

Case Series Drug Analysis Print

Name: MMR Vaccine DAP

Report Run Date: 27-Jun-2021
Data Lock Date: 25-Jun-2021 18:30:03
Earliest Reaction Date: 14-May-1987
MedDRA Version: MedDRA 24.0
MMR Vaccine DAP: All UK spontaneous suspected adverse reaction reports associated with the MMR vaccine up to and including 25/06/2021

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| Reaction Name | Total | Fatal |
|---|------------|----------|
| Blood disorders | | |
| Anaemias NEC | | |
| Anaemia | 5 | 0 |
| Anaemias haemolytic immune | | |
| Autoimmune haemolytic anaemia | 1 | 0 |
| Anaemias haemolytic mechanical factor | | |
| Haemolytic uraemic syndrome | 2 | 0 |
| Bleeding tendencies | | |
| Increased tendency to bruise | 2 | 0 |
| Coagulopathies | | |
| Antiphospholipid syndrome | 1 | 0 |
| Coagulopathy | 1 | 0 |
| Disseminated intravascular coagulation | 1 | 0 |
| Haematological disorders | | |
| Placental transfusion syndrome | 1 | 0 |
| Leukocytoses NEC | | |
| Leukocytosis | 1 | 0 |
| Monocytosis | 1 | 0 |
| Leukopenias NEC | | |
| Leukopenia | 2 | 0 |
| Lymphopenia | 2 | 0 |
| Lymphatic system disorders NEC | | |
| Lymphadenitis | 3 | 0 |
| Lymphadenopathy | 214 | 0 |
| Lymphoid tissue hyperplasia | 1 | 0 |
| Marrow depression and hypoplastic anaemias | | |
| Aplasia pure red cell | 1 | 0 |
| Aplastic anaemia | 1 | 0 |
| Bone marrow failure | 1 | 0 |
| Cytopenia | 1 | 0 |
| Pancytopenia | 1 | 0 |
| Neutropenias | | |
| Neutropenia | 3 | 0 |
| Polycythaemia (excl rubra vera) | | |
| Polycythaemia | 1 | 0 |
| Spleen disorders | | |
| Splenomegaly | 2 | 0 |
| Thrombocytopenias | | |
| Immune thrombocytopenia | 70 | 0 |
| Thrombocytopenia | 45 | 0 |
| Thrombocytopenic purpura | 7 | 0 |
| Thrombotic thrombocytopenic purpura | 8 | 0 |
| Blood disorders SOC TOTAL | 379 | 0 |

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| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Cardiac disorders | | |
| <i>Cardiac disorders NEC</i> | | |
| Cardiac disorder | 2 | 0 |
| Cardiovascular disorder | 1 | 0 |
| <i>Cardiac signs and symptoms NEC</i> | | |
| Palpitations | 8 | 0 |
| <i>Endocarditis NEC</i> | | |
| Endocarditis noninfective | 1 | 1 |
| <i>Heart failures NEC</i> | | |
| Cardiac failure | 2 | 1 |
| Cardiopulmonary failure | 1 | 0 |
| <i>Noninfectious myocarditis</i> | | |
| Myocarditis | 5 | 2 |
| <i>Noninfectious pericarditis</i> | | |
| Pericarditis | 2 | 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> | | |
| Arrhythmia | 1 | 0 |
| Bradycardia | 16 | 0 |
| Tachycardia | 15 | 0 |
| <i>Supraventricular arrhythmias</i> | | |
| Atrial tachycardia | 1 | 0 |
| Sinus tachycardia | 1 | 0 |
| <i>Ventricular arrhythmias and cardiac arrest</i> | | |
| Cardiac arrest | 2 | 1 |
| Cardio-respiratory arrest | 2 | 1 |
| Ventricular fibrillation | 1 | 0 |
| Ventricular tachycardia | 2 | 0 |
| Cardiac disorders SOC TOTAL | 66 | 6 |

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|---|-------|-------|
| Congenital disorders | | |
| <i>Anorectal disorders congenital</i> | | |
| Preternatural anus | 2 | 0 |
| <i>Autosomal chromosomal abnormalities</i> | | |
| Trisomy 21 | 2 | 0 |
| <i>Bladder disorders congenital</i> | | |
| Congenital vesicoureteric reflux | 1 | 0 |
| <i>Cardiac septal defects congenital</i> | | |
| Atrioventricular septal defect | 2 | 0 |
| <i>Cerebral disorders congenital</i> | | |
| Congenital hydrocephalus | 1 | 0 |
| <i>Congenital disorders NEC</i> | | |
| Congenital anomaly | 2 | 0 |
| Congenital cyst | 1 | 0 |
| VACTERL syndrome | 2 | 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>Gastric disorders congenital</i> | | |
| Pyloric stenosis | 1 | 0 |
| <i>Gastrointestinal tract disorders congenital NEC</i> | | |
| Congenital umbilical hernia | 1 | 0 |
| <i>Gene mutations and other alterations NEC</i> | | |
| Gene mutation | 1 | 0 |
| Mutagenic effect | 2 | 0 |
| <i>Great vessel disorders congenital</i> | | |
| Double outlet right ventricle | 2 | 0 |
| <i>Immune system abnormalities congenital</i> | | |
| Combined immunodeficiency | 1 | 0 |
| Primary immunodeficiency syndrome | 3 | 0 |
| <i>Inborn errors of amino acid metabolism</i> | | |
| Phenylketonuria | 1 | 0 |
| <i>Laryngeal and tracheal disorders congenital</i> | | |
| Laryngomalacia | 1 | 0 |
| <i>Lens disorders congenital</i> | | |
| Cataract congenital | 1 | 0 |
| <i>Lymphatic system disorders congenital</i> | | |
| Cystic lymphangioma | 1 | 1 |
| <i>Male reproductive tract disorders congenital</i> | | |
| Cryptorchism | 1 | 0 |
| Hydrocele | 2 | 0 |
| Hypospadias | 2 | 0 |
| <i>Musculoskeletal and connective tissue disorders of limbs congenital</i> | | |
| Congenital foot malformation | 1 | 0 |
| Developmental hip dysplasia | 3 | 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> | | |
| Spine malformation | 2 | 0 |
| <i>Neurological disorders congenital NEC</i> | | |

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|--|-----------|----------|
| Congenital disorders Congenital disorders cont'd | | |
| Spinal muscular atrophy | 1 | 0 |
| Ocular disorders congenital NEC | | |
| Congenital eye disorder | 1 | 0 |
| Persistent foetal circulation disorders | | |
| Patent ductus arteriosus | 1 | 0 |
| Pulmonary and bronchial disorders congenital | | |
| Congenital pneumonia | 1 | 0 |
| Pulmonary aplasia | 2 | 0 |
| Pulmonary hypoplasia | 2 | 0 |
| Renal disorders congenital | | |
| Congenital cystic kidney disease | 2 | 0 |
| Skin and subcutaneous tissue disorders congenital NEC | | |
| Congenital naevus | 1 | 0 |
| Congenital skin dimples | 2 | 0 |
| Tongue disorders congenital | | |
| Ankyloglossia congenital | 3 | 0 |
| Congenital disorders SOC TOTAL | 66 | 1 |

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|---|------------|----------|
| Ear disorders | | |
| <i>Ear disorders NEC</i> | | |
| Ear congestion | 2 | 0 |
| Ear discomfort | 3 | 0 |
| Ear pain | 20 | 0 |
| Ear swelling | 3 | 0 |
| Otorrhoea | 4 | 0 |
| Ototoxicity | 1 | 0 |
| <i>Eustachian tube disorders</i> | | |
| Eustachian tube dysfunction | 1 | 0 |
| <i>External ear disorders NEC</i> | | |
| Auricular swelling | 1 | 0 |
| Excessive cerumen production | 1 | 0 |
| <i>Hearing losses</i> | | |
| Deafness | 14 | 0 |
| Deafness bilateral | 1 | 0 |
| Deafness neurosensory | 20 | 0 |
| Deafness transitory | 2 | 0 |
| Deafness unilateral | 2 | 0 |
| Hypoacusis | 11 | 0 |
| Sudden hearing loss | 1 | 0 |
| <i>Hyperacusia</i> | | |
| Hyperacusis | 2 | 0 |
| <i>Inner ear disorders NEC</i> | | |
| Inner ear disorder | 1 | 0 |
| Vestibular disorder | 1 | 0 |
| <i>Inner ear signs and symptoms</i> | | |
| Tinnitus | 5 | 0 |
| Vertigo | 7 | 0 |
| <i>Tympanic membrane disorders (excl infections)</i> | | |
| Tympanic membrane disorder | 1 | 0 |
| Tympanic membrane perforation | 1 | 0 |
| Ear disorders SOC TOTAL | 105 | 0 |

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|---|--------------|--------------|
| Endocrine disorders | | |
| <i>Acute and chronic thyroiditis</i> | | |
| Autoimmune thyroiditis | 1 | 0 |
| <i>Adrenal cortical hyperfunctions</i> | | |
| Cushingoid | 1 | 0 |
| <i>Adrenal gland disorders NEC</i> | | |
| Adrenal disorder | 1 | 0 |
| <i>Endocrine abnormalities of puberty</i> | | |
| Precocious puberty | 1 | 0 |
| <i>Thyroid disorders NEC</i> | | |
| Goitre | 1 | 0 |
| <i>Thyroid hyperfunction disorders</i> | | |
| Hyperthyroidism | 1 | 0 |
| <i>Thyroid hypofunction disorders</i> | | |
| Hypothyroidism | 1 | 0 |
| Endocrine disorders SOC TOTAL | 7 | 0 |

