

Case Series Drug Analysis Print

Name: FOI 21/864 Trivalent Influenza (inactivated) Vaccine DAP

Report Run Date: 17-Aug-2021

Data Lock Date: 09-Aug-2021 18:30:04

Earliest Reaction Date: 29-Oct-1978

MedDRA Version: MedDRA 24.0

FOI 21/864 Trivalent Influenza (inactivated) Vaccine DAP: All spontaneous suspected UK Adverse Drug Reaction (ADR) reports associated with trivalent influenza virus (inactivated) vaccine

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| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Blood disorders | | |
| <i>Anaemias NEC</i> | | |
| Anaemia | 2 | 0 |
| <i>Anaemias haemolytic NEC</i> | | |
| Haemolytic anaemia | 1 | 0 |
| <i>Leukocytoses NEC</i> | | |
| Neutrophilia | 1 | 0 |
| <i>Lymphatic system disorders NEC</i> | | |
| Lymph node pain | 2 | 0 |
| Lymphadenopathy | 18 | 0 |
| <i>Marrow depression and hypoplastic anaemias</i> | | |
| Aplastic anaemia | 1 | 0 |
| Pancytopenia | 1 | 0 |
| <i>Neutropenias</i> | | |
| Neutropenia | 2 | 0 |
| <i>Thrombocytopenias</i> | | |
| Immune thrombocytopenia | 2 | 0 |
| Thrombocytopenia | 2 | 0 |
| Thrombotic thrombocytopenic purpura | 1 | 0 |
| Blood disorders SOC TOTAL | 33 | 0 |

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|---|-----------|----------|
| Cardiac disorders | | |
| <i>Cardiac disorders NEC</i> | | |
| Cardiac disorder | 2 | 0 |
| <i>Cardiac signs and symptoms NEC</i> | | |
| Palpitations | 23 | 0 |
| <i>Coronary artery disorders NEC</i> | | |
| Arteriosclerosis coronary artery | 1 | 0 |
| Coronary artery thrombosis | 1 | 1 |
| <i>Heart failures NEC</i> | | |
| Cardiac failure | 3 | 0 |
| <i>Ischaemic coronary artery disorders</i> | | |
| Angina pectoris | 1 | 0 |
| Myocardial infarction | 6 | 1 |
| Myocardial ischaemia | 2 | 1 |
| <i>Left ventricular failures</i> | | |
| Left ventricular failure | 1 | 1 |
| <i>Mitral valvular disorders</i> | | |
| Mitral valve prolapse | 1 | 0 |
| <i>Myocardial disorders NEC</i> | | |
| Cardiac septal hypertrophy | 1 | 0 |
| <i>Noninfectious myocarditis</i> | | |
| Myocarditis | 1 | 0 |
| <i>Noninfectious pericarditis</i> | | |
| Pericarditis | 2 | 0 |
| <i>Rate and rhythm disorders NEC</i> | | |
| Arrhythmia | 2 | 0 |
| Bradycardia | 1 | 0 |
| Extrasystoles | 1 | 0 |
| Tachycardia | 9 | 0 |
| Tachycardia paroxysmal | 1 | 0 |
| <i>Supraventricular arrhythmias</i> | | |
| Atrial fibrillation | 10 | 0 |
| Supraventricular tachycardia | 1 | 0 |
| <i>Ventricular arrhythmias and cardiac arrest</i> | | |
| Cardiac arrest | 7 | 4 |
| Ventricular extrasystoles | 1 | 0 |
| Cardiac disorders SOC TOTAL | 78 | 8 |

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|--|----------|----------|
| Congenital disorders | | |
| <i>Congenital disorders NEC</i> | | |
| Congenital anomaly | 1 | 0 |
| <i>Musculoskeletal and connective tissue disorders of skull congenital</i> | | |
| Plagiocephaly | 1 | 0 |
| Congenital disorders SOC TOTAL | 2 | 0 |

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|-------------------------------------|-----------|----------|
| Ear disorders | | |
| <i>Ear disorders NEC</i> | | |
| Ear congestion | 2 | 0 |
| Ear discomfort | 2 | 0 |
| Ear pain | 3 | 0 |
| Ear swelling | 1 | 0 |
| <i>Hearing losses</i> | | |
| Deafness neurosensory | 2 | 0 |
| Deafness unilateral | 4 | 0 |
| <i>Inner ear disorders NEC</i> | | |
| Meniere's disease | 2 | 0 |
| <i>Inner ear signs and symptoms</i> | | |
| Tinnitus | 3 | 0 |
| Vertigo | 24 | 0 |
| Ear disorders SOC TOTAL | 43 | 0 |

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|--|-----------|----------|
| Eye disorders | | |
| <i>Choroid and vitreous structural change, deposit and degeneration</i> | | |
| Vitreous floaters | 1 | 0 |
| <i>Conjunctival infections, irritations and inflammations</i> | | |
| Conjunctival hyperaemia | 1 | 0 |
| Conjunctival oedema | 1 | 0 |
| <i>Corneal infections, oedemas and inflammations</i> | | |
| Keratitis | 1 | 0 |
| <i>Glaucomas (excl congenital)</i> | | |
| Glaucoma | 2 | 0 |
| <i>Lacrimation disorders</i> | | |
| Lacrimation increased | 2 | 0 |
| <i>Lid, lash and lacrimal infections, irritations and inflammations</i> | | |
| Eyelid oedema | 1 | 0 |
| Swelling of eyelid | 3 | 0 |
| <i>Ocular disorders NEC</i> | | |
| Eye pain | 2 | 0 |
| Eye swelling | 5 | 0 |
| Periorbital oedema | 3 | 0 |
| Periorbital swelling | 2 | 0 |
| <i>Ocular infections, inflammations and associated manifestations</i> | | |
| Eye discharge | 2 | 0 |
| Eye irritation | 1 | 0 |
| Eye pruritus | 2 | 0 |
| Ocular hyperaemia | 3 | 0 |
| <i>Ocular nerve and muscle disorders</i> | | |
| Eye movement disorder | 1 | 0 |
| <i>Ocular sensation disorders</i> | | |
| Foreign body sensation in eyes | 1 | 0 |
| Photophobia | 2 | 0 |
| <i>Retinal, choroid and vitreous infections and inflammations</i> | | |
| Cystoid macular oedema | 1 | 0 |
| <i>Structural change, deposit and degeneration of eye NEC</i> | | |
| Exophthalmos | 1 | 0 |
| <i>Visual disorders NEC</i> | | |
| Diplopia | 4 | 0 |
| Vision blurred | 10 | 0 |
| <i>Visual impairment and blindness (excl colour blindness)</i> | | |
| Blindness | 3 | 0 |
| Blindness transient | 1 | 0 |
| Blindness unilateral | 1 | 0 |
| Visual impairment | 11 | 0 |
| Eye disorders SOC TOTAL | 68 | 0 |

