

**Case Series Drug Analysis Print**  
**Name: MMRvaxPro Vaccine Analysis Print**

Report Run Date: 23-Nov-2022

Data Lock Date: 16-Nov-2022 18:30:05

Earliest Reaction Date: 23-Mar-2008

MedDRA Version: MedDRA 25.1

MMRvaxPro Vaccine Analysis Print: All UK spontaneous ADR reports for MMRvaxPro since the start of the Yellow Card system to 11/11/2022

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Blood disorders</b>		
<i>Anaemias NEC</i>		
Anaemia	1	0
<i>Leukopenias NEC</i>		
Lymphopenia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	11	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	2	0
<b>Blood disorders SOC TOTAL</b>	<b>15</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Cardiac disorders</b>		
<i>Endocarditis NEC</i>		
Endocarditis noninfective	1	1
<i>Noninfectious pericarditis</i>		
Pericarditis	1	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>		
Bradycardia	3	0
<b>Cardiac disorders SOC TOTAL</b>	<b>8</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i><b>Anorectal disorders congenital</b></i>		
Preternatural anus	2	0
<i><b>Autosomal chromosomal abnormalities</b></i>		
Trisomy 21	2	0
<i><b>Cardiac septal defects congenital</b></i>		
Atrioventricular septal defect	2	0
<i><b>Congenital disorders NEC</b></i>		
Congenital anomaly	1	0
Congenital cyst	1	0
VACTERL syndrome	2	0
<i><b>Connective tissue disorders congenital</b></i>		
Hypermobility syndrome	1	0
<i><b>External ear disorders congenital</b></i>		
Anomaly of external ear congenital	1	0
<i><b>Eyelid disorders congenital</b></i>		
Eyelid ptosis congenital	2	0
<i><b>Gene mutations and other alterations NEC</b></i>		
Gene mutation	1	0
<i><b>Great vessel disorders congenital</b></i>		
Double outlet right ventricle	2	0
<i><b>Immune system abnormalities congenital</b></i>		
Primary immunodeficiency syndrome	3	0
<i><b>Male reproductive tract disorders congenital</b></i>		
Cryptorchism	1	0
Hydrocele	1	0
<i><b>Musculoskeletal and connective tissue disorders of limbs congenital</b></i>		
Developmental hip dysplasia	2	0
Limb hypoplasia congenital	2	0
Limb reduction defect	2	0
Talipes	3	0
<i><b>Musculoskeletal and connective tissue disorders of skull congenital</b></i>		
Plagiocephaly	1	0
<i><b>Musculoskeletal and connective tissue disorders of spine congenital</b></i>		
Congenital musculoskeletal disorder of spine	2	0
<i><b>Persistent foetal circulation disorders</b></i>		
Patent ductus arteriosus	1	0
<i><b>Pulmonary and bronchial disorders congenital</b></i>		
Congenital pneumonia	1	0
Pulmonary aplasia	2	0
Pulmonary hypoplasia	2	0
<i><b>Renal disorders congenital</b></i>		
Congenital cystic kidney disease	2	0
<i><b>Skin and subcutaneous tissue disorders congenital NEC</b></i>		
Congenital naevus	1	0
Congenital skin dimples	2	0
<i><b>Tongue disorders congenital</b></i>		
Ankyloglossia congenital	2	0
<b>Congenital disorders SOC TOTAL</b>	<b>47</b>	<b>0</b>

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<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear pain	1	0
<i>Hearing losses</i>		
Deafness	2	0
Hypoacusis	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	1	0
Vertigo	3	0
<b>Ear disorders SOC TOTAL</b>	<b>8</b>	<b>0</b>