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|---|-------|-------|
| Eye disorders | | |
| <i>Cataract conditions</i> | | |
| Cataract | 2 | 0 |
| <i>Conjunctival infections, irritations and inflammations</i> | | |
| Conjunctivitis allergic | 1 | 0 |
| <i>Corneal structural change, deposit and degeneration</i> | | |
| Xerophthalmia | 1 | 0 |
| <i>Eyelid movement disorders</i> | | |
| Blepharospasm | 1 | 0 |
| Excessive eye blinking | 2 | 0 |
| <i>Glaucomas (excl congenital)</i> | | |
| Glaucoma | 1 | 0 |
| <i>Iris and uveal tract infections, irritations and inflammations</i> | | |
| Iridocyclitis | 3 | 0 |
| <i>Lacrimation disorders</i> | | |
| Lacrimation increased | 10 | 0 |
| <i>Lens structural change, deposit and degeneration (excl cataracts)</i> | | |
| Aphakia | 1 | 0 |
| <i>Lid, lash and lacrimal infections, irritations and inflammations</i> | | |
| Blepharitis | 2 | 0 |
| Erythema of eyelid | 3 | 0 |
| Eyelid oedema | 4 | 0 |
| Swelling of eyelid | 9 | 0 |
| <i>Lid, lash and lacrimal structural disorders</i> | | |
| Dacryostenosis acquired | 1 | 0 |
| <i>Ocular disorders NEC</i> | | |
| Eye disorder | 2 | 0 |
| Eye pain | 18 | 0 |
| Eye swelling | 24 | 0 |
| Ocular discomfort | 1 | 0 |
| Periorbital oedema | 13 | 0 |
| Periorbital swelling | 3 | 0 |
| <i>Ocular infections, inflammations and associated manifestations</i> | | |
| Eye discharge | 8 | 0 |
| Eye inflammation | 2 | 0 |
| Eye irritation | 2 | 0 |
| Eye pruritus | 6 | 0 |
| Ocular hyperaemia | 18 | 0 |
| <i>Ocular nerve and muscle disorders</i> | | |
| Extraocular muscle disorder | 1 | 0 |
| Eye movement disorder | 18 | 0 |
| Ophthalmoplegia | 1 | 0 |
| Opsoclonus myoclonus | 1 | 0 |
| Strabismus | 9 | 0 |
| <i>Ocular sensation disorders</i> | | |
| Asthenopia | 1 | 0 |
| Photophobia | 24 | 0 |
| <i>Orbital structural change, deposit and degeneration</i> | | |
| Lid sulcus deepened | 1 | 0 |
| <i>Pupil disorders</i> | | |
| Mydriasis | 2 | 0 |
| Pupil fixed | 3 | 0 |
| Pupils unequal | 1 | 0 |
| <i>Refractive and accommodative disorders</i> | | |

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| Eye disorders Eye disorders cont'd | | |
| Altered visual depth perception | 1 | 0 |
| Hypermetropia | 1 | 0 |
| Visual disorders NEC | | |
| Diplopia | 3 | 0 |
| Vision blurred | 5 | 0 |
| Visual field disorders | | |
| Visual field defect | 1 | 0 |
| Visual impairment and blindness (excl colour blindness) | | |
| Blindness | 2 | 0 |
| Blindness cortical | 1 | 0 |
| Blindness transient | 1 | 0 |
| Cortical visual impairment | 1 | 0 |
| Visual impairment | 12 | 0 |
| Eye disorders SOC TOTAL | 228 | 0 |

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|---|-------|-------|
| Gastrointestinal disorders | | |
| <i>Abdominal hernias NEC</i> | | |
| Abdominal hernia | 1 | 0 |
| <i>Acute and chronic pancreatitis</i> | | |
| Pancreatitis acute | 1 | 0 |
| Pancreatitis haemorrhagic | 1 | 0 |
| Pancreatitis necrotising | 1 | 0 |
| <i>Anal and rectal signs and symptoms</i> | | |
| Anal inflammation | 1 | 0 |
| <i>Colitis (excl infective)</i> | | |
| Colitis | 4 | 0 |
| Colitis ulcerative | 1 | 0 |
| Crohn's disease | 5 | 0 |
| Inflammatory bowel disease | 4 | 0 |
| <i>Dental disorders NEC</i> | | |
| Tooth disorder | 2 | 0 |
| <i>Diaphragmatic hernias</i> | | |
| Hiatus hernia | 1 | 0 |
| <i>Diarrhoea (excl infective)</i> | | |
| Diarrhoea | 259 | 0 |
| Diarrhoea haemorrhagic | 2 | 0 |
| Diarrhoea neonatal | 1 | 0 |
| <i>Dyspeptic signs and symptoms</i> | | |
| Dyspepsia | 2 | 0 |
| Eructation | 1 | 0 |
| <i>Faecal abnormalities NEC</i> | | |
| Abnormal faeces | 4 | 0 |
| Faecaloma | 3 | 0 |
| Faeces discoloured | 9 | 0 |
| Faeces pale | 1 | 0 |
| Faeces soft | 1 | 0 |
| Mucous stools | 2 | 0 |
| <i>Flatulence, bloating and distension</i> | | |
| Abdominal distension | 10 | 0 |
| Flatulence | 5 | 0 |
| <i>Gastritis (excl infective)</i> | | |
| Gastritis | 1 | 0 |
| <i>Gastrointestinal and abdominal pains (excl oral and throat)</i> | | |
| Abdominal pain | 48 | 0 |
| Abdominal pain lower | 3 | 0 |
| Abdominal pain upper | 35 | 0 |
| <i>Gastrointestinal atonic and hypomotility disorders NEC</i> | | |
| Constipation | 21 | 0 |
| Gastrooesophageal reflux disease | 5 | 0 |
| <i>Gastrointestinal disorders NEC</i> | | |
| Functional gastrointestinal disorder | 2 | 0 |
| Gastrointestinal disorder | 6 | 0 |
| <i>Gastrointestinal dyskinetic disorders</i> | | |
| Change of bowel habit | 2 | 0 |
| Gastrointestinal motility disorder | 2 | 0 |
| <i>Gastrointestinal inflammatory disorders NEC</i> | | |
| Enteritis | 1 | 0 |
| <i>Gastrointestinal necrosis and gangrene (excl gangrenous hernia)</i> | | |
| Gastrointestinal necrosis | 1 | 0 |

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| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| <i>Gastrointestinal signs and symptoms NEC</i> | | |
| Abdominal discomfort | 6 | 0 |
| Anal incontinence | 4 | 0 |
| Dysphagia | 6 | 0 |
| <i>Gastrointestinal spastic and hypermotility disorders</i> | | |
| Defaecation urgency | 1 | 0 |
| Frequent bowel movements | 2 | 0 |
| Irritable bowel syndrome | 1 | 0 |
| <i>Gastrointestinal stenosis and obstruction NEC</i> | | |
| Intestinal obstruction | 1 | 0 |
| Intussusception | 1 | 0 |
| <i>Gastrointestinal vascular occlusion and infarction</i> | | |
| Intestinal ischaemia | 1 | 1 |
| <i>Gingival disorders, signs and symptoms NEC</i> | | |
| Gingival pain | 2 | 0 |
| Gingival swelling | 2 | 0 |
| <i>Gingival haemorrhages</i> | | |
| Gingival bleeding | 3 | 0 |
| <i>Intestinal haemorrhages</i> | | |
| Rectal haemorrhage | 3 | 0 |
| <i>Malabsorption syndromes</i> | | |
| Coeliac disease | 1 | 0 |
| <i>Nausea and vomiting symptoms</i> | | |
| Infantile vomiting | 3 | 0 |
| Nausea | 77 | 0 |
| Regurgitation | 1 | 0 |
| Retching | 2 | 0 |
| Vomiting | 428 | 0 |
| Vomiting projectile | 15 | 0 |
| <i>Non-site specific gastrointestinal haemorrhages</i> | | |
| Gastrointestinal haemorrhage | 1 | 0 |
| Haematemesis | 2 | 0 |
| <i>Oesophagitis (excl infective)</i> | | |
| Oesophagitis | 2 | 0 |
| <i>Oral dryness and saliva altered</i> | | |
| Salivary hypersecretion | 3 | 0 |
| <i>Oral soft tissue disorders NEC</i> | | |
| Chapped lips | 3 | 0 |
| Oral disorder | 2 | 0 |
| <i>Oral soft tissue haemorrhages</i> | | |
| Lip haemorrhage | 1 | 0 |
| Mouth haemorrhage | 2 | 0 |
| <i>Oral soft tissue signs and symptoms</i> | | |
| Hypoaesthesia oral | 4 | 0 |
| Oral mucosal blistering | 6 | 0 |
| Oral mucosal eruption | 3 | 0 |
| Oral pain | 5 | 0 |
| Paraesthesia oral | 12 | 0 |
| <i>Oral soft tissue swelling and oedema</i> | | |
| Lip swelling | 27 | 0 |
| Mouth swelling | 6 | 0 |
| <i>Rectal inflammations NEC</i> | | |
| Proctitis | 1 | 0 |

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|---|-------------|----------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| <i>Salivary gland disorders NEC</i> | | |
| Salivary gland mass | 2 | 0 |
| Salivary gland pain | 1 | 0 |
| <i>Salivary gland enlargements</i> | | |
| Parotid gland enlargement | 70 | 0 |
| Salivary gland enlargement | 12 | 0 |
| Submaxillary gland enlargement | 1 | 0 |
| <i>Stomatitis and ulceration</i> | | |
| Aphthous ulcer | 3 | 0 |
| Lip ulceration | 2 | 0 |
| Mouth ulceration | 16 | 0 |
| Stomatitis | 6 | 0 |
| <i>Tongue disorders</i> | | |
| Tongue disorder | 1 | 0 |
| Tongue geographic | 1 | 0 |
| Tongue ulceration | 4 | 0 |
| <i>Tongue signs and symptoms</i> | | |
| Glossodynia | 1 | 0 |
| Strawberry tongue | 1 | 0 |
| Swollen tongue | 7 | 0 |
| Tongue coated | 1 | 0 |
| Tongue discolouration | 2 | 0 |
| Tongue eruption | 3 | 0 |
| <i>Umbilical hernias</i> | | |
| Umbilical hernia | 2 | 0 |
| Gastrointestinal disorders SOC TOTAL | 1225 | 1 |

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| General disorders | | |
| Administration site reactions NEC | | |
| Administration site rash | 1 | 0 |
| Adverse effect absent | | |
| No adverse event | 3 | 0 |
| Application and instillation site reactions | | |
| Application site erythema | 1 | 0 |
| Asthenic conditions | | |
| Asthenia | 34 | 0 |
| Chronic fatigue syndrome | 2 | 0 |
| Decreased activity | 1 | 0 |
| Fatigue | 112 | 0 |
| Malaise | 309 | 0 |
| Death and sudden death | | |
| Death | 8 | 8 |
| Sudden death | 2 | 2 |
| Sudden infant death syndrome | 4 | 4 |
| Febrile disorders | | |
| Pyrexia | 1565 | 0 |
| Feelings and sensations NEC | | |
| Chills | 45 | 0 |
| Feeling abnormal | 31 | 0 |
| Feeling cold | 4 | 0 |
| Feeling drunk | 1 | 0 |
| Feeling hot | 51 | 0 |
| Feeling jittery | 1 | 0 |
| Feeling of body temperature change | 5 | 0 |
| Hangover | 1 | 0 |
| Thirst | 4 | 0 |
| Thirst decreased | 2 | 0 |
| Gait disturbances | | |
| Gait disturbance | 32 | 0 |
| Gait inability | 22 | 0 |
| Loss of control of legs | 1 | 0 |
| General signs and symptoms NEC | | |
| Condition aggravated | 3 | 0 |
| Crepitations | 1 | 0 |
| Crying | 97 | 0 |
| Developmental delay | 27 | 0 |
| Developmental regression | 5 | 0 |
| Disease complication | 1 | 0 |
| Foaming at mouth | 1 | 0 |
| Glassy eyes | 1 | 0 |
| High-pitched crying | 7 | 0 |
| Ill-defined disorder | 1 | 0 |
| Illness | 44 | 0 |
| Induration | 6 | 0 |
| Influenza like illness | 34 | 0 |
| Irritability postvaccinal | 2 | 0 |
| Local reaction | 79 | 0 |
| Moaning | 2 | 0 |
| Multiple organ dysfunction syndrome | 1 | 1 |
| Peripheral swelling | 173 | 0 |
| Screaming | 70 | 0 |

