

Case Series Drug Analysis Print

Name: MMR Vaccine Analysis Print FOI 23/135

Report Run Date: 09-Mar-2023
Data Lock Date: 03-Mar-2023 18:30:05
Earliest Reaction Date: 20-Jun-1990
MedDRA Version: MedDRA 25.1

MMR Vaccine Analysis All UK spontaneous reports for MMR vaccine from
Print FOI 23/135: 01/01/2020 up to and including DLP 03/03/2023

Case Series Drug Analysis Print

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Report Run Date: 09-Mar-2023
 Earliest Reaction Date: 20-Jun-1990

Data Lock Date: 03-Mar-2023 18:30:05
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Reaction Name	Total	Fatal
Blood disorders		
<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	2	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenitis	1	0
Lymphadenopathy	21	0
<i>Marrow depression and hypoplastic anaemias</i>		
Cytopenia	1	0
<i>Spleen disorders</i>		
Splenomegaly	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	4	0
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	36	0

Case Series Drug Analysis Print

Name: MMR Vaccine Analysis Print FOI 23/135

Report Run Date: 09-Mar-2023

Data Lock Date: 03-Mar-2023 18:30:05

Earliest Reaction Date: 20-Jun-1990

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	1	0
<i>Heart failures NEC</i>		
Cardiopulmonary failure	1	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	1	0
<i>Rate and rhythm disorders NEC</i>		
Tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardio-respiratory arrest	1	0
Cardiac disorders SOC TOTAL	5	0

Case Series Drug Analysis Print

Name: MMR Vaccine Analysis Print FOI 23/135

Report Run Date: 09-Mar-2023

Data Lock Date: 03-Mar-2023 18:30:05

Earliest Reaction Date: 20-Jun-1990

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Congenital disorders		
<i>Cerebellar disorders congenital</i>		
Hereditary ataxia	1	0
Congenital disorders SOC TOTAL	1	0

Case Series Drug Analysis Print

Name: MMR Vaccine Analysis Print FOI 23/135

Report Run Date: 09-Mar-2023
 Earliest Reaction Date: 20-Jun-1990

Data Lock Date: 03-Mar-2023 18:30:05
 MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	4	0
Ear swelling	2	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	1	0
<i>Hearing losses</i>		
Deafness	1	0
Deafness unilateral	1	0
Hypoacusis	1	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
Ear disorders SOC TOTAL	19	0

Case Series Drug Analysis Print

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Report Run Date: 09-Mar-2023
 Earliest Reaction Date: 20-Jun-1990

Data Lock Date: 03-Mar-2023 18:30:05
 MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Eye disorders		
<i>Eyelid movement disorders</i>		
Excessive eye blinking	1	0
<i>Lacrimation disorders</i>		
Lacrimation increased	2	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Erythema of eyelid	1	0
Swelling of eyelid	2	0
<i>Ocular disorders NEC</i>		
Eye pain	6	0
Eye swelling	6	0
Periorbital swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	1	0
Eye inflammation	1	0
Eye irritation	1	0
Ocular hyperaemia	2	0
<i>Ocular nerve and muscle disorders</i>		
Extraocular muscle disorder	1	0
Eye movement disorder	2	0
Strabismus	1	0
<i>Ocular sensation disorders</i>		
Photophobia	2	0
<i>Refractive and accommodative disorders</i>		
Hypermetropia	1	0
<i>Visual disorders NEC</i>		
Vision blurred	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness transient	1	0
Visual impairment	2	0
Eye disorders SOC TOTAL	35	0

Case Series Drug Analysis Print

Name: MMR Vaccine Analysis Print FOI 23/135

Report Run Date: 09-Mar-2023
Earliest Reaction Date: 20-Jun-1990

Data Lock Date: 03-Mar-2023 18:30:05
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	33	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	1	0
Faecaloma	1	0
Faeces discoloured	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	3	0
Abdominal pain upper	5	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	2	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	3	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	1	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	1	0
Irritable bowel syndrome	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	10	0
Vomiting	41	0
Vomiting projectile	8	0
<i>Oral soft tissue disorders NEC</i>		
Oral papule	1	0
<i>Oral soft tissue signs and symptoms</i>		
Oral pain	1	0
Paraesthesia oral	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	2	0
<i>Peritoneal and retroperitoneal disorders</i>		
Ascites	1	0
<i>Salivary gland enlargements</i>		
Salivary gland enlargement	1	0
Submaxillary gland enlargement	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	2	0
Stomatitis	1	0
<i>Tongue signs and symptoms</i>		
Strawberry tongue	1	0
Gastrointestinal disorders SOC TOTAL	126	0

