

Case Series Drug Analysis Print
Name: MMR Vaccine Analysis Print

Report Run Date: 14-Nov-2023
Data Lock Date: 13-Nov-2023 18:30:03
Earliest Reaction Date: 20-Jun-1990
MedDRA Version: MedDRA 26.1

MMR Vaccine Analysis All UK spontaneous suspected Adverse Drug Reaction
Print: (ADR) reports associated with the MMR vaccine
between 01/01/2019 and 13/11/2023.

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	2	0
<i>Eosinophilic disorders</i>		
Eosinophilia	1	0
<i>Haematological disorders</i>		
Blood disorder	1	0
<i>Haemolyses NEC</i>		
Haemolysis	1	0
<i>Leukocytoses NEC</i>		
Monocytosis	1	0
T-cell lymphocytosis	1	0
<i>Leukopenias NEC</i>		
Lymphopenia	4	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenitis	1	0
Lymphadenopathy	36	0
<i>Marrow depression and hypoplastic anaemias</i>		
Cytopenia	1	0
<i>Spleen disorders</i>		
Splenomegaly	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	6	0
Thrombocytopenia	2	0
Thrombocytopenic purpura	1	0
Blood disorders SOC TOTAL	59	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac disorders NEC</i>		
Cardiovascular disorder	1	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	2	0
<i>Endocarditis NEC</i>		
Endocarditis noninfective	1	1
<i>Heart failures NEC</i>		
Cardiac failure	1	0
Cardiopulmonary failure	1	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	2	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	1	0
Tachycardia	2	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardio-respiratory arrest	1	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	13	1

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cerebellar disorders congenital</i>		
Hereditary ataxia	1	0
<i>Immune system abnormalities congenital</i>		
Primary immunodeficiency syndrome	1	0
<i>Lymphatic system disorders congenital</i>		
Lymphatic malformation	1	1
Congenital disorders SOC TOTAL	3	1