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|--|-------|-------|
| Gastrointestinal disorders | | |
| <i>Colitis (excl infective)</i> | | |
| Colitis microscopic | 1 | 0 |
| <i>Dental pain and sensation disorders</i> | | |
| Toothache | 1 | 0 |
| <i>Diarrhoea (excl infective)</i> | | |
| Diarrhoea | 111 | 0 |
| Diarrhoea haemorrhagic | 1 | 0 |
| <i>Dyspeptic signs and symptoms</i> | | |
| Dyspepsia | 2 | 0 |
| <i>Faecal abnormalities NEC</i> | | |
| Faeces discoloured | 3 | 0 |
| Faeces hard | 1 | 0 |
| <i>Flatulence, bloating and distension</i> | | |
| Abdominal distension | 5 | 0 |
| Flatulence | 2 | 0 |
| <i>Gastritis (excl infective)</i> | | |
| Gastritis | 1 | 0 |
| <i>Gastrointestinal and abdominal pains (excl oral and throat)</i> | | |
| Abdominal pain | 18 | 0 |
| Abdominal pain lower | 4 | 0 |
| Abdominal pain upper | 23 | 0 |
| Gastrointestinal pain | 3 | 0 |
| <i>Gastrointestinal atonic and hypomotility disorders NEC</i> | | |
| Constipation | 4 | 0 |
| Gastric dilatation | 1 | 0 |
| <i>Gastrointestinal disorders NEC</i> | | |
| Gastrointestinal disorder | 3 | 0 |
| Stomach mass | 1 | 0 |
| <i>Gastrointestinal dyskinetic disorders</i> | | |
| Change of bowel habit | 1 | 0 |
| <i>Gastrointestinal signs and symptoms NEC</i> | | |
| Abdominal discomfort | 10 | 0 |
| Dysphagia | 3 | 0 |
| <i>Gastrointestinal spastic and hypermotility disorders</i> | | |
| Defaecation urgency | 1 | 0 |
| Frequent bowel movements | 1 | 0 |
| Irritable bowel syndrome | 2 | 0 |
| <i>Intestinal haemorrhages</i> | | |
| Rectal haemorrhage | 1 | 0 |
| <i>Nausea and vomiting symptoms</i> | | |
| Acetonaemic vomiting | 1 | 0 |
| Nausea | 137 | 0 |
| Vomiting | 100 | 0 |
| Vomiting projectile | 1 | 0 |
| <i>Non-site specific gastrointestinal haemorrhages</i> | | |
| Haematemesis | 1 | 0 |
| Haematochezia | 1 | 0 |
| <i>Oral dryness and saliva altered</i> | | |
| Dry mouth | 3 | 0 |
| Salivary hypersecretion | 1 | 0 |
| <i>Oral soft tissue signs and symptoms</i> | | |
| Hypoaesthesia oral | 2 | 0 |
| Lip erythema | 2 | 0 |

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|---|------------|----------|
| Gastrointestinal disorders | | |
| Gastrointestinal disorders cont'd | | |
| Lip pain | 1 | 0 |
| Oral pain | 2 | 0 |
| Paraesthesia oral | 3 | 0 |
| Oral soft tissue swelling and oedema | | |
| Lip swelling | 12 | 0 |
| Mouth swelling | 4 | 0 |
| Salivary gland enlargements | | |
| Parotid gland enlargement | 1 | 0 |
| Submaxillary gland enlargement | 1 | 0 |
| Stomatitis and ulceration | | |
| Mouth ulceration | 5 | 0 |
| Stomatitis | 1 | 0 |
| Tongue disorders | | |
| Tongue haemorrhage | 1 | 0 |
| Tongue ulceration | 1 | 0 |
| Tongue signs and symptoms | | |
| Glossodynia | 1 | 0 |
| Swollen tongue | 8 | 0 |
| Tongue discolouration | 1 | 0 |
| Tongue oedema | 1 | 0 |
| Gastrointestinal disorders SOC TOTAL | 496 | 0 |

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|--|-------|-------|
| General disorders | | |
| <i>Asthenic conditions</i> | | |
| Asthenia | 50 | 0 |
| Fatigue | 143 | 0 |
| Malaise | 189 | 0 |
| <i>Body temperature altered</i> | | |
| Hypothermia | 1 | 0 |
| <i>Death and sudden death</i> | | |
| Death | 4 | 4 |
| Sudden death | 10 | 10 |
| <i>Febrile disorders</i> | | |
| Pyrexia | 129 | 0 |
| <i>Feelings and sensations NEC</i> | | |
| Chills | 120 | 0 |
| Feeling abnormal | 18 | 0 |
| Feeling cold | 30 | 0 |
| Feeling drunk | 1 | 0 |
| Feeling hot | 21 | 0 |
| Feeling of body temperature change | 5 | 0 |
| Sensation of foreign body | 1 | 0 |
| Thirst | 1 | 0 |
| <i>Gait disturbances</i> | | |
| Gait disturbance | 4 | 0 |
| <i>General signs and symptoms NEC</i> | | |
| Condition aggravated | 4 | 0 |
| Crying | 1 | 0 |
| General physical health deterioration | 1 | 0 |
| Illness | 15 | 0 |
| Induration | 3 | 0 |
| Influenza like illness | 99 | 0 |
| Local reaction | 18 | 0 |
| Moaning | 1 | 0 |
| Peripheral swelling | 34 | 0 |
| Swelling | 27 | 0 |
| Swelling face | 19 | 0 |
| <i>Hernias NEC</i> | | |
| Hernia | 1 | 0 |
| <i>Inflammations</i> | | |
| Inflammation | 9 | 0 |
| Soft tissue inflammation | 1 | 0 |
| <i>Injection site reactions</i> | | |
| Injected limb mobility decreased | 7 | 0 |
| Injection site bruising | 2 | 0 |
| Injection site discolouration | 1 | 0 |
| Injection site dryness | 1 | 0 |
| Injection site erythema | 10 | 0 |
| Injection site haemorrhage | 1 | 0 |
| Injection site hypersensitivity | 1 | 0 |
| Injection site induration | 2 | 0 |
| Injection site inflammation | 7 | 0 |
| Injection site irritation | 2 | 0 |
| Injection site mass | 3 | 0 |
| Injection site movement impairment | 1 | 0 |
| Injection site pain | 26 | 0 |