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<b>Eye disorders</b>		
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	2	0
<i>Lid, lash and lacrimal structural disorders</i>		
Dacryostenosis acquired	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye pruritus	1	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	3	0
Strabismus	2	0
<i>Ocular sensation disorders</i>		
Asthenopia	1	0
Photophobia	3	0
<i>Pupil disorders</i>		
Mydriasis	1	0
<i>Visual disorders NEC</i>		
Vision blurred	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Visual impairment	1	0
<b>Eye disorders SOC TOTAL</b>	<b>18</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	14	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	2	0
Abdominal pain lower	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Gastrooesophageal reflux disease	3	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	1	0
Anal incontinence	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	10	0
Retching	1	0
Vomiting	21	0
Vomiting projectile	1	0
<i>Oral soft tissue disorders NEC</i>		
Oral disorder	1	0
<i>Oral soft tissue signs and symptoms</i>		
Oral mucosal blistering	3	0
Oral pain	1	0
Paraesthesia oral	2	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	6	0
Mouth swelling	1	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	3	0
Submaxillary gland enlargement	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	2	0
<i>Tongue signs and symptoms</i>		
Strawberry tongue	1	0
<i>Umbilical hernias</i>		
Umbilical hernia	2	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>80</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<b>Administration site reactions NEC</b>		
Administration site urticaria	2	0
<b>Adverse effect absent</b>		
No adverse event	3	0
<b>Asthenic conditions</b>		
Asthenia	4	0
Fatigue	7	0
Malaise	13	0
<b>Febrile disorders</b>		
Pyrexia	64	0
<b>Feelings and sensations NEC</b>		
Chills	2	0
Feeling abnormal	2	0
Feeling drunk	1	0
Feeling hot	1	0
<b>Gait disturbances</b>		
Gait disturbance	1	0
<b>General signs and symptoms NEC</b>		
Condition aggravated	1	0
Crepitations	1	0
Crying	5	0
Illness	2	0
Induration	1	0
Influenza like illness	10	0
Irritability postvaccinal	1	0
Local reaction	2	0
Peripheral swelling	10	0
Screaming	2	0
Swelling	4	0
Swelling face	4	0
<b>Inflammations</b>		
Inflammation	3	0
<b>Injection site reactions</b>		
Injection site erythema	10	0
Injection site inflammation	2	0
Injection site irritation	1	0
Injection site mass	1	0
Injection site pain	2	0
Injection site pruritus	1	0
Injection site rash	3	0
Injection site reaction	2	0
Injection site swelling	7	0
Injection site urticaria	1	0
Injection site vesicles	1	0
Injection site warmth	1	0
<b>Mass conditions NEC</b>		
Mass	1	0
<b>Pain and discomfort NEC</b>		
Chest discomfort	3	0
Chest pain	5	0
Pain	5	0
Tenderness	2	0
<b>Therapeutic and nontherapeutic responses</b>		



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<b>General disorders</b> General disorders cont'd		
Adverse event	1	0
Therapy non-responder	2	0
Vaccination failure	1	0
<b><i>Vaccination site reactions</i></b>		
Extensive swelling of vaccinated limb	1	0
Vaccination site bruising	3	0
Vaccination site discomfort	1	0
Vaccination site erythema	12	0
Vaccination site haematoma	1	0
Vaccination site inflammation	2	0
Vaccination site mass	4	0
Vaccination site pain	5	0
Vaccination site rash	3	0
Vaccination site reaction	1	0
Vaccination site swelling	7	0
<b>General disorders SOC TOTAL</b>	<b>238</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	1	0
<i>Hepatic enzymes and function abnormalities</i>		
Hypertransaminasaemia	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	2	0
<b>Hepatic disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Hypersensitivity	4	0
<i><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Food allergy	1	0
Milk allergy	1	0
Reaction to excipient	1	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	8	0
<i><b>Immune and associated conditions NEC</b></i>		
Haemophagocytic lymphohistiocytosis	1	1
<b>Immune system disorders SOC TOTAL</b>	<b>16</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Abdominal and gastrointestinal infections</b></i>		
Gastroenteritis	1	0
<i><b>Bacterial infections NEC</b></i>		
Cellulitis	10	0
Injection site cellulitis	1	0
Vaccination site cellulitis	3	0
<i><b>Borrelial infections</b></i>		
Lyme disease	1	0
<i><b>Central nervous system and spinal infections</b></i>		
Encephalitis	5	0
Meningitis aseptic	1	0
<i><b>Ear infections</b></i>		
Ear infection	2	0
Otitis media	2	0
<i><b>Epstein-Barr viral infections</b></i>		
Infectious mononucleosis	1	0
<i><b>Eye and eyelid infections</b></i>		
Conjunctivitis	3	0
Eye infection	1	0
<i><b>Herpes viral infections</b></i>		
Human herpesvirus 6 infection	1	0
Varicella	2	0
<i><b>Infections NEC</b></i>		
Infection	1	0
Respiratory tract infection	1	0
Vaccination site infection	2	0
Vestibulitis	1	0
<i><b>Lower respiratory tract and lung infections</b></i>		
Lower respiratory tract infection	1	0
Pneumonia	1	0
<i><b>Male reproductive tract infections</b></i>		
Orchitis	1	0
<i><b>Mumps viral infections</b></i>		
Encephalitis mumps	1	0
Mumps	3	0
<i><b>Rubella viral infections</b></i>		
Encephalomyelitis rubella	1	0
<i><b>Rubeola viral infections</b></i>		
Measles	8	0
Measles post vaccine	1	0
<i><b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b></i>		
Sepsis neonatal	1	0
<i><b>Upper respiratory tract infections</b></i>		
Nasopharyngitis	2	0
Rhinitis	1	0
Tonsillitis	2	0
Upper respiratory tract infection	2	0
<i><b>Urinary tract infections</b></i>		
Urinary tract infection	1	0
<i><b>Viral infections NEC</b></i>		
Bronchiolitis	2	0
Encephalitis viral	1	0
Gastroenteritis viral	1	0