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	1	0
Ear pain	10	0
Ear swelling	3	0
Otorrhoea	1	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	1	0
<i>Hearing losses</i>		
Deafness	3	0
Deafness transitory	1	0
Deafness unilateral	2	0
Hypoacusis	2	0
<i>Inner ear disorders NEC</i>		
Meniere's disease	1	0
Vestibular disorder	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	4	0
Vertigo	2	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane disorder	1	0
Tympanic membrane perforation	1	0
Ear disorders SOC TOTAL	34	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Eyelid movement disorders</i>		
Excessive eye blinking	1	0
<i>Lacrimation disorders</i>		
Lacrimation increased	3	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Erythema of eyelid	1	0
Swelling of eyelid	3	0
<i>Ocular disorders NEC</i>		
Eye pain	7	0
Eye swelling	9	0
Periorbital swelling	2	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	3	0
Eye inflammation	1	0
Eye irritation	1	0
Ocular hyperaemia	5	0
<i>Ocular nerve and muscle disorders</i>		
Extraocular muscle disorder	1	0
Eye movement disorder	4	0
Opsoclonus myoclonus	1	0
Strabismus	1	0
<i>Ocular sensation disorders</i>		
Photophobia	3	0
<i>Refractive and accommodative disorders</i>		
Hypermetropia	1	0
<i>Visual disorders NEC</i>		
Vision blurred	2	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness transient	1	0
Cortical visual impairment	1	0
Visual impairment	4	0
Eye disorders SOC TOTAL	55	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Colitis (excl infective)</i>		
Inflammatory bowel disease	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	60	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	2	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	1	0
Faecaloma	1	0
Faeces discoloured	2	0
Mucous stools	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	4	0
Abdominal pain upper	12	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	7	0
Gastrooesophageal reflux disease	2	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	4	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	2	0
Gastrointestinal motility disorder	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	1	0
Anal incontinence	1	0
Dysphagia	1	0
Odynophagia	1	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	1	0
Irritable bowel syndrome	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	1	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	24	0
Vomiting	76	0
Vomiting projectile	10	0
<i>Oral soft tissue disorders NEC</i>		
Lip blister	1	0
Oral papule	1	0
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	1	0
<i>Oral soft tissue signs and symptoms</i>		
Oral mucosal blistering	1	0
Oral pain	2	0
Paraesthesia oral	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	6	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Peritoneal and retroperitoneal disorders</i>		
Ascites	1	0
<i>Rectal inflammations NEC</i>		
Proctitis	1	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	1	0
Salivary gland enlargement	1	0
Submaxillary gland enlargement	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	3	0
Stomatitis	1	0
<i>Tongue disorders</i>		
Tongue disorder	1	0
Tongue geographic	1	0
<i>Tongue signs and symptoms</i>		
Strawberry tongue	1	0
Tongue eruption	2	0
Gastrointestinal disorders SOC TOTAL	247	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site erythema	1	0
Administration site rash	1	0
Administration site urticaria	2	0
<i>Application and instillation site reactions</i>		
Application site erythema	1	0
Application site rash	1	0
<i>Asthenic conditions</i>		
Asthenia	11	0
Fatigue	44	0
Malaise	48	0
<i>Febrile disorders</i>		
Pyrexia	478	0
<i>Feelings and sensations NEC</i>		
Chills	12	0
Feeling abnormal	2	0
Feeling cold	2	0
Feeling hot	10	0
Feeling of body temperature change	2	0
Sensation of foreign body	1	0
Thirst	1	0
Thirst decreased	2	0
<i>Gait disturbances</i>		
Gait disturbance	10	0
Gait inability	10	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	3	0
Crying	42	0
Developmental delay	3	0
Developmental regression	7	0
Energy increased	1	0
General physical health deterioration	1	0
High-pitched crying	6	0
Illness	15	0
Influenza like illness	8	0
Irritability postvaccinal	1	0
Multiple organ dysfunction syndrome	1	1
Peripheral swelling	48	0
Screaming	12	0
Swelling	26	0
Swelling face	16	0
<i>Inflammations</i>		
Inflammation	11	0
Polyserositis	1	0
Systemic inflammatory response syndrome	1	0
<i>Injection site reactions</i>		
Injection site bruising	4	0
Injection site discolouration	1	0
Injection site discomfort	2	0
Injection site eczema	1	0
Injection site erythema	17	0
Injection site indentation	1	0
Injection site inflammation	4	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site mass	8	0
Injection site pain	6	0
Injection site pruritus	4	0
Injection site rash	8	0
Injection site reaction	1	0
Injection site swelling	13	0
Injection site vesicles	1	0
Injection site warmth	5	0
Oedema NEC		
Oedema	1	0
Pain and discomfort NEC		
Chest discomfort	3	0
Chest pain	2	0
Discomfort	6	0
Facial pain	1	0
Non-cardiac chest pain	1	0
Pain	42	0
Tenderness	2	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	14	0
Adverse event	2	0
Adverse reaction	1	0
Drug ineffective	1	0
No reaction on previous exposure to drug	1	0
Post vaccination challenge strain shedding	1	0
Vaccination failure	6	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	1	0
Vaccination site bruising	7	0
Vaccination site discomfort	1	0
Vaccination site erythema	52	0
Vaccination site haematoma	1	0
Vaccination site hypertrichosis	1	0
Vaccination site induration	5	0
Vaccination site inflammation	6	0
Vaccination site joint erythema	1	0
Vaccination site mass	17	0
Vaccination site movement impairment	2	0
Vaccination site nodule	1	0
Vaccination site pain	20	0
Vaccination site pruritus	5	0
Vaccination site rash	21	0
Vaccination site reaction	3	0
Vaccination site swelling	51	0
Vaccination site urticaria	2	0
Vaccination site vesicles	1	0
Vaccination site warmth	15	0
General disorders SOC TOTAL	1215	1

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	1	0
Hypertransaminasaemia	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatosplenomegaly	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	1	0
Hepatic disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergy to metals	2	0
Hypersensitivity	21	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	2	0
Drug hypersensitivity	1	0
Food allergy	1	0
Milk allergy	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	11	0
<i>Atopic disorders</i>		
Atopy	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Decreased immune responsiveness	1	0
Haemophagocytic lymphohistiocytosis	5	2
Immune system disorder	2	0
Multisystem inflammatory syndrome	1	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	2	0
Immune system disorders SOC TOTAL	52	2

