

Case Series Drug Analysis Print

Name: FOI 23/945 - MMRVaxPro Vaccine Analysis Print

Report Run Date: 20-Dec-2023

Data Lock Date: 07-Dec-2023 18:30:03

Earliest Reaction Date: 23-Mar-2008

MedDRA Version: MedDRA 26.1

FOI 23/945 - All UK spontaneous suspected Adverse Drug Reaction
MMRVaxPro Vaccine (ADR) reports associated with the MMRVaxPro
Analysis Print: vaccine up to and including 07/12/2023.

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| Reaction Name | Total | Fatal |
|---------------------------------------|-----------|----------|
| Blood disorders | | |
| <i>Anaemias NEC</i> | | |
| Anaemia | 1 | 0 |
| <i>Leukopenias NEC</i> | | |
| Lymphopenia | 1 | 0 |
| <i>Lymphatic system disorders NEC</i> | | |
| Lymphadenopathy | 12 | 0 |
| <i>Thrombocytopenias</i> | | |
| Immune thrombocytopenia | 2 | 0 |
| Blood disorders SOC TOTAL | 16 | 0 |

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|--------------------------------------|----------|----------|
| Cardiac disorders | | |
| <i>Endocarditis NEC</i> | | |
| Endocarditis noninfective | 1 | 1 |
| <i>Noninfectious pericarditis</i> | | |
| Pericarditis | 1 | 0 |
| <i>Pericardial disorders NEC</i> | | |
| Pericardial effusion | 1 | 0 |
| <i>Pulmonary valvular disorders</i> | | |
| Pulmonary valve stenosis | 2 | 0 |
| <i>Rate and rhythm disorders NEC</i> | | |
| Bradycardia | 3 | 0 |
| Cardiac disorders SOC TOTAL | 8 | 1 |

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| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Congenital disorders | | |
| <i>Anorectal disorders congenital</i> | | |
| Preternatural anus | 2 | 0 |
| <i>Autosomal chromosomal abnormalities</i> | | |
| Trisomy 21 | 2 | 0 |
| <i>Cardiac septal defects congenital</i> | | |
| Atrioventricular septal defect | 2 | 0 |
| <i>Congenital disorders NEC</i> | | |
| Congenital anomaly | 1 | 0 |
| Congenital cyst | 1 | 0 |
| VACTERL syndrome | 2 | 0 |
| <i>Connective tissue disorders congenital</i> | | |
| Hypermobility syndrome | 1 | 0 |
| <i>External ear disorders congenital</i> | | |
| Anomaly of external ear congenital | 1 | 0 |
| <i>Eyelid disorders congenital</i> | | |
| Eyelid ptosis congenital | 2 | 0 |
| <i>Gene mutations and other alterations NEC</i> | | |
| Gene mutation | 1 | 0 |
| <i>Great vessel disorders congenital</i> | | |
| Double outlet right ventricle | 2 | 0 |
| <i>Immune system abnormalities congenital</i> | | |
| Primary immunodeficiency syndrome | 3 | 0 |
| <i>Male reproductive tract disorders congenital</i> | | |
| Cryptorchism | 1 | 0 |
| Hydrocele | 1 | 0 |
| <i>Musculoskeletal and connective tissue disorders of limbs congenital</i> | | |
| Developmental hip dysplasia | 2 | 0 |
| Limb hypoplasia congenital | 2 | 0 |
| Limb reduction defect | 2 | 0 |
| Talipes | 3 | 0 |
| <i>Musculoskeletal and connective tissue disorders of skull congenital</i> | | |
| Plagiocephaly | 1 | 0 |
| <i>Musculoskeletal and connective tissue disorders of spine congenital</i> | | |
| Congenital musculoskeletal disorder of spine | 2 | 0 |
| <i>Oral cavity disorders congenital NEC</i> | | |
| Tethered oral tissue | 2 | 0 |
| <i>Persistent foetal circulation disorders</i> | | |
| Patent ductus arteriosus | 1 | 0 |
| <i>Pulmonary and bronchial disorders congenital</i> | | |
| Congenital pneumonia | 1 | 0 |
| Pulmonary aplasia | 2 | 0 |
| Pulmonary hypoplasia | 2 | 0 |
| <i>Renal disorders congenital</i> | | |
| Congenital cystic kidney disease | 2 | 0 |
| <i>Skin and subcutaneous tissue disorders congenital NEC</i> | | |
| Congenital naevus | 1 | 0 |
| Congenital skin dimples | 2 | 0 |
| Congenital disorders SOC TOTAL | 47 | 0 |

