

Case Series Drug Analysis Print

Name: FOI 2024/00225 All serious MMR vaccine reports

Report Run Date: 25-Jun-2024

Data Lock Date: 21-Jun-2024 18:30:03

Earliest Reaction Date: 14-May-1987

MedDRA Version: MedDRA 27.0

FOI 2024/00225 All serious MMR vaccine reports: All serious UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with MMR vaccination up to and including 24/05/2024

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	5	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	1	0
<i>Anaemias haemolytic mechanical factor</i>		
Haemolytic uraemic syndrome	2	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	2	0
<i>Coagulopathies</i>		
Antiphospholipid syndrome	1	0
Coagulopathy	1	0
Disseminated intravascular coagulation	1	0
<i>Eosinophilic disorders</i>		
Eosinophilia	1	0
<i>Haematological disorders</i>		
Blood disorder	1	0
Placental transfusion syndrome	1	0
<i>Haemolyses NEC</i>		
Haemolysis	1	0
<i>Leukocytoses NEC</i>		
Monocytosis	2	0
T-cell lymphocytosis	1	0
<i>Leukopenias NEC</i>		
Leukopenia	2	0
Lymphopenia	4	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenitis	4	0
Lymphadenopathy	231	0
Lymphoid tissue hyperplasia	1	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplasia pure red cell	1	0
Aplastic anaemia	1	0
Bone marrow failure	1	0
Cytopenia	2	0
Pancytopenia	1	0
<i>Neutropenias</i>		
Neutropenia	3	0
<i>Polycythaemia (excl rubra vera)</i>		
Polycythaemia	1	0
<i>Spleen disorders</i>		
Splenomegaly	3	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	71	0
Thrombocytopenia	46	0
Thrombocytopenic purpura	7	0
Thrombotic thrombocytopenic purpura	8	0
Blood disorders SOC TOTAL	407	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac disorders NEC</i>		
Cardiac disorder	2	0
Cardiovascular disorder	1	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	8	0
<i>Endocarditis NEC</i>		
Endocarditis noninfective	1	1
<i>Heart failures NEC</i>		
Cardiac failure	2	1
Cardiopulmonary failure	2	0
<i>Noninfectious myocarditis</i>		
Myocarditis	5	2
<i>Noninfectious pericarditis</i>		
Pericarditis	2	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	2	0
<i>Pulmonary valvular disorders</i>		
Pulmonary valve stenosis	2	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	1	0
Bradycardia	17	0
Extrasystoles	1	0
Tachycardia	16	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Atrial tachycardia	1	0
Sinus tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	2	1
Cardio-respiratory arrest	2	1
Ventricular fibrillation	1	0
Ventricular tachycardia	2	0
Cardiac disorders SOC TOTAL	72	6

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Anorectal disorders congenital</i>		
Preternatural anus	2	0
<i>Autosomal chromosomal abnormalities</i>		
Trisomy 21	2	0
<i>Bladder disorders congenital</i>		
Congenital vesicoureteric reflux	1	0
<i>Cardiac septal defects congenital</i>		
Atrioventricular septal defect	2	0
<i>Cerebral disorders congenital</i>		
Congenital hydrocephalus	1	0
<i>Congenital disorders NEC</i>		
Congenital anomaly	2	0
Congenital cyst	1	0
VACTERL syndrome	2	0
<i>Connective tissue disorders congenital</i>		
Hypermobility syndrome	1	0
<i>External ear disorders congenital</i>		
Anomaly of external ear congenital	1	0
<i>Eyelid disorders congenital</i>		
Eyelid ptosis congenital	2	0
<i>Gastric disorders congenital</i>		
Pyloric stenosis	1	0
<i>Gastrointestinal tract disorders congenital NEC</i>		
Congenital umbilical hernia	1	0
<i>Gene mutations and other alterations NEC</i>		
Gene mutation	1	0
Mutagenic effect	2	0
<i>Great vessel disorders congenital</i>		
Double outlet right ventricle	2	0
<i>Immune system abnormalities congenital</i>		
Combined immunodeficiency	1	0
Primary immunodeficiency syndrome	3	0
<i>Inborn errors of amino acid metabolism</i>		
Phenylketonuria	1	0
<i>Laryngeal and tracheal disorders congenital</i>		
Laryngomalacia	1	0
<i>Lens disorders congenital</i>		
Cataract congenital	1	0
<i>Lymphatic system disorders congenital</i>		
Lymphatic malformation	1	1
<i>Male reproductive tract disorders congenital</i>		
Cryptorchism	1	0
Hydrocele	2	0
Hypospadias	2	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Congenital foot malformation	1	0
Developmental hip dysplasia	3	0
Limb hypoplasia congenital	2	0
Limb reduction defect	2	0
Talipes	3	0
<i>Musculoskeletal and connective tissue disorders of skull congenital</i>		
Plagiocephaly	1	0
<i>Musculoskeletal and connective tissue disorders of spine congenital</i>		

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Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
Congenital musculoskeletal disorder of spine	2	0
Ocular disorders congenital NEC		
Congenital eye disorder	1	0
Oral cavity disorders congenital NEC		
Tethered oral tissue	2	0
Persistent foetal circulation disorders		
Patent ductus arteriosus	1	0
Pulmonary and bronchial disorders congenital		
Congenital pneumonia	1	0
Pulmonary aplasia	2	0
Pulmonary hypoplasia	2	0
Renal disorders congenital		
Congenital cystic kidney disease	2	0
Skin and subcutaneous tissue disorders congenital NEC		
Congenital naevus	1	0
Congenital skin dimples	2	0
Congenital disorders SOC TOTAL	65	1

