

Case Series Drug Analysis Print

Name: DTaP/IPV/Hib/HepB Vaccine Analysis Print

Report Run Date: 20-Apr-2023
Data Lock Date: 17-Apr-2023 18:30:03
Earliest Reaction Date: 27-Jan-2015
MedDRA Version: MedDRA 25.1

DTaP/IPV/Hib/HepB All UK spontaneous suspected Adverse Drug Reaction
Vaccine Analysis Print: (ADR) reports associated with the 6-in-1 vaccine up to
and including 17/04/2023.

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| Reaction Name | Total | Fatal |
|--|----------|----------|
| Blood disorders | | |
| <i>Leukocytoses NEC</i> | | |
| Lymphocytic infiltration | 1 | 0 |
| <i>Lymphatic system disorders NEC</i> | | |
| Lymphadenopathy | 3 | 0 |
| <i>Marrow depression and hypoplastic anaemias</i> | | |
| Myelosuppression | 1 | 0 |
| <i>Neutropenias</i> | | |
| Neutropenia | 1 | 0 |
| <i>Thrombocytopenias</i> | | |
| Immune thrombocytopenia | 2 | 0 |
| Blood disorders SOC TOTAL | 8 | 0 |

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| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Cardiac disorders | | |
| <i>Rate and rhythm disorders NEC</i> | | |
| Bradycardia | 2 | 0 |
| Tachycardia | 8 | 0 |
| <i>Ventricular arrhythmias and cardiac arrest</i> | | |
| Cardiac arrest | 1 | 1 |
| Cardiac arrest neonatal | 1 | 1 |
| Cardio-respiratory arrest | 2 | 1 |
| Ventricular fibrillation | 1 | 0 |
| Cardiac disorders SOC TOTAL | 15 | 3 |

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| Reaction Name | Total | Fatal |
|---------------------------------------|----------|----------|
| Congenital disorders | | |
| <i>Tongue disorders congenital</i> | | |
| Ankyloglossia 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 pain | 1 | 0 |
| Ear swelling | 4 | 0 |
| Ear disorders SOC TOTAL | 5 | 0 |

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|--|-----------|----------|
| Eye disorders | | |
| <i>Cataract conditions</i> | | |
| Cataract | 1 | 0 |
| <i>Conjunctival and corneal bleeding and vascular disorders</i> | | |
| Conjunctival haemorrhage | 1 | 0 |
| <i>Ocular bleeding and vascular disorders NEC</i> | | |
| Eye haemorrhage | 1 | 0 |
| <i>Ocular disorders NEC</i> | | |
| Dark circles under eyes | 1 | 0 |
| Eye oedema | 1 | 0 |
| Eye swelling | 1 | 0 |
| Ocular discomfort | 1 | 0 |
| <i>Ocular infections, inflammations and associated manifestations</i> | | |
| Ocular hyperaemia | 1 | 0 |
| <i>Ocular nerve and muscle disorders</i> | | |
| Eye movement disorder | 3 | 0 |
| Gaze palsy | 3 | 0 |
| Strabismus | 1 | 0 |
| <i>Ocular sensation disorders</i> | | |
| Photophobia | 1 | 0 |
| <i>Pupil disorders</i> | | |
| Miosis | 1 | 0 |
| Mydriasis | 1 | 0 |
| <i>Visual disorders NEC</i> | | |
| Vision blurred | 1 | 0 |
| <i>Visual impairment and blindness (excl colour blindness)</i> | | |
| Visual impairment | 1 | 0 |
| Eye disorders SOC TOTAL | 20 | 0 |

