

Case Series Drug Analysis Print

Name: FOI 21/740 Pneumovax

Report Run Date: 09-Jul-2021
Data Lock Date: 08-Jul-2021 18:30:03
Earliest Reaction Date: 23-Nov-1979
MedDRA Version: MedDRA 24.0

FOI 21/740
Pneumovax: All spontaneous UK suspected adverse drug reaction reports associated with Pneumovax up to and including the 08/07/2021

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| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Blood disorders | | |
| Anaemias NEC | | |
| Anaemia | 3 | 0 |
| Anaemias haemolytic NEC | | |
| Haemolytic anaemia | 1 | 0 |
| Anaemias haemolytic immune | | |
| Coombs positive haemolytic anaemia | 1 | 0 |
| Bleeding tendencies | | |
| Increased tendency to bruise | 1 | 0 |
| Coagulopathies | | |
| Factor VIII inhibition | 1 | 0 |
| Eosinophilic disorders | | |
| Eosinophilia | 2 | 0 |
| Haemolyses NEC | | |
| Haemolysis | 2 | 0 |
| Lymphatic system disorders NEC | | |
| Lymph node pain | 1 | 0 |
| Lymphadenitis | 1 | 0 |
| Lymphadenopathy | 26 | 0 |
| Lymphadenopathy mediastinal | 1 | 0 |
| Marrow depression and hypoplastic anaemias | | |
| Aplastic anaemia | 1 | 0 |
| Neutropenias | | |
| Agranulocytosis | 1 | 0 |
| Febrile neutropenia | 1 | 0 |
| Neutropenia | 1 | 0 |
| Sickle cell trait and disorders | | |
| Sickle cell anaemia with crisis | 2 | 0 |
| Spleen disorders | | |
| Splenomegaly | 1 | 0 |
| Thrombocytopenias | | |
| Immune thrombocytopenia | 1 | 0 |
| Thrombocytopenia | 3 | 0 |
| Blood disorders SOC TOTAL | 51 | 0 |

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|---|-----------|----------|
| Cardiac disorders | | |
| <i>Cardiac signs and symptoms NEC</i> | | |
| Palpitations | 9 | 0 |
| <i>Coronary artery disorders NEC</i> | | |
| Arteriosclerosis coronary artery | 1 | 0 |
| Coronary artery disease | 1 | 0 |
| Coronary artery thrombosis | 1 | 0 |
| <i>Heart failures NEC</i> | | |
| Cardiac failure acute | 1 | 1 |
| Ventricular failure | 1 | 0 |
| <i>Ischaemic coronary artery disorders</i> | | |
| Angina pectoris | 2 | 0 |
| Myocardial infarction | 4 | 3 |
| Myocardial ischaemia | 4 | 1 |
| <i>Left ventricular failures</i> | | |
| Left ventricular failure | 1 | 0 |
| <i>Myocardial disorders NEC</i> | | |
| Myocardial fibrosis | 1 | 0 |
| <i>Noninfectious myocarditis</i> | | |
| Myocarditis | 1 | 0 |
| <i>Noninfectious pericarditis</i> | | |
| Pericarditis | 1 | 0 |
| <i>Pericardial disorders NEC</i> | | |
| Cardiac tamponade | 1 | 0 |
| <i>Rate and rhythm disorders NEC</i> | | |
| Bradycardia | 2 | 0 |
| Cardiac flutter | 1 | 0 |
| Tachycardia | 14 | 0 |
| <i>Supraventricular arrhythmias</i> | | |
| Atrial fibrillation | 3 | 0 |
| Sinus tachycardia | 1 | 0 |
| Supraventricular tachycardia | 2 | 0 |
| <i>Ventricular arrhythmias and cardiac arrest</i> | | |
| Ventricular extrasystoles | 1 | 0 |
| Cardiac disorders SOC TOTAL | 53 | 5 |

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|---|----------|----------|
| Congenital disorders | | |
| <i>Cardiac septal defects congenital</i> | | |
| Ventricular septal defect | 1 | 0 |
| <i>Haemoglobinopathies congenital</i> | | |
| Sickle cell anaemia | 1 | 0 |
| <i>Renal and urinary tract disorders congenital NEC</i> | | |
| Urinary tract malformation | 1 | 0 |
| Congenital disorders SOC TOTAL | 3 | 0 |

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|-------------------------------------|--------------|--------------|
| Ear disorders | | |
| <i>Ear disorders NEC</i> | | |
| Ear congestion | 1 | 0 |
| Ear disorder | 1 | 0 |
| Ear pain | 1 | 0 |
| <i>Hearing losses</i> | | |
| Deafness | 1 | 0 |
| Deafness neurosensory | 1 | 0 |
| Deafness unilateral | 1 | 0 |
| <i>Inner ear disorders NEC</i> | | |
| Meniere's disease | 1 | 0 |
| <i>Inner ear signs and symptoms</i> | | |
| Tinnitus | 4 | 0 |
| Vertigo | 7 | 0 |
| Ear disorders SOC TOTAL | 18 | 0 |

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|---------------------------------------|----------|----------|
| Endocrine disorders | | |
| <i>Adrenal cortical hypofunctions</i> | | |
| Adrenocortical insufficiency acute | 1 | 0 |
| Endocrine disorders SOC TOTAL | 1 | 0 |

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|--|-----------|----------|
| Eye disorders | | |
| <i>Choroid and vitreous structural change, deposit and degeneration</i> | | |
| Vitreous floaters | 1 | 0 |
| <i>Lid, lash and lacrimal infections, irritations and inflammations</i> | | |
| Swelling of eyelid | 1 | 0 |
| <i>Ocular disorders NEC</i> | | |
| Eye disorder | 1 | 0 |
| Eye oedema | 1 | 0 |
| Eye pain | 1 | 0 |
| Eye swelling | 1 | 0 |
| Periorbital oedema | 2 | 0 |
| Vitreous disorder | 1 | 0 |
| <i>Ocular infections, inflammations and associated manifestations</i> | | |
| Eye pruritus | 1 | 0 |
| Ocular hyperaemia | 1 | 0 |
| <i>Ocular nerve and muscle disorders</i> | | |
| Eye movement disorder | 2 | 0 |
| <i>Ocular sensation disorders</i> | | |
| Photophobia | 8 | 0 |
| <i>Orbital structural change, deposit and degeneration</i> | | |
| Orbital oedema | 1 | 0 |
| <i>Pupil disorders</i> | | |
| Mydriasis | 1 | 0 |
| <i>Retinal, choroid and vitreous infections and inflammations</i> | | |
| Necrotising retinitis | 1 | 0 |
| <i>Scleral infections, irritations and inflammations</i> | | |
| Scleritis | 1 | 0 |
| <i>Visual disorders NEC</i> | | |
| Diplopia | 1 | 0 |
| Photopsia | 2 | 0 |
| Vision blurred | 6 | 0 |
| <i>Visual field disorders</i> | | |
| Visual field defect | 1 | 0 |
| <i>Visual impairment and blindness (excl colour blindness)</i> | | |
| Blindness | 1 | 0 |
| Visual acuity reduced | 1 | 0 |
| Visual impairment | 1 | 0 |
| <i>Visual pathway disorders</i> | | |
| Optic nerve disorder | 1 | 0 |
| Eye disorders SOC TOTAL | 39 | 0 |