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear congestion	2	0
Ear discomfort	3	0
Ear pain	23	0
Ear swelling	4	0
Otorrhoea	4	0
Ototoxicity	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube dysfunction	1	0
<i>External ear disorders NEC</i>		
Auricular swelling	1	0
Excessive cerumen production	1	0
<i>Hearing losses</i>		
Deafness	14	0
Deafness bilateral	1	0
Deafness neurosensory	21	0
Deafness transitory	2	0
Deafness unilateral	4	0
Hypoacusis	12	0
Sudden hearing loss	1	0
<i>Hyperacusia</i>		
Hyperacusis	2	0
<i>Inner ear disorders NEC</i>		
Inner ear disorder	1	0
Meniere's disease	1	0
Vestibular disorder	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	6	0
Vertigo	6	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane disorder	2	0
Tympanic membrane perforation	1	0
Ear disorders SOC TOTAL	115	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<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>Endocrine abnormalities of puberty</i>		
Precocious puberty	1	0
<i>Thyroid disorders NEC</i>		
Goitre	1	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	1	0
Endocrine disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Cataract conditions</i>		
Cataract	2	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctivitis allergic	1	0
<i>Corneal structural change, deposit and degeneration</i>		
Xerophthalmia	1	0
<i>Eyelid movement disorders</i>		
Excessive eye blinking	1	0
<i>Glaucomas (excl congenital)</i>		
Glaucoma	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iridocyclitis	3	0
<i>Lacrimation disorders</i>		
Lacrimation increased	8	0
<i>Lens structural change, deposit and degeneration (excl cataracts)</i>		
Aphakia	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	1	0
Erythema of eyelid	3	0
Eyelid oedema	4	0
Swelling of eyelid	9	0
<i>Lid, lash and lacrimal structural disorders</i>		
Dacryostenosis acquired	1	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haemorrhage	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	2	0
Eye pain	17	0
Eye swelling	31	0
Ocular discomfort	1	0
Periorbital oedema	16	0
Periorbital swelling	3	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	7	0
Eye inflammation	2	0
Eye irritation	2	0
Eye pruritus	5	0
Ocular hyperaemia	20	0
<i>Ocular nerve and muscle disorders</i>		
Extraocular muscle disorder	1	0
Eye movement disorder	21	0
Ophthalmoplegia	1	0
Strabismus	6	0
<i>Ocular sensation disorders</i>		
Asthenopia	1	0
Photophobia	19	0
<i>Orbital structural change, deposit and degeneration</i>		
Lid sulcus deepened	1	0
<i>Pupil disorders</i>		
Anisocoria	1	0
Mydriasis	2	0
Pupil fixed	3	0
<i>Refractive and accommodative disorders</i>		

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Eye disorders Eye disorders cont'd		
Altered visual depth perception	1	0
Hypermetropia	1	0
Visual disorders NEC		
Diplopia	3	0
Vision blurred	6	0
Visual field disorders		
Visual field defect	1	0
Visual impairment and blindness (excl colour blindness)		
Blindness	2	0
Blindness cortical	1	0
Blindness transient	1	0
Cortical visual impairment	1	0
Visual impairment	14	0
Eye disorders SOC TOTAL	230	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal hernias NEC</i>		
Abdominal hernia	1	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis acute	1	0
Pancreatitis haemorrhagic	1	0
Pancreatitis necrotising	1	0
<i>Colitis (excl infective)</i>		
Colitis	4	0
Colitis ulcerative	1	0
Crohn's disease	5	0
Inflammatory bowel disease	4	0
<i>Dental disorders NEC</i>		
Tooth disorder	2	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	174	0
Diarrhoea haemorrhagic	2	0
Infantile diarrhoea	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	3	0
Eructation	1	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	4	0
Faecaloma	3	0
Faeces discoloured	11	0
Faeces pale	1	0
Mucous stools	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	9	0
Flatulence	5	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	1	0
Oesophageal haemorrhage	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	33	0
Abdominal pain lower	2	0
Abdominal pain upper	31	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	23	0
Gastrooesophageal reflux disease	5	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	2	0
Gastrointestinal disorder	7	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	2	0
Gastrointestinal motility disorder	2	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Enteritis	1	0
<i>Gastrointestinal necrosis and gangrene (excl gangrenous hernia)</i>		
Gastrointestinal necrosis	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	5	0
Anal incontinence	4	0
Dysphagia	5	0
Odynophagia	1	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	1	0
Frequent bowel movements	2	0
Irritable bowel syndrome	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	1	0
Intussusception	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	3	0
Gingival swelling	2	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	2	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	3	0
<i>Malabsorption syndromes</i>		
Coeliac disease	1	0
<i>Nausea and vomiting symptoms</i>		
Infantile vomiting	3	0
Nausea	61	0
Regurgitation	1	0
Retching	1	0
Vomiting	284	0
Vomiting projectile	19	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	1	0
Haematemesis	2	0
<i>Oesophagitis (excl infective)</i>		
Oesophagitis	2	0
<i>Oral dryness and saliva altered</i>		
Salivary hypersecretion	2	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	2	0
Oral disorder	2	0
Oral papule	1	0
<i>Oral soft tissue haemorrhages</i>		
Lip haemorrhage	1	0
Mouth haemorrhage	2	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	2	0
Oral mucosal blistering	7	0
Oral mucosal eruption	3	0
Oral pain	5	0
Paraesthesia oral	9	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	27	0
Mouth swelling	5	0
<i>Peritoneal and retroperitoneal disorders</i>		
Ascites	1	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Rectal inflammations NEC</i>		
Proctitis	1	0
<i>Salivary gland disorders NEC</i>		
Salivary gland pain	1	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	13	0
Salivary gland enlargement	4	0
Submaxillary gland enlargement	1	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	1	0
Lip ulceration	1	0
Mouth ulceration	12	0
Stomatitis	3	0
<i>Tongue disorders</i>		
Tongue disorder	1	0
Tongue geographic	1	0
Tongue ulceration	5	0
<i>Tongue signs and symptoms</i>		
Glossodynia	2	0
Strawberry tongue	1	0
Swollen tongue	7	0
Tongue coated	2	0
Tongue eruption	2	0
Tongue erythema	1	0
<i>Umbilical hernias</i>		
Umbilical hernia	2	0
Gastrointestinal disorders SOC TOTAL	885	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site erythema	1	0
<i>Adverse effect absent</i>		
No adverse event	3	0
<i>Asthenic conditions</i>		
Asthenia	30	0
Chronic fatigue syndrome	6	0
Decreased activity	1	0
Fatigue	104	0
Malaise	189	0
<i>Death and sudden death</i>		
Death	8	8
Sudden death	2	2
Sudden infant death syndrome	4	4
<i>Febrile disorders</i>		
Pyrexia	1125	0
<i>Feelings and sensations NEC</i>		
Chills	34	0
Feeling abnormal	16	0
Feeling cold	3	0
Feeling drunk	1	0
Feeling hot	41	0
Feeling of body temperature change	6	0
Hangover	1	0
Thirst	4	0
Thirst decreased	4	0
<i>Gait disturbances</i>		
Gait disturbance	30	0
Gait inability	21	0
Loss of control of legs	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	4	0
Crepitations	1	0
Crying	86	0
Developmental delay	30	0
Developmental regression	8	0
Energy increased	1	0
Foaming at mouth	1	0
General physical health deterioration	1	0
Glassy eyes	1	0
High-pitched crying	8	0
Ill-defined disorder	1	0
Illness	37	0
Induration	5	0
Influenza like illness	30	0
Irritability postvaccinal	1	0
Local reaction	14	0
Moaning	2	0
Multiple organ dysfunction syndrome	1	1
Peripheral swelling	101	0
Screaming	39	0
Secretion discharge	2	0
Swelling	62	0

