

## Case Series Drug Analysis Print

### Name: MMR Vaccine Drug Analysis Print

Report Run Date: 14-Aug-2017

Data Lock Date: 11-Aug-2017 19:00:04

Earliest Reaction Date: 31-May-1998

MedDRA Version: MedDRA 20.0

MMR Vaccine Drug Analysis Print: All UK Spontaneous cases concerning the MMR vaccine received between 01/09/2012 and 07/08/2017.

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<b><i>Anaemias NEC</i></b>		
Anaemia	1	0
<b><i>Anaemias haemolytic immune</i></b>		
Autoimmune haemolytic anaemia	1	0
<b><i>Haematological disorders</i></b>		
Placental transfusion syndrome	1	0
<b><i>Lymphatic system disorders NEC</i></b>		
Lymphadenitis	1	0
Lymphadenopathy	40	0
<b><i>Marrow depression and hypoplastic anaemias</i></b>		
Cytopenia	1	0
<b><i>Thrombocytopenias</i></b>		
Immune thrombocytopenic purpura	8	0
Thrombocytopenic purpura	1	0
<b>Blood disorders SOC TOTAL</b>	<b>54</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac disorders NEC</i>		
Cardiac disorder	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cyanosis	6	0
Palpitations	1	0
<i>Noninfectious pericarditis</i>		
Pericarditis	1	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	1	0
Tachycardia	4	0
<i>Supraventricular arrhythmias</i>		
Atrial tachycardia	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>15</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i><b>Autosomal chromosomal abnormalities</b></i>		
Trisomy 21	2	0
<i><b>Bladder disorders congenital</b></i>		
Congenital vesicoureteric reflux	1	0
<i><b>Chromosomal abnormalities NEC</b></i>		
Gene mutation	1	0
<i><b>Congenital disorders NEC</b></i>		
Congenital anomaly	1	0
Congenital cyst	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>Gastrointestinal tract disorders congenital NEC</b></i>		
Congenital umbilical hernia	1	0
<i><b>Immune system abnormalities congenital</b></i>		
Combined immunodeficiency	1	0
Primary immunodeficiency syndrome	2	0
<i><b>Inborn errors of amino acid metabolism</b></i>		
Phenylketonuria	1	0
<i><b>Laryngeal and tracheal disorders congenital</b></i>		
Laryngomalacia	1	0
<i><b>Lens disorders congenital</b></i>		
Cataract congenital	1	0
<i><b>Male reproductive tract disorders congenital</b></i>		
Cryptorchism	1	0
Hydrocele	2	0
Hypospadias	2	0
<i><b>Musculoskeletal and connective tissue disorders of limbs congenital</b></i>		
Congenital foot malformation	1	0
Developmental hip dysplasia	1	0
Talipes	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
<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>32</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i><b>Ear disorders NEC</b></i>		
Ear discomfort	3	0
Ear pain	4	0
Otorrhoea	2	0
<i><b>Eustachian tube disorders</b></i>		
Eustachian tube dysfunction	1	0
<i><b>Hearing losses</b></i>		
Deafness	3	0
Deafness neurosensory	2	0
Deafness unilateral	1	0
Hypoacusis	5	0
<i><b>Hyperacusia</b></i>		
Hyperacusis	2	0
<i><b>Inner ear signs and symptoms</b></i>		
Vertigo	2	0
<b>Ear disorders SOC TOTAL</b>	<b>25</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
<i>Adrenal cortical hyperfunctions</i>		
Cushingoid	1	0
<i>Adrenal gland disorders NEC</i>		
Adrenal disorder	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i>Blindness (excl colour blindness)</i>		
Blindness	1	0
Blindness cortical	1	0
<i>Cataract conditions</i>		
Cataract	1	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctivitis allergic	1	0
<i>Glaucomas (excl congenital)</i>		
Glaucoma	1	0
<i>Lacrimation disorders</i>		
Lacrimation increased	3	0
<i>Lens structural change, deposit and degeneration (excl cataracts)</i>		
Aphakia	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Erythema of eyelid	2	0
Eyelid oedema	4	0
<i>Lid, lash and lacrimal structural disorders</i>		
Dacryostenosis acquired	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	2	0
Eye pain	5	0
Eye swelling	9	0
Ocular discomfort	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	5	0
Eye inflammation	1	0
Eye pruritus	2	0
Ocular hyperaemia	6	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	2	0
Strabismus	4	0
<i>Ocular sensation disorders</i>		
Photophobia	9	0
<i>Orbital structural change, deposit and degeneration</i>		
Lid sulcus deepened	1	0
<i>Pupil disorders</i>		
Mydriasis	1	0
Pupil fixed	2	0
Pupils unequal	1	0
<i>Refractive and accommodative disorders</i>		
Altered visual depth perception	1	0
<i>Visual disorders NEC</i>		
Diplopia	1	0
Visual impairment	3	0
<b>Eye disorders SOC TOTAL</b>	<b>72</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Abdominal hernias NEC</i>		
Abdominal hernia	1	0
<i>Colitis (excl infective)</i>		
Colitis	2	0
<i>Dental disorders NEC</i>		
Tooth disorder	1	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	59	0
Diarrhoea neonatal	1	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	2	0
Faeces discoloured	6	0
Faeces pale	1	0
Faeces soft	1	0
Mucous stools	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	6	0
Flatulence	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	10	0
Abdominal pain lower	1	0
Abdominal pain upper	13	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	7	0
Gastrooesophageal reflux disease	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	2	0
Anal incontinence	2	0
Dysphagia	2	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	1	0
<i>Gingival pains</i>		
Gingival pain	1	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	1	0
<i>Malabsorption syndromes</i>		
Coeliac disease	1	0
<i>Nausea and vomiting symptoms</i>		
Infantile vomiting	3	0
Nausea	24	0
Regurgitation	1	0
Retching	1	0
Vomiting	99	0
Vomiting projectile	5	0
<i>Oral dryness and saliva altered</i>		
Salivary hypersecretion	3	0
<i>Oral soft tissue disorders NEC</i>		