Case Series Drug Analysis Print

Name: MMR Vaccine Analysis Print FOI 23/135

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 Earliest Reaction Date: 20-Jun-1990

Data Lock Date: 03-Mar-2023 18:30:05
 MedDRA Version: MedDRA 25.1

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	6	0
Fatigue	29	0
Malaise	21	0
<i>Febrile disorders</i>		
Pyrexia	253	0
<i>Feelings and sensations NEC</i>		
Chills	3	0
Feeling cold	2	0
Feeling hot	5	0
Sensation of foreign body	1	0
Thirst	1	0
Thirst decreased	2	0
<i>Gait disturbances</i>		
Gait disturbance	7	0
Gait inability	7	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	2	0
Crying	30	0
Developmental delay	1	0
Developmental regression	4	0
Energy increased	1	0
General physical health deterioration	1	0
High-pitched crying	4	0
Illness	7	0
Influenza like illness	3	0
Irritability postvaccinal	1	0
Multiple organ dysfunction syndrome	1	1
Peripheral swelling	27	0
Screaming	9	0
Swelling	8	0
Swelling face	11	0
<i>Inflammations</i>		
Inflammation	5	0
Polyserositis	1	0
Systemic inflammatory response syndrome	1	0
<i>Injection site reactions</i>		
Injection site bruising	2	0
Injection site discomfort	1	0
Injection site erythema	9	0
Injection site inflammation	3	0
Injection site mass	6	0
Injection site pain	3	0
Injection site pruritus	2	0
Injection site rash	4	0
Injection site reaction	1	0

Case Series Drug Analysis Print

Name: MMR Vaccine Analysis Print FOI 23/135

Report Run Date: 09-Mar-2023
 Earliest Reaction Date: 20-Jun-1990

Data Lock Date: 03-Mar-2023 18:30:05
 MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site swelling	9	0
Injection site warmth	2	0
Oedema NEC		
Oedema	1	0
Pain and discomfort NEC		
Chest discomfort	2	0
Discomfort	4	0
Facial pain	1	0
Pain	20	0
Tenderness	1	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	17	0
Adverse event	1	0
Drug ineffective	1	0
No reaction on previous exposure to drug	1	0
Post vaccination challenge strain shedding	1	0
Vaccination failure	2	0
Vaccination site reactions		
Vaccination site bruising	5	0
Vaccination site discomfort	1	0
Vaccination site erythema	24	0
Vaccination site hypertrichosis	1	0
Vaccination site induration	2	0
Vaccination site inflammation	3	0
Vaccination site joint erythema	1	0
Vaccination site mass	7	0
Vaccination site pain	13	0
Vaccination site pruritus	2	0
Vaccination site rash	12	0
Vaccination site reaction	2	0
Vaccination site swelling	21	0
Vaccination site urticaria	1	0
Vaccination site vesicles	1	0
Vaccination site warmth	8	0
General disorders SOC TOTAL	658	1

Case Series Drug Analysis Print

Name: MMR Vaccine Analysis Print FOI 23/135

Report Run Date: 09-Mar-2023

Data Lock Date: 03-Mar-2023 18:30:05

Earliest Reaction Date: 20-Jun-1990

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Hepatobiliary signs and symptoms</i>		
Hepatosplenomegaly	1	0
Hepatic disorders SOC TOTAL	1	0

Case Series Drug Analysis Print

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Report Run Date: 09-Mar-2023
 Earliest Reaction Date: 20-Jun-1990