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|-------------------------------------|----------|----------|
| Ear disorders | | |
| <i>Ear disorders NEC</i> | | |
| Ear pain | 1 | 0 |
| <i>Hearing losses</i> | | |
| Deafness | 2 | 0 |
| Hypoacusis | 1 | 0 |
| <i>Inner ear signs and symptoms</i> | | |
| Tinnitus | 1 | 0 |
| Vertigo | 3 | 0 |
| Ear disorders SOC TOTAL | 8 | 0 |

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|---|-----------|----------|
| Eye disorders | | |
| <i>Lid, lash and lacrimal infections, irritations and inflammations</i> | | |
| Swelling of eyelid | 2 | 0 |
| <i>Lid, lash and lacrimal structural disorders</i> | | |
| Dacryostenosis acquired | 1 | 0 |
| <i>Ocular disorders NEC</i> | | |
| Eye disorder | 1 | 0 |
| Eye swelling | 1 | 0 |
| <i>Ocular infections, inflammations and associated manifestations</i> | | |
| Eye pruritus | 1 | 0 |
| <i>Ocular nerve and muscle disorders</i> | | |
| Eye movement disorder | 3 | 0 |
| Strabismus | 2 | 0 |
| <i>Ocular sensation disorders</i> | | |
| Asthenopia | 1 | 0 |
| Photophobia | 3 | 0 |
| <i>Pupil disorders</i> | | |
| 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 | 18 | 0 |

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|--|-----------|----------|
| Gastrointestinal disorders | | |
| <i>Diarrhoea (excl infective)</i> | | |
| Diarrhoea | 14 | 0 |
| <i>Faecal abnormalities NEC</i> | | |
| Faeces discoloured | 1 | 0 |
| <i>Gastrointestinal and abdominal pains (excl oral and throat)</i> | | |
| Abdominal pain | 2 | 0 |
| Abdominal pain lower | 1 | 0 |
| <i>Gastrointestinal atonic and hypomotility disorders NEC</i> | | |
| Gastrooesophageal reflux disease | 3 | 0 |
| <i>Gastrointestinal signs and symptoms NEC</i> | | |
| Abdominal discomfort | 1 | 0 |
| Anal incontinence | 1 | 0 |
| <i>Gingival disorders, signs and symptoms NEC</i> | | |
| Gingival pain | 1 | 0 |
| <i>Nausea and vomiting symptoms</i> | | |
| Nausea | 12 | 0 |
| Retching | 1 | 0 |
| Vomiting | 20 | 0 |
| Vomiting projectile | 1 | 0 |
| <i>Oral soft tissue disorders NEC</i> | | |
| Oral disorder | 1 | 0 |
| <i>Oral soft tissue signs and symptoms</i> | | |
| Oral mucosal blistering | 3 | 0 |
| Oral pain | 1 | 0 |
| Paraesthesia oral | 1 | 0 |
| <i>Oral soft tissue swelling and oedema</i> | | |
| Lip swelling | 6 | 0 |
| <i>Salivary gland enlargements</i> | | |
| Parotid gland enlargement | 3 | 0 |
| Submaxillary gland enlargement | 1 | 0 |
| <i>Stomatitis and ulceration</i> | | |
| Mouth ulceration | 2 | 0 |
| <i>Tongue signs and symptoms</i> | | |
| Strawberry tongue | 1 | 0 |
| <i>Umbilical hernias</i> | | |
| Umbilical hernia | 2 | 0 |
| Gastrointestinal disorders SOC TOTAL | 79 | 0 |

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|--|-------|-------|
| General disorders | | |
| <i>Administration site reactions NEC</i> | | |
| Administration site urticaria | 2 | 0 |
| <i>Adverse effect absent</i> | | |
| No adverse event | 3 | 0 |
| <i>Asthenic conditions</i> | | |
| Asthenia | 4 | 0 |
| Fatigue | 7 | 0 |
| Malaise | 15 | 0 |
| <i>Febrile disorders</i> | | |
| Pyrexia | 67 | 0 |
| <i>Feelings and sensations NEC</i> | | |
| Chills | 2 | 0 |
| Feeling abnormal | 1 | 0 |
| Feeling drunk | 1 | 0 |
| Feeling hot | 1 | 0 |
| Feeling of body temperature change | 1 | 0 |
| <i>Gait disturbances</i> | | |
| Gait disturbance | 1 | 0 |
| <i>General signs and symptoms NEC</i> | | |
| Condition aggravated | 1 | 0 |
| Crepitations | 1 | 0 |
| Crying | 5 | 0 |
| Illness | 2 | 0 |
| Induration | 1 | 0 |
| Influenza like illness | 10 | 0 |
| Irritability postvaccinal | 1 | 0 |
| Local reaction | 2 | 0 |
| Peripheral swelling | 10 | 0 |
| Screaming | 2 | 0 |
| Swelling | 4 | 0 |
| Swelling face | 4 | 0 |
| <i>Inflammations</i> | | |
| Inflammation | 3 | 0 |
| <i>Injection site reactions</i> | | |
| Injection site erythema | 9 | 0 |
| Injection site inflammation | 2 | 0 |
| Injection site irritation | 1 | 0 |
| Injection site mass | 1 | 0 |
| Injection site pain | 3 | 0 |
| Injection site pruritus | 1 | 0 |
| Injection site rash | 3 | 0 |
| Injection site reaction | 2 | 0 |
| Injection site swelling | 7 | 0 |
| Injection site urticaria | 1 | 0 |
| Injection site vesicles | 1 | 0 |
| Injection site warmth | 1 | 0 |
| <i>Mass conditions NEC</i> | | |
| Mass | 1 | 0 |
| <i>Pain and discomfort NEC</i> | | |
| Chest discomfort | 4 | 0 |
| Chest pain | 5 | 0 |
| Pain | 5 | 0 |
| Tenderness | 2 | 0 |