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|--|-------|-------|
| Gastrointestinal disorders | | |
| <i>Abdominal findings abnormal</i> | | |
| Abdominal mass | 1 | 0 |
| <i>Acute and chronic pancreatitis</i> | | |
| Pancreatitis | 1 | 1 |
| <i>Colitis (excl infective)</i> | | |
| Colitis ulcerative | 1 | 0 |
| <i>Diarrhoea (excl infective)</i> | | |
| Diarrhoea | 22 | 0 |
| <i>Dyspeptic signs and symptoms</i> | | |
| Dyspepsia | 1 | 0 |
| <i>Faecal abnormalities NEC</i> | | |
| Mucous stools | 2 | 0 |
| <i>Flatulence, bloating and distension</i> | | |
| Abdominal distension | 2 | 0 |
| Flatulence | 1 | 0 |
| <i>Gastrointestinal and abdominal pains (excl oral and throat)</i> | | |
| Abdominal pain | 7 | 0 |
| Abdominal pain lower | 2 | 0 |
| Abdominal pain upper | 3 | 0 |
| Abdominal tenderness | 1 | 0 |
| <i>Gastrointestinal atonic and hypomotility disorders NEC</i> | | |
| Constipation | 1 | 0 |
| Gastrooesophageal reflux disease | 2 | 0 |
| <i>Gastrointestinal signs and symptoms NEC</i> | | |
| Abdominal discomfort | 6 | 0 |
| Anal incontinence | 1 | 0 |
| Dysphagia | 1 | 0 |
| <i>Gastrointestinal spastic and hypermotility disorders</i> | | |
| Irritable bowel syndrome | 1 | 0 |
| <i>Gingival haemorrhages</i> | | |
| Gingival bleeding | 1 | 0 |
| <i>Nausea and vomiting symptoms</i> | | |
| Nausea | 98 | 0 |
| Vomiting | 69 | 0 |
| <i>Oral soft tissue signs and symptoms</i> | | |
| Lip erythema | 1 | 0 |
| Lip pain | 1 | 0 |
| Oral mucosal blistering | 1 | 0 |
| Oral pain | 1 | 0 |
| Paraesthesia oral | 1 | 0 |
| <i>Oral soft tissue swelling and oedema</i> | | |
| Lip swelling | 2 | 0 |
| Palatal oedema | 1 | 0 |
| <i>Peritoneal and retroperitoneal disorders</i> | | |
| Ascites | 1 | 0 |
| <i>Peritoneal and retroperitoneal haemorrhages</i> | | |
| Retroperitoneal haematoma | 1 | 0 |
| <i>Stomatitis and ulceration</i> | | |
| Mouth ulceration | 4 | 0 |
| Stomatitis | 2 | 0 |
| <i>Tongue disorders</i> | | |
| Glossitis | 1 | 0 |
| Tongue ulceration | 1 | 0 |

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| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| <i>Tongue signs and symptoms</i> | | |
| Swollen tongue | 2 | 0 |
| Tongue blistering | 2 | 0 |
| Tongue oedema | 1 | 0 |
| Gastrointestinal disorders SOC TOTAL | 247 | 1 |

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|--|-------|-------|
| General disorders | | |
| Administration site reactions NEC | | |
| Administration site pain | 1 | 0 |
| Administration site rash | 1 | 0 |
| Administration site swelling | 1 | 0 |
| Application and instillation site reactions | | |
| Application site erythema | 1 | 0 |
| Asthenic conditions | | |
| Asthenia | 37 | 0 |
| Fatigue | 47 | 0 |
| Malaise | 183 | 0 |
| Body temperature altered | | |
| Hypothermia | 1 | 0 |
| Death and sudden death | | |
| Death | 2 | 2 |
| Sudden death | 1 | 1 |
| Febrile disorders | | |
| Pyrexia | 302 | 0 |
| Feelings and sensations NEC | | |
| Chills | 95 | 0 |
| Feeling abnormal | 11 | 0 |
| Feeling cold | 13 | 0 |
| Feeling drunk | 1 | 0 |
| Feeling hot | 45 | 0 |
| Feeling of body temperature change | 9 | 0 |
| Thirst | 1 | 0 |
| Gait disturbances | | |
| Gait disturbance | 6 | 0 |
| Gait inability | 1 | 0 |
| Loss of control of legs | 1 | 0 |
| General signs and symptoms NEC | | |
| Condition aggravated | 6 | 0 |
| Foaming at mouth | 1 | 0 |
| Illness | 7 | 0 |
| Induration | 6 | 0 |
| Influenza like illness | 67 | 0 |
| Local reaction | 153 | 0 |
| Multiple organ dysfunction syndrome | 1 | 1 |
| Peripheral swelling | 260 | 0 |
| Screaming | 1 | 0 |
| Swelling | 85 | 0 |
| Swelling face | 5 | 0 |
| Inflammations | | |
| Inflammation | 53 | 0 |
| Systemic inflammatory response syndrome | 3 | 0 |
| Injection site reactions | | |
| Injected limb mobility decreased | 8 | 0 |
| Injection site abscess sterile | 1 | 0 |
| Injection site atrophy | 1 | 0 |
| Injection site bruising | 1 | 0 |
| Injection site discolouration | 2 | 0 |
| Injection site erythema | 70 | 0 |
| Injection site haematoma | 2 | 0 |
| Injection site haemorrhage | 1 | 0 |