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|--|------------|----------|
| Gastrointestinal disorders | | |
| <i>Diarrhoea (excl infective)</i> | | |
| Diarrhoea | 50 | 0 |
| Diarrhoea haemorrhagic | 1 | 0 |
| <i>Dyspeptic signs and symptoms</i> | | |
| Dyspepsia | 2 | 0 |
| <i>Faecal abnormalities NEC</i> | | |
| Abnormal faeces | 5 | 0 |
| Faecaloma | 1 | 0 |
| Faeces discoloured | 11 | 0 |
| Faeces hard | 1 | 0 |
| Faeces pale | 1 | 0 |
| Mucous stools | 8 | 0 |
| <i>Flatulence, bloating and distension</i> | | |
| Abdominal distension | 1 | 0 |
| Flatulence | 7 | 0 |
| <i>Gastrointestinal and abdominal pains (excl oral and throat)</i> | | |
| Abdominal pain | 11 | 0 |
| Abdominal pain upper | 14 | 0 |
| <i>Gastrointestinal atonic and hypomotility disorders NEC</i> | | |
| Constipation | 12 | 0 |
| Gastrooesophageal reflux disease | 7 | 0 |
| <i>Gastrointestinal disorders NEC</i> | | |
| Gastric disorder | 1 | 0 |
| Gastrointestinal disorder | 2 | 0 |
| <i>Gastrointestinal dyskinetic disorders</i> | | |
| Infant dyschezia | 1 | 0 |
| <i>Gastrointestinal signs and symptoms NEC</i> | | |
| Abdominal discomfort | 3 | 0 |
| <i>Gastrointestinal spastic and hypermotility disorders</i> | | |
| Frequent bowel movements | 2 | 0 |
| <i>Gingival disorders, signs and symptoms NEC</i> | | |
| Gingival discolouration | 1 | 0 |
| <i>Nausea and vomiting symptoms</i> | | |
| Nausea | 3 | 0 |
| Retching | 1 | 0 |
| Vomiting | 49 | 0 |
| Vomiting projectile | 16 | 0 |
| <i>Non-site specific gastrointestinal haemorrhages</i> | | |
| Haematochezia | 6 | 0 |
| <i>Oral dryness and saliva altered</i> | | |
| Salivary hypersecretion | 1 | 0 |
| <i>Oral soft tissue signs and symptoms</i> | | |
| Oral pain | 1 | 0 |
| <i>Oral soft tissue swelling and oedema</i> | | |
| Lip swelling | 2 | 0 |
| <i>Salivary gland enlargements</i> | | |
| Salivary gland enlargement | 1 | 0 |
| <i>Stomatitis and ulceration</i> | | |
| Stomatitis | 1 | 0 |
| <i>Tongue signs and symptoms</i> | | |
| Protrusion tongue | 1 | 0 |
| Gastrointestinal disorders SOC TOTAL | 224 | 0 |

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|--|-------|-------|
| General disorders | | |
| <i>Asthenic conditions</i> | | |
| Asthenia | 8 | 0 |
| Decreased activity | 1 | 0 |
| Fatigue | 8 | 0 |
| Malaise | 13 | 0 |
| <i>Body temperature altered</i> | | |
| Hyperthermia | 1 | 0 |
| <i>Death and sudden death</i> | | |
| Death | 4 | 4 |
| Sudden death | 4 | 4 |
| Sudden infant death syndrome | 4 | 4 |
| <i>Febrile disorders</i> | | |
| Pyrexia | 141 | 0 |
| <i>Feelings and sensations NEC</i> | | |
| Chills | 6 | 0 |
| Feeling abnormal | 2 | 0 |
| Feeling cold | 1 | 0 |
| Feeling hot | 5 | 0 |
| Thirst decreased | 2 | 0 |
| <i>Gait disturbances</i> | | |
| Gait disturbance | 3 | 0 |
| Gait inability | 1 | 0 |
| <i>General signs and symptoms NEC</i> | | |
| Condition aggravated | 3 | 0 |
| Crying | 71 | 0 |
| Developmental delay | 2 | 0 |
| Developmental regression | 1 | 0 |
| General physical health deterioration | 1 | 0 |
| Glassy eyes | 3 | 0 |
| High-pitched crying | 10 | 0 |
| Illness | 4 | 0 |
| Induration | 2 | 0 |
| Influenza like illness | 1 | 0 |
| Moaning | 2 | 0 |
| Multiple organ dysfunction syndrome | 1 | 0 |
| Peripheral swelling | 19 | 0 |
| Screaming | 23 | 0 |
| Secretion discharge | 1 | 0 |
| Swelling | 10 | 0 |
| Swelling face | 4 | 0 |
| <i>Inflammations</i> | | |
| Inflammation | 10 | 0 |
| Systemic inflammatory response syndrome | 1 | 0 |
| <i>Injection site reactions</i> | | |
| Injection site discolouration | 1 | 0 |
| Injection site induration | 1 | 0 |
| Injection site mass | 4 | 0 |
| Injection site pain | 1 | 0 |
| Injection site pruritus | 1 | 0 |
| Injection site reaction | 1 | 0 |
| Injection site swelling | 2 | 0 |
| Injection site vesicles | 1 | 0 |
| <i>Oedema NEC</i> | | |

