

Case Series Drug Analysis Print

Name: FOI 21/877 - MMR Vaccine DAP 2018

Report Run Date: 09-Aug-2021

Data Lock Date: 08-Aug-2021 18:30:04

Earliest Reaction Date: 21-Feb-2003

MedDRA Version: MedDRA 24.0

FOI 21/877 - MMR Vaccine DAP 2018: All spontaneous suspected UK Adverse Drug Reaction (ADR) reports associated with the MMR vaccine in 2018

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Reaction Name	Total	Fatal
Blood disorders		
<i>Leukopenias NEC</i>		
Leukopenia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	8	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	3	0
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	13	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	2	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	1	0
Tachycardia	3	0
<i>Supraventricular arrhythmias</i>		
Sinus tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	1
Cardiac disorders SOC TOTAL	8	1

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	1	0
Ear pain	2	0
Otorrhoea	1	0
<i>Hearing losses</i>		
Deafness	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	1	0
Ear disorders SOC TOTAL	6	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	1	0
<i>Ocular disorders NEC</i>		
Eye pain	1	0
Eye swelling	2	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	1	0
Ocular hyperaemia	1	0
<i>Ocular nerve and muscle disorders</i>		
Strabismus	1	0
Eye disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Colitis (excl infective)</i>		
Crohn's disease	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	27	0
<i>Dyspeptic signs and symptoms</i>		
Eructation	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	1	0
Flatulence	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	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Gastrointestinal motility disorder	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Anal incontinence	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	4	0
Vomiting	30	0
Vomiting projectile	2	0
<i>Oral soft tissue signs and symptoms</i>		
Oral mucosal blistering	1	0
Oral mucosal eruption	1	0
Paraesthesia oral	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	1	0
Mouth swelling	1	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	1	0
Salivary gland enlargement	1	0
<i>Stomatitis and ulceration</i>		
Lip ulceration	1	0
Mouth ulceration	1	0
Stomatitis	1	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	1	0
Gastrointestinal disorders SOC TOTAL	89	0

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Reaction Name	Total	Fatal
General disorders		
<i>Asthenic conditions</i>		
Asthenia	4	0
Decreased activity	1	0
Fatigue	18	0
Malaise	19	0
<i>Febrile disorders</i>		
Pyrexia	140	0
<i>Feelings and sensations NEC</i>		
Chills	3	0
Feeling abnormal	4	0
Feeling cold	1	0
Feeling hot	6	0
Thirst	1	0
Thirst decreased	1	0
<i>Gait disturbances</i>		
Gait disturbance	2	0
Gait inability	2	0
<i>General signs and symptoms NEC</i>		
Crying	12	0
Developmental delay	2	0
Illness	3	0
Induration	2	0
Influenza like illness	1	0
Local reaction	1	0
Peripheral swelling	21	0
Screaming	2	0
Swelling	7	0
Swelling face	4	0
<i>Inflammations</i>		
Inflammation	1	0
<i>Injection site reactions</i>		
Injection site erythema	2	0
<i>Mass conditions NEC</i>		
Mass	1	0
Nodule	1	0
<i>Pain and discomfort NEC</i>		
Chest discomfort	1	0
Discomfort	1	0
Facial pain	1	0
Pain	14	0
Tenderness	3	0
<i>Therapeutic and nontherapeutic responses</i>		
Vaccination failure	5	0
<i>Vaccination site reactions</i>		
Vaccination site erythema	26	0
Vaccination site induration	4	0
Vaccination site inflammation	4	0
Vaccination site mass	4	0
Vaccination site pain	6	0
Vaccination site pruritus	2	0
Vaccination site rash	6	0
Vaccination site reaction	3	0
Vaccination site swelling	19	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site vesicles	1	0
Vaccination site warmth	10	0
General disorders SOC TOTAL	372	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	4	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	6	0
<i>Immune and associated conditions NEC</i>		
Immunisation reaction	1	0
Immune system disorders SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Diarrhoea infectious	1	0
Gastroenteritis	1	0
<i>Bacterial infections NEC</i>		
Cellulitis	15	0
Skin bacterial infection	1	0
Vaccination site cellulitis	7	0
<i>Borrelial infections</i>		
Lyme disease	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	1	0
Meningitis	1	0
<i>Ear infections</i>		
Ear infection	1	0
Otitis media	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	3	0
<i>Herpes viral infections</i>		
Varicella	1	0
<i>Infections NEC</i>		
Vaccination site infection	3	0
<i>Infectious transmissions</i>		
Infection via vaccinee	1	0
<i>Influenza viral infections</i>		
Influenza	1	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	1	0
<i>Mumps viral infections</i>		
Mumps	3	0
<i>Rubeola viral infections</i>		
Measles	13	0
Measles post vaccine	2	0
<i>Skin structures and soft tissue infections</i>		
Pustule	1	0
Skin infection	1	0
<i>Streptococcal infections</i>		
Streptococcal infection	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	4	0
Pharyngitis	1	0
Tonsillitis	1	0
<i>Urinary tract infections</i>		
Urinary tract infection	1	0
Infections SOC TOTAL	68	0

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Reaction Name	Total	Fatal
Injuries		
<i>Medication errors, product use errors and issues NEC</i>		
Inadequate aseptic technique in use of product	1	0
Wrong technique in product usage process	1	0
<i>Product administration errors and issues</i>		
Inappropriate schedule of product administration	1	0
Wrong patient received product	1	0
Wrong product administered	1	0
<i>Product storage errors and issues in the product use system</i>		
Product storage error	1	0
<i>Skin injuries NEC</i>		
Contusion	5	0
<i>Vaccination related complications</i>		
Vaccination complication	1	0
Injuries SOC TOTAL	12	0