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| General disorders General disorders cont'd | | |
| Injection site hypersensitivity | 1 | 0 |
| Injection site induration | 6 | 0 |
| Injection site inflammation | 66 | 0 |
| Injection site joint swelling | 1 | 0 |
| Injection site joint warmth | 1 | 0 |
| Injection site mass | 9 | 0 |
| Injection site movement impairment | 3 | 0 |
| Injection site necrosis | 2 | 0 |
| Injection site oedema | 4 | 0 |
| Injection site pain | 83 | 0 |
| Injection site pruritus | 8 | 0 |
| Injection site rash | 13 | 0 |
| Injection site reaction | 108 | 0 |
| Injection site scar | 3 | 0 |
| Injection site swelling | 57 | 0 |
| Injection site ulcer | 3 | 0 |
| Injection site urticaria | 1 | 0 |
| Injection site vesicles | 3 | 0 |
| Injection site warmth | 17 | 0 |
| Interactions | | |
| Drug interaction | 2 | 0 |
| Mass conditions NEC | | |
| Mass | 3 | 0 |
| Nodule | 1 | 0 |
| Necrosis NEC | | |
| Necrosis | 1 | 0 |
| Oedema NEC | | |
| Localised oedema | 8 | 0 |
| Oedema | 13 | 0 |
| Oedema peripheral | 14 | 0 |
| Pain and discomfort NEC | | |
| Axillary pain | 11 | 0 |
| Chest discomfort | 20 | 0 |
| Chest pain | 21 | 0 |
| Discomfort | 3 | 0 |
| Facial pain | 2 | 0 |
| Non-cardiac chest pain | 1 | 0 |
| Pain | 121 | 0 |
| Tenderness | 25 | 0 |
| Therapeutic and nontherapeutic responses | | |
| Adverse drug reaction | 1 | 0 |
| Drug ineffective | 7 | 0 |
| Therapeutic response decreased | 1 | 0 |
| Therapy non-responder | 4 | 0 |
| Vaccination failure | 9 | 0 |
| Ulcers NEC | | |
| Ulcer | 2 | 0 |
| Vaccination site reactions | | |
| Extensive swelling of vaccinated limb | 1 | 0 |
| Vaccination site bruising | 2 | 0 |
| Vaccination site discolouration | 1 | 0 |
| Vaccination site discomfort | 1 | 0 |
| Vaccination site erythema | 34 | 0 |

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|---|-------------|----------|
| General disorders General disorders cont'd | | |
| Vaccination site induration | 4 | 0 |
| Vaccination site inflammation | 7 | 0 |
| Vaccination site irritation | 1 | 0 |
| Vaccination site joint movement impairment | 3 | 0 |
| Vaccination site mass | 4 | 0 |
| Vaccination site movement impairment | 5 | 0 |
| Vaccination site pain | 53 | 0 |
| Vaccination site phlebitis | 1 | 0 |
| Vaccination site pruritus | 1 | 0 |
| Vaccination site rash | 11 | 0 |
| Vaccination site reaction | 8 | 0 |
| Vaccination site scab | 1 | 0 |
| Vaccination site swelling | 42 | 0 |
| Vaccination site warmth | 17 | 0 |
| General disorders SOC TOTAL | 2350 | 4 |

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|--|-----------|----------|
| Hepatic disorders | | |
| <i>Bile duct infections and inflammations</i> | | |
| Biliary colic | 1 | 0 |
| <i>Cholecystitis and cholelithiasis</i> | | |
| Cholecystitis | 1 | 0 |
| Cholelithiasis | 2 | 0 |
| <i>Cholestasis and jaundice</i> | | |
| Jaundice | 3 | 0 |
| <i>Hepatic and hepatobiliary disorders NEC</i> | | |
| Liver disorder | 1 | 0 |
| <i>Hepatic failure and associated disorders</i> | | |
| Acute hepatic failure | 1 | 1 |
| Hepatic failure | 1 | 0 |
| Hepatorenal syndrome | 2 | 0 |
| <i>Hepatic fibrosis and cirrhosis</i> | | |
| Hepatic cirrhosis | 1 | 1 |
| <i>Hepatocellular damage and hepatitis NEC</i> | | |
| Hepatitis | 1 | 0 |
| Hepatitis chronic active | 1 | 0 |
| Hepatic disorders SOC TOTAL | 15 | 2 |

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|--|-----------|----------|
| Immune system disorders | | |
| <i>Allergic conditions NEC</i> | | |
| Hypersensitivity | 43 | 0 |
| Serum sickness | 1 | 0 |
| <i>Allergies to foods, food additives, drugs and other chemicals</i> | | |
| Allergy to vaccine | 1 | 0 |
| <i>Anaphylactic and anaphylactoid responses</i> | | |
| Anaphylactic reaction | 12 | 0 |
| Anaphylactic shock | 5 | 1 |
| Anaphylactoid reaction | 3 | 0 |
| <i>Atopic disorders</i> | | |
| Seasonal allergy | 1 | 0 |
| <i>Blood isoimmune reactions</i> | | |
| Alloimmunisation | 1 | 0 |
| <i>Immune and associated conditions NEC</i> | | |
| Immune system disorder | 1 | 0 |
| Immune system disorders SOC TOTAL | 68 | 1 |

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| Infections | | |
| <i>Bacterial infections NEC</i> | | |
| Administration site cellulitis | 1 | 0 |
| Arthritis bacterial | 1 | 0 |
| Bacterial infection | 1 | 0 |
| Cellulitis | 111 | 0 |
| Cellulitis gangrenous | 1 | 0 |
| Injection site cellulitis | 25 | 0 |
| Pneumonia bacterial | 1 | 0 |
| Post procedural cellulitis | 1 | 0 |
| Vaccination site cellulitis | 14 | 0 |
| <i>Bone and joint infections</i> | | |
| Arthritis infective | 1 | 0 |
| <i>Central nervous system and spinal infections</i> | | |
| Encephalitis | 3 | 0 |
| Encephalomyelitis | 1 | 0 |
| <i>Clostridia infections</i> | | |
| Clostridium difficile infection | 1 | 0 |
| Gas gangrene | 1 | 1 |
| <i>Dental and oral soft tissue infections</i> | | |
| Parotitis | 1 | 0 |
| <i>Ear infections</i> | | |
| Ear infection | 1 | 0 |
| Labyrinthitis | 1 | 0 |
| Otitis media | 1 | 0 |
| Otitis media acute | 1 | 0 |
| <i>Eye and eyelid infections</i> | | |
| Conjunctivitis | 1 | 0 |
| <i>Haemophilus infections</i> | | |
| Haemophilus infection | 1 | 0 |
| Haemophilus sepsis | 1 | 0 |
| Septic arthritis haemophilus | 1 | 0 |
| <i>Herpes viral infections</i> | | |
| Herpes zoster | 7 | 0 |
| Oral herpes | 1 | 0 |
| Varicella zoster virus infection | 1 | 0 |
| <i>Infections NEC</i> | | |
| Abscess | 6 | 0 |
| Abscess limb | 1 | 0 |
| Infection | 7 | 0 |
| Injection site abscess | 2 | 0 |
| Localised infection | 2 | 0 |
| Respiratory tract infection | 3 | 0 |
| Systemic infection | 1 | 0 |
| Vaccination site abscess | 1 | 0 |
| Vaccination site infection | 1 | 0 |
| <i>Influenza viral infections</i> | | |
| Influenza | 3 | 0 |
| <i>Lower respiratory tract and lung infections</i> | | |
| Bronchitis | 6 | 0 |
| Lower respiratory tract infection | 12 | 0 |
| Pneumonia | 24 | 5 |
| <i>Male reproductive tract infections</i> | | |
| Orchitis | 1 | 0 |