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|--|------------|-----------|
| General disorders General disorders cont'd | | |
| Oedema | 1 | 0 |
| Oedema peripheral | 1 | 0 |
| <i>Pain and discomfort NEC</i> | | |
| Axillary pain | 1 | 0 |
| Discomfort | 6 | 0 |
| Pain | 25 | 0 |
| Tenderness | 2 | 0 |
| <i>Therapeutic and nontherapeutic responses</i> | | |
| Adverse drug reaction | 3 | 0 |
| Drug ineffective | 1 | 0 |
| Vaccination failure | 5 | 0 |
| <i>Vaccination site reactions</i> | | |
| Extensive swelling of vaccinated limb | 3 | 0 |
| Vaccination site discomfort | 1 | 0 |
| Vaccination site erythema | 15 | 0 |
| Vaccination site haemorrhage | 1 | 0 |
| Vaccination site induration | 2 | 0 |
| Vaccination site inflammation | 5 | 0 |
| Vaccination site mass | 11 | 0 |
| Vaccination site pain | 8 | 0 |
| Vaccination site pruritus | 1 | 0 |
| Vaccination site rash | 4 | 0 |
| Vaccination site swelling | 11 | 0 |
| Vaccination site vesicles | 1 | 0 |
| Vaccination site warmth | 3 | 0 |
| General disorders SOC TOTAL | 496 | 12 |

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| Hepatic disorders | | |
| <i>Cholestasis and jaundice</i> | | |
| Jaundice | 1 | 0 |
| Jaundice cholestatic | 1 | 0 |
| <i>Hepatocellular damage and hepatitis NEC</i> | | |
| Hepatitis | 1 | 0 |
| Hepatic disorders SOC TOTAL | 3 | 0 |

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|---|-----------|----------|
| Immune system disorders | | |
| <i>Allergic conditions NEC</i> | | |
| Allergy to metals | 1 | 0 |
| Hypersensitivity | 9 | 0 |
| Multiple allergies | 1 | 0 |
| <i>Allergies to foods, food additives, drugs and other chemicals</i> | | |
| Allergy to vaccine | 2 | 0 |
| Food allergy | 4 | 0 |
| Milk allergy | 3 | 0 |
| <i>Anaphylactic and anaphylactoid responses</i> | | |
| Anaphylactic reaction | 10 | 0 |
| Anaphylactic shock | 1 | 0 |
| <i>Atopic disorders</i> | | |
| Atopy | 1 | 0 |
| Seasonal allergy | 1 | 0 |
| <i>Immune and associated conditions NEC</i> | | |
| Bacille Calmette-Guerin scar reactivation | 1 | 0 |
| Haemophagocytic lymphohistiocytosis | 1 | 1 |
| Immune system disorder | 1 | 0 |
| <i>Immunodeficiency disorders NEC</i> | | |
| Immunodeficiency | 1 | 0 |
| Immune system disorders SOC TOTAL | 37 | 1 |