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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Oral disorder	1	0
<b>Oral soft tissue pain and paraesthesia</b>		
Oral pain	1	0
Paraesthesia oral	4	0
<b>Oral soft tissue signs and symptoms</b>		
Hypoaesthesia oral	1	0
Oral mucosal blistering	3	0
Oral mucosal eruption	1	0
<b>Oral soft tissue swelling and oedema</b>		
Lip swelling	10	0
Mouth swelling	1	0
<b>Salivary gland disorders NEC</b>		
Salivary gland pain	1	0
<b>Salivary gland enlargements</b>		
Parotid gland enlargement	5	0
<b>Stomatitis and ulceration</b>		
Mouth ulceration	1	0
<b>Tongue signs and symptoms</b>		
Glossodynia	1	0
Swollen tongue	2	0
Tongue eruption	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>297</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Adverse effect absent</b></i>		
No adverse event	3	0
<i><b>Asthenic conditions</b></i>		
Asthenia	9	0
Fatigue	35	0
Malaise	87	0
<i><b>Death and sudden death</b></i>		
Death	4	4
Sudden death	1	1
<i><b>Febrile disorders</b></i>		
Pyrexia	303	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	15	0
Feeling abnormal	9	0
Feeling drunk	1	0
Feeling hot	13	0
Feeling of body temperature change	1	0
Hangover	1	0
Thirst	1	0
Thirst decreased	1	0
<i><b>Gait disturbances</b></i>		
Abasia	7	0
Gait disturbance	7	0
Loss of control of legs	1	0
<i><b>General signs and symptoms NEC</b></i>		
Condition aggravated	1	0
Crepitations	1	0
Crying	23	0
Developmental delay	2	0
Glassy eyes	1	0
Induration	2	0
Influenza like illness	13	0
Irritability postvaccinal	1	0
Local reaction	5	0
Local swelling	22	0
Peripheral swelling	35	0
Secretion discharge	2	0
Swelling	9	0
<i><b>Inflammations</b></i>		
Inflammation	4	0
<i><b>Infusion site reactions</b></i>		
Infusion site erythema	1	0
<i><b>Injection site reactions</b></i>		
Injection site bruising	4	0
Injection site discolouration	2	0
Injection site erythema	14	0
Injection site induration	3	0
Injection site inflammation	4	0
Injection site mass	5	0
Injection site pain	10	0
Injection site pruritus	2	0
Injection site rash	5	0
Injection site reaction	3	0

