Report Run Date: 22-Dec-2021

Data Lock Date: 21-Dec-2021 18:30:04

Earliest Reaction Date: 14-Mar-2012 MedDRA Version: MedDRA 24.1

MMR Vaccine Vaccine MMR vaccine analysis print (VAP). All UK, Analysis Print: spontaneous suspected ADR reports associated with MMR vaccine received between 01/08/2020-

31/07/2021. Date of data extraction: 21/12/2021.

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Reaction Name	Total	Fatal
Blood disorders		
Lymphatic system disorders NEC		
Lymphadenitis	1	0
Lymphadenopathy	7	0
Thrombocytopenias		
Immune thrombocytopenia	1	0
Blood disorders SOC TOTAL	9	0

Name: MMR Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021 Data Lock Date: 21-Dec-2021 18:30:04 Earliest Reaction Date: 14-Mar-2012 MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Cardiac disorders		
Ventricular arrhythmias and cardiac arrest		
Cardio-respiratory arrest	1	0
Cardiac disorders SOC TOTAL	1	0

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Report Run Date: 22-Dec-2021 Data Lock Date: 21-Dec-2021 18:30:04 Earliest Reaction Date: 14-Mar-2012 MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Congenital disorders		
Neurological disorders congenital NEC		
Spinal muscular atrophy	1	0
Congenital disorders SOC TOTAL	1	l o

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Reaction Name	Total	Fatal
Ear disorders		
Ear disorders NEC		
Ear swelling	1	0
Hearing losses		
Deafness	1	0
Inner ear signs and symptoms		
Tinnitus	1	0
Vertigo	1	0
Ear disorders SOC TOTAL	4	0

Name: MMR Vaccine Vaccine Analysis Print

Report Run Date: 22-Dec-2021
Earliest Reaction Date: 14-Mar-2012

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Eve disorders		
Lid, lash and lacrimal infections, irritations and inflammations		
Swelling of eyelid	1	0
Ocular disorders NEC		
Eye pain	1	0
Eye disorders SOC TOTAL	2	0

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Earliest Reaction Date: 14-Mar-2012 MedDRA Version: MedDRA 24.1		
Reaction Name	<u>Total</u>	<u>Fatal</u>
Gastrointestinal disorders		
Diarrhoea (excl infective)		
Diarrhoea	9	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	2	0
Abdominal pain upper	2	0
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	1	0
Gastrointestinal disorders NEC		
Gastrointestinal disorder	1	0
Gastrointestinal dyskinetic disorders		
Change of bowel habit	1	0
Gastrointestinal signs and symptoms NEC		
Dysphagia	1	0
Gastrointestinal vascular occlusion and infarction		
Intestinal ischaemia	1	1
Nausea and vomiting symptoms		
Nausea	2	0
Vomiting	11	0
Vomiting projectile	4	0
Oral soft tissue swelling and oedema		
Lip swelling	2	0
Peritoneal and retroperitoneal disorders		
Ascites	1	0
Stomatitis and ulceration		
Stomatitis	1	0
Gastrointestinal disorders SOC TOTAL	39	1

Earliest Reaction Date: 14-Mar-2012	MedDRA Version: MedDRA 24.1	
Reaction Name	Total	Fatal
General disorders		
Administration site reactions NEC		
Administration site rash	1	0
Asthenic conditions		
Asthenia	3	0
Fatigue	6	_
Malaise	4	. 0
Febrile disorders		
Pyrexia	76	0
Feelings and sensations NEC	10	
Feeling cold	1	0
Feeling hot		. 0
Thirst	1	0
Thirst decreased	1	_
Gait disturbances	'	0
Gait disturbance	4	
	1	0
Gait inability	4	0
General signs and symptoms NEC	4	0
Condition aggravated	144	0
Crying	11	
Developmental regression	3	_
Disease complication	1	0
General physical health deterioration	1	0
High-pitched crying	2	
Illness	5	_
Influenza like illness	1	0
Irritability postvaccinal	1	0
Multiple organ dysfunction syndrome	1	1
Peripheral swelling	13	
Screaming	3	0
Secretion discharge	1	0
Swelling	1	0
Swelling face	1	0
Inflammations		
Inflammation	3	0
Injection site reactions		
Injection site bruising	1	0
Injection site discomfort	1	0
Injection site erythema	3	
Injection site inflammation	3 2	0
Injection site mass	2	2 0
Injection site pain	1	
Injection site swelling	2	2 0
Injection site warmth	1	0
Pain and discomfort NEC		
Discomfort	1	0
Facial pain	1	0
Pain	8	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	15	0
Drug ineffective	1	0
No reaction on previous exposure to drug	1	o o
Post vaccination challenge strain shedding		0
Vaccination failure	1	o o