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General disorders General disorders cont'd		
Swelling face	70	0
Inflammations		
Granuloma	1	0
Inflammation	20	0
Polyserositis	1	0
Systemic inflammatory response syndrome	1	0
Infusion site reactions		
Infusion site erythema	1	0
Injection site reactions		
Injection site bruising	2	0
Injection site cyst	1	0
Injection site discolouration	1	0
Injection site discomfort	1	0
Injection site eczema	1	0
Injection site erythema	20	0
Injection site indentation	1	0
Injection site induration	2	0
Injection site inflammation	11	0
Injection site mass	6	0
Injection site oedema	1	0
Injection site pain	10	0
Injection site pruritus	4	0
Injection site rash	8	0
Injection site reaction	28	0
Injection site swelling	20	0
Injection site urticaria	1	0
Injection site vesicles	5	0
Injection site warmth	2	0
Interactions		
Drug interaction	2	0
Potentiating drug interaction	1	0
Mass conditions NEC		
Mass	6	0
Nodule	1	0
Mucosal findings abnormal		
Mucosal disorder	1	0
Mucosal haemorrhage	1	0
Oedema NEC		
Face oedema	19	0
Generalised oedema	1	0
Gravitational oedema	1	0
Oedema	5	0
Oedema peripheral	11	0
Pain and discomfort NEC		
Chest discomfort	11	0
Chest pain	14	0
Discomfort	23	0
Facial pain	2	0
Non-cardiac chest pain	1	0
Pain	87	0
Tenderness	15	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	5	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Adverse event	2	0
Adverse reaction	1	0
Drug ineffective	10	0
No reaction on previous exposure to drug	1	0
Post vaccination challenge strain shedding	1	0
Therapy non-responder	5	0
Vaccination failure	196	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	3	0
Vaccination site bruising	6	0
Vaccination site erythema	41	0
Vaccination site haematoma	1	0
Vaccination site induration	5	0
Vaccination site inflammation	6	0
Vaccination site mass	13	0
Vaccination site movement impairment	1	0
Vaccination site nodule	1	0
Vaccination site pain	21	0
Vaccination site paraesthesia	1	0
Vaccination site pruritus	3	0
Vaccination site rash	13	0
Vaccination site reaction	3	0
Vaccination site swelling	40	0
Vaccination site urticaria	1	0
Vaccination site vesicles	1	0
Vaccination site warmth	15	0
General disorders SOC TOTAL	2888	15

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	1	0
<i>Cholestasis and jaundice</i>		
Jaundice	5	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	3	0
Hypertransaminasaemia	1	0
<i>Hepatic failure and associated disorders</i>		
Hepatic failure	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatomegaly	1	0
Hepatosplenomegaly	2	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	3	0
Hepatitis acute	1	0
Reye's syndrome	1	1
Hepatic disorders SOC TOTAL	19	1

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Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	1	0
Allergy to metals	1	0
Hypersensitivity	44	0
Multiple allergies	1	0
Serum sickness-like reaction	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	2	0
Food allergy	2	0
Milk allergy	2	0
Reaction to excipient	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	102	1
Anaphylactic shock	6	0
Anaphylactoid reaction	11	0
<i>Atopic disorders</i>		
Atopy	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	3	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	1	0
Decreased immune responsiveness	1	0
Haemophagocytic lymphohistiocytosis	6	3
Immune system disorder	3	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	3	0
<i>Primary immunodeficiency syndromes</i>		
Selective IgG subclass deficiency	1	0
Immune system disorders SOC TOTAL	193	4