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<b>General disorders</b> General disorders cont'd		
Injection site swelling	20	0
Injection site vesicles	2	0
Injection site warmth	1	0
<b>Mass conditions NEC</b>		
Mass	4	0
<b>Mucosal findings abnormal</b>		
Mucous membrane disorder	1	0
<b>Pain and discomfort NEC</b>		
Chest discomfort	2	0
Chest pain	8	0
Discomfort	10	0
Facial pain	1	0
Non-cardiac chest pain	1	0
Pain	27	0
Tenderness	9	0
<b>Therapeutic and nontherapeutic responses</b>		
Drug ineffective	3	0
Therapy non-responder	17	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	3	0
Vaccination site bruising	1	0
Vaccination site discomfort	3	0
Vaccination site erythema	18	0
Vaccination site induration	4	0
Vaccination site inflammation	3	0
Vaccination site joint erythema	1	0
Vaccination site mass	3	0
Vaccination site pain	15	0
Vaccination site pruritus	3	0
Vaccination site rash	8	0
Vaccination site swelling	14	0
Vaccination site vesicles	1	0
Vaccination site warmth	11	0
<b>General disorders SOC TOTAL</b>	<b>867</b>	<b>5</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	2	0
<b>Hepatic disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Allergic oedema	1	0
Hypersensitivity	10	0
<i><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Allergy to vaccine	2	0
Food allergy	2	0
Milk allergy	1	0
Reaction to drug excipients	1	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	16	0
<i><b>Autoimmune disorders NEC</b></i>		
Autoimmune disorder	1	0
<i><b>Immune and associated conditions NEC</b></i>		
Immune system disorder	1	0
Immunisation reaction	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>36</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Abdominal and gastrointestinal infections</b></i>		
Gastroenteritis	3	0
<i><b>Bacterial infections NEC</b></i>		
Cellulitis	23	0
Citrobacter sepsis	1	0
Injection site cellulitis	3	0
Skin bacterial infection	1	0
Vaccination site cellulitis	5	0
<i><b>Bordetella infections</b></i>		
Pertussis	1	0
<i><b>Cardiac infections</b></i>		
Pericarditis infective	1	0
<i><b>Central nervous system and spinal infections</b></i>		
Encephalitis	5	1
Meningitis aseptic	2	0
Panencephalitis	1	1
<i><b>Dental and oral soft tissue infections</b></i>		
Gingivitis	1	0
Parotitis	1	0
<i><b>Ear infections</b></i>		
Ear infection	9	0
Labyrinthitis	1	0
Otitis media	3	0
Otitis media acute	1	0
Otitis media chronic	1	0
<i><b>Eye and eyelid infections</b></i>		
Conjunctivitis	11	0
Eye infection	2	0
<i><b>Herpes viral infections</b></i>		
Oral herpes	1	0
Varicella	1	0
<i><b>Infections NEC</b></i>		
Infection	2	0
Injection site abscess	1	0
Injection site infection	1	0
<i><b>Infectious transmissions</b></i>		
Infection via vaccinee	1	0
Transmission of an infectious agent via product	1	0
<i><b>Influenza viral infections</b></i>		
H1N1 influenza	1	0
Influenza	1	0
<i><b>Lower respiratory tract and lung infections</b></i>		
Bronchitis	1	0
Lower respiratory tract infection	10	0
Pneumonia	3	0
<i><b>Male reproductive tract infections</b></i>		
Epididymitis	1	0
<i><b>Mumps viral infections</b></i>		
Encephalitis mumps	1	0
Mumps	16	0
<i><b>Pneumocystis infections</b></i>		
Pneumocystis jirovecii pneumonia	1	0
<i><b>Rubella viral infections</b></i>		