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site reactions		
Vaccination site bruising	3	0
Vaccination site discomfort	1	0
Vaccination site erythema	6	0
Vaccination site induration	2	0
Vaccination site inflammation	2	0
Vaccination site joint erythema	1	0
Vaccination site mass	4	0
Vaccination site pain	5	0
Vaccination site pruritus	2	0
Vaccination site rash	2	0
Vaccination site reaction	1	0
Vaccination site swelling	7	0
Vaccination site warmth	3	0
General disorders SOC TOTAL	233	1

Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		
Hypersensitivity	3	0
Allergies to foods, food additives, drugs and other chemicals		
Food allergy	1	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	5	0
Immune and associated conditions NEC		
Haemophagocytic lymphohistiocytosis	1	0
Immunodeficiency disorders NEC		
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	11	0

	MedDRA Version: MedDRA 24.1		
Reaction Name		<u>Total</u>	Fatal
Infections			
Adenoviral infections			
Adenovirus infection		1	0
Bacterial infections NEC			
Cellulitis		4	0
Lower respiratory tract infection bacterial		1	0
Respiratory tract infection bacterial		1	0
Central nervous system and spinal infections			
Encephalitis		3	0
Cytomegaloviral infections			
Cytomegalovirus infection		1	0
Ear infections			
Ear infection		1	0
Otitis media		1	0
Epstein-Barr viral infections			
Epstein-Barr virus infection		1	0
Herpes viral infections			
Herpes simplex		1	0
Human herpesvirus 6 infection reactivation		1	0
Infections NEC			
Infection		1	0
Vaccination site infection		1	0
Lower respiratory tract and lung infections			
Pneumonia		2	0
Pneumonia aspiration		1	0
Respiratory syncytial viral infections			
Respiratory syncytial virus infection		1	0
Rubeola viral infections			
Measles		5	0
Measles post vaccine		1	0
Skin structures and soft tissue infections			
Dermatitis infected		1	0
Streptococcal infections			
Pneumococcal sepsis		1	0
Upper respiratory tract infections			
Epiglottitis		1	0
Nasopharyngitis		2	0
Upper respiratory tract infection		1	0
Viral infections NEC			
Viral rash		1	0
Infections SOC TOTAL		35	0

Reaction Name	Total	Fatal
Injuries		
Cerebral injuries NEC		
Craniocerebral injury	1	0
Exposures associated with pregnancy, delivery and lactation		
Exposure during pregnancy	1	0
Exposure via breast milk	1	0
Medication errors, product use errors and issues NEC		
Medication error	6	0
Non-site specific injuries NEC		
Fall	1	0
Injury	1	0
Product administration errors and issues		
Contraindicated product administered	1	0
Expired product administered	1	0
Inappropriate schedule of product administration	1	0
Incomplete course of vaccination	1	0
Incorrect dose administered	1	0
Product administered at inappropriate site	1	0
Product monitoring errors and issues		
Labelled drug-disease interaction medication error	1	0
Injuries SOC TOTAL	18	0

Reaction Name	Total	Fatal
Investigations		
Heart rate and pulse investigations		
Heart rate abnormal	2	0
Heart rate increased	2	0
Physical examination procedures and organ system status		
Body temperature	1	0
Body temperature decreased	2	0
Body temperature increased	3	0
Weight decreased	1	0
Pituitary analyses anterior		
Blood thyroid stimulating hormone increased	1	0
Respiratory tract and thoracic imaging procedures		
Chest X-ray abnormal	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure increased	1	0
Investigations SOC TOTAL	14	0

Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Decreased appetite	18	0
General nutritional disorders NEC		
Abnormal loss of weight	1	0
Metabolic disorders NEC		
Metabolic disorder	1	0
Total fluid volume decreased		
Dehydration	1	0
Metabolic disorders SOC TOTAL	21	0