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| Infections | | |
| Infections cont'd | | |
| <i>Neisseria infections</i> | | |
| Meningitis meningococcal | 1 | 0 |
| Meningococcal sepsis | 1 | 0 |
| <i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i> | | |
| Bacteraemia | 1 | 0 |
| Sepsis | 7 | 0 |
| Septic shock | 2 | 0 |
| <i>Skin structures and soft tissue infections</i> | | |
| Carbuncle | 1 | 0 |
| Skin infection | 1 | 0 |
| Subcutaneous abscess | 1 | 0 |
| <i>Streptococcal infections</i> | | |
| Meningitis pneumococcal | 7 | 0 |
| Pneumococcal infection | 4 | 0 |
| Pneumococcal sepsis | 1 | 1 |
| Pneumonia pneumococcal | 1 | 0 |
| Pneumonia streptococcal | 1 | 1 |
| <i>Tuberculous infections</i> | | |
| Erythema induratum | 9 | 0 |
| <i>Upper respiratory tract infections</i> | | |
| Laryngitis | 2 | 0 |
| Nasopharyngitis | 8 | 0 |
| Rhinitis | 1 | 0 |
| <i>Urinary tract infections</i> | | |
| Urinary tract infection | 4 | 0 |
| <i>Vascular infections</i> | | |
| Lymphangitis | 3 | 0 |
| <i>Viral infections NEC</i> | | |
| Gastroenteritis viral | 1 | 0 |
| Viral infection | 1 | 0 |
| Viral rash | 1 | 0 |
| Infections SOC TOTAL | 310 | 8 |

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| Injuries | | |
| <i>Exposures associated with pregnancy, delivery and lactation</i> | | |
| Exposure during pregnancy | 3 | 0 |
| Foetal exposure during pregnancy | 2 | 0 |
| <i>Medication errors, product use errors and issues NEC</i> | | |
| Circumstance or information capable of leading to medication error | 1 | 0 |
| Medication error | 1 | 0 |
| Product use issue | 1 | 0 |
| Vaccination error | 1 | 0 |
| Wrong technique in product usage process | 1 | 0 |
| <i>Nerve injuries NEC</i> | | |
| Nerve injury | 1 | 0 |
| <i>Non-site specific injuries NEC</i> | | |
| Fall | 1 | 0 |
| <i>Non-site specific procedural complications</i> | | |
| Wound decomposition | 1 | 0 |
| <i>Off label uses</i> | | |
| Off label use | 3 | 0 |
| <i>Product administration errors and issues</i> | | |
| Inappropriate schedule of product administration | 5 | 0 |
| Product administered at inappropriate site | 2 | 0 |
| Product administered to patient of inappropriate age | 1 | 0 |
| Product administration error | 3 | 0 |
| Wrong product administered | 2 | 0 |
| <i>Product prescribing errors and issues</i> | | |
| Product prescribing error | 1 | 0 |
| <i>Skin injuries NEC</i> | | |
| Contusion | 14 | 0 |
| Scar | 2 | 0 |
| <i>Vaccination related complications</i> | | |
| Vaccination complication | 3 | 0 |
| Injuries SOC TOTAL | 49 | 0 |

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| Investigations | | |
| <i>Autoimmunity analyses</i> | | |
| Antinuclear antibody positive | 1 | 0 |
| <i>Bacteria identification and serology (excl mycobacteria)</i> | | |
| Streptococcus test positive | 2 | 0 |
| <i>Blood gas and acid base analyses</i> | | |
| Oxygen saturation decreased | 4 | 0 |
| <i>Carbohydrate tolerance analyses (incl diabetes)</i> | | |
| Blood glucose decreased | 1 | 0 |
| Blood glucose fluctuation | 1 | 0 |
| Blood glucose increased | 2 | 0 |
| <i>Cardiac auscultatory investigations</i> | | |
| Cardiac murmur | 1 | 0 |
| <i>Cell marker analyses</i> | | |
| Prostatic specific antigen increased | 1 | 0 |
| <i>Chemistry analyses NEC</i> | | |
| Inflammatory marker increased | 2 | 0 |
| <i>Cholesterol analyses</i> | | |
| High density lipoprotein decreased | 1 | 0 |
| <i>Coagulation and bleeding analyses</i> | | |
| Fibrin D dimer increased | 1 | 0 |
| International normalised ratio increased | 2 | 0 |
| <i>Haematological analyses NEC</i> | | |
| Red blood cell sedimentation rate increased | 1 | 0 |
| <i>Heart rate and pulse investigations</i> | | |
| Heart rate increased | 8 | 0 |
| Heart rate irregular | 2 | 0 |
| <i>Immunology analyses NEC</i> | | |
| Antibody test abnormal | 1 | 0 |
| Antibody test negative | 2 | 0 |
| <i>Liver function analyses</i> | | |
| Alanine aminotransferase increased | 1 | 0 |
| Liver function test abnormal | 1 | 0 |
| <i>Microbiology and serology tests NEC</i> | | |
| Seroconversion test negative | 1 | 0 |
| <i>Mineral and electrolyte analyses</i> | | |
| Blood potassium increased | 1 | 0 |
| <i>Physical examination procedures and organ system status</i> | | |
| Body temperature fluctuation | 1 | 0 |
| Body temperature increased | 33 | 0 |
| Grip strength decreased | 1 | 0 |
| Weight decreased | 2 | 0 |
| <i>Platelet analyses</i> | | |
| Platelet count decreased | 1 | 0 |
| <i>Protein analyses NEC</i> | | |
| C-reactive protein increased | 3 | 0 |
| <i>Renal function analyses</i> | | |
| Blood creatinine increased | 2 | 0 |
| <i>Skeletal and cardiac muscle analyses</i> | | |
| Blood creatine phosphokinase increased | 2 | 0 |
| <i>Urinalysis NEC</i> | | |
| Blood urine present | 1 | 0 |
| Protein urine present | 1 | 0 |
| <i>Vascular tests NEC (incl blood pressure)</i> | | |