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Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Rubella	2	0
<b><i>Rubeola viral infections</i></b>		
Measles	38	0
Measles post vaccine	4	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Sepsis	2	1
Sepsis neonatal	1	0
<b><i>Skin structures and soft tissue infections</i></b>		
Skin infection	1	0
<b><i>Streptococcal infections</i></b>		
Scarlet fever	1	0
<b><i>Tuberculous infections</i></b>		
Erythema induratum	1	0
<b><i>Upper respiratory tract infections</i></b>		
Croup infectious	2	0
Pharyngitis	2	0
Rhinitis	4	0
Tonsillitis	9	0
Upper respiratory tract infection	4	0
<b><i>Urinary tract infections</i></b>		
Urinary tract infection	1	0
<b><i>Viral infections NEC</i></b>		
Bronchiolitis	1	0
Gastroenteritis viral	1	0
Post viral fatigue syndrome	1	0
Viral infection	4	0
Viral rash	1	0
Viral upper respiratory tract infection	15	0
<b>Infections SOC TOTAL</b>	<b>214</b>	<b>3</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i>Conditions caused by cold</i>		
Chillblains	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during breast feeding	1	0
Exposure during pregnancy	38	0
Foetal exposure during pregnancy	26	0
Maternal exposure before pregnancy	7	0
<i>Medication errors, product use errors and issues NEC</i>		
Inadequate aseptic technique in use of product	1	0
Medication error	7	0
Vaccination error	2	0
<i>Nerve injuries NEC</i>		
Nerve injury	1	0
<i>Product administration errors and issues</i>		
Drug administered to patient of inappropriate age	3	0
Drug administration error	1	0
Expired product administered	1	0
Extra dose administered	1	0
Inappropriate schedule of drug administration	3	0
Incomplete course of vaccination	1	0
Wrong drug administered	2	0
<i>Product monitoring errors and issues</i>		
Labelled drug-disease interaction medication error	1	0
Labelled drug-drug interaction medication error	1	0
<i>Reproductive system and breast injuries</i>		
Perineal injury	2	0
<i>Skin injuries NEC</i>		
Contusion	10	0
Laceration	2	0
<i>Vaccination related complications</i>		
Vaccination failure	6	0
<b>Injuries SOC TOTAL</b>	<b>118</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Autoimmunity analyses</b></i>		
Rheumatoid factor increased	1	0
<i><b>Blood gas and acid base analyses</b></i>		
Oxygen saturation decreased	1	0
<i><b>Carbohydrate tolerance analyses (incl diabetes)</b></i>		
Blood glucose decreased	2	0
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 monitoring abnormal	2	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	3	0
Heart rate increased	3	0
Heart rate irregular	2	0
<i><b>Immunology analyses NEC</b></i>		
Antibody test negative	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature	1	0
Body temperature abnormal	2	0
Body temperature decreased	2	0
Body temperature fluctuation	1	0
Body temperature increased	38	0
Breath sounds abnormal	2	0
Grip strength decreased	1	0
Head circumference abnormal	1	0
Respiratory rate decreased	1	0
Respiratory rate increased	4	0
Weight decreased	2	0
Weight increased	1	0
<i><b>Platelet analyses</b></i>		
Platelet count decreased	3	0
<i><b>Protein analyses NEC</b></i>		
C-reactive protein increased	2	0
<i><b>Red blood cell analyses</b></i>		
Haemoglobin S	1	0
<i><b>Tissue enzyme analyses NEC</b></i>		
Blood alkaline phosphatase increased	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	2	0
Blood pressure increased	2	0
<i><b>Virus identification and serology</b></i>		
Rubella antibody negative	2	0
<b>Investigations SOC TOTAL</b>	<b>89</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	101	0
Hypophagia	4	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Diabetes mellitus	1	0
Type 1 diabetes mellitus	1	0
<i><b>Fluid intake decreased</b></i>		
Fluid intake reduced	6	0
<i><b>Fluid intake increased</b></i>		
Polydipsia	1	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Cow's milk intolerance	2	0
Food intolerance	2	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	2	0
Feeding disorder	3	0
Food aversion	1	0
Poor feeding infant	3	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	3	0
<b>Metabolic disorders SOC TOTAL</b>	<b>130</b>	<b>0</b>

# Case Series Drug Analysis Print

## Name: MMR Vaccine Drug Analysis Print

Report Run Date: 14-Aug-2017  
Earliest Reaction Date: 31-May-1998

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MedDRA Version: MedDRA 20.0

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	4	0
Arthropathy	1	0
<i><b>Joint related disorders NEC</b></i>		
Hypermobility syndrome	1	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	30	0
Joint crepitation	1	0
Joint stiffness	4	0
Joint swelling	5	0
<i><b>Muscle pains</b></i>		
Myalgia	14	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle atrophy	1	0
Muscle spasms	2	0
Muscle twitching	2	0
<i><b>Muscle tone abnormalities</b></i>		
Floppy infant	2	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	8	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Back pain	6	0
Limb discomfort	2	0
Pain in extremity	24	0
<i><b>Musculoskeletal and connective tissue signs and symptoms NEC</b></i>		
Growth retardation	1	0
Mobility decreased	2	0
Musculoskeletal stiffness	12	0
Weight bearing difficulty	6	0
<i><b>Rheumatoid arthropathies</b></i>		
Juvenile idiopathic arthritis	1	0
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>131</b>	<b>0</b>