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Reaction Name	Total	Fatal
Infections		
<i>Adenoviral infections</i>		
Adenovirus infection	2	0
<i>Bacterial infections NEC</i>		
Administration site cellulitis	1	0
Cellulitis	17	0
Gastrointestinal bacterial overgrowth	1	0
Injection site cellulitis	1	0
Meningitis bacterial	1	0
Vaccination site cellulitis	2	0
<i>Borrelial infections</i>		
Relapsing fever	1	0
<i>Candida infections</i>		
Candida infection	1	0
Oral candidiasis	2	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	12	0
Encephalitis brain stem	1	0
Meningitis	1	0
Myelitis	1	0
<i>Coronavirus infections</i>		
COVID-19	2	0
<i>Cytomegaloviral infections</i>		
Cytomegalovirus infection	3	0
<i>Dental and oral soft tissue infections</i>		
Parotitis	2	0
<i>Ear infections</i>		
Ear infection	5	0
Labyrinthitis	1	0
Otitis media	2	0
Otitis media acute	1	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr viraemia	1	0
Epstein-Barr virus infection	5	0
Epstein-Barr virus infection reactivation	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	13	0
Eye infection	1	0
<i>Fungal infections NEC</i>		
Fungal infection	1	0
<i>Herpes viral infections</i>		
Herpes simplex	2	0
Human herpesvirus 6 infection	3	0
Human herpesvirus 6 infection reactivation	1	0
Varicella	2	0
Varicella zoster virus infection	1	0
<i>Infections NEC</i>		
Abscess	1	0
Abscess limb	1	0
Infection	1	0
Localised infection	1	0
Vaccination site infection	4	0
<i>Infectious transmissions</i>		
Infection transmission via personal contact	1	0

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Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Influenza viral infections</i>		
Influenza	3	0
<i>Lower respiratory tract and lung infections</i>		
Atypical pneumonia	1	0
Lower respiratory tract infection	4	0
Pneumonia	2	0
<i>Male reproductive tract infections</i>		
Orchitis	2	0
<i>Mumps viral infections</i>		
Encephalitis mumps	1	0
Mumps	10	1
<i>Respiratory syncytial viral infections</i>		
Respiratory syncytial virus infection	2	0
<i>Rubella viral infections</i>		
Encephalomyelitis rubella	1	0
Rubella	3	0
<i>Rubeola viral infections</i>		
Measles	33	0
Measles post vaccine	5	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Septic shock	1	0
Urosepsis	1	1
<i>Skin structures and soft tissue infections</i>		
Dermatitis infected	1	0
Eczema infected	1	0
Vaccination site pustule	1	0
<i>Tuberculous infections</i>		
Meningitis tuberculous	1	0
Tuberculosis	1	0
<i>Upper respiratory tract infections</i>		
Croup infectious	2	0
Epiglottitis	2	0
Nasopharyngitis	8	0
Rhinitis	1	0
Sinusitis	1	0
Tonsillitis	4	0
Upper respiratory tract infection	5	0
<i>Urinary tract infections</i>		
Urinary tract infection	1	0
<i>Vascular infections</i>		
Haematoma infection	1	0
<i>Viral infections NEC</i>		
Encephalitis viral	1	0
Viral infection	2	0
Viral rash	3	0
Viral upper respiratory tract infection	1	0
Infections SOC TOTAL	206	2

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Reaction Name	Total	Fatal
Injuries		
<i>Accidental exposures to product</i>		
Accidental exposure to product	1	0
<i>Cerebral injuries NEC</i>		
Cranio-cerebral injury	1	0
<i>Cranial nerve injuries</i>		
Optic nerve injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	2	0
Exposure via breast milk	1	0
Foetal exposure during pregnancy	1	0
<i>Eye injuries NEC</i>		
Eye contusion	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	10	0
Product use in unapproved indication	4	0
Vaccination error	1	0
Wrong technique in product usage process	1	0
<i>Non-site specific injuries NEC</i>		
Fall	1	0
Injury	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
Contraindicated product administered	1	0
Expired product administered	1	0
Extra dose administered	1	0
Inappropriate schedule of product administration	8	0
Incomplete course of vaccination	1	0
Incorrect dose administered	2	0
Incorrect dose administered by product	1	0
Product administered at inappropriate site	3	0
<i>Product monitoring errors and issues</i>		
Labelled drug-disease interaction medication error	1	0
Labelled drug-drug interaction issue	1	0
<i>Site specific injuries NEC</i>		
Central nervous system injury	1	0
<i>Skin injuries NEC</i>		
Contusion	8	0
Scar	2	0
Injuries SOC TOTAL	61	0