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| General disorders General disorders cont'd | | |
| Injection site pruritus | 2 | 0 |
| Injection site rash | 3 | 0 |
| Injection site reaction | 31 | 0 |
| Injection site swelling | 5 | 0 |
| Injection site vesicles | 2 | 0 |
| Injection site warmth | 5 | 0 |
| Interactions | | |
| Alcohol interaction | 1 | 0 |
| Drug interaction | 5 | 0 |
| Mass conditions NEC | | |
| Mass | 1 | 0 |
| Oedema NEC | | |
| Face oedema | 3 | 0 |
| Gravitational oedema | 1 | 0 |
| Localised oedema | 2 | 0 |
| Oedema | 5 | 0 |
| Pain and discomfort NEC | | |
| Axillary pain | 3 | 0 |
| Chest discomfort | 15 | 0 |
| Chest pain | 23 | 0 |
| Discomfort | 6 | 0 |
| Facial pain | 3 | 0 |
| Pain | 96 | 0 |
| Tenderness | 4 | 0 |
| Therapeutic and nontherapeutic responses | | |
| Drug ineffective | 2 | 0 |
| Immediate post-injection reaction | 1 | 0 |
| Therapeutic response unexpected | 1 | 0 |
| Vaccination failure | 1 | 0 |
| Ulcers NEC | | |
| Ulcer | 1 | 0 |
| Vaccination site reactions | | |
| Extensive swelling of vaccinated limb | 1 | 0 |
| Shoulder injury related to vaccine administration | 2 | 0 |
| Vaccination site bruising | 11 | 0 |
| Vaccination site coldness | 1 | 0 |
| Vaccination site cyst | 1 | 0 |
| Vaccination site discomfort | 1 | 0 |
| Vaccination site eczema | 1 | 0 |
| Vaccination site erythema | 52 | 0 |
| Vaccination site hypersensitivity | 1 | 0 |
| Vaccination site hypoaesthesia | 2 | 0 |
| Vaccination site induration | 10 | 0 |
| Vaccination site inflammation | 9 | 0 |
| Vaccination site irritation | 1 | 0 |
| Vaccination site joint pain | 3 | 0 |
| Vaccination site joint swelling | 1 | 0 |
| Vaccination site mass | 10 | 0 |
| Vaccination site movement impairment | 11 | 0 |
| Vaccination site pain | 87 | 0 |
| Vaccination site papule | 1 | 0 |
| Vaccination site pruritus | 10 | 0 |
| Vaccination site rash | 5 | 0 |

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|---|-------------|-----------|
| General disorders General disorders cont'd | | |
| Vaccination site reaction | 2 | 0 |
| Vaccination site scab | 1 | 0 |
| Vaccination site scar | 1 | 0 |
| Vaccination site swelling | 56 | 0 |
| Vaccination site urticaria | 2 | 0 |
| Vaccination site warmth | 16 | 0 |
| General disorders SOC TOTAL | 1545 | 14 |

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|--|-----------|----------|
| Hepatic disorders | | |
| <i>Cholecystitis and cholelithiasis</i> | | |
| Cholelithiasis | 1 | 0 |
| <i>Cholestasis and jaundice</i> | | |
| Jaundice | 5 | 0 |
| Jaundice cholestatic | 1 | 0 |
| <i>Hepatic enzymes and function abnormalities</i> | | |
| Hepatic function abnormal | 3 | 0 |
| <i>Hepatic failure and associated disorders</i> | | |
| Acute hepatic failure | 2 | 1 |
| <i>Hepatobiliary signs and symptoms</i> | | |
| Hepatic pain | 1 | 0 |
| <i>Hepatocellular damage and hepatitis NEC</i> | | |
| Autoimmune hepatitis | 1 | 0 |
| Hepatic steatosis | 1 | 0 |
| Hepatitis | 5 | 0 |
| Hepatic disorders SOC TOTAL | 20 | 1 |

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|---|-----------|----------|
| Immune system disorders | | |
| <i>Allergic conditions NEC</i> | | |
| Hypersensitivity | 27 | 0 |
| Serum sickness-like reaction | 1 | 0 |
| Type IV hypersensitivity reaction | 1 | 0 |
| <i>Allergies to foods, food additives, drugs and other chemicals</i> | | |
| Drug hypersensitivity | 1 | 0 |
| Food allergy | 1 | 0 |
| Reaction to excipient | 3 | 0 |
| <i>Anaphylactic and anaphylactoid responses</i> | | |
| Anaphylactic reaction | 31 | 0 |
| <i>Autoimmune disorders NEC</i> | | |
| Autoimmune disorder | 2 | 0 |
| <i>Immune and associated conditions NEC</i> | | |
| Haemophagocytic lymphohistiocytosis | 1 | 1 |
| Immune system disorder | 4 | 0 |
| Immune-mediated adverse reaction | 1 | 0 |
| <i>Immunodeficiency disorders NEC</i> | | |
| Immunodeficiency | 1 | 0 |
| Immune system disorders SOC TOTAL | 74 | 1 |

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|---|-------|-------|
| Infections | | |
| <i>Abdominal and gastrointestinal infections</i> | | |
| Diverticulitis | 2 | 0 |
| <i>Bacterial infections NEC</i> | | |
| Bacterial infection | 1 | 0 |
| Cellulitis | 7 | 0 |
| Gangrene | 1 | 0 |
| Injection site cellulitis | 1 | 0 |
| <i>Central nervous system and spinal infections</i> | | |
| Encephalitis | 3 | 0 |
| Encephalomyelitis | 1 | 0 |
| Meningitis | 1 | 1 |
| <i>Coronavirus infections</i> | | |
| COVID-19 | 2 | 0 |
| Coronavirus infection | 1 | 0 |
| <i>Ear infections</i> | | |
| Labyrinthitis | 1 | 0 |
| Otitis media | 1 | 0 |
| <i>Eye and eyelid infections</i> | | |
| Conjunctivitis | 4 | 0 |
| <i>Female reproductive tract infections</i> | | |
| Amniotic cavity infection | 1 | 0 |
| <i>Haemophilus infections</i> | | |
| Pneumonia haemophilus | 1 | 0 |
| <i>Herpes viral infections</i> | | |
| Herpes simplex | 2 | 0 |
| Herpes zoster | 12 | 0 |
| Ophthalmic herpes zoster | 2 | 0 |
| Oral herpes | 4 | 0 |
| <i>Infections NEC</i> | | |
| Abscess limb | 1 | 0 |
| Infection | 1 | 0 |
| Lymph gland infection | 1 | 0 |
| Purulence | 1 | 0 |
| Vaccination site infection | 2 | 0 |
| <i>Infectious transmissions</i> | | |
| Infection via vaccinee | 1 | 0 |
| Suspected transmission of an infectious agent via product | 1 | 0 |
| <i>Influenza viral infections</i> | | |
| Influenza | 22 | 0 |
| Pneumonia influenzal | 3 | 0 |
| <i>Lower respiratory tract and lung infections</i> | | |
| Bronchitis | 6 | 0 |
| Lower respiratory tract infection | 14 | 0 |
| Pneumonia | 11 | 4 |
| <i>Muscle and soft tissue infections</i> | | |
| Soft tissue infection | 1 | 0 |
| <i>Pneumocystis infections</i> | | |
| Pneumocystis jirovecii pneumonia | 1 | 0 |
| <i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i> | | |
| Sepsis | 5 | 1 |
| <i>Staphylococcal infections</i> | | |
| Furuncle | 1 | 0 |
| <i>Upper respiratory tract infections</i> | | |