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MedDRA Version: MedDRA 20.0

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>		
<i><b>Absence seizures</b></i>		
Petit mal epilepsy	1	0
<i><b>Central nervous system inflammatory disorders NEC</b></i>		
Arachnoiditis	1	0
<i><b>Central nervous system vascular disorders NEC</b></i>		
Vertebrobasilar insufficiency	1	0
<i><b>Coordination and balance disturbances</b></i>		
Ataxia	2	0
Balance disorder	6	0
Coordination abnormal	3	0
Hand-eye coordination impaired	1	0
<i><b>Cortical dysfunction NEC</b></i>		
Aphasia	3	0
Dyspraxia	2	0
<i><b>Disturbances in consciousness NEC</b></i>		
Altered state of consciousness	1	0
Consciousness fluctuating	1	0
Lethargy	35	0
Loss of consciousness	4	0
Somnolence	23	0
Syncope	14	0
<i><b>Dyskinesias and movement disorders NEC</b></i>		
Dyskinesia	4	0
Hypokinesia	2	0
Psychomotor hyperactivity	3	0
<i><b>Dystonias</b></i>		
Opisthotonus	1	0
<i><b>Encephalopathies NEC</b></i>		
Encephalopathy neonatal	1	0
Hypoxic-ischaemic encephalopathy	1	0
<i><b>Facial cranial nerve disorders</b></i>		
Facial paralysis	1	0
<i><b>Generalised tonic-clonic seizures</b></i>		
Generalised tonic-clonic seizure	5	0
<i><b>Headaches NEC</b></i>		
Headache	39	0
Sinus headache	1	0
<i><b>Memory loss (excl dementia)</b></i>		
Amnesia	3	0
<i><b>Mental impairment (excl dementia and memory loss)</b></i>		
Cognitive disorder	1	0
Disturbance in attention	4	0
Mental impairment	1	0
<i><b>Migraine headaches</b></i>		
Migraine	4	0
<i><b>Muscle tone abnormal</b></i>		
Hypotonia	14	0
<i><b>Narcolepsy and hypersomnia</b></i>		
Hypersomnia	3	0
<i><b>Nervous system disorders NEC</b></i>		
Nervous system disorder	1	0
<i><b>Neurological signs and symptoms NEC</b></i>		
Decorticate posture	1	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Dizziness	15	0
Dizziness postural	1	0
Drooling	1	0
Exaggerated startle response	1	0
Head discomfort	2	0
Hyporesponsive to stimuli	1	0
Inability to crawl	1	0
Myoclonus	1	0
Neurological decompensation	1	0
Presyncope	2	0
Unresponsive to stimuli	10	0
<b>Neuromuscular disorders NEC</b>		
Hypotonic-hyporesponsive episode	1	0
<b>Paraesthesias and dysaesthesias</b>		
Burning sensation	2	0
Hyperaesthesia	2	0
Hypoaesthesia	4	0
Paraesthesia	4	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Hemiparesis	2	0
<b>Seizures and seizure disorders NEC</b>		
Convulsion in childhood	1	0
Convulsion neonatal	1	0
Epilepsy	3	0
Febrile convulsion	19	0
Idiopathic generalised epilepsy	2	0
Partial seizures	2	0
Seizure	17	0
Seizure anoxic	2	0
Seizure like phenomena	1	0
<b>Sensory abnormalities NEC</b>		
Dysgeusia	2	0
Neuralgia	1	0
Sensory disturbance	1	0
Sensory loss	1	0
<b>Speech and language abnormalities</b>		
Aphonia	1	0
Dysarthria	1	0
Slow speech	1	0
Speech disorder	5	0
Speech disorder developmental	2	0
<b>Tremor (excl congenital)</b>		
Tremor	12	0
<b>Nervous system disorders SOC TOTAL</b>	<b>314</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortion related conditions and complications</i>		
Blighted ovum	1	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	19	0
Imminent abortion	1	0
<i>Amniotic fluid and cavity disorders of pregnancy NEC</i>		
Oligohydramnios	1	0
<i>Foetal complications NEC</i>		
Foetal distress syndrome	1	0
Foetal hypokinesia	2	0
<i>Foetal growth complications</i>		
Foetal growth restriction	2	0
<i>Foetal position and presentation abnormalities</i>		
Breech presentation	2	0
Face presentation	1	0
High foetal head	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	5	0
<i>Haemorrhagic complications of pregnancy</i>		
Premature separation of placenta	1	0
<i>High risk pregnancies</i>		
High risk pregnancy	1	0
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	2	0
<i>Labour onset and length abnormalities</i>		
Premature delivery	1	0
Premature labour	2	0
Premature rupture of membranes	1	0
Prolonged labour	5	0
<i>Maternal complications of delivery NEC</i>		
Breech delivery	1	0
<i>Multiple pregnancies</i>		
Multiple pregnancy	2	0
<i>Neonatal gastrointestinal disorders</i>		
Meconium increased	1	0
<i>Neonatal hepatobiliary disorders</i>		
Jaundice neonatal	1	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	2	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	2	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	1	0
<i>Stillbirth and foetal death</i>		
Foetal death	1	1
Stillbirth	2	2
<b>Pregnancy conditions SOC TOTAL</b>	<b>62</b>	<b>3</b>