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|--|------------|----------|
| General disorders General disorders cont'd | | |
| <i>Therapeutic and nontherapeutic responses</i> | | |
| Adverse event | 1 | 0 |
| Therapy non-responder | 2 | 0 |
| Vaccination failure | 1 | 0 |
| <i>Vaccination site reactions</i> | | |
| Extensive swelling of vaccinated limb | 1 | 0 |
| Vaccination site bruising | 3 | 0 |
| Vaccination site discomfort | 1 | 0 |
| Vaccination site erythema | 12 | 0 |
| Vaccination site haematoma | 1 | 0 |
| Vaccination site inflammation | 2 | 0 |
| Vaccination site mass | 4 | 0 |
| Vaccination site pain | 5 | 0 |
| Vaccination site rash | 3 | 0 |
| Vaccination site reaction | 1 | 0 |
| Vaccination site swelling | 7 | 0 |
| General disorders SOC TOTAL | 244 | 0 |

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|--|----------|----------|
| Hepatic disorders | | |
| <i>Cholecystitis and cholelithiasis</i> | | |
| Cholecystitis | 1 | 0 |
| <i>Hepatic enzymes and function abnormalities</i> | | |
| Hypertransaminasaemia | 1 | 0 |
| <i>Hepatocellular damage and hepatitis NEC</i> | | |
| Hepatitis | 2 | 0 |
| Hepatic disorders SOC TOTAL | 4 | 0 |

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|--|-----------|----------|
| Immune system disorders | | |
| <i>Allergic conditions NEC</i> | | |
| Hypersensitivity | 4 | 0 |
| <i>Allergies to foods, food additives, drugs and other chemicals</i> | | |
| Food allergy | 1 | 0 |
| Milk allergy | 1 | 0 |
| Reaction to excipient | 1 | 0 |
| <i>Anaphylactic and anaphylactoid responses</i> | | |
| Anaphylactic reaction | 10 | 0 |
| <i>Immune and associated conditions NEC</i> | | |
| Haemophagocytic lymphohistiocytosis | 1 | 1 |
| Immune system disorders SOC TOTAL | 18 | 1 |

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|---|-------|-------|
| Infections | | |
| <i>Abdominal and gastrointestinal infections</i> | | |
| Gastroenteritis | 1 | 0 |
| <i>Bacterial infections NEC</i> | | |
| Cellulitis | 10 | 0 |
| Injection site cellulitis | 1 | 0 |
| Vaccination site cellulitis | 3 | 0 |
| <i>Borrelial infections</i> | | |
| Lyme disease | 1 | 0 |
| <i>Central nervous system and spinal infections</i> | | |
| Encephalitis | 5 | 0 |
| Meningitis aseptic | 1 | 0 |
| <i>Ear infections</i> | | |
| Ear infection | 2 | 0 |
| Otitis media | 2 | 0 |
| <i>Epstein-Barr viral infections</i> | | |
| Infectious mononucleosis | 1 | 0 |
| <i>Eye and eyelid infections</i> | | |
| Conjunctivitis | 3 | 0 |
| Eye infection | 1 | 0 |
| <i>Herpes viral infections</i> | | |
| Human herpesvirus 6 infection | 1 | 0 |
| Varicella | 2 | 0 |
| <i>Infections NEC</i> | | |
| Infection | 1 | 0 |
| Respiratory tract infection | 1 | 0 |
| Vaccination site infection | 2 | 0 |
| Vestibulitis | 1 | 0 |
| <i>Lower respiratory tract and lung infections</i> | | |
| Lower respiratory tract infection | 1 | 0 |
| Pneumonia | 1 | 0 |
| <i>Male reproductive tract infections</i> | | |
| Orchitis | 1 | 0 |
| <i>Mumps viral infections</i> | | |
| Encephalitis mumps | 1 | 0 |
| Mumps | 3 | 0 |
| <i>Rubella viral infections</i> | | |
| Encephalomyelitis rubella | 1 | 0 |
| <i>Rubeola viral infections</i> | | |
| Measles | 8 | 0 |
| Measles post vaccine | 1 | 0 |
| <i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i> | | |
| Sepsis neonatal | 1 | 0 |
| <i>Upper respiratory tract infections</i> | | |
| Nasopharyngitis | 2 | 0 |
| Rhinitis | 1 | 0 |
| Tonsillitis | 2 | 0 |
| Upper respiratory tract infection | 2 | 0 |
| <i>Urinary tract infections</i> | | |
| Urinary tract infection | 1 | 0 |
| <i>Viral infections NEC</i> | | |
| Bronchiolitis | 2 | 0 |
| Encephalitis viral | 1 | 0 |
| Gastroenteritis viral | 1 | 0 |

