |
| Parkinson's disease | 1 | 0 |
| <i>Peripheral neuropathies NEC</i> | | |
| Neuropathy peripheral | 2 | 0 |
| <i>Seizures and seizure disorders NEC</i> | | |
| Convulsions local | 1 | 0 |
| Epilepsy | 6 | 0 |
| Partial seizures | 1 | 0 |
| Psychogenic seizure | 1 | 0 |
| Seizure | 17 | 0 |
| Seizure like phenomena | 1 | 0 |
| <i>Sensory abnormalities NEC</i> | | |
| Ageusia | 6 | 0 |
| Dysgeusia | 10 | 0 |
| Electric shock sensation | 1 | 0 |
| Neuralgia | 8 | 0 |
| Restless legs syndrome | 2 | 0 |
| Sensory disturbance | 4 | 0 |
| Sensory loss | 1 | 0 |
| Taste disorder | 3 | 0 |
| <i>Speech and language abnormalities</i> | | |
| Dysarthria | 5 | 0 |
| <i>Transient cerebrovascular events</i> | | |
| Transient ischaemic attack | 7 | 0 |
| <i>Tremor (excl congenital)</i> | | |
| Tremor | 51 | 0 |
| <i>Trigeminal disorders</i> | | |
| Trigeminal neuralgia | 1 | 0 |
| Nervous system disorders SOC TOTAL | 953 | 3 |

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| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Pregnancy conditions | | |
| <i>Abortions spontaneous</i> | | |
| Abortion spontaneous | 8 | 0 |
| <i>Maternal complications of pregnancy NEC</i> | | |
| Biochemical pregnancy | 1 | 0 |
| Preterm premature rupture of membranes | 1 | 0 |
| <i>Normal pregnancy, labour and delivery</i> | | |
| Pregnancy | 1 | 0 |
| Pregnancy conditions SOC TOTAL | 11 | 0 |

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| Reaction Name | Total | Fatal |
|--|--------------|--------------|
| <i>Product quality issues NEC</i> | | |
| Product complaint | 3 | 0 |
| Product origin unknown | 1 | 0 |
| <i>Product supply and availability issues</i> | | |
| Product availability issue | 1 | 0 |
| null SOC TOTAL | 5 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders | | |
| <i>Abnormal behaviour NEC</i> | | |
| Abnormal behaviour | 1 | 0 |
| <i>Anxiety symptoms</i> | | |
| Agitation | 1 | 0 |
| Anxiety | 14 | 0 |
| Nervousness | 5 | 0 |
| Stress | 3 | 0 |
| <i>Behaviour and socialisation disturbances</i> | | |
| Personality change | 1 | 0 |
| <i>Cognitive and attention disorders and disturbances NEC</i> | | |
| Mental fatigue | 2 | 0 |
| <i>Confusion and disorientation</i> | | |
| Confusional state | 21 | 0 |
| Disorientation | 7 | 0 |
| <i>Deliria</i> | | |
| Delirium | 2 | 0 |
| <i>Depressive disorders</i> | | |
| Depression | 5 | 0 |
| <i>Dissociative states</i> | | |
| Dissociative amnesia | 1 | 0 |
| <i>Disturbances in initiating and maintaining sleep</i> | | |
| Insomnia | 15 | 0 |
| Middle insomnia | 1 | 0 |
| <i>Dyssomnias</i> | | |
| Poor quality sleep | 3 | 0 |
| <i>Emotional and mood disturbances NEC</i> | | |
| Anger | 1 | 0 |
| Emotional disorder | 1 | 0 |
| Irritability | 1 | 0 |
| Mood altered | 2 | 0 |
| <i>Fluctuating mood symptoms</i> | | |
| Mood swings | 2 | 0 |
| <i>Hallucinations (excl sleep-related)</i> | | |
| Hallucination | 5 | 0 |
| <i>Increased physical activity levels</i> | | |
| Restlessness | 4 | 0 |
| <i>Mental disorders NEC</i> | | |
| Mental disorder | 2 | 0 |
| <i>Mood alterations with depressive symptoms</i> | | |
| Depressed mood | 7 | 0 |
| Negative thoughts | 1 | 0 |
| <i>Mood disorders NEC</i> | | |
| Apathy | 1 | 0 |
| <i>Panic attacks and disorders</i> | | |
| Panic attack | 4 | 0 |
| <i>Parasomnias</i> | | |
| Abnormal dreams | 1 | 0 |
| Nightmare | 1 | 0 |
| Somnambulism | 1 | 0 |
| <i>Perception disturbances NEC</i> | | |
| Autoscopy | 1 | 0 |
| <i>Psychotic disorder NEC</i> | | |
| Acute psychosis | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| <i>Sleep disorders NEC</i> | | |
| Sleep disorder | 4 | 0 |
| <i>Stress disorders</i> | | |
| Post-traumatic stress disorder | 1 | 0 |
| <i>Suicidal and self-injurious behaviour</i> | | |
| Intentional self-injury | 1 | 0 |
| Suicidal ideation | 2 | 0 |
| Suicide attempt | 2 | 0 |
| <i>Thinking disturbances</i> | | |
| Bradyphrenia | 3 | 0 |
| Psychiatric disorders SOC TOTAL | 131 | 0 |