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| Reaction Name | Total | Fatal |
|---|--------------|--------------|
| Investigations Investigations cont'd | | |
| Blood pressure abnormal | 1 | 0 |
| Blood pressure decreased | 1 | 0 |
| Blood pressure increased | 4 | 0 |
| <i>White blood cell analyses</i> | | |
| White blood cell count increased | 4 | 0 |
| Investigations SOC TOTAL | 94 | 0 |

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 MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Metabolic disorders | | |
| <i>Appetite disorders</i> | | |
| Decreased appetite | 32 | 0 |
| Hypophagia | 1 | 0 |
| <i>Diabetes mellitus (incl subtypes)</i> | | |
| Diabetes mellitus | 1 | 0 |
| Diabetes mellitus inadequate control | 6 | 0 |
| <i>Disorders of purine metabolism</i> | | |
| Gout | 2 | 0 |
| <i>Fluid intake increased</i> | | |
| Polydipsia | 1 | 0 |
| <i>General nutritional disorders NEC</i> | | |
| Abnormal loss of weight | 1 | 0 |
| Feeding disorder | 1 | 0 |
| <i>Hypoglycaemic conditions NEC</i> | | |
| Hypoglycaemia | 1 | 0 |
| <i>Potassium imbalance</i> | | |
| Hyperkalaemia | 1 | 0 |
| <i>Total fluid volume decreased</i> | | |
| Dehydration | 4 | 0 |
| <i>Total fluid volume increased</i> | | |
| Fluid retention | 1 | 0 |
| Metabolic disorders SOC TOTAL | 52 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Muscle & tissue disorders | | |
| <i>Arthropathies NEC</i> | | |
| Arthritis | 5 | 0 |
| Arthropathy | 3 | 0 |
| Polyarthritis | 5 | 0 |
| Seronegative arthritis | 1 | 0 |
| <i>Bone disorders NEC</i> | | |
| Osteonecrosis | 1 | 0 |
| <i>Bone related signs and symptoms</i> | | |
| Bone pain | 2 | 0 |
| Bone swelling | 1 | 0 |
| Pain in jaw | 2 | 0 |
| <i>Bursal disorders</i> | | |
| Bursitis | 5 | 0 |
| <i>Connective tissue disorders NEC</i> | | |
| Myofascitis | 1 | 0 |
| Polymyalgia rheumatica | 3 | 0 |
| <i>Joint related disorders NEC</i> | | |
| Joint lock | 1 | 0 |
| Periarthritis | 10 | 0 |
| Rotator cuff syndrome | 1 | 0 |
| Temporomandibular joint syndrome | 1 | 0 |
| <i>Joint related signs and symptoms</i> | | |
| Arthralgia | 86 | 0 |
| Joint effusion | 1 | 0 |
| Joint stiffness | 2 | 0 |
| Joint swelling | 18 | 0 |
| <i>Lupus erythematosus (incl subtypes)</i> | | |
| Systemic lupus erythematosus | 1 | 0 |
| <i>Muscle infections and inflammations</i> | | |
| Myositis | 6 | 0 |
| <i>Muscle pains</i> | | |
| Myalgia | 92 | 0 |
| <i>Muscle related signs and symptoms NEC</i> | | |
| Muscle atrophy | 1 | 0 |
| Muscle disorder | 1 | 0 |
| Muscle fatigue | 4 | 0 |
| Muscle mass | 1 | 0 |
| Muscle spasms | 6 | 0 |
| Muscle swelling | 1 | 0 |
| Muscle tightness | 1 | 0 |
| Muscle twitching | 1 | 0 |
| <i>Muscle weakness conditions</i> | | |
| Muscular weakness | 16 | 0 |
| <i>Musculoskeletal and connective tissue conditions NEC</i> | | |
| Limb mass | 1 | 0 |
| Mobility decreased | 8 | 0 |
| Musculoskeletal stiffness | 29 | 0 |
| Weight bearing difficulty | 29 | 0 |
| <i>Musculoskeletal and connective tissue pain and discomfort</i> | | |
| Back pain | 17 | 0 |
| Limb discomfort | 11 | 0 |
| Musculoskeletal chest pain | 3 | 0 |
| Musculoskeletal discomfort | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Muscle & tissue disorders | | |
| Muscle & tissue disorders cont'd | | |
| Musculoskeletal pain | 1 | 0 |
| Neck pain | 10 | 0 |
| Pain in extremity | 213 | 0 |
| Myopathies | | |
| Myopathy | 1 | 0 |
| Rhabdomyolysis | 1 | 0 |
| Osteoarthropathies | | |
| Osteoarthritis | 2 | 0 |
| Rheumatoid arthropathies | | |
| Rheumatoid arthritis | 4 | 0 |
| Soft tissue disorders NEC | | |
| Soft tissue disorder | 1 | 0 |
| Spondyloarthropathies | | |
| Arthritis reactive | 1 | 0 |
| Synovial disorders | | |
| Synovitis | 1 | 0 |
| Tendon disorders | | |
| Tendon disorder | 1 | 0 |
| Muscle & tissue disorders SOC TOTAL | 615 | 0 |