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| General disorders General disorders cont'd | | |
| Secretion discharge | 2 | 0 |
| Swelling | 101 | 0 |
| Swelling face | 62 | 0 |
| Inflamations | | |
| Granuloma | 1 | 0 |
| Inflammation | 31 | 0 |
| Infusion site reactions | | |
| Infusion site erythema | 1 | 0 |
| Injection site reactions | | |
| Injection site abscess sterile | 2 | 0 |
| Injection site bruising | 8 | 0 |
| Injection site cyst | 1 | 0 |
| Injection site discolouration | 4 | 0 |
| Injection site discomfort | 2 | 0 |
| Injection site erythema | 65 | 0 |
| Injection site indentation | 1 | 0 |
| Injection site induration | 7 | 0 |
| Injection site inflammation | 53 | 0 |
| Injection site irritation | 1 | 0 |
| Injection site mass | 15 | 0 |
| Injection site oedema | 2 | 0 |
| Injection site pain | 43 | 0 |
| Injection site pruritus | 11 | 0 |
| Injection site rash | 21 | 0 |
| Injection site reaction | 200 | 0 |
| Injection site swelling | 57 | 0 |
| Injection site urticaria | 1 | 0 |
| Injection site vesicles | 7 | 0 |
| Injection site warmth | 8 | 0 |
| Interactions | | |
| Drug interaction | 2 | 0 |
| Potentiating drug interaction | 1 | 0 |
| Mass conditions NEC | | |
| Cyst | 1 | 0 |
| Mass | 6 | 0 |
| Nodule | 2 | 0 |
| Mucosal findings abnormal | | |
| Mucosal disorder | 1 | 0 |
| Mucosal haemorrhage | 1 | 0 |
| Oedema NEC | | |
| Face oedema | 19 | 0 |
| Generalised oedema | 1 | 0 |
| Gravitational oedema | 1 | 0 |
| Oedema | 14 | 0 |
| Oedema peripheral | 23 | 0 |
| Pain and discomfort NEC | | |
| Chest discomfort | 10 | 0 |
| Chest pain | 14 | 0 |
| Discomfort | 21 | 0 |
| Facial pain | 3 | 0 |
| Non-cardiac chest pain | 2 | 0 |
| Pain | 108 | 0 |
| Tenderness | 22 | 0 |

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| General disorders General disorders cont'd | | |
| <i>Therapeutic and nontherapeutic responses</i> | | |
| Adverse drug reaction | 26 | 0 |
| Adverse event | 2 | 0 |
| Drug ineffective | 20 | 0 |
| No reaction on previous exposure to drug | 1 | 0 |
| Post vaccination challenge strain shedding | 1 | 0 |
| Therapy non-responder | 23 | 0 |
| Vaccination failure | 193 | 0 |
| <i>Vaccination site reactions</i> | | |
| Extensive swelling of vaccinated limb | 4 | 0 |
| Vaccination site bruising | 10 | 0 |
| Vaccination site discomfort | 4 | 0 |
| Vaccination site erythema | 91 | 0 |
| Vaccination site granuloma | 1 | 0 |
| Vaccination site haematoma | 1 | 0 |
| Vaccination site hypertrichosis | 1 | 0 |
| Vaccination site induration | 13 | 0 |
| Vaccination site inflammation | 14 | 0 |
| Vaccination site joint erythema | 2 | 0 |
| Vaccination site mass | 24 | 0 |
| Vaccination site movement impairment | 2 | 0 |
| Vaccination site nodule | 1 | 0 |
| Vaccination site pain | 37 | 0 |
| Vaccination site pruritus | 10 | 0 |
| Vaccination site rash | 28 | 0 |
| Vaccination site reaction | 6 | 0 |
| Vaccination site swelling | 76 | 0 |
| Vaccination site urticaria | 1 | 0 |
| Vaccination site vesicles | 3 | 0 |
| Vaccination site warmth | 33 | 0 |
| General disorders SOC TOTAL | 4384 | 15 |

Case Series Drug Analysis Print

Name: MMR Vaccine DAP

Report Run Date: 27-Jun-2021
 Earliest Reaction Date: 14-May-1987

Data Lock Date: 25-Jun-2021 18:30:03
 MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Hepatic disorders | | |
| <i>Cholecystitis and cholelithiasis</i> | | |
| Cholecystitis | 1 | 0 |
| <i>Cholestasis and jaundice</i> | | |
| Jaundice | 5 | 0 |
| <i>Hepatic enzymes and function abnormalities</i> | | |
| Hepatic function abnormal | 3 | 0 |
| <i>Hepatic failure and associated disorders</i> | | |
| Hepatic failure | 1 | 0 |
| <i>Hepatobiliary signs and symptoms</i> | | |
| Hepatomegaly | 1 | 0 |
| Hepatosplenomegaly | 1 | 0 |
| <i>Hepatocellular damage and hepatitis NEC</i> | | |
| Hepatitis | 3 | 0 |
| Hepatitis acute | 1 | 0 |
| Reye's syndrome | 1 | 1 |
| Hepatic disorders SOC TOTAL | 17 | 1 |

Case Series Drug Analysis Print

Name: MMR Vaccine DAP

Report Run Date: 27-Jun-2021
Earliest Reaction Date: 14-May-1987

Data Lock Date: 25-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|------------|----------|
| Immune system disorders | | |
| <i>Allergic conditions NEC</i> | | |
| Allergic oedema | 1 | 0 |
| Allergy to metals | 1 | 0 |
| Hypersensitivity | 63 | 0 |
| Multiple allergies | 1 | 0 |
| Serum sickness-like reaction | 1 | 0 |
| <i>Allergies to foods, food additives, drugs and other chemicals</i> | | |
| Allergy to vaccine | 3 | 0 |
| Food allergy | 2 | 0 |
| Milk allergy | 2 | 0 |
| Reaction to excipient | 1 | 0 |
| <i>Anaphylactic and anaphylactoid responses</i> | | |
| Anaphylactic reaction | 97 | 1 |
| Anaphylactic shock | 6 | 0 |
| Anaphylactoid reaction | 11 | 0 |
| <i>Autoimmune disorders NEC</i> | | |
| Autoimmune disorder | 2 | 0 |
| <i>Immune and associated conditions NEC</i> | | |
| Decreased immune responsiveness | 1 | 0 |
| Haemophagocytic lymphohistiocytosis | 3 | 2 |
| Immune system disorder | 3 | 0 |
| Immunisation reaction | 2 | 0 |
| <i>Immunodeficiency disorders NEC</i> | | |
| Immunodeficiency | 3 | 0 |
| <i>Primary immunodeficiency syndromes</i> | | |
| Selective IgG subclass deficiency | 1 | 0 |
| Immune system disorders SOC TOTAL | 204 | 3 |

Case Series Drug Analysis Print

Name: MMR Vaccine DAP

Report Run Date: 27-Jun-2021
Earliest Reaction Date: 14-May-1987

Data Lock Date: 25-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Infections | | |
| <i>Abdominal and gastrointestinal infections</i> | | |
| Diarrhoea infectious | 2 | 0 |
| Gastroenteritis | 6 | 0 |
| <i>Adenoviral infections</i> | | |
| Adenovirus infection | 1 | 0 |
| <i>Bacterial infections NEC</i> | | |
| Administration site cellulitis | 1 | 0 |
| Cellulitis | 92 | 0 |
| Citrobacter sepsis | 1 | 0 |
| Injection site cellulitis | 17 | 0 |
| Meningitis bacterial | 3 | 0 |
| Respiratory tract infection bacterial | 1 | 0 |
| Skin bacterial infection | 2 | 0 |
| Vaccination site cellulitis | 15 | 0 |
| <i>Bone and joint infections</i> | | |
| Intervertebral discitis | 3 | 0 |
| <i>Bordetella infections</i> | | |
| Pertussis | 1 | 0 |
| <i>Borrelial infections</i> | | |
| Lyme disease | 1 | 0 |
| Relapsing fever | 2 | 0 |
| <i>Candida infections</i> | | |
| Candida infection | 1 | 0 |
| Oral candidiasis | 3 | 0 |
| Vulvovaginal candidiasis | 1 | 0 |
| <i>Cardiac infections</i> | | |
| Pericarditis infective | 1 | 0 |
| <i>Central nervous system and spinal infections</i> | | |
| Encephalitis | 38 | 3 |
| Encephalomyelitis | 1 | 0 |
| Meningitis | 50 | 0 |
| Meningitis aseptic | 8 | 0 |
| Myelitis | 1 | 0 |
| Panencephalitis | 1 | 1 |
| <i>Cytomegaloviral infections</i> | | |
| Cytomegalovirus infection | 1 | 0 |
| <i>Dental and oral soft tissue infections</i> | | |
| Gingivitis | 1 | 0 |
| Parotitis | 872 | 0 |
| Sialoadenitis | 2 | 0 |
| <i>Ear infections</i> | | |
| Ear infection | 19 | 0 |
| Labyrinthitis | 1 | 0 |
| Mastoiditis | 1 | 0 |
| Otitis media | 30 | 0 |
| Otitis media acute | 2 | 0 |
| Otitis media chronic | 1 | 0 |
| <i>Epstein-Barr viral infections</i> | | |
| Epstein-Barr virus infection | 1 | 0 |
| Infectious mononucleosis | 1 | 0 |
| <i>Eye and eyelid infections</i> | | |
| Conjunctivitis | 61 | 0 |
| Eye infection | 4 | 0 |