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| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Renal & urinary disorders | | |
| <i>Bladder and urethral symptoms</i> | | |
| Dysuria | 1 | 0 |
| Incontinence | 2 | 0 |
| Pollakiuria | 2 | 0 |
| Urinary incontinence | 4 | 0 |
| Urinary retention | 2 | 0 |
| Urine flow decreased | 1 | 0 |
| <i>Bladder disorders NEC</i> | | |
| Bladder disorder | 1 | 0 |
| Urinary bladder haemorrhage | 1 | 0 |
| <i>Glomerulonephritis and nephrotic syndrome</i> | | |
| Nephrotic syndrome | 2 | 0 |
| <i>Nephritis NEC</i> | | |
| Lupus nephritis | 1 | 0 |
| Nephritis | 1 | 0 |
| <i>Renal failure and impairment</i> | | |
| Acute kidney injury | 2 | 0 |
| Oliguria | 1 | 0 |
| Renal failure | 1 | 0 |
| Renal impairment | 2 | 0 |
| <i>Renal lithiasis</i> | | |
| Nephrolithiasis | 2 | 0 |
| <i>Renal neoplasms</i> | | |
| Renal cyst | 1 | 0 |
| <i>Renal vascular and ischaemic conditions</i> | | |
| Renal infarct | 2 | 0 |
| Renal vein thrombosis | 1 | 0 |
| <i>Urinary abnormalities</i> | | |
| Chromaturia | 2 | 0 |
| Haematuria | 3 | 0 |
| Urine odour abnormal | 1 | 0 |
| <i>Urinary tract signs and symptoms NEC</i> | | |
| Nocturia | 1 | 0 |
| Renal pain | 3 | 0 |
| Renal & urinary disorders SOC TOTAL | 40 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Reproductive & breast disorders | | |
| <i>Breast disorders NEC</i> | | |
| Breast mass | 2 | 0 |
| <i>Breast infections and inflammations</i> | | |
| Plasma cell mastitis | 1 | 0 |
| <i>Breast signs and symptoms</i> | | |
| Breast pain | 5 | 0 |
| Breast swelling | 1 | 0 |
| Breast tenderness | 1 | 0 |
| <i>Erection and ejaculation conditions and disorders</i> | | |
| Erection increased | 1 | 0 |
| <i>Fallopian tube and ovary infections and inflammations</i> | | |
| Noninfective oophoritis | 1 | 0 |
| <i>Menopausal effects NEC</i> | | |
| Menopausal symptoms | 2 | 0 |
| Premature menopause | 3 | 0 |
| <i>Menopausal effects on the genitourinary tract</i> | | |
| Postmenopausal haemorrhage | 2 | 0 |
| <i>Menstruation and uterine bleeding NEC</i> | | |
| Dysmenorrhoea | 25 | 0 |
| Intermenstrual bleeding | 13 | 0 |
| Menstrual discomfort | 1 | 0 |
| Menstrual disorder | 21 | 0 |
| Menstruation irregular | 30 | 0 |
| Premenstrual syndrome | 3 | 0 |
| <i>Menstruation with decreased bleeding</i> | | |
| Amenorrhoea | 9 | 0 |
| Hypomenorrhoea | 4 | 0 |
| Menstruation delayed | 31 | 0 |
| Oligomenorrhoea | 1 | 0 |
| <i>Menstruation with increased bleeding</i> | | |
| Heavy menstrual bleeding | 49 | 0 |
| Polymenorrhoea | 9 | 0 |
| <i>Ovarian and fallopian tube cysts and neoplasms</i> | | |
| Ovarian cyst ruptured | 1 | 0 |
| <i>Ovarian and fallopian tube disorders NEC</i> | | |
| Ovulation disorder | 1 | 0 |
| Ovulation pain | 1 | 0 |
| <i>Pelvis and broad ligament disorders NEC</i> | | |
| Adnexa uteri pain | 1 | 0 |
| Pelvic haemorrhage | 1 | 0 |
| <i>Prostatic signs, symptoms and disorders NEC</i> | | |
| Prostatic pain | 1 | 0 |
| <i>Reproductive tract signs and symptoms NEC</i> | | |
| Genital swelling | 1 | 0 |
| Pelvic pain | 2 | 0 |
| <i>Testicular and epididymal disorders NEC</i> | | |
| Testicular pain | 1 | 0 |
| <i>Uterine disorders NEC</i> | | |
| Uterine pain | 1 | 0 |
| <i>Vulvovaginal disorders NEC</i> | | |
| Vaginal haemorrhage | 11 | 0 |
| Vulvovaginal disorder | 1 | 0 |
| <i>Vulvovaginal signs and symptoms</i> | | |