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| Reaction Name | | Total | Fatal |
|-----------------------------|-------------------|-----------|----------|
| Infections | Infections cont'd | | |
| | Viral infection | 2 | 0 |
| Infections SOC TOTAL | | 71 | 0 |

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|---|-----------|----------|
| Injuries | | |
| <i>Accidental exposures to product</i> | | |
| Accidental exposure to product | 1 | 0 |
| <i>Exposures associated with pregnancy, delivery and lactation</i> | | |
| Exposure during pregnancy | 36 | 0 |
| Foetal exposure during pregnancy | 26 | 0 |
| Maternal exposure before pregnancy | 9 | 0 |
| Maternal exposure timing unspecified | 1 | 0 |
| <i>Medication errors, product use errors and issues NEC</i> | | |
| Inadequate aseptic technique in use of product | 1 | 0 |
| Medication error | 2 | 0 |
| Vaccination error | 2 | 0 |
| <i>Non-site specific injuries NEC</i> | | |
| Fall | 1 | 0 |
| <i>Occupational exposures</i> | | |
| Occupational exposure to product | 1 | 0 |
| <i>Pathways and sources of exposure</i> | | |
| Exposure via skin contact | 1 | 0 |
| <i>Product administration errors and issues</i> | | |
| Booster dose missed | 2 | 0 |
| Extra dose administered | 1 | 0 |
| Inappropriate schedule of product administration | 4 | 0 |
| Incorrect dose administered by product | 1 | 0 |
| Wrong patient received product | 1 | 0 |
| Wrong product administered | 2 | 0 |
| <i>Product monitoring errors and issues</i> | | |
| Labelled drug-drug interaction issue | 1 | 0 |
| <i>Reproductive system and breast injuries</i> | | |
| Perineal injury | 1 | 0 |
| <i>Skin injuries NEC</i> | | |
| Contusion | 1 | 0 |
| Skin laceration | 1 | 0 |
| Injuries SOC TOTAL | 96 | 0 |

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|---|-----------|----------|
| Investigations | | |
| <i>Carbohydrate tolerance analyses (incl diabetes)</i> | | |
| Blood glucose fluctuation | 1 | 0 |
| <i>Cardiac auscultatory investigations</i> | | |
| Cardiac murmur | 2 | 0 |
| <i>Foetal and neonatal diagnostic procedures</i> | | |
| Foetal heart rate decreased | 1 | 0 |
| Foetal monitoring abnormal | 1 | 0 |
| <i>Haematological analyses NEC</i> | | |
| Red blood cell sedimentation rate increased | 1 | 0 |
| <i>Heart rate and pulse investigations</i> | | |
| Heart rate decreased | 2 | 0 |
| Heart rate increased | 1 | 0 |
| Heart rate irregular | 2 | 0 |
| <i>Physical examination procedures and organ system status</i> | | |
| Body temperature increased | 2 | 0 |
| <i>Platelet analyses</i> | | |
| Platelet count decreased | 1 | 0 |
| <i>Urinalysis NEC</i> | | |
| Protein urine | 1 | 0 |
| <i>Vascular tests NEC (incl blood pressure)</i> | | |
| Blood pressure decreased | 1 | 0 |
| Blood pressure increased | 2 | 0 |
| <i>Virus identification and serology</i> | | |
| Measles antibody positive | 1 | 0 |
| Mumps antibody test negative | 2 | 0 |
| Investigations SOC TOTAL | 21 | 0 |