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|---|-----------|----------|
| Infections | | |
| <i>Bacterial infections NEC</i> | | |
| Cellulitis | 7 | 0 |
| Meningitis bacterial | 1 | 0 |
| Skin bacterial infection | 1 | 0 |
| Vaccination site cellulitis | 1 | 0 |
| <i>Bordetella infections</i> | | |
| Pertussis | 2 | 0 |
| <i>Central nervous system and spinal infections</i> | | |
| Meningitis | 2 | 0 |
| Meningitis aseptic | 2 | 0 |
| <i>Ear infections</i> | | |
| Ear infection | 1 | 0 |
| <i>Enteroviral infections NEC</i> | | |
| Meningitis enteroviral | 1 | 0 |
| <i>Haemophilus infections</i> | | |
| Haemophilus infection | 4 | 0 |
| Meningitis haemophilus | 1 | 0 |
| <i>Infections NEC</i> | | |
| Abscess | 3 | 0 |
| Abscess limb | 2 | 0 |
| Infection | 1 | 0 |
| Vaccination site abscess | 1 | 0 |
| Vaccination site infection | 2 | 0 |
| <i>Influenza viral infections</i> | | |
| Influenza | 1 | 0 |
| <i>Lower respiratory tract and lung infections</i> | | |
| Bronchitis | 1 | 0 |
| Lower respiratory tract infection | 1 | 0 |
| Pneumonia | 1 | 0 |
| Pneumonia aspiration | 1 | 0 |
| <i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i> | | |
| Sepsis | 1 | 0 |
| <i>Skin structures and soft tissue infections</i> | | |
| Eczema infected | 1 | 0 |
| Skin infection | 3 | 0 |
| <i>Staphylococcal infections</i> | | |
| Staphylococcal infection | 1 | 0 |
| <i>Upper respiratory tract infections</i> | | |
| Croup infectious | 1 | 0 |
| Nasopharyngitis | 1 | 0 |
| Tonsillitis | 1 | 0 |
| <i>Urinary tract infections</i> | | |
| Urinary tract infection | 2 | 0 |
| <i>Viral infections NEC</i> | | |
| Bronchiolitis | 3 | 0 |
| Viral rash | 1 | 0 |
| Infections SOC TOTAL | 52 | 0 |

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| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Injuries | | |
| <i>Exposures associated with pregnancy, delivery and lactation</i> | | |
| Exposure via breast milk | 1 | 0 |
| Foetal exposure during pregnancy | 1 | 0 |
| Maternal exposure during breast feeding | 1 | 0 |
| <i>Medication errors, product use errors and issues NEC</i> | | |
| Medication error | 6 | 0 |
| Wrong technique in product usage process | 2 | 0 |
| <i>Muscle, tendon and ligament injuries</i> | | |
| Muscle injury | 2 | 0 |
| <i>Non-site specific injuries NEC</i> | | |
| Wound secretion | 1 | 0 |
| <i>Overdoses NEC</i> | | |
| Overdose | 1 | 0 |
| <i>Product administration errors and issues</i> | | |
| Accidental overdose | 1 | 0 |
| Inappropriate schedule of product administration | 1 | 0 |
| Incorrect dose administered | 6 | 0 |
| Product administered at inappropriate site | 1 | 0 |
| Product administered to patient of inappropriate age | 3 | 0 |
| <i>Product preparation errors and issues</i> | | |
| Product preparation issue | 6 | 0 |
| <i>Product prescribing errors and issues</i> | | |
| Product prescribing error | 1 | 0 |
| <i>Product storage errors and issues in the product use system</i> | | |
| Product storage error | 1 | 0 |
| <i>Skin injuries NEC</i> | | |
| Contusion | 7 | 0 |
| Scratch | 1 | 0 |
| Skin injury | 1 | 0 |
| Injuries SOC TOTAL | 44 | 0 |

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|---|-----------|----------|
| Investigations | | |
| <i>Blood gas and acid base analyses</i> | | |
| Oxygen saturation decreased | 2 | 0 |
| <i>Heart rate and pulse investigations</i> | | |
| Heart rate decreased | 1 | 0 |
| Heart rate increased | 2 | 0 |
| Pulse abnormal | 1 | 0 |
| <i>Hepatobiliary function diagnostic procedures</i> | | |
| Alanine aminotransferase increased | 1 | 0 |
| <i>Immunoglobulin analyses</i> | | |
| Blood immunoglobulin G increased | 2 | 0 |
| <i>Mineral and electrolyte analyses</i> | | |
| Blood magnesium decreased | 1 | 0 |
| <i>Physical examination procedures and organ system status</i> | | |
| Body temperature abnormal | 1 | 0 |
| Body temperature decreased | 1 | 0 |
| Body temperature fluctuation | 1 | 0 |
| Body temperature increased | 9 | 0 |
| Breath sounds abnormal | 1 | 0 |
| Respiratory rate decreased | 1 | 0 |
| Respiratory rate increased | 4 | 0 |
| <i>Protein analyses NEC</i> | | |
| C-reactive protein increased | 2 | 0 |
| <i>Red blood cell analyses</i> | | |
| Haemoglobin decreased | 1 | 0 |
| <i>Urinary tract function analyses NEC</i> | | |
| Urine output decreased | 3 | 0 |
| <i>White blood cell analyses</i> | | |
| Lymphocyte count increased | 1 | 0 |
| Investigations SOC TOTAL | 35 | 0 |