COVID-19 Brand Unspecified Vaccine Analysis Print

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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Reproductive & breast disorders | | |
| Reproductive & breast disorders cont'd | | |
| Vaginal discharge | 1 | 0 |
| Reproductive & breast disorders SOC TOTAL | 239 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Respiratory disorders | | |
| <i>Breathing abnormalities</i> | | |
| Dyspnoea | 83 | 1 |
| Dyspnoea exertional | 1 | 0 |
| Hyperventilation | 1 | 0 |
| Hypopnoea | 1 | 0 |
| Respiration abnormal | 1 | 0 |
| Respiratory arrest | 1 | 0 |
| Sleep apnoea syndrome | 1 | 0 |
| Tachypnoea | 1 | 0 |
| <i>Bronchospasm and obstruction</i> | | |
| Asthma | 6 | 0 |
| Chronic obstructive pulmonary disease | 2 | 1 |
| Wheezing | 6 | 0 |
| <i>Conditions associated with abnormal gas exchange</i> | | |
| Asphyxia | 1 | 1 |
| Hypoxia | 1 | 0 |
| <i>Coughing and associated symptoms</i> | | |
| Cough | 31 | 0 |
| Haemoptysis | 2 | 0 |
| Productive cough | 6 | 0 |
| <i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i> | | |
| Reflux laryngitis | 1 | 0 |
| <i>Lower respiratory tract inflammatory and immunologic conditions</i> | | |
| Pneumonitis | 1 | 0 |
| <i>Lower respiratory tract signs and symptoms</i> | | |
| Pulmonary pain | 2 | 0 |
| <i>Nasal congestion and inflammations</i> | | |
| Nasal congestion | 3 | 0 |
| <i>Nasal disorders NEC</i> | | |
| Epistaxis | 12 | 0 |
| <i>Paranasal sinus disorders (excl infections and neoplasms)</i> | | |
| Sinus congestion | 1 | 0 |
| <i>Parenchymal lung disorders NEC</i> | | |
| Emphysema | 1 | 0 |
| Pulmonary fibrosis | 1 | 0 |
| <i>Pharyngeal disorders (excl infections and neoplasms)</i> | | |
| Pharyngeal swelling | 1 | 0 |
| <i>Pneumothorax and pleural effusions NEC</i> | | |
| Pleural effusion | 1 | 0 |
| <i>Pulmonary oedemas</i> | | |
| Pulmonary congestion | 1 | 0 |
| <i>Pulmonary thrombotic and embolic conditions</i> | | |
| Pulmonary embolism | 18 | 3 |
| Pulmonary thrombosis | 1 | 1 |
| <i>Respiratory tract disorders NEC</i> | | |
| Lung disorder | 2 | 0 |
| Pulmonary mass | 1 | 0 |
| Respiratory tract irritation | 1 | 0 |
| <i>Upper respiratory tract signs and symptoms</i> | | |
| Aphonia | 1 | 0 |
| Catarrh | 1 | 0 |
| Dysphonia | 2 | 0 |