Case Series Drug Analysis Print

Name: MMR Vaccine DAP

Report Run Date: 27-Jun-2021
Earliest Reaction Date: 14-May-1987

Data Lock Date: 25-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Infections Infections cont'd | | |
| Retinitis | 1 | 0 |
| Fungal infections NEC | | |
| Fungal infection | 1 | 0 |
| Fungal skin infection | 1 | 0 |
| Haemophilus infections | | |
| Haemophilus sepsis | 1 | 0 |
| Herpes viral infections | | |
| Herpes simplex | 1 | 0 |
| Herpes zoster | 5 | 0 |
| Human herpesvirus 6 infection | 2 | 0 |
| Human herpesvirus 6 infection reactivation | 1 | 0 |
| Human herpesvirus 7 infection | 1 | 0 |
| Oral herpes | 3 | 0 |
| Varicella | 7 | 0 |
| Infections NEC | | |
| Abscess | 6 | 0 |
| Infection | 7 | 0 |
| Infection susceptibility increased | 1 | 0 |
| Injection site abscess | 5 | 0 |
| Injection site infection | 2 | 0 |
| Localised infection | 2 | 0 |
| Respiratory tract infection | 1 | 0 |
| Toxic shock syndrome | 1 | 0 |
| Vaccination site infection | 9 | 0 |
| Vestibulitis | 1 | 0 |
| Infectious transmissions | | |
| Infection transmission via personal contact | 1 | 0 |
| Infection via vaccinee | 2 | 0 |
| Transmission of an infectious agent via product | 1 | 0 |
| Inflammatory disorders following infection | | |
| Subacute sclerosing panencephalitis | 2 | 0 |
| Influenza viral infections | | |
| H1N1 influenza | 1 | 0 |
| Influenza | 4 | 0 |
| Lower respiratory tract and lung infections | | |
| Bronchitis | 5 | 0 |
| Lower respiratory tract infection | 15 | 0 |
| Pneumonia | 15 | 1 |
| Male reproductive tract infections | | |
| Epididymitis | 1 | 0 |
| Orchitis | 28 | 0 |
| Molluscum contagiosum viral infections | | |
| Molluscum contagiosum | 2 | 0 |
| Mumps viral infections | | |
| Encephalitis mumps | 2 | 0 |
| Meningitis mumps | 5 | 0 |
| Mumps | 268 | 1 |
| Orchitis mumps | 1 | 0 |
| Neisseria infections | | |
| Meningitis meningococcal | 3 | 0 |
| Meningococcal sepsis | 3 | 1 |
| Parvoviral infections | | |
| Erythema infectiosum | 1 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 27-Jun-2021
Earliest Reaction Date: 14-May-1987

Data Lock Date: 25-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Infections | | |
| Infections cont'd | | |
| <i>Pneumocystis infections</i> | | |
| Pneumocystis jirovecii pneumonia | 1 | 0 |
| <i>Respiratory syncytial viral infections</i> | | |
| Respiratory syncytial virus infection | 1 | 0 |
| <i>Rubella viral infections</i> | | |
| Encephalomyelitis rubella | 1 | 0 |
| Rubella | 54 | 0 |
| <i>Rubeola viral infections</i> | | |
| Measles | 243 | 0 |
| Measles post vaccine | 11 | 0 |
| Pneumonia measles | 1 | 1 |
| <i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i> | | |
| Sepsis | 6 | 1 |
| Sepsis neonatal | 1 | 0 |
| Septic shock | 2 | 0 |
| Viraemia | 1 | 0 |
| <i>Skin structures and soft tissue infections</i> | | |
| Dermatitis infected | 1 | 0 |
| Eczema infected | 2 | 0 |
| Pustule | 1 | 0 |
| Pyoderma | 1 | 0 |
| Rash pustular | 2 | 0 |
| Skin infection | 4 | 0 |
| Subcutaneous abscess | 1 | 0 |
| Vaccination site pustule | 1 | 0 |
| <i>Staphylococcal infections</i> | | |
| Staphylococcal abscess | 1 | 0 |
| <i>Streptococcal infections</i> | | |
| Pneumococcal sepsis | 1 | 0 |
| Pneumonia pneumococcal | 1 | 0 |
| Scarlet fever | 1 | 0 |
| Streptococcal infection | 1 | 0 |
| <i>Tuberculous infections</i> | | |
| Erythema induratum | 8 | 0 |
| <i>Upper respiratory tract infections</i> | | |
| Croup infectious | 7 | 0 |
| Epiglottitis | 1 | 0 |
| Laryngitis | 1 | 0 |
| Nasopharyngitis | 33 | 0 |
| Pharyngitis | 20 | 0 |
| Rhinitis | 30 | 0 |
| Sinusitis | 1 | 0 |
| Tonsillitis | 19 | 0 |
| Upper respiratory tract infection | 19 | 0 |
| <i>Urinary tract infections</i> | | |
| Urinary tract infection | 5 | 0 |
| <i>Viral infections NEC</i> | | |
| Bronchiolitis | 2 | 0 |
| Ear infection viral | 1 | 0 |
| Encephalitis viral | 2 | 0 |
| Gastroenteritis viral | 2 | 0 |
| Gianotti-Crosti syndrome | 2 | 0 |
| Meningitis viral | 15 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 27-Jun-2021
Earliest Reaction Date: 14-May-1987

Data Lock Date: 25-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|-------------|-----------|
| Infections Infections cont'd | | |
| Pneumonia viral | 1 | 0 |
| Post viral fatigue syndrome | 4 | 0 |
| Viral infection | 15 | 0 |
| Viral myocarditis | 2 | 1 |
| Viral rash | 8 | 0 |
| Viral tonsillitis | 1 | 0 |
| Viral upper respiratory tract infection | 1 | 0 |
| Infections SOC TOTAL | 2209 | 10 |

Case Series Drug Analysis Print

Name: MMR Vaccine DAP

Report Run Date: 27-Jun-2021
Earliest Reaction Date: 14-May-1987

Data Lock Date: 25-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Injuries | | |
| <i>Accidental exposures to product</i> | | |
| Accidental exposure to product | 1 | 0 |
| <i>Cerebral injuries NEC</i> | | |
| Craniocerebral injury | 1 | 0 |
| <i>Conditions caused by cold</i> | | |
| Chillblains | 1 | 0 |
| <i>Cranial nerve injuries</i> | | |
| Optic nerve injury | 1 | 0 |
| <i>Exposures associated with pregnancy, delivery and lactation</i> | | |
| Exposure during pregnancy | 66 | 0 |
| Exposure via breast milk | 1 | 0 |
| Foetal exposure during pregnancy | 39 | 0 |
| Maternal exposure before pregnancy | 15 | 0 |
| Maternal exposure during breast feeding | 1 | 0 |
| Maternal exposure timing unspecified | 3 | 0 |
| <i>Limb fractures and dislocations</i> | | |
| Foot fracture | 1 | 0 |
| <i>Medication errors, product use errors and issues NEC</i> | | |
| Inadequate aseptic technique in use of product | 2 | 0 |
| Medication error | 15 | 0 |
| Vaccination error | 2 | 0 |
| Wrong technique in product usage process | 1 | 0 |
| <i>Nerve injuries NEC</i> | | |
| Nerve injury | 2 | 0 |
| <i>Non-site specific injuries NEC</i> | | |
| Fall | 9 | 0 |
| Injury | 2 | 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 |
| Contraindicated product administered | 1 | 0 |
| Expired product administered | 4 | 0 |
| Extra dose administered | 2 | 0 |
| Inappropriate schedule of product administration | 12 | 0 |
| Incomplete course of vaccination | 3 | 0 |
| Incorrect dose administered | 2 | 0 |
| Product administered at inappropriate site | 2 | 0 |
| Product administered to patient of inappropriate age | 2 | 0 |
| Product administration error | 1 | 0 |
| Wrong patient received product | 1 | 0 |
| Wrong product administered | 5 | 0 |
| <i>Product monitoring errors and issues</i> | | |
| Labelled drug-disease interaction medication error | 2 | 0 |
| Labelled drug-drug interaction medication error | 1 | 0 |
| <i>Product storage errors and issues in the product use system</i> | | |
| Product storage error | 1 | 0 |
| <i>Reproductive system and breast injuries</i> | | |
| Perineal injury | 2 | 0 |
| <i>Site specific injuries NEC</i> | | |
| Central nervous system injury | 1 | 0 |

Case Series Drug Analysis Print

Name: MMR Vaccine DAP

Report Run Date: 27-Jun-2021
Earliest Reaction Date: 14-May-1987

Data Lock Date: 25-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|--|------------|----------|
| Injuries Injuries cont'd | | |
| Head injury | 1 | 0 |
| Skin injuries NEC | | |
| Contusion | 41 | 0 |
| Scar | 2 | 0 |
| Skin laceration | 2 | 0 |
| Vaccination related complications | | |
| Vaccination complication | 3 | 0 |
| Injuries SOC TOTAL | 258 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 27-Jun-2021
Earliest Reaction Date: 14-May-1987

Data Lock Date: 25-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations | | |
| <i>Autoimmunity analyses</i> | | |
| Rheumatoid factor increased | 1 | 0 |
| <i>Blood gas and acid base analyses</i> | | |
| Oxygen saturation decreased | 3 | 0 |
| <i>Carbohydrate tolerance analyses (incl diabetes)</i> | | |
| Blood glucose decreased | 3 | 0 |
| Blood glucose fluctuation | 1 | 0 |
| Blood glucose increased | 1 | 0 |
| <i>Cardiac auscultatory investigations</i> | | |
| Cardiac murmur | 6 | 0 |
| <i>Cerebrospinal fluid tests (excl microbiology)</i> | | |
| CSF cell count increased | 1 | 0 |
| CSF test abnormal | 1 | 0 |
| <i>Digestive enzymes</i> | | |
| Amylase increased | 1 | 0 |
| <i>Foetal and neonatal diagnostic procedures</i> | | |
| Foetal heart rate decreased | 2 | 0 |
| Foetal monitoring abnormal | 3 | 0 |
| <i>Haematological analyses NEC</i> | | |
| Red blood cell sedimentation rate increased | 3 | 0 |
| <i>Heart rate and pulse investigations</i> | | |
| Heart rate abnormal | 2 | 0 |
| Heart rate decreased | 10 | 0 |
| Heart rate increased | 13 | 0 |
| Heart rate irregular | 5 | 0 |
| Pulse abnormal | 6 | 0 |
| Radial pulse abnormal | 1 | 0 |
| <i>Immunoglobulin analyses</i> | | |
| Blood immunoglobulin G increased | 1 | 0 |
| <i>Immunology analyses NEC</i> | | |
| Antibody test negative | 1 | 0 |
| Immunology test abnormal | 1 | 0 |
| <i>Immunology skin tests NEC</i> | | |
| Skin test positive | 2 | 0 |
| <i>Investigations NEC</i> | | |
| Blood test abnormal | 1 | 0 |
| Quality of life decreased | 1 | 0 |
| <i>Liver function analyses</i> | | |
| Liver function test abnormal | 2 | 0 |
| Transaminases increased | 1 | 0 |
| <i>Neurologic diagnostic procedures</i> | | |
| Electroencephalogram abnormal | 1 | 0 |
| <i>Physical examination procedures and organ system status</i> | | |
| Body temperature | 4 | 0 |
| Body temperature abnormal | 2 | 0 |
| Body temperature decreased | 7 | 0 |
| Body temperature fluctuation | 6 | 0 |
| Body temperature increased | 135 | 0 |
| Breath sounds abnormal | 2 | 0 |
| Grip strength decreased | 1 | 0 |
| Head circumference abnormal | 1 | 0 |
| Lymph node palpable | 1 | 0 |
| Respiratory rate decreased | 1 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 27-Jun-2021
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MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|------------|----------|
| Investigations | | |
| Investigations cont'd | | |
| Respiratory rate increased | 7 | 0 |
| Weight decreased | 7 | 0 |
| Weight increased | 1 | 0 |
| <i>Pituitary analyses anterior</i> | | |
| Blood thyroid stimulating hormone increased | 1 | 0 |
| <i>Platelet analyses</i> | | |
| Platelet count abnormal | 1 | 0 |
| Platelet count decreased | 10 | 0 |
| <i>Protein analyses NEC</i> | | |
| C-reactive protein increased | 6 | 0 |
| <i>Red blood cell analyses</i> | | |
| Haemoglobin S | 1 | 0 |
| <i>Respiratory tract and thoracic imaging procedures</i> | | |
| Chest X-ray abnormal | 1 | 0 |
| <i>Skeletal and cardiac muscle analyses</i> | | |
| Blood creatine phosphokinase increased | 1 | 0 |
| <i>Tissue enzyme analyses NEC</i> | | |
| Blood alkaline phosphatase increased | 2 | 0 |
| <i>Toxicology laboratory analyses</i> | | |
| Blood aluminium increased | 1 | 0 |
| Blood heavy metal increased | 1 | 0 |
| <i>Urinalysis NEC</i> | | |
| Protein urine | 1 | 0 |
| <i>Urinary tract function analyses NEC</i> | | |
| Urine output decreased | 1 | 0 |
| <i>Vascular tests NEC (incl blood pressure)</i> | | |
| Blood pressure decreased | 3 | 0 |
| Blood pressure increased | 10 | 0 |
| <i>Virus identification and serology</i> | | |
| Measles antibody negative | 3 | 0 |
| Measles antibody positive | 1 | 0 |
| Mumps antibody test negative | 4 | 0 |
| Rubella antibody negative | 8 | 0 |
| Rubella antibody positive | 1 | 0 |
| <i>White blood cell analyses</i> | | |
| Lymphocyte morphology abnormal | 1 | 0 |
| Investigations SOC TOTAL | 307 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 27-Jun-2021
Earliest Reaction Date: 14-May-1987