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Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Viral infection	2	0
<b>Infections SOC TOTAL</b>	<b>71</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i><b>Accidental exposures to product</b></i>		
Accidental exposure to product	1	0
<i><b>Exposures associated with pregnancy, delivery and lactation</b></i>		
Exposure during pregnancy	35	0
Foetal exposure during pregnancy	26	0
Maternal exposure before pregnancy	9	0
Maternal exposure timing unspecified	1	0
<i><b>Medication errors, product use errors and issues NEC</b></i>		
Inadequate aseptic technique in use of product	1	0
Medication error	2	0
Vaccination error	2	0
<i><b>Non-site specific injuries NEC</b></i>		
Fall	1	0
<i><b>Occupational exposures</b></i>		
Occupational exposure to product	1	0
<i><b>Pathways and sources of exposure</b></i>		
Exposure via skin contact	1	0
<i><b>Product administration errors and issues</b></i>		
Booster dose missed	2	0
Extra dose administered	1	0
Inappropriate schedule of product administration	4	0
Incorrect dose administered by product	1	0
Wrong patient received product	1	0
Wrong product administered	2	0
<i><b>Reproductive system and breast injuries</b></i>		
Perineal injury	1	0
<i><b>Skin injuries NEC</b></i>		
Contusion	1	0
Skin laceration	1	0
<b>Injuries SOC TOTAL</b>	<b>94</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Carbohydrate tolerance analyses (incl diabetes)</b></i>		
Blood glucose fluctuation	1	0
<i><b>Cardiac auscultatory investigations</b></i>		
Cardiac murmur	2	0
<i><b>Foetal and neonatal diagnostic procedures</b></i>		
Foetal heart rate decreased	1	0
Foetal monitoring abnormal	1	0
<i><b>Haematological analyses NEC</b></i>		
Red blood cell sedimentation rate increased	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate decreased	2	0
Heart rate increased	1	0
Heart rate irregular	2	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature decreased	1	0
Body temperature increased	2	0
<i><b>Platelet analyses</b></i>		
Platelet count decreased	1	0
<i><b>Urinalysis NEC</b></i>		
Protein urine	1	0
<i><b>Vascular tests NEC (incl blood pressure)</b></i>		
Blood pressure decreased	1	0
Blood pressure increased	2	0
<i><b>Virus identification and serology</b></i>		
Measles antibody positive	1	0
Mumps antibody test negative	2	0
<b>Investigations SOC TOTAL</b>	<b>22</b>	<b>0</b>

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<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	13	0
Hypophagia	2	0
<i><b>Fluid intake increased</b></i>		
Polydipsia	1	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Dairy intolerance	1	0
Food intolerance	1	0
<i><b>General nutritional disorders NEC</b></i>		
Failure to thrive	1	0
<i><b>Sodium imbalance</b></i>		
Hyponatraemia	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>20</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	1	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	15	0
Joint stiffness	1	0
Joint swelling	1	0
<i><b>Muscle pains</b></i>		
Myalgia	7	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle fatigue	1	0
Muscle spasms	1	0
Muscle twitching	2	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	4	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Musculoskeletal stiffness	1	0
Weight bearing difficulty	3	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Back pain	3	0
Neck pain	6	0
Pain in extremity	11	0
<i><b>Rheumatoid arthropathies</b></i>		
Rheumatoid arthritis	1	0
<i><b>Soft tissue disorders NEC</b></i>		
Groin pain	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>59</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Reproductive neoplasms female benign NEC</i>		
Benign hydatidiform mole	1	0
<b>Neoplasms SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<b><i>Central nervous system haemorrhages and cerebrovascular accidents</i></b>		
Cerebral infarction	1	0
<b><i>Central nervous system inflammatory disorders NEC</i></b>		
Arachnoiditis	1	0
<b><i>Coordination and balance disturbances</i></b>		
Balance disorder	2	0
Coordination abnormal	1	0
Hand-eye coordination impaired	1	0
<b><i>Cortical dysfunction NEC</i></b>		
Aphasia	1	0
Dyspraxia	1	0
<b><i>Disturbances in consciousness NEC</i></b>		
Depressed level of consciousness	2	0
Lethargy	7	0
Loss of consciousness	2	0
Somnolence	3	0
Syncope	6	0
<b><i>Dyskinesias and movement disorders NEC</i></b>		
Dyskinesia	2	0
Hypokinesia	1	0
Psychomotor hyperactivity	1	0
<b><i>Dystonias</i></b>		
Opisthotonus	1	0
<b><i>Encephalopathies NEC</i></b>		
Encephalopathy neonatal	1	0
Hypoxic-ischaemic encephalopathy	1	0
<b><i>Facial cranial nerve disorders</i></b>		
Facial paralysis	1	0
<b><i>Headaches NEC</i></b>		
Headache	14	0
<b><i>Memory loss (excl dementia)</i></b>		
Amnesia	1	0
<b><i>Mental impairment (excl dementia and memory loss)</i></b>		
Disturbance in attention	1	0
<b><i>Migraine headaches</i></b>		
Migraine	4	0
<b><i>Muscle tone abnormal</i></b>		
Hypotonia	4	0
<b><i>Neurological signs and symptoms NEC</i></b>		
Dizziness	11	0
Drooling	1	0
Head discomfort	1	0
Unresponsive to stimuli	3	0
<b><i>Paraesthesias and dysaesthesias</i></b>		
Burning sensation	1	0
Hypoaesthesia	3	0
Paraesthesia	8	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Paralysis	1	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Epilepsy	3	0
Neonatal seizure	1	0
Partial seizures	1	0