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| Metabolic disorders | | |
| <i>Appetite disorders</i> | | |
| Decreased appetite | 15 | 0 |
| Hypophagia | 2 | 0 |
| <i>Fluid intake increased</i> | | |
| Polydipsia | 1 | 0 |
| <i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i> | | |
| Dairy intolerance | 1 | 0 |
| Food intolerance | 1 | 0 |
| <i>General nutritional disorders NEC</i> | | |
| Failure to thrive | 1 | 0 |
| <i>Sodium imbalance</i> | | |
| Hyponatraemia | 1 | 0 |
| Metabolic disorders SOC TOTAL | 22 | 0 |

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| Muscle & tissue disorders | | |
| <i>Arthropathies NEC</i> | | |
| Arthritis | 1 | 0 |
| <i>Joint related signs and symptoms</i> | | |
| Arthralgia | 15 | 0 |
| Joint stiffness | 1 | 0 |
| Joint swelling | 1 | 0 |
| <i>Muscle pains</i> | | |
| Myalgia | 7 | 0 |
| <i>Muscle related signs and symptoms NEC</i> | | |
| Muscle fatigue | 1 | 0 |
| Muscle spasms | 1 | 0 |
| Muscle twitching | 2 | 0 |
| <i>Muscle weakness conditions</i> | | |
| Muscular weakness | 4 | 0 |
| <i>Musculoskeletal and connective tissue conditions NEC</i> | | |
| Musculoskeletal stiffness | 1 | 0 |
| Weight bearing difficulty | 3 | 0 |
| <i>Musculoskeletal and connective tissue pain and discomfort</i> | | |
| Back pain | 3 | 0 |
| Neck pain | 5 | 0 |
| Pain in extremity | 11 | 0 |
| <i>Rheumatoid arthropathies</i> | | |
| Rheumatoid arthritis | 1 | 0 |
| <i>Soft tissue disorders NEC</i> | | |
| Groin pain | 1 | 0 |
| Muscle & tissue disorders SOC TOTAL | 58 | 0 |

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|---|----------|----------|
| Neoplasms | | |
| <i>Reproductive neoplasms female benign NEC</i> | | |
| Benign hydatidiform mole | 1 | 0 |
| Neoplasms SOC TOTAL | 1 | 0 |

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| Nervous system disorders | | |
| <i>Central nervous system haemorrhages and cerebrovascular accidents</i> | | |
| Cerebral infarction | 1 | 0 |
| <i>Central nervous system inflammatory disorders NEC</i> | | |
| Arachnoiditis | 1 | 0 |
| <i>Coordination and balance disturbances</i> | | |
| Balance disorder | 2 | 0 |
| Coordination abnormal | 1 | 0 |
| Hand-eye coordination impaired | 1 | 0 |
| <i>Cortical dysfunction NEC</i> | | |
| Aphasia | 1 | 0 |
| Dyspraxia | 1 | 0 |
| <i>Disturbances in consciousness NEC</i> | | |
| Depressed level of consciousness | 2 | 0 |
| Lethargy | 7 | 0 |
| Loss of consciousness | 2 | 0 |
| Somnolence | 3 | 0 |
| Syncope | 6 | 0 |
| <i>Dyskinesias and movement disorders NEC</i> | | |
| Dyskinesia | 2 | 0 |
| Hypokinesia | 1 | 0 |
| Psychomotor hyperactivity | 1 | 0 |
| <i>Dystonias</i> | | |
| Opisthotonus | 1 | 0 |
| <i>Encephalopathies NEC</i> | | |
| Encephalopathy neonatal | 1 | 0 |
| Hypoxic-ischaemic encephalopathy | 1 | 0 |
| <i>Facial cranial nerve disorders</i> | | |
| Facial paralysis | 1 | 0 |
| <i>Headaches NEC</i> | | |
| Headache | 14 | 0 |
| <i>Memory loss (excl dementia)</i> | | |
| Amnesia | 1 | 0 |
| <i>Mental impairment (excl dementia and memory loss)</i> | | |
| Disturbance in attention | 1 | 0 |
| <i>Migraine headaches</i> | | |
| Migraine | 4 | 0 |
| <i>Muscle tone abnormal</i> | | |
| Hypotonia | 4 | 0 |
| <i>Neurological signs and symptoms NEC</i> | | |
| Brain fog | 1 | 0 |
| Dizziness | 11 | 0 |
| Drooling | 1 | 0 |
| Head discomfort | 1 | 0 |
| Unresponsive to stimuli | 3 | 0 |
| <i>Paraesthesias and dysaesthesias</i> | | |
| Burning sensation | 1 | 0 |
| Hypoaesthesia | 3 | 0 |
| Paraesthesia | 8 | 0 |
| <i>Paralysis and paresis (excl cranial nerve)</i> | | |
| Paralysis | 1 | 0 |
| <i>Seizures and seizure disorders NEC</i> | | |
| Epilepsy | 3 | 0 |
| Neonatal seizure | 1 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 20-Dec-2023