Data Lock Date: 25-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|------------|----------|
| Metabolic disorders | | |
| <i>Appetite disorders</i> | | |
| Decreased appetite | 327 | 0 |
| Diet refusal | 1 | 0 |
| Food refusal | 2 | 0 |
| Hyperphagia | 1 | 0 |
| Hypophagia | 6 | 0 |
| Increased appetite | 1 | 0 |
| <i>Calcium metabolism disorders</i> | | |
| Hypocalcaemia | 1 | 0 |
| <i>Cell metabolism disorders NEC</i> | | |
| Mitochondrial cytopathy | 1 | 0 |
| <i>Diabetes mellitus (incl subtypes)</i> | | |
| Diabetes mellitus | 10 | 0 |
| Type 1 diabetes mellitus | 6 | 0 |
| <i>Fat soluble vitamin deficiencies and disorders</i> | | |
| Vitamin D deficiency | 1 | 0 |
| <i>Fluid intake decreased</i> | | |
| Fluid intake reduced | 8 | 0 |
| <i>Fluid intake increased</i> | | |
| Polydipsia | 1 | 0 |
| <i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i> | | |
| Dairy intolerance | 2 | 0 |
| Food intolerance | 6 | 0 |
| <i>General nutritional disorders NEC</i> | | |
| Abnormal loss of weight | 4 | 0 |
| Failure to thrive | 1 | 0 |
| Feeding disorder | 6 | 0 |
| Food aversion | 3 | 0 |
| Poor feeding infant | 8 | 0 |
| Weight gain poor | 1 | 0 |
| <i>Hypoglycaemic conditions NEC</i> | | |
| Hypoglycaemia | 2 | 0 |
| <i>Iron deficiencies</i> | | |
| Iron deficiency | 1 | 0 |
| <i>Metabolic acidoses (excl diabetic acidoses)</i> | | |
| Metabolic acidosis | 3 | 0 |
| <i>Metabolic disorders NEC</i> | | |
| Metabolic disorder | 2 | 0 |
| <i>Protein metabolism disorders NEC</i> | | |
| Hyperammonaemia | 1 | 0 |
| <i>Sodium imbalance</i> | | |
| Hyponatraemia | 3 | 0 |
| <i>Total fluid volume decreased</i> | | |
| Dehydration | 9 | 0 |
| <i>Total fluid volume increased</i> | | |
| Fluid retention | 1 | 0 |
| Metabolic disorders SOC TOTAL | 419 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 27-Jun-2021
Earliest Reaction Date: 14-May-1987

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Muscle & tissue disorders | | |
| <i>Arthropathies NEC</i> | | |
| Arthritis | 19 | 0 |
| Arthropathy | 9 | 0 |
| <i>Bone disorders NEC</i> | | |
| Exostosis | 1 | 0 |
| <i>Bone related signs and symptoms</i> | | |
| Bone pain | 1 | 0 |
| Pain in jaw | 3 | 0 |
| Pubic pain | 1 | 0 |
| <i>Cartilage disorders</i> | | |
| Costochondritis | 1 | 0 |
| <i>Connective tissue disorders NEC</i> | | |
| Myofascitis | 1 | 0 |
| <i>Joint related disorders NEC</i> | | |
| Hypermobility syndrome | 1 | 0 |
| <i>Joint related signs and symptoms</i> | | |
| Arthralgia | 109 | 0 |
| Joint effusion | 1 | 0 |
| Joint noise | 2 | 0 |
| Joint stiffness | 7 | 0 |
| Joint swelling | 22 | 0 |
| <i>Lupus erythematosus (incl subtypes)</i> | | |
| Systemic lupus erythematosus | 1 | 0 |
| <i>Muscle pains</i> | | |
| Myalgia | 36 | 0 |
| <i>Muscle related signs and symptoms NEC</i> | | |
| Diastasis recti abdominis | 1 | 0 |
| Muscle atrophy | 1 | 0 |
| Muscle fatigue | 1 | 0 |
| Muscle spasms | 6 | 0 |
| Muscle swelling | 1 | 0 |
| Muscle tightness | 3 | 0 |
| Muscle twitching | 15 | 0 |
| <i>Muscle tone abnormalities</i> | | |
| Floppy infant | 7 | 0 |
| Muscle rigidity | 6 | 0 |
| Nuchal rigidity | 1 | 0 |
| Torticollis | 1 | 0 |
| Trismus | 2 | 0 |
| <i>Muscle weakness conditions</i> | | |
| Muscular weakness | 27 | 0 |
| <i>Musculoskeletal and connective tissue conditions NEC</i> | | |
| Growth retardation | 1 | 0 |
| Limb mass | 1 | 0 |
| Mobility decreased | 2 | 0 |
| Musculoskeletal stiffness | 23 | 0 |
| Posture abnormal | 2 | 0 |
| Toe walking | 1 | 0 |
| Weight bearing difficulty | 17 | 0 |
| <i>Musculoskeletal and connective tissue pain and discomfort</i> | | |
| Back pain | 21 | 0 |
| Limb discomfort | 9 | 0 |
| Musculoskeletal chest pain | 2 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 27-Jun-2021
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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Muscle & tissue disorders | | |
| Muscle & tissue disorders cont'd | | |
| Musculoskeletal pain | 1 | 0 |
| Neck pain | 21 | 0 |
| Pain in extremity | 91 | 0 |
| <i>Osteoarthropathies</i> | | |
| Osteoarthritis | 2 | 0 |
| <i>Rheumatoid arthropathies</i> | | |
| Juvenile idiopathic arthritis | 5 | 0 |
| Rheumatoid arthritis | 1 | 0 |
| <i>Soft tissue disorders NEC</i> | | |
| Groin pain | 2 | 0 |
| Neck mass | 1 | 0 |
| <i>Spondyloarthropathies</i> | | |
| Arthritis reactive | 2 | 0 |
| Muscle & tissue disorders SOC TOTAL | 492 | 0 |

Case Series Drug Analysis Print

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Earliest Reaction Date: 14-May-1987

Data Lock Date: 25-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|----------|----------|
| Neoplasms | | |
| <i>Cardiovascular neoplasms benign</i> | | |
| Haemangioma | 1 | 0 |
| <i>Hepatoblastomas</i> | | |
| Hepatoblastoma | 1 | 0 |
| <i>Leukaemias acute lymphocytic</i> | | |
| Acute lymphocytic leukaemia | 1 | 0 |
| <i>Reproductive neoplasms female benign NEC</i> | | |
| Benign hydatidiform mole | 1 | 0 |
| <i>Skin neoplasms malignant and unspecified (excl melanoma)</i> | | |
| Neoplasm skin | 1 | 0 |
| Neoplasms SOC TOTAL | 5 | 0 |