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|---|-----------|----------|
| Metabolic disorders | | |
| <i>Appetite disorders</i> | | |
| Appetite disorder | 1 | 0 |
| Decreased appetite | 28 | 0 |
| Food refusal | 2 | 0 |
| Hypophagia | 2 | 0 |
| Increased appetite | 1 | 0 |
| <i>Fluid intake decreased</i> | | |
| Fluid intake reduced | 4 | 0 |
| <i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i> | | |
| Dairy intolerance | 1 | 0 |
| Food intolerance | 2 | 0 |
| <i>General nutritional disorders NEC</i> | | |
| Feeding disorder | 1 | 0 |
| Food aversion | 1 | 0 |
| Poor feeding infant | 21 | 0 |
| Weight gain poor | 1 | 0 |
| <i>Metabolic acidoses (excl diabetic acidoses)</i> | | |
| Lactic acidosis | 1 | 0 |
| Metabolic acidosis | 1 | 0 |
| <i>Total fluid volume decreased</i> | | |
| Dehydration | 1 | 0 |
| Metabolic disorders SOC TOTAL | 68 | 0 |

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|---|-----------|----------|
| Muscle & tissue disorders | | |
| <i>Joint related disorders NEC</i> | | |
| Periarthritis | 1 | 0 |
| <i>Joint related signs and symptoms</i> | | |
| Joint swelling | 2 | 0 |
| <i>Muscle related signs and symptoms NEC</i> | | |
| Muscle spasms | 5 | 0 |
| Muscle twitching | 3 | 0 |
| <i>Muscle tone abnormalities</i> | | |
| Floppy infant | 18 | 0 |
| Muscle rigidity | 2 | 0 |
| <i>Muscle weakness conditions</i> | | |
| Muscular weakness | 2 | 0 |
| <i>Musculoskeletal and connective tissue conditions NEC</i> | | |
| Infantile back arching | 4 | 0 |
| Limb mass | 1 | 0 |
| Musculoskeletal stiffness | 4 | 0 |
| Posture abnormal | 1 | 0 |
| Weight bearing difficulty | 2 | 0 |
| <i>Musculoskeletal and connective tissue pain and discomfort</i> | | |
| Flank pain | 1 | 0 |
| Musculoskeletal pain | 1 | 0 |
| Pain in extremity | 10 | 0 |
| <i>Soft tissue disorders NEC</i> | | |
| Groin pain | 1 | 0 |
| Muscle & tissue disorders SOC TOTAL | 58 | 0 |