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| Infections | | |
| Infections cont'd | | |
| Laryngitis | 2 | 0 |
| Nasopharyngitis | 19 | 0 |
| Pharyngitis | 5 | 0 |
| Rhinitis | 3 | 0 |
| Sinusitis | 2 | 0 |
| Tonsillitis | 1 | 0 |
| Upper respiratory tract infection | 6 | 0 |
| Urinary tract infections | | |
| Cystitis | 3 | 0 |
| Kidney infection | 1 | 0 |
| Pyelonephritis | 1 | 0 |
| Urinary tract infection | 5 | 0 |
| Viral infections NEC | | |
| Encephalitis viral | 1 | 0 |
| Meningitis viral | 1 | 0 |
| Post viral fatigue syndrome | 2 | 0 |
| Vestibular neuronitis | 1 | 0 |
| Viral labyrinthitis | 1 | 0 |
| Viral rash | 1 | 0 |
| Infections SOC TOTAL | 175 | 6 |

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| Injuries | | |
| <i>Chest and respiratory tract injuries NEC</i> | | |
| Chest injury | 1 | 0 |
| <i>Exposures associated with pregnancy, delivery and lactation</i> | | |
| Exposure during pregnancy | 9 | 0 |
| Foetal exposure during pregnancy | 2 | 0 |
| Maternal exposure during pregnancy | 1 | 0 |
| <i>Gastrointestinal and hepatobiliary procedural complications</i> | | |
| Procedural vomiting | 1 | 0 |
| <i>Muscle, tendon and ligament injuries</i> | | |
| Muscle injury | 1 | 0 |
| Muscle strain | 2 | 0 |
| Tendon rupture | 1 | 0 |
| <i>Nerve injuries NEC</i> | | |
| Nerve injury | 3 | 0 |
| <i>Non-site specific injuries NEC</i> | | |
| Fall | 8 | 0 |
| <i>Non-site specific procedural complications</i> | | |
| Administration related reaction | 1 | 0 |
| <i>Overdoses NEC</i> | | |
| Overdose | 1 | 0 |
| <i>Poisoning and toxicity</i> | | |
| Alcohol poisoning | 1 | 0 |
| Toxicity to various agents | 1 | 0 |
| <i>Product administration errors and issues</i> | | |
| Contraindicated product administered | 2 | 0 |
| Expired product administered | 2 | 0 |
| Extra dose administered | 4 | 0 |
| Incorrect dose administered | 4 | 0 |
| Incorrect product formulation administered | 1 | 0 |
| Incorrect route of product administration | 1 | 0 |
| Product administered at inappropriate site | 4 | 0 |
| Product administered to patient of inappropriate age | 8 | 0 |
| Product administration error | 1 | 0 |
| <i>Site specific injuries NEC</i> | | |
| Face injury | 1 | 0 |
| Head injury | 4 | 0 |
| Limb injury | 1 | 0 |
| <i>Skin injuries NEC</i> | | |
| Contusion | 4 | 0 |
| Skin abrasion | 1 | 0 |
| <i>Vaccination related complications</i> | | |
| Vaccination complication | 1 | 0 |
| Injuries SOC TOTAL | 72 | 0 |

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| Investigations | | |
| <i>Blood gas and acid base analyses</i> | | |
| Blood gases abnormal | 1 | 0 |
| Carbon dioxide decreased | 1 | 0 |
| Oxygen saturation decreased | 2 | 0 |
| <i>Carbohydrate tolerance analyses (incl diabetes)</i> | | |
| Blood glucose increased | 3 | 0 |
| <i>Central nervous system imaging procedures</i> | | |
| Magnetic resonance imaging head abnormal | 1 | 0 |
| <i>Coagulation and bleeding analyses</i> | | |
| International normalised ratio increased | 1 | 0 |
| <i>ECG investigations</i> | | |
| Electrocardiogram QT prolonged | 1 | 0 |
| <i>Heart rate and pulse investigations</i> | | |
| Heart rate decreased | 8 | 0 |
| Heart rate increased | 9 | 0 |
| Heart rate irregular | 3 | 0 |
| <i>Imaging procedures NEC</i> | | |
| Computerised tomogram abnormal | 1 | 0 |
| Ultrasound scan abnormal | 1 | 0 |
| <i>Investigations NEC</i> | | |
| Blood test abnormal | 1 | 0 |
| <i>Liver function analyses</i> | | |
| Liver function test abnormal | 5 | 0 |
| <i>Mineral and electrolyte analyses</i> | | |
| Blood potassium decreased | 1 | 0 |
| Blood sodium decreased | 1 | 0 |
| <i>Musculoskeletal and soft tissue imaging procedures</i> | | |
| Spinal X-ray abnormal | 1 | 0 |
| <i>Neurologic diagnostic procedures</i> | | |
| Romberg test positive | 1 | 0 |
| <i>Physical examination procedures and organ system status</i> | | |
| Body temperature decreased | 1 | 0 |
| Body temperature fluctuation | 1 | 0 |
| Body temperature increased | 13 | 0 |
| Grip strength decreased | 2 | 0 |
| Respiratory rate increased | 1 | 0 |
| Weight decreased | 2 | 0 |
| Weight increased | 1 | 0 |
| <i>Protein analyses NEC</i> | | |
| C-reactive protein increased | 1 | 0 |
| Protein total increased | 1 | 0 |
| <i>Respiratory and pulmonary function diagnostic procedures</i> | | |
| Peak expiratory flow rate decreased | 1 | 0 |
| Pulmonary function test decreased | 1 | 0 |
| <i>Urinalysis NEC</i> | | |
| Urine analysis abnormal | 2 | 0 |
| <i>Urinary tract function analyses NEC</i> | | |
| Urine output decreased | 2 | 0 |
| <i>Vascular tests NEC (incl blood pressure)</i> | | |
| Blood pressure decreased | 2 | 0 |
| Blood pressure increased | 6 | 0 |
| <i>White blood cell analyses</i> | | |
| Lymphocyte count decreased | 1 | 0 |

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Report Run Date: 17-Aug-2021

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|--------------|--------------|
| Investigations Investigations cont'd | | |
| White blood cell count increased | 1 | 0 |
| Investigations SOC TOTAL | 81 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 17-Aug-2021
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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Metabolic disorders | | |
| <i>Appetite disorders</i> | | |
| Decreased appetite | 38 | 0 |
| Food refusal | 1 | 0 |
| Increased appetite | 1 | 0 |
| <i>Diabetes mellitus (incl subtypes)</i> | | |
| Diabetes mellitus | 2 | 0 |
| Diabetes mellitus inadequate control | 1 | 0 |
| <i>Diabetic complications NEC</i> | | |
| Diabetic ketoacidosis | 1 | 0 |
| <i>Disorders of purine metabolism</i> | | |
| Gout | 2 | 0 |
| <i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i> | | |
| Food intolerance | 1 | 0 |
| <i>General nutritional disorders NEC</i> | | |
| Abnormal loss of weight | 5 | 0 |
| Feeding disorder | 3 | 0 |
| <i>Hyperglycaemic conditions NEC</i> | | |
| Hyperglycaemia | 1 | 0 |
| <i>Hypoglycaemic conditions NEC</i> | | |
| Hypoglycaemia | 3 | 1 |
| <i>Sodium imbalance</i> | | |
| Hyponatraemia | 1 | 0 |
| <i>Total fluid volume decreased</i> | | |
| Dehydration | 1 | 0 |
| <i>Total fluid volume increased</i> | | |
| Fluid retention | 1 | 0 |
| Metabolic disorders SOC TOTAL | 62 | 1 |