Deartion Name	Total	Eatal
Reaction Name	<u> Total </u>	<u>Fatal</u>
Muscle & tissue disorders		
Arthropathies NEC		
Arthropathy	1	0
Joint related signs and symptoms		
Arthralgia	1	0
Joint swelling	2	0
Muscle pains		
Myalgia	1	0
Muscle related signs and symptoms NEC		
Muscle atrophy	1	0
Muscle tone abnormalities		
Muscle rigidity	1	0
Muscle weakness conditions		
Muscular weakness	4	0
Musculoskeletal and connective tissue conditions NEC		
Toe walking	1	0
Weight bearing difficulty	2	0
Musculoskeletal and connective tissue pain and discomfort		
Pain in extremity	8	0
Spine and neck deformities		
Scoliosis	1	0
Muscle & tissue disorders SOC TOTAL	23	0

Earliest Reaction Date: 14-Mar-2012 MedDRA Version: MedDRA 24.1		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Nervous system disorders		
Abnormal reflexes		
Areflexia	1	0
Central nervous system haemorrhages and cerebrovascular accidents		
Cerebral ischaemia	1	0
Ischaemic cerebral infarction	1	0
Central nervous system vascular disorders NEC		
Brain hypoxia	1	0
Coordination and balance disturbances		
Balance disorder	1	0
Dysstasia	1	0
Cortical dysfunction NEC		
Aphasia	3	0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	1	0
Demyelination	1	0
Disturbances in consciousness NEC		
Consciousness fluctuating	1	0
Lethargy	8	0
Loss of consciousness	1	0
Somnolence	7	0
Syncope	1	0
Dyskinesias and movement disorders NEC		
Akinesia	1	0
Motor dysfunction	1	0
Encephalitis NEC		
Noninfective encephalitis	1	0
Encephalopathies NEC		
Encephalopathy	1	0
Headaches NEC		
Headache	2	0
Memory loss (excl dementia)		
Amnesia	1	0
Motor neurone diseases		
Motor neurone disease	1	0
Muscle tone abnormal		
Hypotonia	3	0
Narcolepsy and hypersomnia		
Hypersomnia	1	0
Neurological signs and symptoms NEC		
Dizziness	3	0
Inability to crawl	1	0
Infant irritability	3	0
Unresponsive to stimuli	2	0
Neuromuscular disorders NEC		
Hypotonic-hyporesponsive episode	2	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	1	0
Paralysis	1	0
Seizures and seizure disorders NEC		
Febrile convulsion	3	0
Partial seizures	1	0
Seizure	3	0
Seizure like phenomena	1	0

Name: MMR Vaccine Vaccine Analysis Print

Reaction Name	Total	Fatal
Nervous system disorders disorders cont'd		
Status epilepticus	1	0
Sensory abnormalities NEC		
Sensory disturbance	2	0
Sensory loss	1	0
Speech and language abnormalities		
Speech disorder	1	0
Structural brain disorders NEC		
Brain injury		0
Nervous system disorders SOC TOTAL	68	0

Name: MMR Vaccine Vaccine Analysis Print

Reaction Name	Total	Fatal
Product quality issues NEC		
Product quality issue	1	0
null SOC TOTAL	1	l o

Earliest Reaction Date: 14-Mar-2012 MedDRA Version: MedDRA 24.1		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Psychiatric disorders		
Abnormal behaviour NEC		
Abnormal behaviour	2	0
Anxiety symptoms		
Agitation	1	0
Behaviour and socialisation disturbances		
Social avoidant behaviour	1	0
Confusion and disorientation		
Confusional state	2	0
Disturbances in initiating and maintaining sleep		
Insomnia	4	0
Eating disorders NEC		
Eating disorder	1	0
Emotional and mood disturbances NEC		
Emotional distress	3	0
Irritability	14	0
Increased physical activity levels		
Restlessness	1	0
Mental disorders NEC		
Mental disorder	1	0
Parasomnias		
Nightmare	1	0
Sleep terror	2	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	2	0
Psychiatric symptoms NEC		
Decreased eye contact	1	0
Sleep disorders NEC		
Sleep disorder	1	0
Speech articulation and rhythm disturbances		
Dysphemia	1	0
Psychiatric disorders SOC TOTAL	38	0