Data Lock Date: 07-Dec-2023 18:30:03

Earliest Reaction Date: 23-Mar-2008

MedDRA Version: MedDRA 26.1

| Reaction Name | Total | Fatal |
|---|------------|----------|
| Nervous system disorders | | |
| Nervous system disorders cont'd | | |
| Partial seizures | 1 | 0 |
| Seizure | 8 | 0 |
| Sensory abnormalities NEC | | |
| Dysgeusia | 1 | 0 |
| Sensory loss | 1 | 0 |
| Speech and language abnormalities | | |
| Dysarthria | 1 | 0 |
| Slow speech | 1 | 0 |
| Speech disorder developmental | 1 | 0 |
| Tremor (excl congenital) | | |
| Tremor | 1 | 0 |
| Nervous system disorders SOC TOTAL | 109 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Pregnancy conditions | | |
| <i>Abortions spontaneous</i> | | |
| Abortion spontaneous | 20 | 0 |
| Abortion threatened | 1 | 0 |
| Imminent abortion | 1 | 0 |
| <i>Amniotic fluid and cavity disorders of pregnancy NEC</i> | | |
| Oligohydramnios | 1 | 0 |
| <i>Foetal complications NEC</i> | | |
| Foetal distress syndrome | 1 | 0 |
| Foetal hypokinesia | 1 | 0 |
| <i>Foetal growth complications</i> | | |
| Foetal growth restriction | 3 | 0 |
| <i>Foetal position and presentation abnormalities</i> | | |
| Breech presentation | 1 | 0 |
| <i>Gestational age and weight conditions</i> | | |
| Premature baby | 5 | 0 |
| <i>Haemorrhagic complications of pregnancy</i> | | |
| Premature separation of placenta | 1 | 0 |
| <i>Hypertension associated disorders of pregnancy</i> | | |
| Pre-eclampsia | 3 | 0 |
| <i>Labour onset and length abnormalities</i> | | |
| Premature delivery | 1 | 0 |
| Premature labour | 2 | 0 |
| Premature rupture of membranes | 1 | 0 |
| Prolonged labour | 6 | 0 |
| <i>Maternal complications of labour NEC</i> | | |
| Labour complication | 1 | 0 |
| <i>Maternal complications of pregnancy NEC</i> | | |
| Complication of pregnancy | 1 | 0 |
| <i>Multiple pregnancies</i> | | |
| Multiple pregnancy | 2 | 0 |
| <i>Neonatal gastrointestinal disorders</i> | | |
| Meconium increased | 1 | 0 |
| <i>Neonatal hepatobiliary disorders</i> | | |
| Jaundice neonatal | 1 | 0 |
| <i>Normal newborn status</i> | | |
| Normal newborn | 1 | 0 |
| <i>Normal pregnancy, labour and delivery</i> | | |
| Pregnancy | 2 | 0 |
| <i>Postpartum complications NEC</i> | | |
| Postpartum haemorrhage | 2 | 0 |
| <i>Pregnancy complicated by maternal disorders</i> | | |
| Gestational diabetes | 1 | 0 |
| <i>Stillbirth and foetal death</i> | | |
| Stillbirth | 2 | 2 |
| Pregnancy conditions SOC TOTAL | 62 | 2 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|---|----------|----------|
| <i>Device physical property and chemical issues</i> | | |
| Needle issue | 1 | 0 |
| Syringe issue | 1 | 0 |
| <i>Product quality issues NEC</i> | | |
| Product quality issue | 2 | 0 |
| null SOC TOTAL | 4 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Psychiatric disorders | | |
| <i>Abnormal behaviour NEC</i> | | |
| Abnormal behaviour | 4 | 0 |
| Regressive behaviour | 1 | 0 |
| Staring | 1 | 0 |
| <i>Affect alterations NEC</i> | | |
| Affect lability | 1 | 0 |
| <i>Anxiety symptoms</i> | | |
| Agitation | 1 | 0 |
| Anxiety | 4 | 0 |
| <i>Attention deficit and disruptive behaviour disorders</i> | | |
| Attention deficit hyperactivity disorder | 1 | 0 |
| <i>Behaviour and socialisation disturbances</i> | | |
| Aggression | 2 | 0 |
| Attention-seeking behaviour | 1 | 0 |
| <i>Confusion and disorientation</i> | | |
| Confusional state | 1 | 0 |
| Disorientation | 2 | 0 |
| <i>Depressive disorders</i> | | |
| Depression | 1 | 0 |
| <i>Disturbances in initiating and maintaining sleep</i> | | |
| Insomnia | 2 | 0 |
| <i>Dyssomnias</i> | | |
| Poor quality sleep | 1 | 0 |
| <i>Eating disorders NEC</i> | | |
| Selective eating disorder | 1 | 0 |
| <i>Emotional and mood disturbances NEC</i> | | |
| Dysphoria | 1 | 0 |
| Emotional distress | 3 | 0 |
| Irritability | 7 | 0 |
| <i>Increased physical activity levels</i> | | |
| Restlessness | 1 | 0 |
| <i>Mood alterations with depressive symptoms</i> | | |
| Anhedonia | 1 | 0 |
| Depressed mood | 2 | 0 |
| Tearfulness | 2 | 0 |
| <i>Obsessive-compulsive disorders and symptoms</i> | | |
| Obsessive-compulsive disorder | 1 | 0 |
| Obsessive-compulsive symptom | 1 | 0 |
| <i>Pervasive developmental disorders NEC</i> | | |
| Autism spectrum disorder | 6 | 0 |
| <i>Psychotic disorder NEC</i> | | |
| Psychotic disorder | 1 | 0 |
| <i>Sleep disorders NEC</i> | | |
| Sleep disorder | 3 | 0 |
| <i>Stereotypies and automatisms</i> | | |
| Head banging | 1 | 0 |
| Posturing | 1 | 0 |
| Psychiatric disorders SOC TOTAL | 55 | 0 |