Case Series Drug Analysis Print

Name: FOI 2024/00225 All serious MMR vaccine reports

Report Run Date: 25-Jun-2024

Data Lock Date: 21-Jun-2024 18:30:03

Earliest Reaction Date: 14-May-1987

MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Diarrhoea infectious	2	0
Gastroenteritis	7	0
Large intestine infection	1	1
<i>Adenoviral infections</i>		
Adenovirus infection	2	0
<i>Bacterial infections NEC</i>		
Administration site cellulitis	1	0
Cellulitis	96	0
Citrobacter sepsis	1	0
Gastrointestinal bacterial overgrowth	1	0
Injection site cellulitis	17	0
Meningitis bacterial	4	0
Skin bacterial infection	1	0
Vaccination site cellulitis	10	0
<i>Bone and joint infections</i>		
Intervertebral discitis	2	0
<i>Bordetella infections</i>		
Pertussis	1	0
<i>Borrelial infections</i>		
Lyme disease	1	0
Relapsing fever	2	0
<i>Candida infections</i>		
Candida infection	1	0
Oral candidiasis	3	0
Vulvovaginal candidiasis	1	0
<i>Cardiac infections</i>		
Pericarditis infective	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	45	3
Encephalitis brain stem	1	0
Encephalomyelitis	1	0
Meningitis	51	0
Meningitis aseptic	8	0
Myelitis	2	0
Panencephalitis	1	1
<i>Coronavirus infections</i>		
COVID-19	2	0
<i>Cytomegaloviral infections</i>		
Cytomegalovirus infection	3	0
<i>Dental and oral soft tissue infections</i>		
Gingivitis	1	0
Parotitis	55	0
Sialoadenitis	2	0
<i>Ear infections</i>		
Ear infection	19	0
Labyrinthitis	2	0
Mastoiditis	1	0
Otitis media	29	0
Otitis media acute	3	0
Otitis media chronic	4	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr viraemia	1	0

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Data Lock Date: 21-Jun-2024 18:30:03

Earliest Reaction Date: 14-May-1987

MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Epstein-Barr virus infection	5	0
Epstein-Barr virus infection reactivation	1	0
Infectious mononucleosis	1	0
Eye and eyelid infections		
Conjunctivitis	69	0
Eye infection	5	0
Retinitis	1	0
Fungal infections NEC		
Fungal infection	1	0
Haemophilus infections		
Haemophilus sepsis	1	0
Herpes viral infections		
Herpes simplex	2	0
Herpes zoster	6	0
Human herpesvirus 6 infection	4	0
Human herpesvirus 6 infection reactivation	1	0
Human herpesvirus 7 infection	1	0
Oral herpes	2	0
Varicella	9	0
Varicella zoster virus infection	1	0
Infections NEC		
Abscess	3	0
Abscess limb	1	0
Infection	7	0
Infection susceptibility increased	1	0
Injection site abscess	2	0
Injection site infection	2	0
Localised infection	2	0
Toxic shock syndrome	1	0
Vaccination site infection	6	0
Infectious transmissions		
Infection transmission via personal contact	1	0
Infection via vaccinee	2	0
Transmission of an infectious agent via product	1	0
Inflammatory disorders following infection		
Subacute sclerosing panencephalitis	2	0
Influenza viral infections		
H1N1 influenza	1	0
Influenza	5	0
Lower respiratory tract and lung infections		
Atypical pneumonia	1	0
Bronchitis	5	0
Lower respiratory tract infection	17	0
Pneumonia	15	1
Male reproductive tract infections		
Epididymitis	1	0
Orchitis	11	0
Mumps viral infections		
Encephalitis mumps	2	0
Meningitis mumps	5	0
Mumps	214	1
Orchitis mumps	1	0
Neisseria infections		

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Earliest Reaction Date: 14-May-1987

MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Meningitis meningococcal	3	0
Meningococcal sepsis	3	1
<i>Pneumocystis infections</i>		
Pneumocystis jirovecii pneumonia	1	0
<i>Respiratory syncytial viral infections</i>		
Respiratory syncytial virus infection	2	0
<i>Rubella viral infections</i>		
Encephalomyelitis rubella	1	0
Rubella	13	0
<i>Rubeola viral infections</i>		
Measles	256	0
Measles post vaccine	12	0
Pneumonia measles	1	1
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	6	1
Sepsis neonatal	1	0
Septic shock	2	0
Urosepsis	1	1
Viraemia	1	0
<i>Skin structures and soft tissue infections</i>		
Eczema infected	2	0
Pustule	1	0
Pyoderma	1	0
Skin infection	2	0
Subcutaneous abscess	1	0
Vaccination site pustule	1	0
<i>Staphylococcal infections</i>		
Staphylococcal abscess	1	0
<i>Streptococcal infections</i>		
Pneumonia pneumococcal	1	0
Scarlet fever	1	0
Streptococcal infection	1	0
<i>Tuberculous infections</i>		
Erythema induratum	8	0
Meningitis tuberculous	1	0
Tuberculosis	1	0
<i>Upper respiratory tract infections</i>		
Croup infectious	7	0
Epiglottitis	2	0
Nasopharyngitis	31	0
Pharyngitis	14	0
Rhinitis	24	0
Sinusitis	1	0
Tonsillitis	17	0
Upper respiratory tract infection	11	0
<i>Urinary tract infections</i>		
Urinary tract infection	6	0
<i>Vascular infections</i>		
Haematoma infection	1	0
<i>Viral infections NEC</i>		
Bronchiolitis	3	0
Ear infection viral	1	0
Encephalitis viral	2	0

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Earliest Reaction Date: 14-May-1987