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| Reaction Name | Total | Fatal |
|---|----------|----------|
| Neoplasms | | |
| <i>Breast and nipple neoplasms malignant</i> | | |
| Intraductal proliferative breast lesion | 1 | 0 |
| Invasive ductal breast carcinoma | 1 | 0 |
| <i>Lymphomas unspecified NEC</i> | | |
| Lymphoma | 2 | 1 |
| <i>Mesotheliomas malignant and unspecified</i> | | |
| Mesothelioma | 1 | 0 |
| <i>Metastases to specified sites</i> | | |
| Metastases to bone | 1 | 0 |
| <i>Non-small cell neoplasms malignant of the respiratory tract cell type specified</i> | | |
| Lung adenocarcinoma stage IV | 1 | 1 |
| Neoplasms SOC TOTAL | 7 | 2 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders | | |
| <i>Acute polyneuropathies</i> | | |
| Guillain-Barre syndrome | 13 | 2 |
| <i>Central nervous system haemorrhages and cerebrovascular accidents</i> | | |
| Cerebrovascular accident | 6 | 2 |
| <i>Choreiform movements</i> | | |
| Choreoathetosis | 1 | 0 |
| <i>Chronic polyneuropathies</i> | | |
| Chronic inflammatory demyelinating polyradiculoneuropathy | 2 | 0 |
| Diabetic neuropathy | 1 | 0 |
| <i>Coordination and balance disturbances</i> | | |
| Ataxia | 2 | 0 |
| Balance disorder | 3 | 0 |
| Dysstasia | 1 | 0 |
| <i>Cortical dysfunction NEC</i> | | |
| Aphasia | 1 | 0 |
| <i>Demyelinating disorders NEC</i> | | |
| Acute disseminated encephalomyelitis | 1 | 1 |
| <i>Disturbances in consciousness NEC</i> | | |
| Lethargy | 22 | 0 |
| Loss of consciousness | 11 | 0 |
| Somnolence | 18 | 0 |
| Stupor | 2 | 0 |
| Syncope | 21 | 0 |
| <i>Dyskinesias and movement disorders NEC</i> | | |
| Hypokinesia | 8 | 0 |
| Movement disorder | 2 | 0 |
| <i>Facial cranial nerve disorders</i> | | |
| Facial paralysis | 1 | 0 |
| Facial paresis | 2 | 0 |
| <i>Generalised tonic-clonic seizures</i> | | |
| Generalised tonic-clonic seizure | 2 | 0 |
| <i>Headaches NEC</i> | | |
| Cluster headache | 1 | 0 |
| Headache | 122 | 0 |
| Sinus headache | 1 | 0 |
| <i>Memory loss (excl dementia)</i> | | |
| Amnesia | 1 | 0 |
| <i>Mental impairment (excl dementia and memory loss)</i> | | |
| Disturbance in attention | 5 | 0 |
| <i>Migraine headaches</i> | | |
| Migraine | 2 | 0 |
| Migraine with aura | 1 | 0 |
| <i>Mononeuropathies</i> | | |
| Nerve compression | 1 | 0 |
| Peroneal nerve palsy | 1 | 0 |
| <i>Motor neurone diseases</i> | | |
| Motor neurone disease | 1 | 0 |
| <i>Multiple sclerosis acute and progressive</i> | | |
| Multiple sclerosis | 1 | 0 |
| <i>Myelitis (incl infective)</i> | | |
| Myelitis transverse | 1 | 0 |
| <i>Nervous system disorders NEC</i> | | |
| Nervous system disorder | 1 | 0 |

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| Reaction Name | Total | Fatal |
|---|------------|----------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Neurologic visual problems NEC | | |
| Tunnel vision | 1 | 0 |
| Neurological signs and symptoms NEC | | |
| Dizziness | 52 | 0 |
| Dizziness postural | 2 | 0 |
| Head discomfort | 2 | 0 |
| Meningism | 1 | 0 |
| Myoclonus | 1 | 0 |
| Neurological symptom | 1 | 0 |
| Presyncope | 3 | 0 |
| Slow response to stimuli | 1 | 0 |
| Optic nerve disorders NEC | | |
| Optic neuritis | 1 | 0 |
| Paraesthesias and dysaesthesias | | |
| Burning sensation | 7 | 0 |
| Hyperaesthesia | 1 | 0 |
| Hypoaesthesia | 21 | 0 |
| Paraesthesia | 26 | 0 |
| Paralysis and paresis (excl cranial nerve) | | |
| Hemiparesis | 1 | 0 |
| Hemiplegia | 1 | 0 |
| Monoplegia | 3 | 0 |
| Paralysis | 3 | 0 |
| Parkinson's disease and parkinsonism | | |
| Cogwheel rigidity | 1 | 0 |
| Parkinson's disease | 1 | 0 |
| Peripheral neuropathies NEC | | |
| Brachial plexopathy | 1 | 0 |
| Neuralgic amyotrophy | 2 | 0 |
| Neuritis | 1 | 0 |
| Neuropathy peripheral | 1 | 0 |
| Polyneuropathy | 1 | 0 |
| Seizures and seizure disorders NEC | | |
| Epilepsy | 3 | 0 |
| Febrile convulsion | 1 | 0 |
| Seizure | 6 | 0 |
| Status epilepticus | 1 | 0 |
| Sensory abnormalities NEC | | |
| Allodynia | 1 | 0 |
| Electric shock sensation | 1 | 0 |
| Neuralgia | 4 | 0 |
| Sensory disturbance | 4 | 0 |
| Sensory loss | 2 | 0 |
| Speech and language abnormalities | | |
| Dysarthria | 3 | 0 |
| Slow speech | 1 | 0 |
| Speech disorder | 1 | 0 |
| Spinal cord and nerve root disorders NEC | | |
| Radiculitis brachial | 2 | 0 |
| Radiculopathy | 1 | 0 |
| Tremor (excl congenital) | | |
| Tremor | 22 | 0 |
| Nervous system disorders SOC TOTAL | 448 | 5 |

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| Reaction Name | Total | Fatal |
|--|--------------|--------------|
| Pregnancy conditions | | |
| <i>Abortions spontaneous</i> | | |
| Abortion spontaneous | 1 | 0 |
| <i>Foetal complications NEC</i> | | |
| Foetal distress syndrome | 1 | 0 |
| <i>Labour onset and length abnormalities</i> | | |
| Premature delivery | 1 | 0 |
| <i>Maternal complications of delivery NEC</i> | | |
| Complication of delivery | 1 | 0 |
| <i>Maternal complications of pregnancy NEC</i> | | |
| Hyperemesis gravidarum | 1 | 0 |
| <i>Neonatal hepatobiliary disorders</i> | | |
| Jaundice neonatal | 1 | 0 |
| Pregnancy conditions SOC TOTAL | 6 | 0 |