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Reaction Name	Total	Fatal
Investigations		
<i>Blood gas and acid base analyses</i>		
Carbon dioxide increased	1	0
Oxygen saturation decreased	1	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose decreased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate abnormal	2	0
Heart rate increased	5	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	3	0
Body temperature abnormal	2	0
Body temperature decreased	4	0
Body temperature fluctuation	2	0
Body temperature increased	29	0
Respiratory rate increased	2	0
Skin temperature	1	0
Weight decreased	2	0
<i>Pituitary analyses anterior</i>		
Blood thyroid stimulating hormone increased	1	0
<i>Platelet analyses</i>		
Platelet count decreased	2	0
<i>Toxicology laboratory analyses</i>		
Blood aluminium increased	1	0
Heavy metal increased	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output decreased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure increased	1	0
<i>Virus identification and serology</i>		
Morbillivirus test positive	1	0
Mumps antibody test negative	2	0
Rubivirus test positive	1	0
Rubulavirus test positive	1	0
Investigations SOC TOTAL	67	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	150	0
Food refusal	1	0
Hypophagia	3	0
Increased appetite	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	1	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Dairy intolerance	1	0
Food intolerance	2	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	2	0
Feeding disorder	3	0
Food aversion	1	0
Poor feeding infant	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Metabolic acidosis	2	0
<i>Metabolic disorders NEC</i>		
Metabolic disorder	1	0
<i>Protein metabolism disorders NEC</i>		
Hyperammonaemia	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	2	0
<i>Total fluid volume increased</i>		
Fluid retention	1	0
Metabolic disorders SOC TOTAL	175	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	2	0
Arthropathy	2	0
<i>Bone related signs and symptoms</i>		
Bone pain	1	0
Pubic pain	1	0
<i>Cartilage disorders</i>		
Costochondritis	1	0
<i>Extremity deformities</i>		
Foot deformity	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	22	0
Joint noise	1	0
Joint stiffness	5	0
Joint swelling	5	0
<i>Muscle pains</i>		
Myalgia	12	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	1	0
Muscle spasms	1	0
Muscle twitching	1	0
<i>Muscle tone abnormalities</i>		
Floppy infant	2	0
Muscle rigidity	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	14	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	2	0
Musculoskeletal stiffness	3	0
Toe walking	1	0
Weight bearing difficulty	5	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	4	0
Limb discomfort	3	0
Musculoskeletal chest pain	1	0
Neck pain	3	0
Pain in extremity	35	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	1	0
<i>Soft tissue disorders NEC</i>		
Groin pain	1	0
Muscle & tissue disorders SOC TOTAL	132	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	1	0
<i>Absence seizures</i>		
Petit mal epilepsy	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral infarction	1	0
<i>Central nervous system vascular disorders NEC</i>		
Brain hypoxia	1	0
<i>Choreiform movements</i>		
Chorea	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	3	0
Coordination abnormal	1	0
Developmental coordination disorder	1	0
Dysstasia	2	0
<i>Cortical dysfunction NEC</i>		
Aphasia	11	0
Sensory processing disorder	4	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	1	0
<i>Disturbances in consciousness NEC</i>		
Consciousness fluctuating	1	0
Depressed level of consciousness	1	0
Lethargy	36	0
Loss of consciousness	7	0
Somnolence	18	0
Syncope	9	0
<i>Dyskinesias and movement disorders NEC</i>		
Akinesia	1	0
Clumsiness	1	0
Dyskinesia	1	0
Hypokinesia	3	0
<i>Encephalitis NEC</i>		
Noninfective encephalitis	2	0
<i>Encephalopathies NEC</i>		
Encephalopathy	3	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	1	0
Facial paralysis	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	1	0
<i>Headaches NEC</i>		
Headache	24	0
<i>Increased intracranial pressure disorders</i>		
Vasogenic cerebral oedema	1	0
<i>Intellectual disabilities</i>		
Intellectual disability	2	0
<i>Memory loss (excl dementia)</i>		
Amnesia	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0