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Reaction Name	Total	Fatal
<i>Product quality issues NEC</i>		
Product quality issue	2	0
<b>null SOC TOTAL</b>	<b>2</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	11	0
Breath holding	1	0
Staring	4	0
<b><i>Affect alterations NEC</i></b>		
Affect lability	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	3	0
Anxiety	4	0
Nervousness	2	0
<b><i>Attention deficit and disruptive behaviour disorders</i></b>		
Attention deficit/hyperactivity disorder	1	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	3	0
Antisocial behaviour	1	0
Personality change	2	0
Social avoidant behaviour	3	0
<b><i>Communications disorders</i></b>		
Mutism	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	3	0
Disorientation	6	0
<b><i>Deliria</i></b>		
Delirium	1	0
<b><i>Depressive disorders</i></b>		
Depression	1	0
<b><i>Dissociative states</i></b>		
Dissociation	1	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Initial insomnia	1	0
Insomnia	25	0
Middle insomnia	2	0
<b><i>Eating disorders NEC</i></b>		
Eating disorder	1	0
Selective eating disorder	1	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Anger	1	0
Dysphoria	1	0
Emotional disorder	4	0
Emotional distress	6	0
Irritability	39	0
Moaning	2	0
Mood altered	5	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Fear	1	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	10	0
<b><i>Mental disorders NEC</i></b>		
Mental disorder	1	0
Mental status changes	2	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Anhedonia	1	0
Decreased interest	1	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Depressed mood	5	0
Tearfulness	10	0
<b>Mood disorders NEC</b>		
Listless	4	0
<b>Obsessive-compulsive disorders and symptoms</b>		
Body dysmorphic disorder	1	0
Obsessive-compulsive symptom	1	0
Trichotillomania	1	0
<b>Panic attacks and disorders</b>		
Panic attack	2	0
<b>Parasomnias</b>		
Nightmare	1	0
Sleep terror	1	0
<b>Perception disturbances</b>		
Hallucination	1	0
Hallucination, visual	1	0
Time perception altered	1	0
<b>Pervasive developmental disorders NEC</b>		
Autism spectrum disorder	20	0
<b>Psychiatric elimination disorders</b>		
Enuresis	1	0
<b>Psychiatric symptoms NEC</b>		
Decreased eye contact	2	0
<b>Sleep disorders NEC</b>		
Sleep disorder	11	0
<b>Somatic symptom disorders</b>		
Conversion disorder	1	0
<b>Speech articulation and rhythm disturbances</b>		
Screaming	11	0
<b>Stereotypies and automatisms</b>		
Head banging	2	0
<b>Thinking disturbances</b>		
Thinking abnormal	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>231</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Dysuria	1	0
Pollakiuria	1	0
Urinary incontinence	1	0
<i>Renal structural abnormalities and trauma</i>		
Pyelocaliectasis	1	0
<i>Urinary abnormalities</i>		
Haematuria	1	0
Proteinuria	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	3	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>9</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive tract signs and symptoms NEC</i>		
Genital rash	2	0
Genital swelling	1	0
Oedema genital	1	0
<i>Scrotal disorders NEC</i>		
Scrotal swelling	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	4	0
Testicular swelling	7	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	4	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>20</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	16	0
Hypopnoea	2	0
Respiration abnormal	1	0
Respiratory arrest	2	0
Respiratory distress	2	0
Sleep apnoea syndrome	3	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	2	0
Wheezing	11	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Asphyxia	2	0
Hypoxia	2	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	43	0
Productive cough	2	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		
Lower respiratory tract inflammation	1	0
Pneumonitis	1	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Hiccups	1	0
Rales	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	4	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	8	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