Case Series Drug Analysis Print

Name: MMR Vaccine DAP

Report Run Date: 27-Jun-2021
Earliest Reaction Date: 14-May-1987

Data Lock Date: 25-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| <i>Abnormal reflexes</i> | | |
| Areflexia | 1 | 0 |
| <i>Absence seizures</i> | | |
| Petit mal epilepsy | 6 | 0 |
| <i>Acute polyneuropathies</i> | | |
| Guillain-Barre syndrome | 6 | 1 |
| <i>Central nervous system haemorrhages and cerebrovascular accidents</i> | | |
| Cerebral infarction | 1 | 0 |
| Cerebral ischaemia | 1 | 0 |
| Cerebrovascular accident | 1 | 0 |
| Ischaemic cerebral infarction | 1 | 0 |
| <i>Central nervous system inflammatory disorders NEC</i> | | |
| Arachnoiditis | 1 | 0 |
| <i>Central nervous system vascular disorders NEC</i> | | |
| Brain hypoxia | 1 | 0 |
| Vertebrobasilar insufficiency | 1 | 0 |
| <i>Choreiform movements</i> | | |
| Chorea | 2 | 0 |
| <i>Coma states</i> | | |
| Coma | 1 | 0 |
| <i>Coordination and balance disturbances</i> | | |
| Ataxia | 24 | 0 |
| Balance disorder | 24 | 0 |
| Cerebellar ataxia | 1 | 0 |
| Cerebellar syndrome | 1 | 0 |
| Coordination abnormal | 9 | 0 |
| Dysstasia | 4 | 0 |
| Hand-eye coordination impaired | 1 | 0 |
| Nystagmus | 1 | 0 |
| <i>Cortical dysfunction NEC</i> | | |
| Aphasia | 19 | 0 |
| Dyslexia | 1 | 0 |
| Dyspraxia | 3 | 0 |
| Sensory processing disorder | 2 | 0 |
| <i>Demyelinating disorders NEC</i> | | |
| Acute disseminated encephalomyelitis | 1 | 0 |
| <i>Disturbances in consciousness NEC</i> | | |
| Altered state of consciousness | 2 | 0 |
| Consciousness fluctuating | 2 | 0 |
| Depressed level of consciousness | 9 | 0 |
| Lethargy | 135 | 0 |
| Loss of consciousness | 31 | 0 |
| Somnolence | 100 | 0 |
| Syncope | 102 | 0 |
| <i>Dyskinesias and movement disorders NEC</i> | | |
| Akinesia | 2 | 0 |
| Clumsiness | 2 | 0 |
| Dyskinesia | 11 | 0 |
| Extrapyramidal disorder | 1 | 0 |
| Fine motor delay | 1 | 0 |
| Fine motor skill dysfunction | 1 | 0 |
| Hyperkinesia | 3 | 0 |
| Hypokinesia | 7 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Motor dysfunction | 1 | 0 |
| Movement disorder | 2 | 0 |
| Psychomotor hyperactivity | 16 | 0 |
| <i>Dystonias</i> | | |
| Opisthotonus | 3 | 0 |
| <i>Encephalopathies NEC</i> | | |
| Encephalopathy | 27 | 0 |
| Encephalopathy neonatal | 1 | 0 |
| Hypoxic-ischaemic encephalopathy | 1 | 0 |
| <i>Eye movement disorders</i> | | |
| VIth nerve paralysis | 3 | 0 |
| <i>Facial cranial nerve disorders</i> | | |
| Bell's palsy | 5 | 0 |
| Facial paralysis | 7 | 0 |
| Facial spasm | 2 | 0 |
| <i>Generalised tonic-clonic seizures</i> | | |
| Generalised tonic-clonic seizure | 26 | 0 |
| <i>Headaches NEC</i> | | |
| Headache | 133 | 0 |
| Sinus headache | 2 | 0 |
| <i>Hydrocephalic conditions</i> | | |
| Hydrocephalus | 2 | 0 |
| <i>Increased intracranial pressure disorders</i> | | |
| Brain oedema | 1 | 1 |
| <i>Lumbar spinal cord and nerve root disorders</i> | | |
| Sciatica | 1 | 0 |
| <i>Memory loss (excl dementia)</i> | | |
| Amnesia | 4 | 0 |
| <i>Mental impairment (excl dementia and memory loss)</i> | | |
| Cognitive disorder | 5 | 0 |
| Disturbance in attention | 10 | 0 |
| Mental impairment | 3 | 0 |
| <i>Migraine headaches</i> | | |
| Migraine | 8 | 0 |
| <i>Mixed cranial nerve disorders</i> | | |
| Bulbar palsy | 1 | 0 |
| <i>Mononeuropathies</i> | | |
| Mononeuropathy multiplex | 1 | 0 |
| <i>Muscle tone abnormal</i> | | |
| Hypotonia | 43 | 0 |
| <i>Myelitis (incl infective)</i> | | |
| Myelitis transverse | 4 | 0 |
| <i>Narcolepsy and hypersomnia</i> | | |
| Hypersomnia | 8 | 0 |
| <i>Nervous system disorders NEC</i> | | |
| Cerebral disorder | 1 | 0 |
| Nervous system disorder | 6 | 0 |
| Psychomotor skills impaired | 1 | 0 |
| <i>Neurological signs and symptoms NEC</i> | | |
| Decorticate posture | 1 | 0 |
| Dizziness | 68 | 0 |
| Dizziness postural | 2 | 0 |
| Droling | 2 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Exaggerated startle response | 1 | 0 |
| Head discomfort | 3 | 0 |
| Hyporesponsive to stimuli | 2 | 0 |
| Inability to crawl | 5 | 0 |
| Infant irritability | 5 | 0 |
| Meningism | 8 | 0 |
| Myoclonus | 6 | 0 |
| Neurological decompensation | 2 | 0 |
| Neurological symptom | 2 | 0 |
| Presyncope | 23 | 0 |
| Slow response to stimuli | 1 | 0 |
| Unresponsive to stimuli | 33 | 0 |
| Neuromuscular disorders NEC | | |
| Hypotonic-hyporesponsive episode | 4 | 0 |
| Muscle spasticity | 1 | 0 |
| Olfactory nerve disorders | | |
| Anosmia | 1 | 0 |
| Parosmia | 1 | 0 |
| Optic nerve disorders NEC | | |
| Optic neuritis | 1 | 0 |
| Paraesthesias and dysaesthesias | | |
| Burning sensation | 3 | 0 |
| Dysaesthesia | 1 | 0 |
| Hyperaesthesia | 4 | 0 |
| Hypoaesthesia | 21 | 0 |
| Paraesthesia | 33 | 0 |
| Paralysis and paresis (excl cranial nerve) | | |
| Diplegia | 1 | 0 |
| Hemiparesis | 10 | 0 |
| Hemiplegia | 2 | 0 |
| Paralysis | 9 | 0 |
| Paresis | 2 | 0 |
| Partial complex seizures | | |
| Focal dyscognitive seizures | 3 | 0 |
| Temporal lobe epilepsy | 1 | 0 |
| Peripheral neuropathies NEC | | |
| Neuralgic amyotrophy | 1 | 0 |
| Neuropathy peripheral | 4 | 0 |
| Polyneuropathy | 3 | 0 |
| Seizures and seizure disorders NEC | | |
| Convulsion in childhood | 1 | 0 |
| Epilepsy | 30 | 0 |
| Febrile convulsion | 190 | 0 |
| Frontal lobe epilepsy | 1 | 0 |
| Idiopathic generalised epilepsy | 2 | 0 |
| Myoclonic epilepsy | 1 | 0 |
| Neonatal seizure | 1 | 0 |
| Partial seizures | 10 | 0 |
| Seizure | 291 | 0 |
| Seizure anoxic | 3 | 0 |
| Seizure like phenomena | 2 | 0 |
| Status epilepticus | 9 | 0 |
| Tonic convulsion | 1 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------------|----------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| <i>Sensory abnormalities NEC</i> | | |
| Dysgeusia | 5 | 0 |
| Hypogeusia | 1 | 0 |
| Neuralgia | 3 | 0 |
| Restless legs syndrome | 1 | 0 |
| Sensory disturbance | 5 | 0 |
| Sensory loss | 5 | 0 |
| <i>Sleep disturbances NEC</i> | | |
| Sleep deficit | 1 | 0 |
| <i>Speech and language abnormalities</i> | | |
| Dysarthria | 3 | 0 |
| Repetitive speech | 1 | 0 |
| Slow speech | 1 | 0 |
| Speech disorder | 18 | 0 |
| Speech disorder developmental | 14 | 0 |
| <i>Structural brain disorders NEC</i> | | |
| Brain injury | 5 | 0 |
| <i>Tremor (excl congenital)</i> | | |
| Tremor | 48 | 0 |
| Nervous system disorders SOC TOTAL | 1774 | 2 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Pregnancy conditions | | |
| <i>Abortion related conditions and complications</i> | | |
| Anembryonic gestation | 1 | 0 |
| <i>Abortions not specified as induced or spontaneous</i> | | |
| Abortion missed | 2 | 0 |
| <i>Abortions spontaneous</i> | | |
| Abortion spontaneous | 39 | 0 |
| Abortion threatened | 2 | 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 | 2 | 0 |
| <i>Foetal growth complications</i> | | |
| Foetal growth restriction | 6 | 0 |
| <i>Foetal position and presentation abnormalities</i> | | |
| Breech presentation | 4 | 0 |
| Face presentation | 1 | 0 |
| High foetal head | 1 | 0 |
| <i>Gestational age and weight conditions</i> | | |
| Low birth weight baby | 1 | 0 |
| Premature baby | 7 | 0 |
| <i>Haemorrhagic complications of pregnancy</i> | | |
| Premature separation of placenta | 2 | 0 |
| <i>High risk pregnancies</i> | | |
| High risk pregnancy | 1 | 0 |
| <i>Hypertension associated disorders of pregnancy</i> | | |
| Gestational hypertension | 1 | 0 |
| Pre-eclampsia | 4 | 0 |
| <i>Labour onset and length abnormalities</i> | | |
| Premature delivery | 3 | 0 |
| Premature labour | 2 | 0 |
| Premature rupture of membranes | 1 | 0 |
| Prolonged labour | 9 | 0 |
| <i>Maternal complications of delivery NEC</i> | | |
| Breech delivery | 1 | 0 |
| <i>Maternal complications of labour NEC</i> | | |
| Labour complication | 5 | 0 |
| <i>Maternal complications of pregnancy NEC</i> | | |
| Complication of pregnancy | 1 | 0 |
| Morning sickness | 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> | | |
| Live birth | 2 | 0 |
| Pregnancy | 5 | 0 |
| <i>Postpartum complications NEC</i> | | |

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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Pregnancy conditions <small>Pregnancy conditions cont'd</small> | | |
| Postpartum haemorrhage | 2 | 0 |
| <i>Pregnancy complicated by maternal disorders</i> | | |
| Gestational diabetes | 1 | 0 |
| <i>Stillbirth and foetal death</i> | | |
| Foetal death | 1 | 1 |
| Stillbirth | 3 | 3 |
| <i>Unintended pregnancies</i> | | |
| Unintended pregnancy | 1 | 0 |
| Pregnancy conditions SOC TOTAL | 120 | 4 |