Case Series Drug Analysis Print

Name: MMR Vaccine Analysis Print

Report Run Date: 14-Nov-2023

Data Lock Date: 13-Nov-2023 18:30:03

Earliest Reaction Date: 20-Jun-1990

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Disturbance in attention	2	0
Mental impairment	2	0
Migraine headaches		
Migraine	1	0
Muscle tone abnormal		
Hypotonia	4	0
Narcolepsy and hypersomnia		
Hypersomnia	4	0
Nervous system disorders NEC		
Nervous system disorder	4	0
Neurodegenerative disorder	1	0
Neurological signs and symptoms NEC		
Dizziness	22	0
Dizziness postural	1	0
Inability to crawl	3	0
Infant irritability	6	0
Myoclonus	1	0
Neurological decompensation	1	0
Neurological symptom	1	0
Pleocytosis	1	0
Unresponsive to stimuli	3	0
Neuromuscular disorders NEC		
Hypotonic-hyporesponsive episode	2	0
Muscle spasticity	1	0
Neuromyopathy	1	0
Olfactory nerve disorders		
Parosmia	1	0
Paraesthesias and dysaesthesias		
Burning sensation	1	0
Hypoaesthesia	8	0
Paraesthesia	7	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	1	0
Monoplegia	1	0
Paralysis	7	0
Peripheral neuropathies NEC		
Neuropathy peripheral	1	0
Polyneuropathy	1	0
Seizures and seizure disorders NEC		
Epilepsy	3	0
Febrile convulsion	29	0
Myoclonic epilepsy	1	0
Partial seizures	4	0
Seizure	25	0
Seizure cluster	1	0
Seizure like phenomena	1	0
Status epilepticus	1	0
Tonic convulsion	1	0
Sensory abnormalities NEC		
Dysgeusia	1	0
Neuralgia	1	0
Sensory disturbance	2	0
Sensory loss	3	0

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Report Run Date: 14-Nov-2023
 Earliest Reaction Date: 20-Jun-1990

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Sleep disturbances NEC</i>		
Sleep deficit	1	0
<i>Speech and language abnormalities</i>		
Dysarthria	1	0
Repetitive speech	1	0
Speech disorder	3	0
Speech disorder developmental	4	0
<i>Structural brain disorders NEC</i>		
Brain injury	4	0
Cerebral atrophy	1	0
<i>Tremor (excl congenital)</i>		
Tremor	8	0
Nervous system disorders SOC TOTAL	329	0

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Earliest Reaction Date: 20-Jun-1990

MedDRA Version: MedDRA 26.1

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	11	0
Breath holding	1	0
Regressive behaviour	1	0
Staring	1	0
<i>Affect alterations NEC</i>		
Affect lability	1	0
<i>Anxiety disorders NEC</i>		
Separation anxiety disorder	1	0
<i>Anxiety symptoms</i>		
Agitation	6	0
Anxiety	3	0
Nervousness	1	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	3	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	3	0
Attention-seeking behaviour	1	0
Personality change	7	0
Social avoidant behaviour	4	0
<i>Communications disorders</i>		
Communication disorder	2	0
<i>Confusion and disorientation</i>		
Confusional state	2	0
Disorientation	4	0
<i>Deliria</i>		
Delirium	1	0
<i>Depressive disorders</i>		
Depression	3	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	23	0
Middle insomnia	2	0
<i>Dyssomnias</i>		
Poor quality sleep	7	0
<i>Eating disorders NEC</i>		
Eating disorder	2	0
<i>Emotional and mood disturbances NEC</i>		
Emotional distress	10	0
Frustration tolerance decreased	1	0
Irritability	77	0
Mood altered	1	0
Morose	1	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	1	0
Social anxiety disorder	1	0
<i>Increased physical activity levels</i>		
Restlessness	10	0
<i>Learning disorders</i>		
Learning disability	1	0
<i>Mental disorders NEC</i>		
Mental disorder	4	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	3	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Tearfulness	2	0
Mood disorders NEC		
Affective disorder	1	0
Listless	1	0
Parasomnias		
Nightmare	3	0
Sleep terror	2	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	30	1
Psychiatric symptoms NEC		
Decreased eye contact	3	0
Sleep disorders NEC		
Sleep disorder	11	0
Speech articulation and rhythm disturbances		
Dysphemia	1	0
Lack of spontaneous speech	1	0
Stereotypies and automatisms		
Bruxism	1	0
Head banging	2	0
Posturing	1	0
Stereotypy	1	0
Suicidal and self-injurious behaviour		
Intentional self-injury	2	0
Self-injurious ideation	1	0
Thinking disturbances		
Intrusive thoughts	1	0
Thinking abnormal	2	0
Tic disorders		
Tic	1	0
Psychiatric disorders SOC TOTAL	267	1