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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Respiratory disorders <small>Respiratory disorders cont'd</small> | | |
| Nasal discomfort | 1 | 0 |
| Oropharyngeal pain | 19 | 0 |
| Paranasal sinus discomfort | 1 | 0 |
| Rhinorrhoea | 9 | 0 |
| Sneezing | 5 | 0 |
| Throat irritation | 3 | 0 |
| Throat tightness | 1 | 0 |
| Yawning | 2 | 0 |
| Respiratory disorders SOC TOTAL | 238 | 7 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Skin disorders | | |
| <i>Acnes</i> | | |
| Acne | 1 | 0 |
| <i>Alopecias</i> | | |
| Alopecia | 8 | 0 |
| Lichen planopilaris | 1 | 0 |
| <i>Angioedemas</i> | | |
| Angioedema | 5 | 0 |
| <i>Apocrine and eccrine gland disorders</i> | | |
| Cold sweat | 12 | 0 |
| Hyperhidrosis | 46 | 0 |
| Night sweats | 3 | 0 |
| <i>Bullous conditions</i> | | |
| Blister | 7 | 0 |
| Blister rupture | 1 | 0 |
| Erythema multiforme | 2 | 0 |
| Pemphigoid | 1 | 0 |
| <i>Connective tissue disorders</i> | | |
| Subacute cutaneous lupus erythematosus | 1 | 0 |
| <i>Dermal and epidermal conditions NEC</i> | | |
| Dry skin | 2 | 0 |
| Pain of skin | 2 | 0 |
| Papule | 4 | 0 |
| Scar pain | 1 | 0 |
| Sensitive skin | 2 | 0 |
| Skin burning sensation | 2 | 0 |
| Skin discolouration | 6 | 0 |
| Skin disorder | 2 | 0 |
| Skin fissures | 1 | 0 |
| Skin indentation | 1 | 0 |
| Skin induration | 2 | 0 |
| Skin reaction | 2 | 0 |
| Skin swelling | 3 | 0 |
| Skin warm | 2 | 0 |
| Yellow skin | 1 | 0 |
| <i>Dermatitis and eczema</i> | | |
| Dermatitis allergic | 5 | 0 |
| Dermatitis atopic | 1 | 0 |
| Eczema | 6 | 0 |
| Eczema nummular | 1 | 0 |
| Eczema weeping | 1 | 0 |
| Seborrhoeic dermatitis | 1 | 0 |
| Skin irritation | 2 | 0 |
| <i>Dermatitis ascribed to specific agent</i> | | |
| Fixed eruption | 1 | 0 |
| <i>Erythemas</i> | | |
| Erythema | 38 | 0 |
| <i>Exfoliative conditions</i> | | |
| Skin exfoliation | 2 | 0 |
| <i>Hyperkeratoses</i> | | |
| Lichenoid keratosis | 1 | 0 |
| <i>Nail and nail bed conditions (excl infections and infestations)</i> | | |
| Onychoclasia | 1 | 0 |
| <i>Papulosquamous conditions</i> | | |

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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Skin disorders Skin disorders cont'd | | |
| Lichen planus | 1 | 0 |
| Lichen sclerosus | 1 | 0 |
| Parapsoriasis | 1 | 0 |
| Pityriasis rubra pilaris | 1 | 0 |
| Photosensitivity and photodermatosis conditions | | |
| Photosensitivity reaction | 1 | 0 |
| Pigmentation changes NEC | | |
| Pigmentation disorder | 1 | 0 |
| Pilar disorders NEC | | |
| Hair growth abnormal | 1 | 0 |
| Pruritus NEC | | |
| Pruritus | 49 | 0 |
| Psoriatic conditions | | |
| Guttate psoriasis | 3 | 0 |
| Psoriasis | 5 | 0 |
| Purpura and related conditions | | |
| Petechiae | 2 | 0 |
| Purpura | 1 | 0 |
| Rashes, eruptions and exanthems NEC | | |
| Rash | 76 | 0 |
| Rash erythematous | 10 | 0 |
| Rash macular | 4 | 0 |
| Rash morbilliform | 1 | 0 |
| Rash papular | 3 | 0 |
| Rash pruritic | 21 | 0 |
| Rash vesicular | 1 | 0 |
| Scaly conditions | | |
| Pityriasis | 1 | 0 |
| Skin and subcutaneous conditions NEC | | |
| Skin mass | 4 | 0 |
| Skin haemorrhages | | |
| Haemorrhage subcutaneous | 1 | 0 |
| Skin haemorrhage | 1 | 0 |
| Skin vasculitides | | |
| Capillaritis | 1 | 0 |
| Skin vasomotor conditions | | |
| Livedo reticularis | 1 | 0 |
| Urticarias | | |
| Cold urticaria | 2 | 0 |
| Urticaria | 23 | 0 |
| Urticaria chronic | 1 | 0 |
| Skin disorders SOC TOTAL | 399 | 0 |