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<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Seizure	8	0
<b>Sensory abnormalities NEC</b>		
Dysgeusia	1	0
Sensory loss	1	0
<b>Speech and language abnormalities</b>		
Dysarthria	1	0
Slow speech	1	0
<b>Tremor (excl congenital)</b>		
Tremor	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>107</b>	<b>0</b>

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<b>Pregnancy conditions</b>		
<b><i>Abortions spontaneous</i></b>		
Abortion spontaneous	20	0
Abortion threatened	1	0
Imminent abortion	1	0
<b><i>Amniotic fluid and cavity disorders of pregnancy NEC</i></b>		
Oligohydramnios	1	0
<b><i>Foetal complications NEC</i></b>		
Foetal distress syndrome	1	0
Foetal hypokinesia	1	0
<b><i>Foetal growth complications</i></b>		
Foetal growth restriction	3	0
<b><i>Foetal position and presentation abnormalities</i></b>		
Breech presentation	1	0
<b><i>Gestational age and weight conditions</i></b>		
Premature baby	5	0
<b><i>Haemorrhagic complications of pregnancy</i></b>		
Premature separation of placenta	1	0
<b><i>Hypertension associated disorders of pregnancy</i></b>		
Pre-eclampsia	3	0
<b><i>Labour onset and length abnormalities</i></b>		
Premature delivery	1	0
Premature labour	2	0
Premature rupture of membranes	1	0
Prolonged labour	6	0
<b><i>Maternal complications of labour NEC</i></b>		
Labour complication	1	0
<b><i>Maternal complications of pregnancy NEC</i></b>		
Complication of pregnancy	1	0
<b><i>Multiple pregnancies</i></b>		
Multiple pregnancy	2	0
<b><i>Neonatal gastrointestinal disorders</i></b>		
Meconium increased	1	0
<b><i>Neonatal hepatobiliary disorders</i></b>		
Jaundice neonatal	1	0
<b><i>Normal newborn status</i></b>		
Normal newborn	1	0
<b><i>Normal pregnancy, labour and delivery</i></b>		
Pregnancy	2	0
<b><i>Postpartum complications NEC</i></b>		
Postpartum haemorrhage	2	0
<b><i>Pregnancy complicated by maternal disorders</i></b>		
Gestational diabetes	1	0
<b><i>Stillbirth and foetal death</i></b>		
Stillbirth	2	2
<b>Pregnancy conditions SOC TOTAL</b>	<b>62</b>	<b>2</b>

# Case Series Drug Analysis Print

## Name: MMRvaxPro Vaccine Analysis Print

Report Run Date: 23-Nov-2022

Data Lock Date: 16-Nov-2022 18:30:05

Earliest Reaction Date: 23-Mar-2008

MedDRA Version: MedDRA 25.1

<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<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
<b>null SOC TOTAL</b>	<b>4</b>	<b>0</b>