MedDRA Version: MedDRA 27.0

Reaction Name		Total	Fatal
Infections	Infections cont'd		
Gastroenteritis viral		1	0
Gianotti-Crosti syndrome		2	0
Meningitis viral		15	0
Pneumonia viral		1	0
Vestibular neuronitis		1	0
Viral infection		15	0
Viral myocarditis		2	1
Viral rash		7	0
Viral tonsillitis		1	0
Viral upper respiratory tract infection		2	0
Infections SOC TOTAL		1297	12

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Earliest Reaction Date: 14-May-1987

MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
Injuries		
<i>Accidental exposures to product</i>		
Accidental exposure to product	2	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	67	0
Exposure via breast milk	2	0
Foetal exposure during pregnancy	39	0
Maternal exposure before pregnancy	15	0
Maternal exposure timing unspecified	3	0
<i>Eye injuries NEC</i>		
Eye contusion	1	0
<i>Limb fractures and dislocations</i>		
Foot fracture	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Inadequate aseptic technique in use of product	2	0
Medication error	19	0
Product use in unapproved indication	3	0
Vaccination error	3	0
Wrong technique in product usage process	2	0
<i>Nerve injuries NEC</i>		
Nerve injury	2	0
<i>Non-site specific injuries NEC</i>		
Fall	7	0
Injury	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>		
Booster dose missed	2	0
Contraindicated product administered	1	0
Expired product administered	1	0
Extra dose administered	3	0
Inappropriate schedule of product administration	12	0
Incomplete course of vaccination	3	0
Incorrect dose administered	2	0
Incorrect dose administered by product	1	0
Product administered at inappropriate site	2	0
Product administered to patient of inappropriate age	2	0
Product administration error	1	0
Wrong patient received product	1	0
Wrong product administered	5	0
<i>Product monitoring errors and issues</i>		
Labelled drug-disease interaction medication error	2	0
Labelled drug-drug interaction medication error	1	0
<i>Product storage errors and issues in the product use system</i>		
Product storage error	1	0
<i>Reproductive system and breast injuries</i>		
Perineal injury	2	0
<i>Site specific injuries NEC</i>		

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Earliest Reaction Date: 14-May-1987

MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Central nervous system injury	1	0
Head injury	1	0
Skin injuries NEC		
Contusion	44	0
Scar	2	0
Skin laceration	2	0
Vaccination related complications		
Immunisation reaction	3	0
Vaccination complication	1	0
Injuries SOC TOTAL	269	0

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Reaction Name	Total	Fatal
Investigations		
<i>Autoimmunity analyses</i>		
Rheumatoid factor increased	1	0
<i>Blood gas and acid base analyses</i>		
Carbon dioxide increased	1	0
Oxygen saturation decreased	3	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose decreased	3	0
Blood glucose fluctuation	1	0
Blood glucose increased	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	6	0
<i>Cerebrospinal fluid tests (excl microbiology)</i>		
CSF cell count increased	1	0
CSF test abnormal	1	0
<i>Digestive enzymes</i>		
Amylase increased	1	0
<i>Foetal and neonatal diagnostic procedures</i>		
Foetal heart rate decreased	2	0
Foetal monitoring abnormal	3	0
<i>Haematological analyses NEC</i>		
Red blood cell sedimentation rate increased	3	0
<i>Heart rate and pulse investigations</i>		
Heart rate abnormal	2	0
Heart rate decreased	10	0
Heart rate increased	12	0
Heart rate irregular	5	0
Pulse abnormal	5	0
Radial pulse abnormal	1	0
<i>Hepatobiliary function diagnostic procedures</i>		
Liver function test abnormal	2	0
<i>Immunoglobulin analyses</i>		
Blood immunoglobulin G increased	1	0
<i>Immunology analyses NEC</i>		
Antibody test negative	1	0
Immunology test abnormal	1	0
<i>Immunology skin tests NEC</i>		
Skin test positive	1	0
<i>Investigations NEC</i>		
Blood test abnormal	1	0
Quality of life decreased	1	0
<i>Neurologic diagnostic procedures</i>		
Electroencephalogram abnormal	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	2	0
Body temperature abnormal	2	0
Body temperature decreased	8	0
Body temperature fluctuation	6	0
Body temperature increased	85	0
Breath sounds abnormal	2	0
Grip strength decreased	1	0
Head circumference abnormal	1	0
Head lag	1	0
Respiratory rate decreased	1	0