Data Lock Date: 03-Mar-2023 18:30:05
 MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergy to metals	1	0
Hypersensitivity	10	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	2	0
Food allergy	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	6	0
<i>Atopic disorders</i>		
Atopy	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Haemophagocytic lymphohistiocytosis	5	2
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	28	2

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Data Lock Date: 03-Mar-2023 18:30:05
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Infections		
<i>Adenoviral infections</i>		
Adenovirus infection	2	0
<i>Bacterial infections NEC</i>		
Cellulitis	6	0
Gastrointestinal bacterial overgrowth	1	0
Meningitis bacterial	1	0
<i>Borrelial infections</i>		
Relapsing fever	1	0
<i>Candida infections</i>		
Oral candidiasis	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	7	0
Meningitis	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	3	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	6	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	2	0
Human herpesvirus 6 infection reactivation	1	0
Varicella	1	0
Varicella zoster virus infection	1	0
<i>Infections NEC</i>		
Infection	1	0
Vaccination site infection	1	0
<i>Influenza viral infections</i>		
Influenza	2	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	2	0
Pneumonia	2	0
<i>Male reproductive tract infections</i>		
Orchitis	1	0
<i>Mumps viral infections</i>		
Mumps	3	0
<i>Respiratory syncytial viral infections</i>		
Respiratory syncytial virus infection	2	0

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 MedDRA Version: MedDRA 25.1

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Infections Infections cont'd		
<i>Rubella viral infections</i>		
Rubella	1	0
<i>Rubeola viral infections</i>		
Measles	14	0
Measles post vaccine	2	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Urosepsis	1	1
<i>Skin structures and soft tissue infections</i>		
Dermatitis infected	1	0
Eczema infected	1	0
<i>Tuberculous infections</i>		
Meningitis tuberculous	1	0
<i>Upper respiratory tract infections</i>		
Epiglottitis	2	0
Nasopharyngitis	6	0
Tonsillitis	2	0
Upper respiratory tract infection	3	0
<i>Vascular infections</i>		
Haematoma infection	1	0
<i>Viral infections NEC</i>		
Viral rash	3	0
Viral upper respiratory tract infection	1	0
Infections SOC TOTAL	109	1

Case Series Drug Analysis Print

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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>		
Craniocerebral 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	1	0
Exposure via breast milk	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
<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>		
Contraindicated product administered	1	0
Expired product administered	1	0
Extra dose administered	1	0
Inappropriate schedule of product administration	6	0
Incomplete course of vaccination	1	0
Incorrect dose administered	1	0
Incorrect dose administered by product	1	0
Product administered at inappropriate site	1	0
<i>Product monitoring errors and issues</i>		
Labelled drug-disease interaction medication error	1	0
<i>Skin injuries NEC</i>		
Contusion	1	0
Scar	1	0
Injuries SOC TOTAL	41	0

Case Series Drug Analysis Print

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Data Lock Date: 03-Mar-2023 18:30:05
 MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Investigations		
<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	4	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	2	0
Body temperature abnormal	2	0
Body temperature decreased	3	0
Body temperature fluctuation	1	0
Body temperature increased	16	0
Skin temperature	1	0
Weight decreased	1	0
<i>Pituitary analyses anterior</i>		
Blood thyroid stimulating hormone increased	1	0
<i>Platelet analyses</i>		
Platelet count 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
Rubivirus test positive	1	0
Rubulavirus test positive	1	0
Investigations SOC TOTAL	39	0

Case Series Drug Analysis Print

Name: MMR Vaccine Analysis Print FOI 23/135

Report Run Date: 09-Mar-2023
 Earliest Reaction Date: 20-Jun-1990

Data Lock Date: 03-Mar-2023 18:30:05
 MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	82	0
Food refusal	1	0
Hypophagia	2	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Dairy intolerance	1	0
Food intolerance	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	1	0
Food aversion	1	0
Poor feeding infant	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	1	0
<i>Total fluid volume increased</i>		
Fluid retention	1	0
Metabolic disorders SOC TOTAL	93	0

Case Series Drug Analysis Print

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Report Run Date: 09-Mar-2023
 Earliest Reaction Date: 20-Jun-1990