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| Nervous system disorders | | |
| <i>Absence seizures</i> | | |
| Petit mal epilepsy | 4 | 0 |
| <i>Coordination and balance disturbances</i> | | |
| Balance disorder | 2 | 0 |
| Nystagmus | 1 | 0 |
| <i>Cortical dysfunction NEC</i> | | |
| Aphasia | 1 | 0 |
| <i>Disturbances in consciousness NEC</i> | | |
| Depressed level of consciousness | 1 | 0 |
| Lethargy | 9 | 0 |
| Loss of consciousness | 3 | 0 |
| Postictal state | 1 | 0 |
| Somnolence | 32 | 0 |
| Syncope | 4 | 0 |
| <i>Dyskinesias and movement disorders NEC</i> | | |
| Dyskinesia | 8 | 0 |
| Movement disorder | 1 | 0 |
| Psychomotor hyperactivity | 1 | 0 |
| <i>Eye movement disorders</i> | | |
| VIth nerve paralysis | 1 | 0 |
| <i>Generalised tonic-clonic seizures</i> | | |
| Generalised tonic-clonic seizure | 6 | 0 |
| <i>Headaches NEC</i> | | |
| Headache | 2 | 0 |
| <i>Intellectual disabilities</i> | | |
| Intellectual disability | 1 | 0 |
| <i>Mental impairment (excl dementia and memory loss)</i> | | |
| Cognitive disorder | 1 | 0 |
| Mental impairment | 1 | 0 |
| <i>Muscle tone abnormal</i> | | |
| Hypotonia | 11 | 0 |
| <i>Narcolepsy and hypersomnia</i> | | |
| Hypersomnia | 1 | 0 |
| <i>Nervous system disorders NEC</i> | | |
| Nervous system disorder | 1 | 0 |
| <i>Neurological signs and symptoms NEC</i> | | |
| Dizziness | 1 | 0 |
| Hyporesponsive to stimuli | 3 | 0 |
| Infant irritability | 1 | 0 |
| Myoclonus | 1 | 0 |
| Slow response to stimuli | 1 | 0 |
| Unresponsive to stimuli | 27 | 0 |
| <i>Neuromuscular disorders NEC</i> | | |
| Hypotonic-hyporesponsive episode | 17 | 0 |
| Muscle spasticity | 1 | 0 |
| <i>Paralysis and paresis (excl cranial nerve)</i> | | |
| Paralysis | 1 | 0 |
| <i>Seizures and seizure disorders NEC</i> | | |
| Epilepsy | 2 | 0 |
| Epileptic encephalopathy | 1 | 0 |
| Febrile convulsion | 12 | 0 |
| Infantile spasms | 3 | 0 |
| Seizure | 19 | 0 |

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| Nervous system disorders <small>Nervous system disorders cont'd</small> | | |
| Status epilepticus | 1 | 0 |
| Sleep disturbances NEC | | |
| Sudden onset of sleep | 1 | 0 |
| Speech and language abnormalities | | |
| Dysarthria | 1 | 0 |
| Speech disorder | 2 | 0 |
| Tremor (excl congenital) | | |
| Tremor | 4 | 0 |
| Nervous system disorders SOC TOTAL | 192 | 0 |

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| Pregnancy conditions | | |
| <i>Gestational age and weight conditions</i> | | |
| Poor weight gain neonatal | 1 | 0 |
| Pregnancy conditions SOC TOTAL | 1 | 0 |

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| <i>Product quality issues NEC</i> | | |
| Product quality issue | 5 | 0 |
| null SOC TOTAL | 5 | 0 |

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Report Run Date: 20-Apr-2023
Earliest Reaction Date: 27-Jan-2015

Data Lock Date: 17-Apr-2023 18:30:03
MedDRA Version: MedDRA 25.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Psychiatric disorders | | |
| <i>Abnormal behaviour NEC</i> | | |
| Abnormal behaviour | 8 | 0 |
| Behaviour disorder | 1 | 0 |
| Breath holding | 3 | 0 |
| Staring | 4 | 0 |
| <i>Affect alterations NEC</i> | | |
| Flat affect | 1 | 0 |
| <i>Anxiety disorders NEC</i> | | |
| Separation anxiety disorder | 1 | 0 |
| <i>Anxiety symptoms</i> | | |
| Agitation | 5 | 0 |
| Anxiety | 2 | 0 |
| Nervousness | 1 | 0 |
| <i>Behaviour and socialisation disturbances</i> | | |
| Personality change | 1 | 0 |
| Social avoidant behaviour | 2 | 0 |
| <i>Cognitive and attention disorders and disturbances NEC</i> | | |
| Daydreaming | 1 | 0 |
| <i>Communications disorders</i> | | |
| Communication disorder | 1 | 0 |
| Mutism | 1 | 0 |
| <i>Disturbances in initiating and maintaining sleep</i> | | |
| Insomnia | 9 | 0 |
| Middle insomnia | 1 | 0 |
| <i>Dyssomnias</i> | | |
| Poor quality sleep | 6 | 0 |
| <i>Emotional and mood disturbances NEC</i> | | |
| Anger | 2 | 0 |
| Emotional distress | 4 | 0 |
| Irritability | 43 | 0 |
| Mood altered | 1 | 0 |
| <i>Fear symptoms and phobic disorders (incl social phobia)</i> | | |
| Phonophobia | 1 | 0 |
| <i>Increased physical activity levels</i> | | |
| Restlessness | 13 | 0 |
| <i>Mood alterations with depressive symptoms</i> | | |
| Decreased interest | 1 | 0 |
| Depressed mood | 1 | 0 |
| <i>Mood disorders NEC</i> | | |
| Listless | 3 | 0 |
| <i>Panic attacks and disorders</i> | | |
| Panic reaction | 1 | 0 |
| <i>Parasomnias</i> | | |
| Sleep terror | 1 | 0 |
| <i>Pervasive developmental disorders NEC</i> | | |
| Autism spectrum disorder | 2 | 0 |
| <i>Psychiatric symptoms NEC</i> | | |
| Decreased eye contact | 1 | 0 |
| <i>Sleep disorders NEC</i> | | |
| Sleep disorder | 7 | 0 |
| <i>Speech articulation and rhythm disturbances</i> | | |
| Dysphemia | 1 | 0 |
| <i>Suicidal and self-injurious behaviour</i> | | |