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MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Respiratory rate increased	7	0
Skin temperature	1	0
Weight decreased	5	0
Weight increased	1	0
Pituitary analyses anterior		
Blood thyroid stimulating hormone increased	1	0
Platelet analyses		
Platelet count abnormal	1	0
Platelet count decreased	10	0
Protein analyses NEC		
C-reactive protein increased	6	0
Red blood cell analyses		
Haemoglobin S	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	1	0
Tissue enzyme analyses NEC		
Blood alkaline phosphatase increased	2	0
Toxicology laboratory analyses		
Blood aluminium increased	1	0
Heavy metal increased	1	0
Urinalysis NEC		
Protein urine	1	0
Urinary tract function analyses NEC		
Urine output decreased	2	0
Vascular tests NEC (incl blood pressure)		
Blood pressure decreased	3	0
Blood pressure increased	10	0
Virus identification and serology		
Measles antibody negative	3	0
Measles antibody positive	1	0
Morbillivirus test positive	1	0
Mumps antibody test negative	4	0
Rubella antibody negative	4	0
Rubella antibody positive	1	0
Rubivirus test positive	1	0
Rubulavirus test positive	1	0
White blood cell analyses		
Lymphocyte morphology abnormal	1	0
Investigations SOC TOTAL	251	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	275	0
Diet refusal	1	0
Food refusal	3	0
Hyperphagia	1	0
Hypophagia	6	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	1	0
<i>Cell metabolism disorders NEC</i>		
Mitochondrial cytopathy	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	11	0
Type 1 diabetes mellitus	6	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	1	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	8	0
<i>Fluid intake increased</i>		
Polydipsia	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Dairy intolerance	3	0
Food intolerance	7	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	5	0
Failure to thrive	1	0
Feeding disorder	7	0
Food aversion	3	0
Poor feeding infant	6	0
Weight gain poor	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	2	0
<i>Iron deficiencies</i>		
Iron deficiency	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Metabolic acidosis	3	0
<i>Metabolic disorders NEC</i>		
Metabolic disorder	1	0
<i>Protein metabolism disorders NEC</i>		
Hyperammonaemia	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	4	0
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	1	0
<i>Total fluid volume decreased</i>		
Dehydration	8	0
<i>Total fluid volume increased</i>		
Fluid retention	2	0
Metabolic disorders SOC TOTAL	371	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	21	0
Arthropathy	9	0
<i>Bone disorders NEC</i>		
Exostosis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	2	0
Pain in jaw	3	0
Pubic pain	1	0
<i>Connective tissue disorders NEC</i>		
Myofascitis	1	0
Polymyalgia rheumatica	1	0
<i>Extremity deformities</i>		
Foot deformity	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	125	0
Joint effusion	1	0
Joint noise	2	0
Joint stiffness	11	0
Joint swelling	23	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	1	0
<i>Muscle pains</i>		
Myalgia	44	0
<i>Muscle related signs and symptoms NEC</i>		
Diastasis recti abdominis	1	0
Muscle atrophy	1	0
Muscle fatigue	1	0
Muscle spasms	7	0
Muscle tightness	1	0
Muscle twitching	15	0
<i>Muscle tone abnormalities</i>		
Floppy infant	8	0
Muscle rigidity	6	0
Nuchal rigidity	1	0
Torticollis	1	0
Trismus	2	0
<i>Muscle weakness conditions</i>		
Muscular weakness	30	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Growth retardation	1	0
Limb mass	1	0
Mobility decreased	3	0
Musculoskeletal stiffness	25	0
Posture abnormal	3	0
Toe walking	1	0
Weight bearing difficulty	16	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	19	0
Limb discomfort	7	0
Musculoskeletal chest pain	2	0
Musculoskeletal pain	1	0
Neck pain	17	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Pain in extremity	81	0
<i>Osteoarthropathies</i>		
Osteoarthritis	2	0
<i>Rheumatoid arthropathies</i>		
Juvenile idiopathic arthritis	5	0
Rheumatoid arthritis	2	0
<i>Soft tissue disorders NEC</i>		
Groin pain	2	0
<i>Spondyloarthropathies</i>		
Arthritis reactive	2	0
Muscle & tissue disorders SOC TOTAL	511	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Cardiovascular neoplasms benign</i>		
Haemangioma	1	0
<i>Hepatoblastomas</i>		
Hepatoblastoma	1	0
<i>Leukaemias acute lymphocytic</i>		
Acute lymphocytic leukaemia	1	0
<i>Reproductive neoplasms female benign NEC</i>		
Benign hydatidiform mole	1	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Neoplasm skin	1	0
Neoplasms SOC TOTAL	5	0

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MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	1	0
<i>Absence seizures</i>		
Petit mal epilepsy	6	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	6	1
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral infarction	1	0
Cerebrovascular accident	1	0
<i>Central nervous system inflammatory disorders NEC</i>		
Arachnoiditis	1	0
<i>Central nervous system vascular disorders NEC</i>		
Brain hypoxia	1	0
Vertebrobasilar insufficiency	1	0
<i>Choreiform movements</i>		
Chorea	2	0
<i>Coma states</i>		
Coma	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	24	0
Balance disorder	20	0
Cerebellar ataxia	1	0
Cerebellar syndrome	1	0
Coordination abnormal	10	0
Dysstasia	4	0
Hand-eye coordination impaired	1	0
Nystagmus	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	23	0
Dyslexia	1	0
Dyspraxia	3	0
Sensory processing disorder	3	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	2	0
Consciousness fluctuating	2	0
Depressed level of consciousness	9	0
Lethargy	114	0
Loss of consciousness	35	0
Somnolence	79	0
Syncope	109	0
<i>Dyskinesias and movement disorders NEC</i>		
Akinesia	2	0
Clumsiness	2	0
Dyskinesia	13	0
Extrapyramidal disorder	1	0
Fine motor delay	1	0
Fine motor skill dysfunction	1	0
Hyperkinesia	1	0
Hypokinesia	8	0
Movement disorder	2	0
Psychomotor hyperactivity	16	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Dystonias</i>		
Opisthotonus	3	0
<i>Encephalitis NEC</i>		
Noninfective encephalitis	2	0
<i>Encephalopathies NEC</i>		
Encephalopathy	29	0
Encephalopathy neonatal	1	0
Hypoxic-ischaemic encephalopathy	1	0
Opsoclonus myoclonus	1	0
<i>Eye movement disorders</i>		
Vlth nerve paralysis	3	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	6	0
Facial paralysis	8	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	27	0
<i>Headaches NEC</i>		
Headache	118	0
Sinus headache	2	0
<i>Hydrocephalic conditions</i>		
Hydrocephalus	2	0
<i>Increased intracranial pressure disorders</i>		
Brain oedema	1	1
Vasogenic cerebral oedema	1	0
<i>Intellectual disabilities</i>		
Intellectual disability	2	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	4	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	6	0
Disturbance in attention	11	0
Mental impairment	4	0
<i>Migraine headaches</i>		
Migraine	9	0
<i>Mixed cranial nerve disorders</i>		
Bulbar palsy	1	0
<i>Mononeuropathies</i>		
Mononeuropathy multiplex	1	0
<i>Muscle tone abnormal</i>		
Hypotonia	44	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	4	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	7	0
<i>Nervous system disorders NEC</i>		
Cerebral disorder	1	0
Nervous system disorder	7	0
Neurodegenerative disorder	1	0
Psychomotor skills impaired	1	0
<i>Neurological signs and symptoms NEC</i>		
Brain fog	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Decorticate posture	1	0
Dizziness	54	0
Dizziness postural	2	0
Drooling	4	0
Exaggerated startle response	1	0
Head discomfort	3	0
Hyporesponsive to stimuli	2	0
Inability to crawl	6	0
Infant irritability	4	0
Meningism	8	0
Myoclonus	6	0
Neurological decompensation	2	0
Neurological symptom	3	0
Pleocytosis	1	0
Presyncope	11	0
Slow response to stimuli	1	0
Unresponsive to stimuli	33	0
Neuromuscular disorders NEC		
Hypotonic-hyporesponsive episode	4	0
Muscle spasticity	1	0
Neuromyopathy	1	0
Olfactory nerve disorders		
Anosmia	1	0
Parosmia	1	0
Optic nerve disorders NEC		
Optic neuritis	1	0
Paraesthesias and dysaesthesias		
Burning sensation	3	0
Dysaesthesia	1	0
Hyperaesthesia	2	0
Hypoaesthesia	17	0
Paraesthesia	27	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	1	0
Hemiparesis	10	0
Hemiplegia	2	0
Monoplegia	3	0
Paralysis	11	0
Paresis	2	0
Partial complex seizures		
Focal dyscognitive seizures	3	0
Temporal lobe epilepsy	2	0
Peripheral neuropathies NEC		
Neuralgic amyotrophy	1	0
Neuropathy peripheral	4	0
Polyneuropathy	3	0
Seizures and seizure disorders NEC		
Convulsion in childhood	1	0
Epilepsy	32	0
Febrile convulsion	207	0
Frontal lobe epilepsy	1	0
Idiopathic generalised epilepsy	2	0
Myoclonic epilepsy	1	0