Data Lock Date: 03-Mar-2023 18:30:05
 MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthropathy	1	0
<i>Extremity deformities</i>		
Foot deformity	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	11	0
Joint noise	1	0
Joint stiffness	3	0
Joint swelling	3	0
<i>Muscle pains</i>		
Myalgia	9	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>		
Muscle rigidity	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	10	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Mobility decreased	2	0
Musculoskeletal stiffness	1	0
Toe walking	1	0
Weight bearing difficulty	2	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	2	0
Limb discomfort	2	0
Neck pain	2	0
Pain in extremity	20	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	1	0
Muscle & tissue disorders SOC TOTAL	76	0

Case Series Drug Analysis Print

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Data Lock Date: 03-Mar-2023 18:30:05
 MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	1	0
<i>Central nervous system vascular disorders NEC</i>		
Brain hypoxia	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	3	0
Coordination abnormal	1	0
Dysstasia	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	6	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	1	0
<i>Disturbances in consciousness NEC</i>		
Consciousness fluctuating	1	0
Lethargy	22	0
Loss of consciousness	3	0
Somnolence	14	0
Syncope	7	0
<i>Dyskinesias and movement disorders NEC</i>		
Akinesia	1	0
Clumsiness	1	0
Hypokinesia	1	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	13	0
<i>Increased intracranial pressure disorders</i>		
Vasogenic cerebral oedema	1	0
<i>Intellectual disabilities</i>		
Intellectual disability	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0
Disturbance in attention	1	0
Mental impairment	1	0
<i>Muscle tone abnormal</i>		
Hypotonia	3	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	4	0
<i>Nervous system disorders NEC</i>		
Nervous system disorder	1	0
Neurodegenerative disorder	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	18	0
Inability to crawl	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Infant irritability	4	0
Myoclonus	1	0
Pleocytosis	1	0
Unresponsive to stimuli	3	0
Neuromuscular disorders NEC		
Hypotonic-hyporesponsive episode	2	0
Neuromyopathy	1	0
Olfactory nerve disorders		
Parosmia	1	0
Paraesthesias and dysaesthesias		
Burning sensation	1	0
Hypoaesthesia	2	0
Paraesthesia	4	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	1	0
Monoplegia	1	0
Paralysis	4	0
Peripheral neuropathies NEC		
Neuropathy peripheral	1	0
Seizures and seizure disorders NEC		
Epilepsy	2	0
Febrile convulsion	15	0
Partial seizures	1	0
Seizure	15	0
Seizure cluster	1	0
Seizure like phenomena	1	0
Status epilepticus	1	0
Tonic convulsion	1	0
Sensory abnormalities NEC		
Dysgeusia	1	0
Sensory disturbance	2	0
Sensory loss	2	0
Speech and language abnormalities		
Dysarthria	1	0
Speech disorder	1	0
Speech disorder developmental	3	0
Structural brain disorders NEC		
Brain injury	2	0
Cerebral atrophy	1	0
Tremor (excl congenital)		
Tremor	3	0
Nervous system disorders SOC TOTAL	200	0

Case Series Drug Analysis Print

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

Case Series Drug Analysis Print

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Data Lock Date: 03-Mar-2023 18:30:05
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	4	0
Breath holding	1	0
<i>Anxiety symptoms</i>		
Agitation	3	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	1	0
Personality change	1	0
Social avoidant behaviour	1	0
<i>Communications disorders</i>		
Communication disorder	1	0
<i>Confusion and disorientation</i>		
Confusional state	2	0
Disorientation	2	0
<i>Depressive disorders</i>		
Depression	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	16	0
Middle insomnia	2	0
<i>Dyssomnias</i>		
Poor quality sleep	3	0
<i>Eating disorders NEC</i>		
Eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Emotional distress	7	0
Irritability	40	0
Mood altered	1	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	1	0
<i>Increased physical activity levels</i>		
Restlessness	4	0
<i>Mental disorders NEC</i>		
Mental disorder	2	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	2	0
Tearfulness	1	0
<i>Parasomnias</i>		
Nightmare	1	0
Sleep terror	2	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	14	1
<i>Psychiatric symptoms NEC</i>		
Decreased eye contact	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	4	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	1	0
<i>Stereotypies and automatisms</i>		
Head banging	1	0
<i>Thinking disturbances</i>		
Thinking abnormal	2	0
<i>Tic disorders</i>		
Tic	1	0