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| Reaction Name | Total | Fatal |
|---|--------------|--------------|
| <i>Device physical property and chemical issues</i> | | |
| Syringe issue | 1 | 0 |
| <i>Product quality issues NEC</i> | | |
| Product complaint | 3 | 0 |
| Product quality issue | 2 | 0 |
| null SOC TOTAL | 6 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders | | |
| <i>Abnormal behaviour NEC</i> | | |
| Abnormal behaviour | 35 | 0 |
| Behaviour disorder | 12 | 0 |
| Breath holding | 4 | 0 |
| Staring | 7 | 0 |
| <i>Affect alterations NEC</i> | | |
| Affect lability | 3 | 0 |
| Flat affect | 1 | 0 |
| <i>Anxiety disorders NEC</i> | | |
| Separation anxiety disorder | 1 | 0 |
| <i>Anxiety symptoms</i> | | |
| Agitation | 15 | 0 |
| Anxiety | 18 | 0 |
| Nervousness | 10 | 0 |
| Stress | 1 | 0 |
| <i>Attention deficit and disruptive behaviour disorders</i> | | |
| Attention deficit hyperactivity disorder | 5 | 0 |
| <i>Behaviour and socialisation disturbances</i> | | |
| Aggression | 14 | 0 |
| Antisocial behaviour | 2 | 0 |
| Personality change | 8 | 0 |
| Social avoidant behaviour | 10 | 0 |
| <i>Communications disorders</i> | | |
| Communication disorder | 2 | 0 |
| Mutism | 1 | 0 |
| <i>Confusion and disorientation</i> | | |
| Confusional state | 13 | 0 |
| Disorientation | 14 | 0 |
| <i>Decreased physical activity levels</i> | | |
| Catatonia | 1 | 0 |
| <i>Deliria</i> | | |
| Delirium | 7 | 0 |
| <i>Depressive disorders</i> | | |
| Depression | 10 | 0 |
| <i>Dissociative states</i> | | |
| Depersonalisation/derealisation disorder | 4 | 0 |
| Dissociation | 1 | 0 |
| <i>Disturbances in initiating and maintaining sleep</i> | | |
| Initial insomnia | 1 | 0 |
| Insomnia | 59 | 0 |
| Middle insomnia | 4 | 0 |
| <i>Dyssomnias</i> | | |
| Poor quality sleep | 7 | 0 |
| <i>Eating disorders NEC</i> | | |
| Eating disorder | 2 | 0 |
| Selective eating disorder | 1 | 0 |
| <i>Emotional and mood disturbances NEC</i> | | |
| Anger | 1 | 0 |
| Dysphoria | 1 | 0 |
| Emotional disorder | 4 | 0 |
| Emotional distress | 18 | 0 |
| Frustration tolerance decreased | 1 | 0 |
| Irritability | 209 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Psychiatric disorders ^{Psychiatric disorders cont'd} | | |
| Mood altered | 5 | 0 |
| Morose | 1 | 0 |
| <i>Fear symptoms and phobic disorders (incl social phobia)</i> | | |
| Fear | 3 | 0 |
| Social anxiety disorder | 1 | 0 |
| <i>Fluctuating mood symptoms</i> | | |
| Mood swings | 1 | 0 |
| <i>Hallucinations (excl sleep-related)</i> | | |
| Hallucination | 10 | 0 |
| Hallucination, visual | 3 | 0 |
| <i>Increased physical activity levels</i> | | |
| Restlessness | 21 | 0 |
| <i>Learning disorders</i> | | |
| Learning disability | 3 | 0 |
| Learning disorder | 3 | 0 |
| <i>Mental disorders NEC</i> | | |
| Mental disorder | 5 | 0 |
| Mental status changes | 2 | 0 |
| <i>Mood alterations with depressive symptoms</i> | | |
| Anhedonia | 1 | 0 |
| Decreased interest | 2 | 0 |
| Depressed mood | 11 | 0 |
| Tearfulness | 14 | 0 |
| <i>Mood disorders NEC</i> | | |
| Affective disorder | 1 | 0 |
| Apathy | 3 | 0 |
| Listless | 12 | 0 |
| <i>Obsessive-compulsive disorders and symptoms</i> | | |
| Body dysmorphic disorder | 1 | 0 |
| Obsessive-compulsive disorder | 1 | 0 |
| Obsessive-compulsive symptom | 1 | 0 |
| Trichotillomania | 1 | 0 |
| <i>Panic attacks and disorders</i> | | |
| Panic attack | 3 | 0 |
| <i>Parasomnias</i> | | |
| Nightmare | 4 | 0 |
| Sleep terror | 4 | 0 |
| <i>Perception disturbances NEC</i> | | |
| Time perception altered | 1 | 0 |
| <i>Pervasive developmental disorders NEC</i> | | |
| Autism spectrum disorder | 129 | 0 |
| <i>Psychiatric elimination disorders</i> | | |
| Enuresis | 3 | 0 |
| <i>Psychiatric symptoms NEC</i> | | |
| Decreased eye contact | 7 | 0 |
| <i>Psychotic disorder NEC</i> | | |
| Psychotic disorder | 1 | 0 |
| <i>Sleep disorders NEC</i> | | |
| Sleep disorder | 30 | 0 |
| <i>Somatic symptom disorders</i> | | |
| Conversion disorder | 1 | 0 |
| <i>Speech articulation and rhythm disturbances</i> | | |
| Dysphemia | 3 | 0 |

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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| Lack of spontaneous speech | 1 | 0 |
| <i>Stereotypies and automatisms</i> | | |
| Bruxism | 1 | 0 |
| Head banging | 7 | 0 |
| Posturing | 1 | 0 |
| Stereotypy | 1 | 0 |
| <i>Suicidal and self-injurious behaviour</i> | | |
| Intentional self-injury | 2 | 0 |
| Self-injurious ideation | 1 | 0 |
| <i>Thinking disturbances</i> | | |
| Intrusive thoughts | 1 | 0 |
| Thinking abnormal | 3 | 0 |
| <i>Tic disorders</i> | | |
| Tic | 1 | 0 |
| Psychiatric disorders SOC TOTAL | 818 | 0 |

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| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Renal & urinary disorders | | |
| <i>Bladder and urethral symptoms</i> | | |
| Dysuria | 1 | 0 |
| Incontinence | 3 | 0 |
| Micturition disorder | 1 | 0 |
| Micturition frequency decreased | 1 | 0 |
| Micturition urgency | 1 | 0 |
| Pollakiuria | 2 | 0 |
| Urinary incontinence | 11 | 0 |
| Urinary retention | 2 | 0 |
| <i>Bladder disorders NEC</i> | | |
| Bladder disorder | 1 | 0 |
| <i>Glomerulonephritis and nephrotic syndrome</i> | | |
| Nephrotic syndrome | 7 | 0 |
| <i>Myoneurogenic bladder disorders</i> | | |
| Bladder dysfunction | 1 | 0 |
| <i>Nephritis NEC</i> | | |
| Tubulointerstitial nephritis | 1 | 0 |
| <i>Nephropathies and tubular disorders NEC</i> | | |
| Renal tubular disorder | 2 | 0 |
| <i>Renal failure and impairment</i> | | |
| Renal impairment | 1 | 0 |
| <i>Renal structural abnormalities and trauma</i> | | |
| Pyelocaliectasis | 1 | 0 |
| <i>Renal vascular and ischaemic conditions</i> | | |
| Renal tubular necrosis | 1 | 0 |
| <i>Urinary abnormalities</i> | | |
| Chromaturia | 1 | 0 |
| Haematuria | 5 | 0 |
| Proteinuria | 2 | 0 |
| <i>Urinary tract signs and symptoms NEC</i> | | |
| Renal pain | 3 | 0 |
| Renal & urinary disorders SOC TOTAL | 48 | 0 |

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| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Reproductive & breast disorders | | |
| <i>Breast disorders NEC</i> | | |
| Breast enlargement | 1 | 0 |
| <i>Breast infections and inflammations</i> | | |
| Nipple inflammation | 1 | 0 |
| <i>Breast signs and symptoms</i> | | |
| Breast swelling | 1 | 0 |
| <i>Cervix neoplasms</i> | | |
| Cervical polyp | 1 | 0 |
| <i>Erection and ejaculation conditions and disorders</i> | | |
| Erectile dysfunction | 1 | 0 |
| <i>Menstruation and uterine bleeding NEC</i> | | |
| Menstrual disorder | 2 | 0 |
| <i>Menstruation with decreased bleeding</i> | | |
| Menstruation delayed | 1 | 0 |
| <i>Menstruation with increased bleeding</i> | | |
| Heavy menstrual bleeding | 1 | 0 |
| <i>Penile and scrotal infections and inflammations</i> | | |
| Balanoposthitis | 1 | 0 |
| <i>Reproductive tract signs and symptoms NEC</i> | | |
| Genital pain | 1 | 0 |
| Genital rash | 2 | 0 |
| Genital swelling | 1 | 0 |
| Oedema genital | 1 | 0 |
| Pelvic pain | 2 | 0 |
| <i>Scrotal disorders NEC</i> | | |
| Scrotal swelling | 3 | 0 |
| <i>Testicular and epididymal disorders NEC</i> | | |
| Testicular disorder | 1 | 0 |
| Testicular pain | 6 | 0 |
| Testicular swelling | 15 | 0 |
| <i>Vulvovaginal disorders NEC</i> | | |
| Vaginal haemorrhage | 6 | 0 |
| <i>Vulvovaginal signs and symptoms</i> | | |
| Vulvovaginal discomfort | 1 | 0 |
| Reproductive & breast disorders SOC TOTAL | 49 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Respiratory disorders | | |
| <i>Breathing abnormalities</i> | | |
| Apnoea | 2 | 0 |
| Apnoeic attack | 3 | 0 |
| Dyspnoea | 64 | 0 |
| Hyperventilation | 3 | 0 |
| Hypopnoea | 10 | 0 |
| Irregular breathing | 1 | 0 |
| Respiration abnormal | 3 | 0 |
| Respiratory arrest | 16 | 1 |
| Respiratory depression | 1 | 0 |
| Respiratory distress | 4 | 0 |
| Sleep apnoea syndrome | 3 | 0 |
| Tachypnoea | 3 | 0 |
| <i>Bronchospasm and obstruction</i> | | |
| Asthma | 16 | 1 |
| Bronchospasm | 11 | 0 |
| Wheezing | 26 | 0 |
| <i>Conditions associated with abnormal gas exchange</i> | | |
| Asphyxia | 2 | 0 |
| Cyanosis central | 3 | 0 |
| Hypoxia | 2 | 0 |
| Respiratory gas exchange disorder | 2 | 0 |
| <i>Coughing and associated symptoms</i> | | |
| Cough | 155 | 0 |
| Haemoptysis | 2 | 0 |
| Productive cough | 3 | 0 |
| Sputum increased | 1 | 0 |
| <i>Laryngeal spasm, oedema and obstruction</i> | | |
| Stridor | 7 | 0 |
| <i>Lower respiratory tract inflammatory and immunologic conditions</i> | | |
| Alveolitis | 1 | 0 |
| Lower respiratory tract inflammation | 1 | 0 |
| Pneumonia aspiration | 1 | 0 |
| Pneumonitis | 3 | 0 |
| <i>Lower respiratory tract signs and symptoms</i> | | |
| Hiccups | 1 | 0 |
| Increased bronchial secretion | 1 | 0 |
| Rales | 1 | 0 |
| <i>Nasal congestion and inflammations</i> | | |
| Nasal congestion | 12 | 0 |
| <i>Nasal disorders NEC</i> | | |
| Epistaxis | 22 | 0 |
| Nasal pruritus | 1 | 0 |
| <i>Neonatal hypoxic conditions</i> | | |
| Neonatal respiratory distress syndrome | 3 | 0 |
| <i>Newborn respiratory disorders NEC</i> | | |
| Bronchopulmonary dysplasia | 1 | 0 |
| Transient tachypnoea of the newborn | 1 | 0 |
| <i>Paranasal sinus disorders (excl infections and neoplasms)</i> | | |
| Sinus congestion | 2 | 0 |
| <i>Parenchymal lung disorders NEC</i> | | |
| Atelectasis | 1 | 0 |
| Interstitial lung disease | 3 | 1 |