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Report Run Date: 25-Jun-2024

Data Lock Date: 21-Jun-2024 18:30:03

Earliest Reaction Date: 14-May-1987

MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Neonatal seizure	1	0
Partial seizures	11	0
Seizure	304	0
Seizure anoxic	3	0
Seizure cluster	1	0
Seizure like phenomena	2	0
Status epilepticus	9	0
Tonic convulsion	2	0
Sensory abnormalities NEC		
Dysgeusia	3	0
Hypogeusia	1	0
Neuralgia	3	0
Restless legs syndrome	1	0
Sensory disturbance	5	0
Sensory loss	5	0
Sleep disturbances NEC		
Sleep deficit	1	0
Speech and language abnormalities		
Dysarthria	3	0
Repetitive speech	1	0
Slow speech	1	0
Speech disorder	18	0
Speech disorder developmental	17	0
Structural brain disorders NEC		
Brain injury	7	0
Cerebral atrophy	2	0
Tremor (excl congenital)		
Tremor	38	0
Nervous system disorders SOC TOTAL	1747	2

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Earliest Reaction Date: 14-May-1987

MedDRA Version: MedDRA 27.0

Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortion related conditions and complications</i>		
Anembryonic gestation	1	0
<i>Abortions not specified as induced or spontaneous</i>		
Abortion missed	2	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	39	0
Abortion threatened	2	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	6	0
<i>Foetal position and presentation abnormalities</i>		
Breech presentation	4	0
Face presentation	1	0
High foetal head	1	0
<i>Gestational age and weight conditions</i>		
Low birth weight baby	1	0
Premature baby	7	0
<i>Haemorrhagic complications of pregnancy</i>		
Premature separation of placenta	2	0
<i>High risk pregnancies</i>		
High risk pregnancy	1	0
<i>Hypertension associated disorders of pregnancy</i>		
Gestational hypertension	1	0
Pre-eclampsia	4	0
<i>Labour onset and length abnormalities</i>		
Premature delivery	3	0
Premature labour	2	0
Premature rupture of membranes	1	0
Prolonged labour	9	0
<i>Maternal complications of delivery NEC</i>		
Breech delivery	1	0
<i>Maternal complications of labour NEC</i>		
Labour complication	5	0
<i>Maternal complications of pregnancy NEC</i>		
Complication of pregnancy	1	0
Morning sickness	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 newborn status</i>		
Normal newborn	1	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	2	0
Pregnancy	4	0
<i>Postpartum complications NEC</i>		

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Reaction Name	Total	Fatal
Pregnancy conditions		
Pregnancy conditions cont'd		
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	3	3
<i>Unintended pregnancies</i>		
Unintended pregnancy	1	0
Pregnancy conditions SOC TOTAL	119	4