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| Reaction Name | Total | Fatal |
|---|--------------|--------------|
| <i>Product contamination and sterility issues</i> | | |
| Product contamination microbial | 1 | 0 |
| <i>Product quality issues NEC</i> | | |
| Product quality issue | 1 | 0 |
| null SOC TOTAL | 2 | 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 | 2 | 0 |
| <i>Behaviour and socialisation disturbances</i> | | |
| Paranoia | 1 | 0 |
| Social avoidant behaviour | 1 | 0 |
| <i>Confusion and disorientation</i> | | |
| Confusional state | 5 | 0 |
| Disorientation | 5 | 0 |
| <i>Decreased physical activity levels</i> | | |
| Catatonia | 1 | 0 |
| <i>Deliria</i> | | |
| Delirium | 2 | 0 |
| <i>Depressive disorders</i> | | |
| Depression | 3 | 0 |
| <i>Dissociative states</i> | | |
| Dissociation | 1 | 0 |
| <i>Disturbances in initiating and maintaining sleep</i> | | |
| Insomnia | 12 | 0 |
| <i>Eating disorders NEC</i> | | |
| Binge eating | 1 | 0 |
| Eating disorder | 1 | 0 |
| <i>Emotional and mood disturbances NEC</i> | | |
| Anger | 1 | 0 |
| Mood altered | 1 | 0 |
| <i>Hallucinations (excl sleep-related)</i> | | |
| Hallucination | 2 | 0 |
| <i>Mood alterations with depressive symptoms</i> | | |
| Depressive symptom | 1 | 0 |
| Tearfulness | 1 | 0 |
| <i>Mood disorders NEC</i> | | |
| Listless | 1 | 0 |
| <i>Parasomnias</i> | | |
| Abnormal dreams | 1 | 0 |
| Nightmare | 1 | 0 |
| <i>Psychotic disorder NEC</i> | | |
| Psychotic disorder | 2 | 0 |
| <i>Sleep disorders NEC</i> | | |
| Sleep disorder | 2 | 0 |
| Psychiatric disorders SOC TOTAL | 50 | 0 |

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| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Renal & urinary disorders | | |
| <i>Bladder and urethral symptoms</i> | | |
| Dysuria | 3 | 0 |
| Incontinence | 1 | 0 |
| Micturition urgency | 1 | 0 |
| Pollakiuria | 3 | 0 |
| Urinary incontinence | 2 | 0 |
| Urinary retention | 1 | 0 |
| <i>Bladder disorders NEC</i> | | |
| Bladder obstruction | 1 | 0 |
| <i>Glomerulonephritis and nephrotic syndrome</i> | | |
| Focal segmental glomerulosclerosis | 1 | 0 |
| Glomerulonephritis rapidly progressive | 1 | 0 |
| Nephrotic syndrome | 3 | 0 |
| <i>Nephritis NEC</i> | | |
| Lupus nephritis | 1 | 0 |
| Tubulointerstitial nephritis | 1 | 0 |
| <i>Renal failure and impairment</i> | | |
| Acute kidney injury | 6 | 0 |
| Chronic kidney disease | 1 | 0 |
| <i>Urinary abnormalities</i> | | |
| Proteinuria | 1 | 0 |
| <i>Urinary tract signs and symptoms NEC</i> | | |
| Polyuria | 1 | 0 |
| Renal pain | 1 | 0 |
| Renal & urinary disorders SOC TOTAL | 29 | 0 |

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| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Reproductive & breast disorders | | |
| <i>Breast disorders NEC</i> | | |
| Breast mass | 1 | 0 |
| <i>Breast signs and symptoms</i> | | |
| Breast pain | 4 | 0 |
| Breast swelling | 1 | 0 |
| <i>Reproductive tract signs and symptoms NEC</i> | | |
| Genital rash | 1 | 0 |
| <i>Testicular and epididymal disorders NEC</i> | | |
| Testicular disorder | 1 | 0 |
| <i>Vaginal and vulval infections and inflammations</i> | | |
| Vulvovaginal inflammation | 1 | 0 |
| <i>Vulvovaginal disorders NEC</i> | | |
| Vulval ulceration | 1 | 0 |
| <i>Vulvovaginal signs and symptoms</i> | | |
| Vulvovaginal burning sensation | 1 | 0 |
| Vulvovaginal erythema | 1 | 0 |
| Reproductive & breast disorders SOC TOTAL | 12 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Respiratory disorders | | |
| <i>Breathing abnormalities</i> | | |
| Dyspnoea | 41 | 0 |
| Dyspnoea exertional | 1 | 0 |
| Hyperventilation | 1 | 0 |
| Respiratory arrest | 1 | 0 |
| Respiratory distress | 2 | 0 |
| <i>Bronchial conditions NEC</i> | | |
| Bronchiectasis | 2 | 0 |
| <i>Bronchospasm and obstruction</i> | | |
| Asthma | 12 | 2 |
| Bronchospasm | 4 | 0 |
| Wheezing | 14 | 0 |
| <i>Conditions associated with abnormal gas exchange</i> | | |
| Hypoxia | 1 | 0 |
| <i>Coughing and associated symptoms</i> | | |
| Cough | 49 | 0 |
| Haemoptysis | 1 | 0 |
| Productive cough | 6 | 0 |
| Sputum discoloured | 1 | 0 |
| <i>Lower respiratory tract inflammatory and immunologic conditions</i> | | |
| Pulmonary eosinophilia | 1 | 0 |
| <i>Lower respiratory tract signs and symptoms</i> | | |
| Increased bronchial secretion | 2 | 0 |
| Pleuritic pain | 1 | 0 |
| <i>Nasal congestion and inflammations</i> | | |
| Nasal congestion | 3 | 0 |
| <i>Parenchymal lung disorders NEC</i> | | |
| Emphysema | 1 | 0 |
| Organising pneumonia | 1 | 0 |
| Pulmonary fibrosis | 7 | 2 |
| <i>Pharyngeal disorders (excl infections and neoplasms)</i> | | |
| Pharyngeal swelling | 1 | 0 |
| Tonsillar inflammation | 1 | 0 |
| <i>Pleural conditions NEC</i> | | |
| Pleural thickening | 1 | 0 |
| <i>Pneumothorax and pleural effusions NEC</i> | | |
| Pleural effusion | 6 | 0 |
| <i>Pulmonary oedemas</i> | | |
| Acute pulmonary oedema | 1 | 0 |
| <i>Respiratory failures (excl neonatal)</i> | | |
| Respiratory failure | 1 | 1 |
| <i>Respiratory tract disorders NEC</i> | | |
| Lung disorder | 1 | 0 |
| Respiratory tract congestion | 1 | 0 |
| <i>Upper respiratory tract signs and symptoms</i> | | |
| Aphonia | 1 | 0 |
| Catarrh | 2 | 0 |
| Dysphonia | 3 | 0 |
| Nasal discomfort | 1 | 0 |
| Oropharyngeal pain | 16 | 0 |
| Rhinorrhoea | 5 | 0 |
| Sneezing | 2 | 0 |
| Throat irritation | 1 | 0 |