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| Reaction Name | Total | Fatal |
|--|----------|----------|
| Renal & urinary disorders | | |
| <i>Bladder and urethral symptoms</i> | | |
| Pollakiuria | 1 | 0 |
| Urinary incontinence | 1 | 0 |
| <i>Urinary abnormalities</i> | | |
| Proteinuria | 1 | 0 |
| <i>Urinary tract signs and symptoms NEC</i> | | |
| Renal pain | 1 | 0 |
| Renal & urinary disorders SOC TOTAL | 4 | 0 |

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MedDRA Version: MedDRA 26.1

| Reaction Name | Total | Fatal |
|--|----------|----------|
| Reproductive & breast disorders | | |
| <i>Breast infections and inflammations</i> | | |
| Nipple inflammation | 1 | 0 |
| <i>Vulvovaginal disorders NEC</i> | | |
| Vaginal haemorrhage | 6 | 0 |
| Reproductive & breast disorders SOC TOTAL | 7 | 0 |

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MedDRA Version: MedDRA 26.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Respiratory disorders | | |
| <i>Breathing abnormalities</i> | | |
| Dyspnoea | 7 | 0 |
| Respiratory arrest | 1 | 0 |
| Tachypnoea | 1 | 0 |
| <i>Bronchospasm and obstruction</i> | | |
| Asthma | 2 | 0 |
| Wheezing | 3 | 0 |
| <i>Conditions associated with abnormal gas exchange</i> | | |
| Asphyxia | 1 | 0 |
| Hypoxia | 1 | 0 |
| <i>Coughing and associated symptoms</i> | | |
| Cough | 11 | 0 |
| <i>Lower respiratory tract inflammatory and immunologic conditions</i> | | |
| Alveolitis | 1 | 0 |
| Pneumonitis | 1 | 0 |
| <i>Nasal congestion and inflammations</i> | | |
| Nasal congestion | 3 | 0 |
| <i>Nasal disorders NEC</i> | | |
| Epistaxis | 1 | 0 |
| <i>Neonatal hypoxic conditions</i> | | |
| Neonatal respiratory distress syndrome | 2 | 0 |
| <i>Newborn respiratory disorders NEC</i> | | |
| Bronchopulmonary dysplasia | 1 | 0 |
| Transient tachypnoea of the newborn | 1 | 0 |
| <i>Parenchymal lung disorders NEC</i> | | |
| Interstitial lung disease | 1 | 0 |
| Lung consolidation | 1 | 0 |
| Organising pneumonia | 1 | 0 |
| Pulmonary alveolar haemorrhage | 1 | 0 |
| <i>Pharyngeal disorders (excl infections and neoplasms)</i> | | |
| Pharyngeal swelling | 2 | 0 |
| Tonsillar hypertrophy | 1 | 0 |
| <i>Pleural conditions NEC</i> | | |
| Pleural adhesion | 1 | 0 |
| <i>Pneumothorax and pleural effusions NEC</i> | | |
| Pleural effusion | 1 | 0 |
| <i>Pulmonary oedemas</i> | | |
| Acute lung injury | 1 | 0 |
| Acute respiratory distress syndrome | 1 | 0 |
| Pulmonary congestion | 1 | 0 |
| Pulmonary oedema | 1 | 0 |
| <i>Pulmonary thrombotic and embolic conditions</i> | | |
| Pulmonary embolism | 1 | 0 |
| <i>Respiratory failures (excl neonatal)</i> | | |
| Respiratory failure | 1 | 0 |
| <i>Upper respiratory tract signs and symptoms</i> | | |
| Catarrh | 1 | 0 |
| Oropharyngeal discomfort | 1 | 0 |
| Oropharyngeal pain | 8 | 0 |
| Rhinorrhoea | 4 | 0 |
| Snoring | 1 | 0 |
| Throat irritation | 2 | 0 |
| Throat tightness | 1 | 0 |