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| Reaction Name | Total | Fatal |
|---------------------------------------|--------------|--------------|
| Social circumstances | | |
| <i>Age related issues</i> | | |
| Menopause | 2 | 0 |
| Postmenopause | 1 | 0 |
| <i>Disability issues</i> | | |
| Bedridden | 2 | 0 |
| <i>Social issues NEC</i> | | |
| Impaired quality of life | 1 | 0 |
| Social circumstances SOC TOTAL | 6 | 0 |

COVID-19 Brand Unspecified Vaccine Analysis Print

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| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Surgical & medical procedures | | |
| <i>Bladder therapeutic procedures</i> | | |
| Bladder training | 1 | 0 |
| <i>Contraceptive methods female</i> | | |
| Contraception | 1 | 0 |
| <i>Immunisations</i> | | |
| COVID-19 immunisation | 1 | 0 |
| Immunisation | 2 | 0 |
| <i>Joint therapeutic procedures</i> | | |
| Knee operation | 1 | 0 |
| <i>Limb therapeutic procedures</i> | | |
| Foot operation | 1 | 0 |
| <i>Nail therapeutic procedures</i> | | |
| Nail operation | 1 | 0 |
| <i>Obstetric therapeutic procedures</i> | | |
| Caesarean section | 1 | 0 |
| <i>Therapeutic procedures NEC</i> | | |
| Bed rest | 1 | 0 |
| Hospitalisation | 1 | 0 |
| Interchange of vaccine products | 5 | 0 |
| Surgical & medical procedures SOC TOTAL | 16 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------------|-----------|
| Vascular disorders | | |
| <i>Aneurysms and dissections non-site specific</i> | | |
| Aneurysm | 1 | 0 |
| <i>Aortic embolism and thrombosis</i> | | |
| Aortic embolus | 1 | 0 |
| Aortic thrombosis | 1 | 0 |
| <i>Circulatory collapse and shock</i> | | |
| Circulatory collapse | 1 | 0 |
| Shock | 3 | 0 |
| <i>Haemorrhages NEC</i> | | |
| Haematoma | 1 | 0 |
| Haemorrhage | 23 | 0 |
| <i>Non-site specific embolism and thrombosis</i> | | |
| Thrombosis | 14 | 0 |
| <i>Non-site specific vascular disorders NEC</i> | | |
| Vascular pain | 2 | 0 |
| Vascular rupture | 1 | 0 |
| Vein discolouration | 1 | 0 |
| <i>Peripheral embolism and thrombosis</i> | | |
| Deep vein thrombosis | 12 | 0 |
| Jugular vein thrombosis | 1 | 0 |
| Thrombophlebitis | 1 | 0 |
| <i>Peripheral vascular disorders NEC</i> | | |
| Cyanosis | 1 | 0 |
| Erythromelalgia | 1 | 0 |
| Flushing | 3 | 0 |
| Hot flush | 8 | 0 |
| <i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i> | | |
| Peripheral coldness | 2 | 0 |
| Peripheral ischaemia | 1 | 0 |
| Raynaud's phenomenon | 1 | 0 |
| <i>Phlebitis NEC</i> | | |
| Phlebitis | 2 | 0 |
| <i>Site specific vascular disorders NEC</i> | | |
| Pallor | 6 | 0 |
| <i>Varicose veins NEC</i> | | |
| Spider vein | 1 | 0 |
| Varicose vein | 1 | 0 |
| <i>Vascular hypertensive disorders NEC</i> | | |
| Hypertension | 22 | 0 |
| <i>Vascular hypotensive disorders</i> | | |
| Hypotension | 3 | 0 |
| <i>Vasculitides NEC</i> | | |
| Vasculitis | 1 | 0 |
| Vascular disorders SOC TOTAL | 116 | 0 |
| TOTAL REACTIONS FOR DRUG | 5548 | 49 |
| TOTAL REPORTS | 1819 | |
| TOTAL FATAL OUTCOME REPORTS | | 49 |