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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Muscle & tissue disorders | | |
| <i>Arthropathies NEC</i> | | |
| Arthritis | 11 | 0 |
| Arthropathy | 4 | 0 |
| Seronegative arthritis | 1 | 0 |
| <i>Bone disorders NEC</i> | | |
| Exostosis | 1 | 0 |
| Jaw disorder | 1 | 0 |
| <i>Bone related signs and symptoms</i> | | |
| Bone pain | 2 | 0 |
| Pain in jaw | 1 | 0 |
| Spinal pain | 2 | 0 |
| <i>Bursal disorders</i> | | |
| Bursitis | 21 | 0 |
| <i>Connective tissue disorders NEC</i> | | |
| Polymyalgia rheumatica | 7 | 0 |
| Sjogren's syndrome | 1 | 0 |
| <i>Intervertebral disc disorders NEC</i> | | |
| Intervertebral disc protrusion | 1 | 0 |
| Intervertebral disc space narrowing | 1 | 0 |
| <i>Joint related disorders NEC</i> | | |
| Periarthritis | 9 | 0 |
| Rotator cuff syndrome | 1 | 0 |
| <i>Joint related signs and symptoms</i> | | |
| Arthralgia | 138 | 0 |
| Joint effusion | 1 | 0 |
| Joint noise | 1 | 0 |
| Joint stiffness | 3 | 0 |
| Joint swelling | 10 | 0 |
| <i>Lupus erythematosus (incl subtypes)</i> | | |
| Systemic lupus erythematosus | 1 | 0 |
| <i>Muscle infections and inflammations</i> | | |
| Myositis | 2 | 0 |
| <i>Muscle pains</i> | | |
| Myalgia | 144 | 0 |
| <i>Muscle related signs and symptoms NEC</i> | | |
| Muscle atrophy | 3 | 0 |
| Muscle fatigue | 1 | 0 |
| Muscle mass | 1 | 0 |
| Muscle spasms | 13 | 0 |
| Muscle swelling | 1 | 0 |
| Muscle tightness | 4 | 0 |
| Muscle twitching | 4 | 0 |
| <i>Muscle tone abnormalities</i> | | |
| Muscle rigidity | 3 | 0 |
| <i>Muscle weakness conditions</i> | | |
| Muscular weakness | 18 | 0 |
| <i>Musculoskeletal and connective tissue conditions NEC</i> | | |
| Extremity contracture | 1 | 0 |
| Mobility decreased | 2 | 0 |
| Musculoskeletal disorder | 1 | 0 |
| Musculoskeletal stiffness | 43 | 0 |
| <i>Musculoskeletal and connective tissue pain and discomfort</i> | | |
| Back pain | 25 | 0 |

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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Muscle & tissue disorders | | |
| Muscle & tissue disorders cont'd | | |
| Limb discomfort | 15 | 0 |
| Musculoskeletal chest pain | 1 | 0 |
| Musculoskeletal discomfort | 4 | 0 |
| Musculoskeletal pain | 1 | 0 |
| Neck pain | 24 | 0 |
| Pain in extremity | 142 | 0 |
| Myopathies | | |
| Myopathy | 2 | 0 |
| Osteoarthropathies | | |
| Osteoarthritis | 2 | 0 |
| Rheumatoid arthropathies | | |
| Rheumatoid arthritis | 7 | 0 |
| Soft tissue disorders NEC | | |
| Axillary mass | 2 | 0 |
| Groin pain | 2 | 0 |
| Soft tissue swelling | 1 | 0 |
| Spondyloarthropathies | | |
| Arthritis reactive | 2 | 0 |
| Tendon disorders | | |
| Tendon disorder | 2 | 0 |
| Tendon pain | 1 | 0 |
| Tendonitis | 3 | 0 |
| Muscle & tissue disorders SOC TOTAL | 695 | 0 |