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Reaction Name	Total	Fatal
Investigations		
<i>Heart rate and pulse investigations</i>		
Heart rate increased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature fluctuation	1	0
Body temperature increased	15	0
Respiratory rate increased	1	0
Investigations SOC TOTAL	18	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	53	0
Food refusal	1	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Type 1 diabetes mellitus	2	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	1	0
Poor feeding infant	2	0
Metabolic disorders SOC TOTAL	60	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Joint related signs and symptoms</i>		
Arthralgia	1	0
Joint swelling	1	0
<i>Muscle pains</i>		
Myalgia	2	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle swelling	1	0
Muscle twitching	1	0
<i>Muscle tone abnormalities</i>		
Floppy infant	2	0
Nuchal rigidity	1	0
Trismus	1	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Limb mass	1	0
Weight bearing difficulty	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	1	0
Limb discomfort	1	0
Neck pain	1	0
Pain in extremity	14	0
Muscle & tissue disorders SOC TOTAL	29	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Neoplasm skin	1	0
Neoplasms SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Coordination and balance disturbances</i>		
Balance disorder	2	0
Coordination abnormal	1	0
Dysstasia	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	4	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	17	0
Somnolence	9	0
<i>Dyskinesias and movement disorders NEC</i>		
Extrapyramidal disorder	1	0
Fine motor delay	1	0
Hypokinesia	2	0
Movement disorder	2	0
<i>Facial cranial nerve disorders</i>		
Facial spasm	1	0
<i>Headaches NEC</i>		
Headache	13	0
Sinus headache	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0
<i>Migraine headaches</i>		
Migraine	1	0
<i>Muscle tone abnormal</i>		
Hypotonia	1	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	1	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	1	0
<i>Nervous system disorders NEC</i>		
Nervous system disorder	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	5	0
Drooling	1	0
Hyporesponsive to stimuli	1	0
Inability to crawl	1	0
Unresponsive to stimuli	2	0
<i>Olfactory nerve disorders</i>		
Anosmia	1	0
<i>Paraesthesias and dysaesthesias</i>		
Paraesthesia	1	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Paralysis	1	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	1	0
Febrile convulsion	3	0
Seizure	7	0
<i>Sensory abnormalities NEC</i>		
Restless legs syndrome	1	0
<i>Speech and language abnormalities</i>		
Speech disorder	2	0
<i>Tremor (excl congenital)</i>		
Tremor	4	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Nervous system disorders SOC TOTAL	92	0

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Reaction Name	Total	Fatal
<i>Product quality issues NEC</i>		
Product complaint	1	0
null SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	7	0
<i>Anxiety disorders NEC</i>		
Separation anxiety disorder	1	0
<i>Anxiety symptoms</i>		
Agitation	1	0
Anxiety	1	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	1	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	1	0
Social avoidant behaviour	2	0
<i>Confusion and disorientation</i>		
Confusional state	3	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	5	0
<i>Dyssomnias</i>		
Poor quality sleep	3	0
<i>Emotional and mood disturbances NEC</i>		
Emotional distress	1	0
Irritability	28	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	1	0
<i>Increased physical activity levels</i>		
Restlessness	2	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	2	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Obsessive-compulsive disorder	1	0
<i>Panic attacks and disorders</i>		
Panic attack	1	0
<i>Parasomnias</i>		
Sleep terror	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	4	0
<i>Psychiatric symptoms NEC</i>		
Decreased eye contact	2	0
<i>Sleep disorders NEC</i>		
Sleep disorder	3	0
Psychiatric disorders SOC TOTAL	71	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Micturition disorder	1	0
Urinary incontinence	1	0
<i>Bladder disorders NEC</i>		
Bladder disorder	1	0
<i>Urinary abnormalities</i>		
Chromaturia	1	0
Renal & urinary disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	4	0
Respiratory arrest	2	0
Tachypnoea	1	0
<i>Bronchospasm and obstruction</i>		
Wheezing	3	0
<i>Coughing and associated symptoms</i>		
Cough	8	0
Productive cough	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	2	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	7	0
Rhinorrhoea	7	0
Respiratory disorders SOC TOTAL	36	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	3	0
Hyperhidrosis	1	0
Night sweats	1	0
<i>Bullous conditions</i>		
Dermatitis bullous	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	2	0
Papule	6	0
Skin discolouration	2	0
Skin induration	2	0
Skin tightness	1	0
Skin warm	10	0
Skin weeping	1	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	4	0
Eczema	3	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	1	0
<i>Erythemas</i>		
Erythema	29	0
<i>Exfoliative conditions</i>		
Skin exfoliation	1	0
<i>Pruritus NEC</i>		
Pruritus	10	0
<i>Purpura and related conditions</i>		
Henoch-Schonlein purpura	1	0
Petechiae	3	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	116	0
Rash erythematous	10	0
Rash macular	7	0
Rash maculo-papular	4	0
Rash morbilliform	45	0
Rash papular	5	0
Rash pruritic	2	0
Rash rubelliform	3	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Skin ulcer	1	0
<i>Urticarias</i>		
Urticaria	6	0
Skin disorders SOC TOTAL	281	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	3	0
Flushing	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	3	0
<i>Site specific vascular disorders NEC</i>		
Pallor	5	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
Vascular disorders SOC TOTAL	13	0
TOTAL REACTIONS FOR DRUG	1193	1
TOTAL REPORTS	398	
TOTAL FATAL OUTCOME REPORTS		1