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| Reaction Name | Total | Fatal |
|---|------------|----------|
| Respiratory disorders Respiratory disorders cont'd | | |
| Throat tightness | 3 | 0 |
| Respiratory disorders SOC TOTAL | 199 | 5 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Skin disorders | | |
| Angioedemas | | |
| Angioedema | 1 | 0 |
| Apocrine and eccrine gland disorders | | |
| Cold sweat | 2 | 0 |
| Hyperhidrosis | 38 | 0 |
| Night sweats | 7 | 0 |
| Bullous conditions | | |
| Blister | 3 | 0 |
| Erythema multiforme | 1 | 0 |
| Stevens-Johnson syndrome | 1 | 0 |
| Toxic epidermal necrolysis | 1 | 0 |
| Dermal and epidermal conditions NEC | | |
| Acute febrile neutrophilic dermatosis | 1 | 0 |
| Dry skin | 2 | 0 |
| Pain of skin | 7 | 0 |
| Sensitive skin | 1 | 0 |
| Skin burning sensation | 1 | 0 |
| Skin discolouration | 5 | 0 |
| Skin disorder | 1 | 0 |
| Skin induration | 14 | 0 |
| Skin lesion | 2 | 0 |
| Skin necrosis | 1 | 0 |
| Skin reaction | 12 | 0 |
| Skin sensitisation | 1 | 0 |
| Skin swelling | 1 | 0 |
| Skin tightness | 3 | 0 |
| Skin warm | 28 | 0 |
| Dermatitis and eczema | | |
| Dermatitis | 3 | 0 |
| Dermatitis allergic | 5 | 0 |
| Eczema | 3 | 0 |
| Skin irritation | 3 | 0 |
| Erythemas | | |
| Erythema | 251 | 0 |
| Exfoliative conditions | | |
| Skin exfoliation | 7 | 0 |
| Panniculitides | | |
| Erythema nodosum | 2 | 0 |
| Pilar disorders NEC | | |
| Hair texture abnormal | 1 | 0 |
| Pruritus NEC | | |
| Pruritus | 35 | 0 |
| Psoriatic conditions | | |
| Erythrodermic psoriasis | 1 | 0 |
| Guttate psoriasis | 1 | 0 |
| Purpura and related conditions | | |
| Henoch-Schonlein purpura | 4 | 0 |
| Petechiae | 1 | 0 |
| Rashes, eruptions and exanthems NEC | | |
| Rash | 50 | 0 |
| Rash erythematous | 14 | 0 |
| Rash macular | 17 | 0 |
| Rash maculo-papular | 3 | 0 |

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| Reaction Name | Total | Fatal |
|---|------------|----------|
| Skin disorders Skin disorders cont'd | | |
| Rash papular | 6 | 0 |
| Rash pruritic | 5 | 0 |
| Skin dystrophies | | |
| Skin wrinkling | 2 | 0 |
| Skin vasculitides | | |
| Vasculitic rash | 4 | 0 |
| Urticarias | | |
| Urticaria | 46 | 0 |
| Urticaria papular | 1 | 0 |
| Urticarial vasculitis | 1 | 0 |
| Skin disorders SOC TOTAL | 600 | 0 |

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Data Lock Date: 08-Jul-2021 18:30:03
MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|----------|----------|
| Social circumstances | | |
| <i>Disability issues</i> | | |
| Bedridden | 1 | 0 |
| Immobile | 2 | 0 |
| Loss of personal independence in daily activities | 1 | 0 |
| <i>Social issues NEC</i> | | |
| Contraindication to vaccination | 2 | 0 |
| Social circumstances SOC TOTAL | 6 | 0 |

Case Series Drug Analysis Print

Name: FOI 21/740 Pneumovax

Report Run Date: 09-Jul-2021
Earliest Reaction Date: 23-Nov-1979

Data Lock Date: 08-Jul-2021 18:30:03
MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|--------------|--------------|
| Surgical & medical procedures | | |
| <i>Blood and blood product treatment</i> | | |
| Transfusion | 1 | 0 |
| <i>Inner ear therapeutic procedures</i> | | |
| Cochlea implant | 1 | 0 |
| <i>Obstetric therapeutic procedures</i> | | |
| Caesarean section | 1 | 0 |
| <i>Therapeutic procedures NEC</i> | | |
| Bed rest | 1 | 0 |
| Medical device removal | 1 | 0 |
| Surgical & medical procedures SOC TOTAL | 5 | 0 |

Case Series Drug Analysis Print

Name: FOI 21/740 Pneumovax

Report Run Date: 09-Jul-2021
Earliest Reaction Date: 23-Nov-1979

Data Lock Date: 08-Jul-2021 18:30:03
MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|-------------|-----------|
| Vascular disorders | | |
| <i>Blood pressure disorders NEC</i> | | |
| Blood pressure fluctuation | 1 | 0 |
| <i>Circulatory collapse and shock</i> | | |
| Circulatory collapse | 11 | 1 |
| Shock | 2 | 0 |
| <i>Haemorrhages NEC</i> | | |
| Haematoma | 1 | 0 |
| <i>Peripheral vascular disorders NEC</i> | | |
| Cyanosis | 3 | 0 |
| Flushing | 10 | 0 |
| Hot flush | 1 | 0 |
| <i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i> | | |
| Peripheral coldness | 7 | 0 |
| <i>Site specific vascular disorders NEC</i> | | |
| Pallor | 7 | 0 |
| <i>Vascular hypertensive disorders NEC</i> | | |
| Hypertension | 5 | 0 |
| <i>Vascular hypotensive disorders</i> | | |
| Hypotension | 10 | 0 |
| Orthostatic hypotension | 2 | 0 |
| <i>Vasculitides NEC</i> | | |
| Behcet's syndrome | 1 | 0 |
| Vasculitis | 2 | 0 |
| Vascular disorders SOC TOTAL | 63 | 1 |
| TOTAL REACTIONS FOR DRUG | 5392 | 34 |
| TOTAL REPORTS | 1852 | |
| TOTAL FATAL OUTCOME REPORTS | | 34 |