Case Series Drug Analysis Print

Name: MMR Vaccine Analysis Print FOI 23/135

Report Run Date: 09-Mar-2023

Data Lock Date: 03-Mar-2023 18:30:05

Earliest Reaction Date: 20-Jun-1990

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
Psychiatric disorders SOC TOTAL	125	1

Case Series Drug Analysis Print

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Report Run Date: 09-Mar-2023
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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Micturition frequency decreased	1	0
Urinary incontinence	2	0
Urinary retention	1	0
<i>Renal failure and impairment</i>		
Oliguria	1	0
Renal injury	1	0
Renal & urinary disorders SOC TOTAL	6	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast pain	1	0
<i>Menstruation with decreased bleeding</i>		
Menstruation delayed	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital rash	1	0
<i>Scrotal disorders NEC</i>		
Scrotal swelling	1	0
Reproductive & breast disorders SOC TOTAL	4	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoeic attack	1	0
Dyspnoea	4	0
Hyperventilation	1	0
Respiratory arrest	2	1
Respiratory distress	2	0
<i>Bronchospasm and obstruction</i>		
Wheezing	1	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	1	0
<i>Coughing and associated symptoms</i>		
Cough	19	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	1	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Pneumonitis	3	0
Pneumonitis aspiration	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	6	0
<i>Nasal disorders NEC</i>		
Epistaxis	4	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	3	0
Pharyngeal inflammation	1	0
Pharyngeal swelling	1	0
Pharyngeal ulceration	1	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	2	0
<i>Pulmonary oedemas</i>		
Acute respiratory distress syndrome	3	1
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	1	0
Respiratory failure	4	2
<i>Respiratory tract disorders NEC</i>		
Respiratory disorder	2	0
Respiratory tract oedema	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	1	0
Catarrh	1	0
Oropharyngeal pain	8	0
Rhinorrhoea	12	0
Snoring	1	0
Throat irritation	1	0
Respiratory disorders SOC TOTAL	89	4

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Skin disorders		
<i>Angioedemas</i>		
Angioedema	2	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	2	0
Hyperhidrosis	5	0
Miliaria	1	0
Night sweats	2	0
<i>Bullous conditions</i>		
Blister	4	0
Erythema multiforme	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	2	0
Macule	1	0
Pain of skin	1	0
Papule	11	0
Scab	3	0
Skin discolouration	4	0
Skin disorder	1	0
Skin lesion	2	0
Skin reaction	1	0
Skin tightness	1	0
Skin warm	7	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	9	0
Dermatitis atopic	1	0
Dermatitis diaper	4	0
Eczema	5	0
Eczema infantile	1	0
Skin irritation	1	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	1	0
<i>Erythemas</i>		
Erythema	29	0
<i>Pilar disorders NEC</i>		
Hair growth abnormal	1	0
<i>Pruritus NEC</i>		
Pruritus	18	0
<i>Purpura and related conditions</i>		
Henoch-Schonlein purpura	2	0
Petechiae	2	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	252	0
Rash erythematous	40	0
Rash macular	12	0
Rash maculo-papular	2	0
Rash morbilliform	71	0
Rash papular	19	0
Rash pruritic	12	0
Rash rubelliform	3	0
Rash scarlatiniform	1	0
Rash vesicular	2	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	2	0

Case Series Drug Analysis Print

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Report Run Date: 09-Mar-2023

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Urticarias</i>		
Urticaria	24	0
Skin disorders SOC TOTAL	565	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Immobile	2	0
Social circumstances SOC TOTAL	2	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Arterial infections and inflammations</i>		
Kawasaki's disease	1	0
<i>Circulatory collapse and shock</i>		
Shock	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	3	0
Flushing	2	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	6	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
Vascular disorders SOC TOTAL	17	0
TOTAL REACTIONS FOR DRUG	2279	9
TOTAL REPORTS	828	
TOTAL FATAL OUTCOME REPORTS		9