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|--|------------|----------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| Intentional self-injury | 1 | 0 |
| <i>Tic disorders</i> | | |
| Tic | 1 | 0 |
| Psychiatric disorders SOC TOTAL | 132 | 0 |

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|--|----------|----------|
| Renal & urinary disorders | | |
| <i>Renal failure and impairment</i> | | |
| Acute kidney injury | 1 | 0 |
| Anuria | 1 | 0 |
| Renal & urinary disorders SOC TOTAL | 2 | 0 |

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|--|--------------|--------------|
| Reproductive & breast disorders | | |
| <i>Reproductive tract disorders NEC (excl neoplasms)</i> | | |
| Genital blister | 1 | 0 |
| <i>Testicular and epididymal disorders NEC</i> | | |
| Testicular pain | 1 | 0 |
| Testicular swelling | 1 | 0 |
| Reproductive & breast disorders SOC TOTAL | 3 | 0 |

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|---|-----------|----------|
| Respiratory disorders | | |
| <i>Breathing abnormalities</i> | | |
| Apnoea | 13 | 0 |
| Dyspnoea | 14 | 0 |
| Hypopnoea | 4 | 0 |
| Irregular breathing | 1 | 0 |
| Respiration abnormal | 3 | 0 |
| Respiratory arrest | 4 | 0 |
| Respiratory distress | 2 | 0 |
| Tachypnoea | 1 | 0 |
| <i>Bronchospasm and obstruction</i> | | |
| Wheezing | 3 | 0 |
| <i>Conditions associated with abnormal gas exchange</i> | | |
| Cyanosis central | 1 | 0 |
| Respiratory acidosis | 1 | 0 |
| <i>Coughing and associated symptoms</i> | | |
| Cough | 12 | 0 |
| Haemoptysis | 1 | 0 |
| Productive cough | 3 | 0 |
| Sputum discoloured | 1 | 0 |
| <i>Laryngeal spasm, oedema and obstruction</i> | | |
| Stridor | 1 | 0 |
| <i>Lower respiratory tract signs and symptoms</i> | | |
| Hiccups | 1 | 0 |
| <i>Nasal congestion and inflammations</i> | | |
| Nasal congestion | 1 | 0 |
| <i>Nasal disorders NEC</i> | | |
| Epistaxis | 2 | 0 |
| <i>Neonatal hypoxic conditions</i> | | |
| Brief resolved unexplained event | 1 | 0 |
| Infantile apnoea | 3 | 0 |
| Neonatal hypoxia | 1 | 0 |
| <i>Paranasal sinus disorders (excl infections and neoplasms)</i> | | |
| Sinus congestion | 1 | 0 |
| <i>Respiratory signs and symptoms NEC</i> | | |
| Use of accessory respiratory muscles | 1 | 0 |
| <i>Upper respiratory tract signs and symptoms</i> | | |
| Choking | 1 | 0 |
| Dysphonia | 1 | 0 |
| Oropharyngeal pain | 2 | 0 |
| Rhinorrhoea | 4 | 0 |
| Respiratory disorders SOC TOTAL | 84 | 0 |