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| Reaction Name | Total | Fatal |
|---|----------|----------|
| Neoplasms | | |
| <i>Leiomyosarcomas</i> | | |
| Leiomyosarcoma | 1 | 0 |
| <i>Ovarian neoplasms malignant (excl germ cell)</i> | | |
| Ovarian cancer | 1 | 1 |
| <i>Paranasal sinus and nasal cavity neoplasms malignant and unspecified</i> | | |
| Nasal sinus cancer | 1 | 0 |
| <i>Respiratory tract and pleural neoplasms malignant cell type unspecified</i> | | |
| NEC | | |
| Lung neoplasm malignant | 1 | 0 |
| <i>Skin neoplasms benign</i> | | |
| Fibrous histiocytoma | 1 | 0 |
| Seborrhoeic keratosis | 1 | 0 |
| Skin papilloma | 1 | 0 |
| <i>Soft tissue sarcomas histology unspecified</i> | | |
| Sarcoma | 1 | 0 |
| Neoplasms SOC TOTAL | 8 | 1 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders | | |
| <i>Abnormal reflexes</i> | | |
| Areflexia | 3 | 0 |
| <i>Abnormal sleep-related events</i> | | |
| Sleep paralysis | 1 | 0 |
| <i>Acute polyneuropathies</i> | | |
| Guillain-Barre syndrome | 18 | 0 |
| Miller Fisher syndrome | 1 | 0 |
| <i>Alzheimer's disease (incl subtypes)</i> | | |
| Dementia Alzheimer's type | 1 | 0 |
| <i>Central nervous system haemorrhages and cerebrovascular accidents</i> | | |
| Cerebellar stroke | 1 | 0 |
| Cerebral haemorrhage | 1 | 0 |
| Cerebral infarction | 1 | 0 |
| Cerebrovascular accident | 6 | 1 |
| Subarachnoid haemorrhage | 1 | 1 |
| <i>Central nervous system vascular disorders NEC</i> | | |
| Cerebrovascular disorder | 1 | 0 |
| <i>Chronic polyneuropathies</i> | | |
| Demyelinating polyneuropathy | 1 | 0 |
| <i>Coordination and balance disturbances</i> | | |
| Ataxia | 4 | 0 |
| Balance disorder | 23 | 0 |
| Coordination abnormal | 3 | 0 |
| Dysstasia | 3 | 0 |
| <i>Cortical dysfunction NEC</i> | | |
| Aphasia | 1 | 0 |
| <i>Cranial nerve disorders NEC</i> | | |
| Cranial nerve disorder | 1 | 0 |
| <i>Dementia (excl Alzheimer's type)</i> | | |
| Vascular dementia | 1 | 0 |
| <i>Demyelinating disorders NEC</i> | | |
| Demyelination | 1 | 0 |
| Neuromyelitis optica spectrum disorder | 1 | 0 |
| <i>Disturbances in consciousness NEC</i> | | |
| Altered state of consciousness | 1 | 0 |
| Consciousness fluctuating | 1 | 0 |
| Depressed level of consciousness | 1 | 0 |
| Lethargy | 34 | 0 |
| Loss of consciousness | 33 | 0 |
| Somnolence | 19 | 0 |
| Syncope | 49 | 0 |
| <i>Dyskinesias and movement disorders NEC</i> | | |
| Clumsiness | 1 | 0 |
| Dyskinesia | 2 | 0 |
| Hypokinesia | 1 | 0 |
| Motor dysfunction | 1 | 0 |
| Movement disorder | 3 | 0 |
| <i>Dystonias</i> | | |
| Dystonia | 1 | 0 |
| <i>Encephalopathies NEC</i> | | |
| Encephalopathy | 3 | 0 |
| <i>Facial cranial nerve disorders</i> | | |
| Bell's palsy | 7 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders <small>Nervous system disorders cont'd</small> | | |
| Facial paralysis | 1 | 0 |
| Generalised tonic-clonic seizures | | |
| Generalised tonic-clonic seizure | 6 | 0 |
| Headaches NEC | | |
| Headache | 193 | 0 |
| Tension headache | 1 | 0 |
| Increased intracranial pressure disorders | | |
| Intracranial pressure increased | 1 | 1 |
| Lumbar spinal cord and nerve root disorders | | |
| Sciatica | 2 | 0 |
| Memory loss (excl dementia) | | |
| Amnesia | 8 | 0 |
| Memory impairment | 1 | 0 |
| Mental impairment (excl dementia and memory loss) | | |
| Cognitive disorder | 1 | 0 |
| Disturbance in attention | 1 | 0 |
| Mental impairment | 2 | 0 |
| Migraine headaches | | |
| Migraine | 5 | 0 |
| Migraine with aura | 1 | 0 |
| Mononeuropathies | | |
| Carpal tunnel syndrome | 2 | 0 |
| Mononeuropathy multiplex | 1 | 0 |
| Multiple sclerosis acute and progressive | | |
| Multiple sclerosis | 1 | 0 |
| Multiple sclerosis relapse | 1 | 0 |
| Muscle tone abnormal | | |
| Hypotonia | 1 | 0 |
| Myelitis (incl infective) | | |
| Myelitis transverse | 2 | 0 |
| Narcolepsy and hypersomnia | | |
| Hypersomnia | 4 | 0 |
| Narcolepsy | 1 | 0 |
| Neurologic visual problems NEC | | |
| Tunnel vision | 2 | 0 |
| Neurological signs and symptoms NEC | | |
| Dizziness | 119 | 0 |
| Dizziness postural | 5 | 0 |
| Drooling | 2 | 0 |
| Head discomfort | 4 | 0 |
| Meningism | 1 | 0 |
| Presyncope | 3 | 0 |
| Slow response to stimuli | 1 | 0 |
| Tongue biting | 1 | 0 |
| Unresponsive to stimuli | 5 | 0 |
| Olfactory nerve disorders | | |
| Parosmia | 1 | 0 |
| Optic nerve disorders NEC | | |
| Optic neuritis | 1 | 0 |
| Paraesthesias and dysaesthesias | | |
| Burning sensation | 8 | 0 |
| Formication | 1 | 0 |
| Hyperaesthesia | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Hypoaesthesia | 27 | 0 |
| Paraesthesia | 47 | 0 |
| <i>Paralysis and paresis (excl cranial nerve)</i> | | |
| Hemiplegia | 2 | 0 |
| Monoplegia | 3 | 0 |
| Paralysis | 2 | 0 |
| <i>Parkinson's disease and parkinsonism</i> | | |
| Parkinson's disease | 1 | 0 |
| <i>Peripheral neuropathies NEC</i> | | |
| Neuralgic amyotrophy | 1 | 0 |
| Neuritis | 1 | 0 |
| Neuropathy peripheral | 5 | 0 |
| Peripheral sensory neuropathy | 1 | 0 |
| <i>Seizures and seizure disorders NEC</i> | | |
| Epilepsy | 3 | 0 |
| Seizure | 16 | 0 |
| Seizure like phenomena | 1 | 0 |
| <i>Sensory abnormalities NEC</i> | | |
| Dysgeusia | 4 | 0 |
| Neuralgia | 11 | 0 |
| Restless legs syndrome | 1 | 0 |
| Sensory disturbance | 3 | 0 |
| Sensory loss | 6 | 0 |
| Taste disorder | 3 | 0 |
| <i>Speech and language abnormalities</i> | | |
| Dysarthria | 3 | 0 |
| Speech disorder | 1 | 0 |
| <i>Spinal cord and nerve root disorders NEC</i> | | |
| Myelopathy | 1 | 0 |
| Radiculitis brachial | 2 | 0 |
| Radiculopathy | 1 | 0 |
| <i>Tremor (excl congenital)</i> | | |
| Tremor | 26 | 0 |
| <i>Trigeminal disorders</i> | | |
| Facial neuralgia | 1 | 0 |
| Trigeminal neuralgia | 1 | 0 |
| Nervous system disorders SOC TOTAL | 796 | 3 |