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	2	0
Staring	1	0
<b><i>Affect alterations NEC</i></b>		
Affect lability	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	1	0
Anxiety	4	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	1	0
Disorientation	2	0
<b><i>Depressive disorders</i></b>		
Depression	1	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	2	0
<b><i>Dyssomnias</i></b>		
Poor quality sleep	1	0
<b><i>Eating disorders NEC</i></b>		
Selective eating disorder	1	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Dysphoria	1	0
Emotional distress	3	0
Irritability	7	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	1	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Anhedonia	1	0
Depressed mood	2	0
Tearfulness	2	0
<b><i>Obsessive-compulsive disorders and symptoms</i></b>		
Obsessive-compulsive disorder	1	0
Obsessive-compulsive symptom	1	0
<b><i>Pervasive developmental disorders NEC</i></b>		
Autism spectrum disorder	6	0
<b><i>Psychotic disorder NEC</i></b>		
Psychotic disorder	1	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	3	0
<b><i>Stereotypies and automatisms</i></b>		
Head banging	1	0
Posturing	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>49</b>	<b>0</b>

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MedDRA Version: MedDRA 25.1

<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Pollakiuria	1	0
Urinary incontinence	1	0
<i>Urinary abnormalities</i>		
Proteinuria	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>



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MedDRA Version: MedDRA 25.1

<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Reproductive &amp; breast disorders</b>		
<i>Breast infections and inflammations</i>		
Nipple inflammation	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	5	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>6</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	5	0
Respiratory arrest	1	0
Tachypnoea	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	2	0
Wheezing	3	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Asphyxia	1	0
Hypoxia	1	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	10	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		
Alveolitis	1	0
Pneumonitis	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	3	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	1	0
<i><b>Neonatal hypoxic conditions</b></i>		
Neonatal respiratory distress syndrome	2	0
<i><b>Newborn respiratory disorders NEC</b></i>		
Bronchopulmonary dysplasia	1	0
Transient tachypnoea of the newborn	1	0
<i><b>Parenchymal lung disorders NEC</b></i>		
Interstitial lung disease	1	0
Lung consolidation	1	0
Organising pneumonia	1	0
Pulmonary alveolar haemorrhage	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal swelling	3	0
Tonsillar hypertrophy	1	0
<i><b>Pleural conditions NEC</b></i>		
Pleural adhesion	1	0
<i><b>Pneumothorax and pleural effusions NEC</b></i>		
Pleural effusion	1	0
<i><b>Pulmonary oedemas</b></i>		
Acute lung injury	1	0
Acute respiratory distress syndrome	1	0
Pulmonary congestion	1	0
Pulmonary oedema	1	0
<i><b>Pulmonary thrombotic and embolic conditions</b></i>		
Pulmonary embolism	1	0
<i><b>Respiratory failures (excl neonatal)</b></i>		
Respiratory failure	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Catarrh	1	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	8	0
Rhinorrhoea	3	0
Snoring	1	0
Throat irritation	2	0
Throat tightness	1	0

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> Respiratory disorders cont'd		
<i>Vascular pulmonary disorders NEC</i>		
Pulmonary arteriopathy	2	0
<b>Respiratory disorders SOC TOTAL</b>	<b>69</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i>Angioedemas</i>		
Angioedema	2	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	2	0
Hyperhidrosis	3	0
<i>Bullous conditions</i>		
Blister	1	0
Erythema multiforme	1	0
<i>Dermal and epidermal conditions NEC</i>		
Macule	1	0
Papule	2	0
Scab	1	0
Skin discolouration	1	0
Skin reaction	1	0
Skin warm	1	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	2	0
Eczema	2	0
Skin irritation	1	0
<i>Erythemas</i>		
Erythema	14	0
<i>Pruritus NEC</i>		
Pruritus	13	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	55	0
Rash erythematous	5	0
Rash macular	5	0
Rash maculo-papular	3	0
Rash morbilliform	12	0
Rash papular	4	0
Rash pruritic	1	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	1	0
<i>Urticarias</i>		
Urticaria	21	0
<b>Skin disorders SOC TOTAL</b>	<b>155</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Social circumstances</b>		
<i>Family and partner issues</i>		
Multiple birth sibling	2	0
<i>Social issues NEC</i>		
Contraindication to vaccination	1	0
<b>Social circumstances SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Induced abortions</i>		
Abortion induced	1	0
<i>Obstetric therapeutic procedures</i>		
Caesarean section	11	0
Episiotomy	1	0
Forceps delivery	1	0
Labour stimulation	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>15</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Circulatory collapse and shock</i>		
Circulatory collapse	1	0
<i>Haemorrhages NEC</i>		
Haemorrhage	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	4	0
Flushing	2	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	7	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	2	0
<b>Vascular disorders SOC TOTAL</b>	<b>19</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>1194</b>	<b>4</b>
<b>TOTAL REPORTS</b>	<b>371</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>4</b>