Name: MMR Vaccine Vaccine Analysis Print

Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Urinary incontinence	1	0
Urinary retention	1	0
Renal & urinary disorders SOC TOTAL	2	0

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Menstruation with decreased bleeding		
Menstruation delayed	1	0
Reproductive tract signs and symptoms NEC		
Genital rash	1	0
Scrotal disorders NEC		
Scrotal swelling	1	0
Reproductive & breast disorders SOC TOTAL	3	0

Earliest Reaction Date: 14-Mar-2012 MedDRA Version: MedDRA 24.1		
Reaction Name	<u> Total</u>	<u>Fatal</u>
Respiratory disorders		
Breathing abnormalities		
Apnoeic attack	1	0
Dyspnoea	1	0
Hyperventilation	1	0
Respiratory arrest	2	1
Tachypnoea	1	0
Bronchial conditions NEC		
Bronchial disorder	1	0
Coughing and associated symptoms		
Cough	5	0
Sputum increased	1	0
Lower respiratory tract inflammatory and immunologic conditions		
Pneumonitis	1	0
Lower respiratory tract signs and symptoms		
Increased bronchial secretion	1	0
Nasal congestion and inflammations		
Nasal congestion	4	0
Nasal disorders NEC		
Epistaxis	1	0
Parenchymal lung disorders NEC		
Atelectasis	1	0
Interstitial lung disease	1	0
Lung consolidation	1	0
Lung infiltration	1	0
Pharyngeal disorders (excl infections and neoplasms)		
Pharyngeal erythema	1	0
Pulmonary oedemas		
Acute respiratory distress syndrome	1	0
Respiratory failures (excl neonatal)		
Respiratory failure	1	0
Upper respiratory tract signs and symptoms		
Oropharyngeal pain	2	0
Respiratory disorders SOC TOTAL	29	1

Earliest Reaction Date: 14-Mar-2012	MedDRA Version: MedDRA 24.1		
Reaction Name		<u>Total</u>	<u>Fatal</u>
Skin disorders			
Angioedemas			
Angioedema		1	0
Apocrine and eccrine gland disorders			
Hyperhidrosis		2	0
Bullous conditions			
Blister		1	0
Erythema multiforme		1	0
Dermal and epidermal conditions NEC			
Dry skin		1	0
Papule		1	0
Skin disorder		1	0
Skin warm		2	0
Dermatitis and eczema			
Dermatitis allergic		5	0
Eczema		1	0
Skin irritation		1	0
Dermatitis ascribed to specific agent			
Drug eruption		1	0
Erythemas			
Erythema		9	0
Pruritus NEC			
Pruritus		3	0
Purpura and related conditions			
Henoch-Schonlein purpura		1	0
Petechiae		1	0
Rashes, eruptions and exanthems NEC			
Rash		67	0
Rash erythematous		8	0
Rash macular		3	0
Rash maculo-papular		1	0
Rash morbilliform		20	0
Rash papular		4	0
Rash pruritic		5	0
Skin vasomotor conditions			
Livedo reticularis		1	0
Urticarias			
Urticaria		10	0
Skin disorders SOC TOTAL		151	0

Reaction Name	Total	Fatal
Surgical & medical procedures		
Lymphoid tissue therapeutic procedures		
Lymphadenectomy	1	0
Respiratory tract therapeutic procedures NEC		
Mechanical ventilation	1	0
Positive airway pressure therapy	1	0
Therapeutic procedures NEC		
Resuscitation	1	0
Stoma closure	1	0
Tracheal therapeutic procedures		
Endotracheal intubation	1	0
Surgical & medical procedures SOC TOTAL	6	l o

Reaction Name	Total	Fatal
Vascular disorders		
Circulatory collapse and shock		
Circulatory collapse	1	0
Peripheral vascular disorders NEC		
Hot flush	1	0
Site specific vascular disorders NEC		
Pallor	4	∤ 0
Vascular disorders SOC TOTAL	6	0
TOTAL REACTIONS FOR DRUG	715	5 3
TOTAL REPORTS	254	,
TOTAL FATAL OUTCOME REPORTS		3