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| Reaction Name | Total | Fatal |
|---|----------|----------|
| Pregnancy conditions | | |
| <i>Abortions spontaneous</i> | | |
| Abortion spontaneous | 3 | 0 |
| <i>Foetal complications NEC</i> | | |
| Foetal distress syndrome | 1 | 0 |
| <i>Labour onset and length abnormalities</i> | | |
| Prolonged labour | 1 | 0 |
| <i>Maternal complications of delivery NEC</i> | | |
| Breech delivery | 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 | 1 | 0 |
| <i>Product label issues</i> | | |
| Product lot number 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 | 2 | 0 |
| Anxiety | 2 | 0 |
| Nervousness | 2 | 0 |
| Stress | 1 | 0 |
| <i>Behaviour and socialisation disturbances</i> | | |
| Aggression | 1 | 0 |
| Soliloquy | 1 | 0 |
| <i>Communications disorders</i> | | |
| Communication disorder | 1 | 0 |
| <i>Confusion and disorientation</i> | | |
| Confusional state | 14 | 0 |
| Disorientation | 6 | 0 |
| <i>Decreased physical activity levels</i> | | |
| Catatonia | 1 | 0 |
| <i>Deliria</i> | | |
| Delirium | 4 | 0 |
| <i>Delusional symptoms</i> | | |
| Delusion | 1 | 0 |
| <i>Depressive disorders</i> | | |
| Depression | 2 | 0 |
| <i>Dissociative states</i> | | |
| Dissociation | 2 | 0 |
| Dissociative disorder | 1 | 0 |
| <i>Disturbances in initiating and maintaining sleep</i> | | |
| Insomnia | 8 | 0 |
| <i>Dyssomnias</i> | | |
| Poor quality sleep | 1 | 0 |
| <i>Eating disorders NEC</i> | | |
| Eating disorder | 1 | 0 |
| <i>Emotional and mood disturbances NEC</i> | | |
| Anger | 1 | 0 |
| Emotional distress | 3 | 0 |
| <i>Fear symptoms and phobic disorders (incl social phobia)</i> | | |
| Fear | 2 | 0 |
| <i>Hallucinations (excl sleep-related)</i> | | |
| Hallucination | 6 | 0 |
| Hallucination, visual | 1 | 0 |
| <i>Increased physical activity levels</i> | | |
| Restlessness | 1 | 0 |
| <i>Mood alterations with depressive symptoms</i> | | |
| Depressed mood | 2 | 0 |
| <i>Mood disorders NEC</i> | | |
| Listless | 2 | 0 |
| <i>Obsessive-compulsive disorders and symptoms</i> | | |
| Obsessive-compulsive disorder | 1 | 0 |
| <i>Panic attacks and disorders</i> | | |
| Panic attack | 1 | 0 |
| Panic reaction | 2 | 0 |
| <i>Parasomnias</i> | | |
| Abnormal dreams | 2 | 0 |

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| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| Nightmare | 2 | 0 |
| <i>Perception disturbances NEC</i> | | |
| Illusion | 1 | 0 |
| <i>Psychotic disorder NEC</i> | | |
| Psychotic disorder | 2 | 0 |
| <i>Sleep disorders NEC</i> | | |
| Sleep disorder | 4 | 0 |
| <i>Thinking disturbances</i> | | |
| Bradyphrenia | 1 | 0 |
| Psychiatric disorders SOC TOTAL | 86 | 0 |

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| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Renal & urinary disorders | | |
| <i>Bladder and urethral symptoms</i> | | |
| Incontinence | 2 | 0 |
| Pollakiuria | 1 | 0 |
| Urinary incontinence | 2 | 0 |
| Urinary retention | 1 | 0 |
| <i>Bladder disorders NEC</i> | | |
| Urinary bladder haemorrhage | 1 | 0 |
| <i>Glomerulonephritis and nephrotic syndrome</i> | | |
| Glomerulonephritis acute | 1 | 1 |
| Nephrotic syndrome | 1 | 0 |
| <i>Renal failure and impairment</i> | | |
| Acute kidney injury | 4 | 0 |
| Chronic kidney disease | 1 | 0 |
| Renal impairment | 2 | 0 |
| <i>Renal lithiasis</i> | | |
| Nephrolithiasis | 1 | 0 |
| <i>Renal obstructive disorders</i> | | |
| Hydronephrosis | 1 | 0 |
| <i>Urinary abnormalities</i> | | |
| Haematuria | 1 | 1 |
| <i>Urinary tract lithiasis (excl renal)</i> | | |
| Ureterolithiasis | 1 | 0 |
| <i>Urinary tract signs and symptoms NEC</i> | | |
| Renal pain | 3 | 0 |
| Renal & urinary disorders SOC TOTAL | 23 | 2 |

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| Reaction Name | Total | Fatal |
|--|----------|----------|
| Reproductive & breast disorders | | |
| <i>Breast signs and symptoms</i> | | |
| Breast pain | 2 | 0 |
| <i>Spermatogenesis and semen disorders</i> | | |
| Haemospermia | 1 | 0 |
| Semen discolouration | 1 | 0 |
| <i>Vulvovaginal signs and symptoms</i> | | |
| Vulvovaginal rash | 1 | 0 |
| Reproductive & breast disorders SOC TOTAL | 5 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Respiratory disorders | | |
| <i>Breathing abnormalities</i> | | |
| Dyspnoea | 51 | 0 |
| Hypopnoea | 1 | 0 |
| Respiration abnormal | 1 | 0 |
| Respiratory arrest | 1 | 0 |
| Sleep apnoea syndrome | 1 | 0 |
| <i>Bronchospasm and obstruction</i> | | |
| Asthma | 14 | 0 |
| Bronchospasm | 9 | 0 |
| Chronic obstructive pulmonary disease | 1 | 0 |
| Wheezing | 11 | 0 |
| <i>Conditions associated with abnormal gas exchange</i> | | |
| Asphyxia | 1 | 1 |
| Respiratory gas exchange disorder | 1 | 0 |
| <i>Coughing and associated symptoms</i> | | |
| Cough | 54 | 0 |
| Haemoptysis | 1 | 0 |
| Productive cough | 9 | 0 |
| <i>Laryngeal spasm, oedema and obstruction</i> | | |
| Laryngeal oedema | 1 | 0 |
| Stridor | 1 | 0 |
| <i>Lower respiratory tract inflammatory and immunologic conditions</i> | | |
| Pneumonia aspiration | 1 | 0 |
| <i>Lower respiratory tract signs and symptoms</i> | | |
| Increased bronchial secretion | 1 | 0 |
| Pleuritic pain | 1 | 0 |
| Rales | 1 | 0 |
| <i>Nasal congestion and inflammations</i> | | |
| Nasal congestion | 7 | 0 |
| <i>Nasal disorders NEC</i> | | |
| Epistaxis | 8 | 0 |
| Nasal ulcer | 1 | 0 |
| <i>Paranasal sinus disorders (excl infections and neoplasms)</i> | | |
| Sinonasal obstruction | 1 | 0 |
| Sinus disorder | 1 | 0 |
| <i>Pharyngeal disorders (excl infections and neoplasms)</i> | | |
| Pharyngeal swelling | 5 | 0 |
| <i>Pulmonary thrombotic and embolic conditions</i> | | |
| Pulmonary embolism | 1 | 1 |
| <i>Respiratory failures (excl neonatal)</i> | | |
| Acute respiratory failure | 2 | 0 |
| Respiratory failure | 2 | 0 |
| <i>Respiratory tract disorders NEC</i> | | |
| Respiratory tract congestion | 1 | 0 |
| <i>Tracheal disorders (excl infections and neoplasms)</i> | | |
| Tracheal oedema | 1 | 0 |
| <i>Upper respiratory tract signs and symptoms</i> | | |
| Aphonia | 1 | 0 |
| Catarrh | 5 | 0 |
| Choking sensation | 2 | 0 |
| Dry throat | 2 | 0 |
| Dysphonia | 2 | 0 |
| Nasal discomfort | 1 | 0 |