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Micturition frequency decreased	1	0
Urinary incontinence	3	0
Urinary retention	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Nephrotic syndrome	1	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	1	0
<i>Nephropathies and tubular disorders NEC</i>		
Renal tubular disorder	2	0
<i>Renal failure and impairment</i>		
Oliguria	1	0
Renal impairment	1	0
Renal injury	1	0
Renal & urinary disorders SOC TOTAL	12	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast pain	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Menstrual disorder	1	0
<i>Menstruation with decreased bleeding</i>		
Menstruation delayed	1	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	2	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital rash	1	0
Pelvic pain	1	0
<i>Scrotal disorders NEC</i>		
Scrotal swelling	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	1	0
Reproductive & breast disorders SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoeic attack	1	0
Dyspnoea	8	0
Hyperventilation	1	0
Hypopnoea	1	0
Irregular breathing	1	0
Respiration abnormal	3	0
Respiratory arrest	7	1
Respiratory distress	2	0
Tachypnoea	1	0
<i>Bronchospasm and obstruction</i>		
Wheezing	3	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	44	0
Haemoptysis	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	1	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Alveolitis	1	0
Pneumonitis	3	0
Pneumonitis aspiration	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	9	0
<i>Nasal disorders NEC</i>		
Epistaxis	6	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	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 erythema	3	0
Pharyngeal inflammation	2	0
Pharyngeal swelling	1	0
Pharyngeal ulceration	1	0
Tonsillar hypertrophy	2	0
<i>Pleural conditions NEC</i>		
Pleural adhesion	1	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	3	0
<i>Pulmonary oedemas</i>		
Acute lung injury	1	0
Acute respiratory distress syndrome	4	1
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>		
Acute respiratory failure	1	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Respiratory failure	5	2
Respiratory tract disorders NEC		
Respiratory disorder	2	0
Respiratory tract oedema	1	0
Upper respiratory tract signs and symptoms		
Aphonia	1	0
Catarrh	2	0
Dry throat	1	0
Nasal discharge discolouration	1	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	18	0
Rhinorrhoea	25	0
Sneezing	3	0
Snoring	1	0
Throat irritation	2	0
Throat tightness	1	0
Upper-airway cough syndrome	1	0
Respiratory disorders SOC TOTAL	187	4

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	1	0
<i>Angioedemas</i>		
Angioedema	3	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	4	0
Hyperhidrosis	7	0
Miliaria	1	0
Night sweats	3	0
<i>Bullous conditions</i>		
Blister	7	0
Erythema multiforme	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	4	0
Macule	1	0
Pain of skin	2	0
Papule	17	0
Scab	3	0
Skin burning sensation	1	0
Skin discolouration	8	0
Skin disorder	2	0
Skin lesion	2	0
Skin reaction	1	0
Skin tightness	2	0
Skin warm	15	0
<i>Dermatitis and eczema</i>		
Dermatitis	1	0
Dermatitis allergic	15	0
Dermatitis atopic	1	0
Dermatitis contact	1	0
Dermatitis diaper	6	0
Eczema	12	0
Eczema infantile	1	0
Seborrhoeic dermatitis	1	0
Skin irritation	2	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	2	0
<i>Erythemas</i>		
Erythema	71	0
<i>Pilar disorders NEC</i>		
Hair growth abnormal	1	0
<i>Pruritus NEC</i>		
Pruritus	32	0
<i>Purpura and related conditions</i>		
Henoch-Schonlein purpura	2	0
Petechiae	4	0
Purpura	2	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	425	0
Rash erythematous	52	0
Rash macular	16	0
Rash maculo-papular	4	0
Rash morbilliform	110	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rash papular	27	0
Rash pruritic	16	0
Rash rubelliform	3	0
Rash scarlatiniform	1	0
Rash vesicular	4	0
Skin vasomotor conditions		
Livedo reticularis	3	0
Urticarias		
Mechanical urticaria	1	0
Urticaria	39	0
Skin disorders SOC TOTAL	940	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Bedridden	1	0
Immobile	3	0
Social circumstances SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Hormonal therapeutic procedures NEC</i>		
Steroid therapy	1	0
Surgical & medical procedures SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Arterial infections and inflammations</i>		
Kawasaki's disease	2	0
<i>Circulatory collapse and shock</i>		
Shock	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	6	0
Flushing	3	0
Hot flush	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	1	0
Poor peripheral circulation	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	11	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	2	0
<i>Vascular hypotensive disorders</i>		
Hypotension	1	0
Vascular disorders SOC TOTAL	29	0
TOTAL REACTIONS FOR DRUG	4105	12
TOTAL REPORTS	1424	
TOTAL FATAL OUTCOME REPORTS		12