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinus congestion	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal disorder	1	0
Pharyngeal erythema	3	0
Pharyngeal oedema	4	0
Pharyngeal paraesthesia	1	0
Tonsillar hypertrophy	3	0
Tonsillar inflammation	2	0
Velopharyngeal incompetence	2	0
<i><b>Respiratory tract disorders NEC</b></i>		
Respiratory tract irritation	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Dry throat	1	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	19	0
Rhinorrhoea	22	0
Sinus pain	1	0
Throat tightness	1	0
Yawning	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>171</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i>Acnes</i>		
Acne	1	0
<i>Angioedemas</i>		
Angioedema	1	0
Swelling face	20	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	4	0
Hyperhidrosis	8	0
Night sweats	1	0
<i>Bullous conditions</i>		
Blister	10	0
Blood blister	1	0
Erythema multiforme	3	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	3	0
Pain of skin	2	0
Papule	6	0
Skin burning sensation	1	0
Skin discolouration	5	0
Skin fissures	1	0
Skin induration	3	0
Skin lesion	1	0
Skin reaction	1	0
Skin tightness	1	0
Skin warm	15	0
<i>Dermatitis and eczema</i>		
Dermatitis	1	0
Dermatitis allergic	8	0
Dermatitis atopic	1	0
Dermatitis diaper	3	0
Eczema	14	0
Eczema infantile	1	0
Eczema weeping	1	0
Skin irritation	1	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	1	0
Drug reaction with eosinophilia and systemic symptoms	1	0
<i>Erythemas</i>		
Erythema	56	0
<i>Exfoliative conditions</i>		
Skin exfoliation	1	0
<i>Hypopigmentation disorders</i>		
Vitiligo	2	0
<i>Papulosquamous conditions</i>		
Lichen sclerosis	1	0
<i>Photosensitivity and photodermatitis conditions</i>		
Photosensitivity reaction	1	0
<i>Pruritus NEC</i>		
Pruritus	35	0
Pruritus generalised	1	0
Rash pruritic	11	0
<i>Purpura and related conditions</i>		
Henoch-Schonlein purpura	3	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Petechiae	4	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Rash	136	0
Rash erythematous	16	0
Rash generalised	45	0
Rash macular	18	0
Rash maculo-papular	12	0
Rash morbilliform	61	0
Rash papular	8	0
Rash rubelliform	1	0
<b><i>Scaly conditions</i></b>		
Pityriasis	1	0
<b><i>Skin vasculitides</i></b>		
Vasculitic rash	1	0
<b><i>Urticarias</i></b>		
Urticaria	26	0
<b>Skin disorders SOC TOTAL</b>	<b>560</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i><b>Disability issues</b></i>		
Immobile	1	0
Mental disability	1	0
Walking disability	2	0
<i><b>Family and partner issues</b></i>		
Multiple birth sibling	2	0
<i><b>Social issues NEC</b></i>		
Contraindication to vaccination	5	0
<b>Social circumstances SOC TOTAL</b>	<b>11</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Blood and blood product treatment</i>		
Transfusion	1	0
<i>Induced abortions</i>		
Abortion induced	2	0
<i>Lymphoid tissue therapeutic procedures</i>		
Splenectomy	1	0
<i>Middle ear therapeutic procedures</i>		
Ear tube insertion	1	0
<i>Obstetric therapeutic procedures</i>		
Caesarean section	14	0
Episiotomy	1	0
Forceps delivery	1	0
Labour stimulation	1	0
<i>Therapeutic procedures NEC</i>		
Surgery	1	0
<i>Tonsillar therapeutic procedures</i>		
Adenoidectomy	1	0
Tonsillectomy	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>25</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Accelerated and malignant hypertension</i>		
Accelerated hypertension	1	0
<i>Arterial inflammations</i>		
Kawasaki's disease	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	1	0
<i>Haemorrhages NEC</i>		
Haemorrhage	3	0
<i>Peripheral vascular disorders NEC</i>		
Hot flush	2	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	27	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>39</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>3532</b>	<b>11</b>
<b>TOTAL REPORTS</b>	<b>1060</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>11</b>