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|--|-------|-------|
| Skin disorders | | |
| <i>Apocrine and eccrine gland disorders</i> | | |
| Cold sweat | 2 | 0 |
| Hyperhidrosis | 3 | 0 |
| <i>Bullous conditions</i> | | |
| Blister | 4 | 0 |
| Dermatitis bullous | 1 | 0 |
| Pemphigoid | 1 | 0 |
| <i>Dermal and epidermal conditions NEC</i> | | |
| Dry skin | 4 | 0 |
| Papule | 3 | 0 |
| Skin burning sensation | 1 | 0 |
| Skin discolouration | 14 | 0 |
| Skin disorder | 1 | 0 |
| Skin induration | 1 | 0 |
| Skin lesion | 1 | 0 |
| Skin plaque | 1 | 0 |
| Skin reaction | 2 | 0 |
| Skin warm | 7 | 0 |
| Skin weeping | 1 | 0 |
| <i>Dermatitis and eczema</i> | | |
| Dermatitis | 1 | 0 |
| Dermatitis allergic | 4 | 0 |
| Dermatitis atopic | 3 | 0 |
| Dermatitis diaper | 1 | 0 |
| Eczema | 12 | 0 |
| Eczema infantile | 1 | 0 |
| <i>Dermatitis ascribed to specific agent</i> | | |
| Palmar-plantar erythrodysesthesia syndrome | 1 | 0 |
| <i>Erythemas</i> | | |
| Erythema | 38 | 0 |
| <i>Exfoliative conditions</i> | | |
| Skin exfoliation | 1 | 0 |
| <i>Pruritus NEC</i> | | |
| Pruritus | 7 | 0 |
| <i>Purpura and related conditions</i> | | |
| Petechiae | 14 | 0 |
| Purpura | 3 | 0 |
| <i>Rashes, eruptions and exanthems NEC</i> | | |
| Rash | 62 | 0 |
| Rash erythematous | 16 | 0 |
| Rash macular | 17 | 0 |
| Rash papular | 7 | 0 |
| Rash pruritic | 3 | 0 |
| Rash vesicular | 5 | 0 |
| <i>Skin and subcutaneous conditions NEC</i> | | |
| Skin mass | 1 | 0 |
| <i>Skin and subcutaneous tissue ulcerations</i> | | |
| Skin erosion | 1 | 0 |
| <i>Skin vasomotor conditions</i> | | |
| Livedo reticularis | 12 | 0 |
| Lividity | 1 | 0 |
| <i>Urticarias</i> | | |
| Urticaria | 22 | 0 |

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| Skin disorders Skin disorders cont'd | | |
| Urticaria chronic | 1 | 0 |
| Urticaria pressure | 1 | 0 |
| Skin disorders SOC TOTAL | 282 | 0 |

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|--|----------|----------|
| Surgical & medical procedures | | |
| <i>Therapeutic procedures NEC</i> | | |
| Injection | 1 | 0 |
| Surgical & medical procedures SOC TOTAL | 1 | 0 |

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| Vascular disorders | | |
| <i>Arterial infections and inflammations</i> | | |
| Kawasaki's disease | 1 | 1 |
| <i>Circulatory collapse and shock</i> | | |
| Circulatory collapse | 2 | 0 |
| <i>Haemorrhages NEC</i> | | |
| Haemorrhage | 1 | 0 |
| <i>Non-site specific necrosis and vascular insufficiency NEC</i> | | |
| Fibromuscular dysplasia | 1 | 0 |
| <i>Peripheral vascular disorders NEC</i> | | |
| Cyanosis | 12 | 0 |
| Flushing | 1 | 0 |
| <i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i> | | |
| Peripheral coldness | 5 | 0 |
| Poor peripheral circulation | 1 | 0 |
| <i>Site specific vascular disorders NEC</i> | | |
| Pallor | 46 | 0 |
| <i>Vascular hypertensive disorders NEC</i> | | |
| Hypertension | 1 | 0 |
| Vascular disorders SOC TOTAL | 71 | 1 |
| TOTAL REACTIONS FOR DRUG | 1839 | 17 |
| TOTAL REPORTS | 660 | |
| TOTAL FATAL OUTCOME REPORTS | | 17 |