Case Series Drug Analysis Print

Name: MMR Vaccine DAP

Report Run Date: 27-Jun-2021
Earliest Reaction Date: 14-May-1987

Data Lock Date: 25-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

| Reaction Name | Total | Fatal |
|---|------------|----------|
| Respiratory disorders Respiratory disorders cont'd | | |
| Lung consolidation | 2 | 0 |
| Organising pneumonia | 1 | 0 |
| Pulmonary alveolar haemorrhage | 1 | 0 |
| Pulmonary fibrosis | 1 | 0 |
| Pharyngeal disorders (excl infections and neoplasms) | | |
| Pharyngeal disorder | 1 | 0 |
| Pharyngeal erythema | 6 | 0 |
| Pharyngeal inflammation | 1 | 0 |
| Pharyngeal oedema | 1 | 0 |
| Pharyngeal paraesthesia | 1 | 0 |
| Pharyngeal swelling | 10 | 0 |
| Tonsillar hypertrophy | 6 | 0 |
| Tonsillar inflammation | 2 | 0 |
| Velopharyngeal incompetence | 2 | 0 |
| Pleural conditions NEC | | |
| Pleural adhesion | 1 | 0 |
| Pneumothorax and pleural effusions NEC | | |
| Pleural effusion | 2 | 0 |
| Pulmonary oedemas | | |
| Acute lung injury | 1 | 0 |
| Acute pulmonary oedema | 1 | 0 |
| Acute respiratory distress syndrome | 2 | 0 |
| Pulmonary congestion | 1 | 0 |
| Pulmonary oedema | 2 | 0 |
| Pulmonary thrombotic and embolic conditions | | |
| Pulmonary embolism | 1 | 0 |
| Respiratory failures (excl neonatal) | | |
| Respiratory failure | 3 | 0 |
| Respiratory tract disorders NEC | | |
| Aspiration | 1 | 1 |
| Respiratory disorder | 4 | 0 |
| Respiratory tract irritation | 1 | 0 |
| Upper respiratory tract signs and symptoms | | |
| Aphonia | 3 | 0 |
| Catarrh | 3 | 0 |
| Choking | 1 | 0 |
| Dry throat | 2 | 0 |
| Dysphonia | 3 | 0 |
| Nasal discharge discolouration | 1 | 0 |
| Oropharyngeal discomfort | 2 | 0 |
| Oropharyngeal pain | 62 | 0 |
| Rhinorrhoea | 72 | 0 |
| Sinus pain | 1 | 0 |
| Sneezing | 4 | 0 |
| Snoring | 1 | 0 |
| Throat irritation | 2 | 0 |
| Throat tightness | 3 | 0 |
| Upper-airway cough syndrome | 1 | 0 |
| Yawning | 1 | 0 |
| Vascular pulmonary disorders NEC | | |
| Pulmonary arteriopathy | 2 | 0 |
| Respiratory disorders SOC TOTAL | 617 | 4 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Skin disorders | | |
| <i>Acnes</i> | | |
| Acne | 2 | 0 |
| <i>Alopecias</i> | | |
| Alopecia | 6 | 0 |
| Alopecia totalis | 1 | 0 |
| <i>Angioedemas</i> | | |
| Angioedema | 23 | 0 |
| <i>Apocrine and eccrine gland disorders</i> | | |
| Cold sweat | 27 | 0 |
| Hyperhidrosis | 43 | 0 |
| Miliaria | 1 | 0 |
| Night sweats | 4 | 0 |
| <i>Bullous conditions</i> | | |
| Blister | 38 | 0 |
| Blood blister | 2 | 0 |
| Dermatitis bullous | 13 | 0 |
| Erythema multiforme | 67 | 0 |
| Stevens-Johnson syndrome | 3 | 0 |
| Toxic epidermal necrolysis | 1 | 0 |
| <i>Connective tissue disorders</i> | | |
| Dermatomyositis | 1 | 0 |
| <i>Dermal and epidermal conditions NEC</i> | | |
| Dry skin | 8 | 0 |
| Pain of skin | 3 | 0 |
| Papule | 27 | 0 |
| Scab | 3 | 0 |
| Skin burning sensation | 2 | 0 |
| Skin discolouration | 13 | 0 |
| Skin disorder | 4 | 0 |
| Skin fissures | 1 | 0 |
| Skin induration | 8 | 0 |
| Skin lesion | 3 | 0 |
| Skin necrosis | 1 | 0 |
| Skin reaction | 17 | 0 |
| Skin tightness | 4 | 0 |
| Skin warm | 40 | 0 |
| Skin weeping | 1 | 0 |
| <i>Dermatitis and eczema</i> | | |
| Dermatitis | 3 | 0 |
| Dermatitis allergic | 32 | 0 |
| Dermatitis atopic | 4 | 0 |
| Dermatitis contact | 1 | 0 |
| Dermatitis diaper | 11 | 0 |
| Eczema | 71 | 0 |
| Eczema infantile | 3 | 0 |
| Eczema weeping | 1 | 0 |
| Seborrhoeic dermatitis | 1 | 0 |
| Skin irritation | 3 | 0 |
| <i>Dermatitis ascribed to specific agent</i> | | |
| Drug eruption | 4 | 0 |
| Drug reaction with eosinophilia and systemic symptoms | 1 | 0 |
| Toxic skin eruption | 1 | 0 |
| <i>Erythemas</i> | | |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Skin disorders Skin disorders cont'd | | |
| Erythema | 264 | 0 |
| Exfoliative conditions | | |
| Dermatitis exfoliative | 2 | 0 |
| Dermatitis exfoliative generalised | 1 | 0 |
| Skin exfoliation | 10 | 0 |
| Hyperkeratoses | | |
| Hyperkeratosis | 2 | 0 |
| Lichenoid keratosis | 1 | 0 |
| Hypopigmentation disorders | | |
| Vitiligo | 2 | 0 |
| Nail and nail bed conditions (excl infections and infestations) | | |
| Nail discolouration | 1 | 0 |
| Panniculitides | | |
| Erythema nodosum | 5 | 0 |
| Papulosquamous conditions | | |
| Erythema annulare | 1 | 0 |
| Erythema marginatum | 1 | 0 |
| Lichen sclerosus | 1 | 0 |
| Pityriasis rosea | 1 | 0 |
| Photosensitivity and photodermatosis conditions | | |
| Photosensitivity reaction | 1 | 0 |
| Pigmentation changes NEC | | |
| Pigmentation disorder | 1 | 0 |
| Pilar disorders NEC | | |
| Hair disorder | 1 | 0 |
| Pruritus NEC | | |
| Pruritus | 105 | 0 |
| Psoriatic conditions | | |
| Guttate psoriasis | 1 | 0 |
| Purpura and related conditions | | |
| Ecchymosis | 1 | 0 |
| Henoch-Schonlein purpura | 11 | 0 |
| Petechiae | 28 | 0 |
| Purpura | 20 | 0 |
| Pustular conditions | | |
| Rash follicular | 1 | 0 |
| Rashes, eruptions and exanthems NEC | | |
| Rash | 1014 | 0 |
| Rash erythematous | 94 | 0 |
| Rash macular | 109 | 0 |
| Rash maculo-papular | 124 | 0 |
| Rash morbilliform | 376 | 0 |
| Rash papular | 42 | 0 |
| Rash pruritic | 28 | 0 |
| Rash rubelliform | 20 | 0 |
| Rash scarlatiniform | 1 | 0 |
| Rash vesicular | 12 | 0 |
| Scaly conditions | | |
| Pityriasis | 1 | 0 |
| Skin and subcutaneous conditions NEC | | |
| Skin mass | 1 | 0 |
| Skin and subcutaneous tissue ulcerations | | |
| Skin ulcer | 1 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|---|------------|----------|
| Skin disorders Skin disorders cont'd | | |
| <i>Skin injuries and mechanical dermatoses</i> | | |
| Decubitus ulcer | 1 | 0 |
| <i>Skin vasculitides</i> | | |
| Nodular vasculitis | 1 | 0 |
| Vasculitic rash | 2 | 0 |
| <i>Skin vasomotor conditions</i> | | |
| Livedo reticularis | 4 | 0 |
| <i>Urticarias</i> | | |
| Mechanical urticaria | 1 | 0 |
| Urticaria | 318 | 0 |
| Skin disorders SOC TOTAL | 315 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|---------------------------------------|--------------|--------------|
| Social circumstances | | |
| <i>Disability issues</i> | | |
| Immobile | 3 | 0 |
| Impaired work ability | 2 | 0 |
| Mental disability | 1 | 0 |
| Walking disability | 2 | 0 |
| <i>Educational issues</i> | | |
| Educational problem | 1 | 0 |
| <i>Family and partner issues</i> | | |
| Multiple birth sibling | 2 | 0 |
| <i>Social issues NEC</i> | | |
| Contraindication to vaccination | 5 | 0 |
| Social circumstances SOC TOTAL | 16 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|--|--------------|--------------|
| Surgical & medical procedures | | |
| <i>Blood and blood product treatment</i> | | |
| Transfusion | 1 | 0 |
| <i>Induced abortions</i> | | |
| Abortion induced | 6 | 0 |
| <i>Lymphoid tissue therapeutic procedures</i> | | |
| Splenectomy | 1 | 0 |
| <i>Middle ear therapeutic procedures</i> | | |
| Ear tube insertion | 1 | 0 |
| <i>Obstetric therapeutic procedures</i> | | |
| Caesarean section | 20 | 0 |
| Episiotomy | 1 | 0 |
| Forceps delivery | 1 | 0 |
| Labour induction | 1 | 0 |
| Labour stimulation | 1 | 0 |
| <i>Therapeutic procedures NEC</i> | | |
| Resuscitation | 1 | 0 |
| Surgery | 1 | 0 |
| <i>Tonsillar therapeutic procedures</i> | | |
| Adenoidectomy | 1 | 0 |
| Tonsillectomy | 1 | 0 |
| Surgical & medical procedures SOC TOTAL | 37 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|---|--------------|-----------|
| Vascular disorders | | |
| <i>Accelerated and malignant hypertension</i> | | |
| Accelerated hypertension | 1 | 0 |
| <i>Arterial infections and inflammations</i> | | |
| Arteritis | 1 | 0 |
| Giant cell arteritis | 1 | 0 |
| Kawasaki's disease | 7 | 0 |
| <i>Circulatory collapse and shock</i> | | |
| Circulatory collapse | 18 | 0 |
| Peripheral circulatory failure | 1 | 0 |
| Shock | 5 | 0 |
| <i>Haemorrhages NEC</i> | | |
| Haemorrhage | 8 | 0 |
| <i>Non-site specific vascular disorders NEC</i> | | |
| Superficial vein prominence | 1 | 0 |
| Vasodilatation | 1 | 0 |
| <i>Peripheral vascular disorders NEC</i> | | |
| Cyanosis | 51 | 0 |
| Flushing | 27 | 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 | 156 | 0 |
| <i>Vascular hypertensive disorders NEC</i> | | |
| Hypertension | 5 | 0 |
| <i>Vascular hypotensive disorders</i> | | |
| Hypotension | 6 | 0 |
| <i>Vasculitides NEC</i> | | |
| Vasculitis | 2 | 0 |
| Vascular disorders SOC TOTAL | 304 | 0 |
| TOTAL REACTIONS FOR DRUG | 17275 | 47 |
| TOTAL REPORTS | 7491 | |
| TOTAL FATAL OUTCOME REPORTS | | 47 |