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| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Respiratory disorders Respiratory disorders cont'd | | |
| <i>Vascular pulmonary disorders NEC</i> | | |
| Pulmonary arteriopathy | 2 | 0 |
| Respiratory disorders SOC TOTAL | 72 | 0 |

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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Skin disorders | | |
| <i>Angioedemas</i> | | |
| Angioedema | 2 | 0 |
| <i>Apocrine and eccrine gland disorders</i> | | |
| Cold sweat | 2 | 0 |
| Hyperhidrosis | 3 | 0 |
| <i>Bullous conditions</i> | | |
| Blister | 1 | 0 |
| Erythema multiforme | 1 | 0 |
| <i>Dermal and epidermal conditions NEC</i> | | |
| Macule | 1 | 0 |
| Papule | 2 | 0 |
| Scab | 1 | 0 |
| Skin discolouration | 1 | 0 |
| Skin reaction | 1 | 0 |
| Skin warm | 1 | 0 |
| <i>Dermatitis and eczema</i> | | |
| Dermatitis allergic | 2 | 0 |
| Eczema | 2 | 0 |
| Skin irritation | 1 | 0 |
| <i>Erythemas</i> | | |
| Erythema | 14 | 0 |
| <i>Pruritus NEC</i> | | |
| Pruritus | 14 | 0 |
| <i>Rashes, eruptions and exanthems NEC</i> | | |
| Rash | 60 | 0 |
| Rash erythematous | 6 | 0 |
| Rash macular | 5 | 0 |
| Rash maculo-papular | 3 | 0 |
| Rash morbilliform | 13 | 0 |
| Rash papular | 4 | 0 |
| Rash pruritic | 1 | 0 |
| <i>Skin vasomotor conditions</i> | | |
| Livedo reticularis | 1 | 0 |
| <i>Urticarias</i> | | |
| Mechanical urticaria | 1 | 0 |
| Urticaria | 20 | 0 |
| Skin disorders SOC TOTAL | 163 | 0 |

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| Reaction Name | Total | Fatal |
|---------------------------------------|----------|----------|
| Social circumstances | | |
| <i>Family and partner issues</i> | | |
| Multiple birth sibling | 2 | 0 |
| <i>Social issues NEC</i> | | |
| Contraindication to vaccination | 1 | 0 |
| Social circumstances SOC TOTAL | 3 | 0 |

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| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Surgical & medical procedures | | |
| <i>Hormonal therapeutic procedures NEC</i> | | |
| Steroid therapy | 1 | 0 |
| <i>Induced abortions</i> | | |
| Abortion induced | 1 | 0 |
| <i>Obstetric therapeutic procedures</i> | | |
| Caesarean section | 11 | 0 |
| Episiotomy | 1 | 0 |
| Forceps delivery | 1 | 0 |
| Labour stimulation | 1 | 0 |
| Surgical & medical procedures SOC TOTAL | 16 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------------|----------|
| Vascular disorders | | |
| <i>Circulatory collapse and shock</i> | | |
| Circulatory collapse | 1 | 0 |
| <i>Haemorrhages NEC</i> | | |
| Haemorrhage | 1 | 0 |
| <i>Peripheral vascular disorders NEC</i> | | |
| Cyanosis | 4 | 0 |
| Flushing | 2 | 0 |
| <i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i> | | |
| Peripheral coldness | 2 | 0 |
| <i>Site specific vascular disorders NEC</i> | | |
| Pallor | 7 | 0 |
| <i>Vascular hypertensive disorders NEC</i> | | |
| Hypertension | 2 | 0 |
| Vascular disorders SOC TOTAL | 19 | 0 |
| TOTAL REACTIONS FOR DRUG | 1225 | 4 |
| TOTAL REPORTS | 387 | |
| TOTAL FATAL OUTCOME REPORTS | | 4 |