Case Series Drug Analysis Print

Name: FOI 21/864 Trivalent Influenza (inactivated) Vaccine DAP

Report Run Date: 17-Aug-2021

Data Lock Date: 09-Aug-2021 18:30:04

Earliest Reaction Date: 29-Oct-1978

MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|------------|----------|
| Respiratory disorders <small>Respiratory disorders cont'd</small> | | |
| Oropharyngeal blistering | 1 | 0 |
| Oropharyngeal pain | 34 | 0 |
| Rhinorrhoea | 22 | 0 |
| Sinus pain | 2 | 0 |
| Sneezing | 12 | 0 |
| Throat irritation | 1 | 0 |
| Throat tightness | 5 | 0 |
| Upper-airway cough syndrome | 3 | 0 |
| Respiratory disorders SOC TOTAL | 285 | 2 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Skin disorders | | |
| <i>Acnes</i> | | |
| Acne | 1 | 0 |
| <i>Alopecias</i> | | |
| Alopecia | 1 | 0 |
| Madarosis | 1 | 0 |
| <i>Angioedemas</i> | | |
| Angioedema | 5 | 0 |
| <i>Apocrine and eccrine gland disorders</i> | | |
| Cold sweat | 9 | 0 |
| Hyperhidrosis | 83 | 0 |
| Night sweats | 7 | 0 |
| <i>Bullous conditions</i> | | |
| Blister | 3 | 0 |
| Blood blister | 1 | 0 |
| Erythema multiforme | 6 | 0 |
| Pemphigoid | 1 | 0 |
| Toxic epidermal necrolysis | 1 | 0 |
| <i>Dermal and epidermal conditions NEC</i> | | |
| Dry skin | 1 | 0 |
| Pain of skin | 3 | 0 |
| Papule | 1 | 0 |
| Scab | 1 | 0 |
| Sensitive skin | 2 | 0 |
| Skin burning sensation | 1 | 0 |
| Skin discolouration | 5 | 0 |
| Skin fissures | 1 | 0 |
| Skin lesion | 1 | 0 |
| Skin reaction | 9 | 0 |
| Skin swelling | 1 | 0 |
| Skin tightness | 1 | 0 |
| Skin warm | 6 | 0 |
| Skin weeping | 1 | 0 |
| <i>Dermatitis and eczema</i> | | |
| Dermatitis | 6 | 0 |
| Dermatitis allergic | 5 | 0 |
| Eczema | 8 | 0 |
| Seborrhoeic dermatitis | 1 | 0 |
| Skin irritation | 4 | 0 |
| <i>Dermatitis ascribed to specific agent</i> | | |
| Drug eruption | 2 | 0 |
| <i>Erythemas</i> | | |
| Erythema | 55 | 0 |
| <i>Exfoliative conditions</i> | | |
| Dermatitis exfoliative | 1 | 0 |
| Skin exfoliation | 1 | 0 |
| <i>Panniculitides</i> | | |
| Erythema nodosum | 1 | 0 |
| <i>Papulosquamous conditions</i> | | |
| Lichen planus | 1 | 0 |
| <i>Pruritus NEC</i> | | |
| Pruritus | 39 | 0 |
| <i>Purpura and related conditions</i> | | |
| Henoch-Schonlein purpura | 4 | 0 |

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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Skin disorders Skin disorders cont'd | | |
| Petechiae | 1 | 0 |
| Purpura | 4 | 0 |
| <i>Pustular conditions</i> | | |
| Acute generalised exanthematous pustulosis | 1 | 0 |
| <i>Rashes, eruptions and exanthems NEC</i> | | |
| Nodular rash | 1 | 0 |
| Rash | 45 | 0 |
| Rash erythematous | 19 | 0 |
| Rash macular | 5 | 0 |
| Rash maculo-papular | 7 | 0 |
| Rash morbilliform | 1 | 0 |
| Rash papular | 4 | 0 |
| Rash pruritic | 11 | 0 |
| Rash vesicular | 4 | 0 |
| <i>Sebaceous gland disorders</i> | | |
| Seborrhoea | 1 | 0 |
| <i>Skin and subcutaneous conditions NEC</i> | | |
| Skin mass | 1 | 0 |
| <i>Skin and subcutaneous tissue ulcerations</i> | | |
| Skin ulcer | 1 | 0 |
| <i>Skin vasculitides</i> | | |
| Cutaneous vasculitis | 1 | 0 |
| <i>Skin vasomotor conditions</i> | | |
| Livedo reticularis | 2 | 0 |
| <i>Urticarias</i> | | |
| Haemorrhagic urticaria | 1 | 0 |
| Urticaria | 53 | 0 |
| Skin disorders SOC TOTAL | 444 | 0 |

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| Reaction Name | Total | Fatal |
|---|----------|----------|
| Social circumstances | | |
| <i>Disability issues</i> | | |
| Hearing disability | 1 | 0 |
| Housebound | 1 | 0 |
| Loss of personal independence in daily activities | 2 | 0 |
| Social circumstances SOC TOTAL | 4 | 0 |

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| Reaction Name | Total | Fatal |
|--|----------|----------|
| Surgical & medical procedures | | |
| <i>Limb therapeutic procedures</i> | | |
| Limb immobilisation | 1 | 0 |
| <i>Obstetric therapeutic procedures</i> | | |
| Caesarean section | 1 | 0 |
| Surgical & medical procedures SOC TOTAL | 2 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------------|-----------|
| Vascular disorders | | |
| <i>Arterial infections and inflammations</i> | | |
| Giant cell arteritis | 2 | 0 |
| <i>Circulatory collapse and shock</i> | | |
| Circulatory collapse | 9 | 0 |
| Neurogenic shock | 1 | 0 |
| Shock | 4 | 0 |
| <i>Haemorrhages NEC</i> | | |
| Haematoma | 1 | 0 |
| Haemorrhage | 2 | 0 |
| <i>Non-site specific embolism and thrombosis</i> | | |
| Thrombosis | 1 | 0 |
| <i>Non-site specific vascular disorders NEC</i> | | |
| Vein disorder | 1 | 0 |
| Vein rupture | 1 | 0 |
| <i>Peripheral vascular disorders NEC</i> | | |
| Flushing | 11 | 0 |
| Hot flush | 5 | 0 |
| <i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i> | | |
| Peripheral coldness | 7 | 0 |
| Poor peripheral circulation | 1 | 0 |
| <i>Site specific vascular disorders NEC</i> | | |
| Pallor | 13 | 0 |
| <i>Varicose veins NEC</i> | | |
| Varicose vein | 1 | 0 |
| <i>Vascular hypertensive disorders NEC</i> | | |
| Hypertension | 5 | 0 |
| <i>Vascular hypotensive disorders</i> | | |
| Hypotension | 11 | 0 |
| Orthostatic hypotension | 1 | 0 |
| <i>Vasculitides NEC</i> | | |
| Granulomatosis with polyangiitis | 1 | 0 |
| Vasculitis | 6 | 0 |
| Vascular disorders SOC TOTAL | 84 | 0 |
| TOTAL REACTIONS FOR DRUG | 5189 | 39 |
| TOTAL REPORTS | 1750 | |
| TOTAL FATAL OUTCOME REPORTS | | 39 |