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Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device connection issue	1	0
<i>Device physical property and chemical issues</i>		
Needle issue	1	0
Syringe issue	2	0
<i>Product quality issues NEC</i>		
Product complaint	3	0
Product quality issue	1	0
null SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	33	0
Behaviour disorder	11	0
Breath holding	2	0
Regressive behaviour	1	0
Staring	7	0
<i>Affect alterations NEC</i>		
Affect lability	3	0
Flat affect	1	0
<i>Anxiety disorders NEC</i>		
Separation anxiety disorder	1	0
<i>Anxiety symptoms</i>		
Agitation	11	0
Anxiety	15	0
Nervousness	6	0
Stress	1	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	9	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	15	0
Antisocial behaviour	2	0
Attention-seeking behaviour	1	0
Personality change	10	0
Self-destructive behaviour	1	0
Social avoidant behaviour	11	0
<i>Communications disorders</i>		
Communication disorder	3	0
Mutism	2	0
<i>Confusion and disorientation</i>		
Confusional state	13	0
Disorientation	14	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	7	0
<i>Depressive disorders</i>		
Depression	12	0
<i>Dissociative states</i>		
Dissociation	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	55	0
Middle insomnia	3	0
<i>Dyssomnias</i>		
Poor quality sleep	7	0
<i>Eating disorders NEC</i>		
Eating disorder	3	0
Selective eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	2	0
Dysphoria	1	0
Emotional disorder	3	0
Emotional distress	17	0
Frustration tolerance decreased	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Irritability	155	0
Mood altered	5	0
Morose	1	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	3	0
Social anxiety disorder	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	10	0
Hallucination, visual	3	0
<i>Increased physical activity levels</i>		
Restlessness	19	0
<i>Infancy, childhood and adolescence psychiatric disorders NEC</i>		
Social (pragmatic) communication disorder	1	0
<i>Learning disorders</i>		
Learning disability	3	0
Learning disorder	3	0
<i>Mental disorders NEC</i>		
Mental disorder	6	0
Mental status changes	2	0
<i>Mood alterations with depressive symptoms</i>		
Anhedonia	1	0
Decreased interest	2	0
Depressed mood	12	0
Tearfulness	12	0
<i>Mood disorders NEC</i>		
Affective disorder	1	0
Apathy	3	0
Listless	9	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Body dysmorphic disorder	1	0
Obsessive-compulsive disorder	1	0
Obsessive-compulsive symptom	1	0
Trichotillomania	1	0
<i>Panic attacks and disorders</i>		
Panic attack	4	0
<i>Parasomnias</i>		
Abnormal dreams	1	0
Nightmare	4	0
Sleep terror	4	0
<i>Perception disturbances NEC</i>		
Time perception altered	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	142	1
<i>Psychiatric symptoms NEC</i>		
Decreased eye contact	8	0
<i>Psychotic disorder NEC</i>		
Psychotic disorder	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	30	0
<i>Somatic symptom disorders</i>		
Conversion disorder	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Speech articulation and rhythm disturbances</i>		
Lack of spontaneous speech	1	0
<i>Stereotypies and automatisms</i>		
Bruxism	1	0
Head banging	7	0
Posturing	1	0
Stereotypy	2	0
<i>Suicidal and self-injurious behaviour</i>		
Intentional self-injury	1	0
Self-injurious ideation	1	0
<i>Thinking disturbances</i>		
Intrusive thoughts	1	0
Thinking abnormal	1	0
<i>Tic disorders</i>		
Tic	2	0
Psychiatric disorders SOC TOTAL	758	1

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Dysuria	1	0
Incontinence	3	0
Micturition disorder	1	0
Micturition frequency decreased	1	0
Pollakiuria	1	0
Urinary incontinence	12	0
Urinary retention	2	0
<i>Bladder disorders NEC</i>		
Bladder disorder	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Nephrotic syndrome	7	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	1	0
<i>Nephritis NEC</i>		
Tubulointerstitial nephritis	1	0
<i>Nephropathies and tubular disorders NEC</i>		
Renal tubular disorder	2	0
<i>Renal failure and impairment</i>		
Oliguria	1	0
Renal impairment	1	0
Renal injury	1	0
<i>Renal structural abnormalities and trauma</i>		
Pyelocaliectasis	1	0
<i>Renal vascular and ischaemic conditions</i>		
Renal tubular necrosis	1	0
<i>Urinary abnormalities</i>		
Chromaturia	1	0
Haematuria	5	0
Proteinuria	2	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	3	0
Renal & urinary disorders SOC TOTAL	49	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast infections and inflammations</i>		
Nipple inflammation	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Erectile dysfunction	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Menstrual disorder	1	0
<i>Menstruation with decreased bleeding</i>		
Menstruation delayed	2	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	2	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital rash	2	0
Genital swelling	1	0
Oedema genital	1	0
Pelvic pain	2	0
<i>Scrotal disorders NEC</i>		
Scrotal swelling	2	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	4	0
Testicular swelling	9	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	7	0
<i>Vulvovaginal signs and symptoms</i>		
Vulvovaginal discomfort	1	0
Reproductive & breast disorders SOC TOTAL	36	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	2	0
Apnoeic attack	3	0
Dyspnoea	51	0
Hyperventilation	3	0
Hypopnoea	9	0
Irregular breathing	1	0
Obstructive sleep apnoea syndrome	1	0
Respiration abnormal	4	0
Respiratory arrest	16	1
Respiratory depression	1	0
Respiratory distress	6	0
Sleep apnoea syndrome	3	0
Tachypnoea	2	0
<i>Bronchospasm and obstruction</i>		
Asthma	16	1
Bronchospasm	11	0
Wheezing	26	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	2	0
Cyanosis central	3	0
Hypoxia	3	0
Respiratory gas exchange disorder	1	0
<i>Coughing and associated symptoms</i>		
Cough	127	0
Haemoptysis	2	0
Productive cough	3	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	8	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Alveolitis	1	0
Lower respiratory tract inflammation	1	0
Pneumonitis	5	0
Pneumonitis aspiration	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	1	0
Pulmonary haemorrhage	1	0
Rales	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	17	0
<i>Nasal disorders NEC</i>		
Epistaxis	22	0
<i>Neonatal hypoxic conditions</i>		
Neonatal respiratory distress syndrome	3	0
<i>Newborn respiratory disorders NEC</i>		
Bronchopulmonary dysplasia	1	0
Transient tachypnoea of the newborn	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	2	0
<i>Parenchymal lung disorders NEC</i>		
Interstitial lung disease	2	1
Lung consolidation	1	0
Organising pneumonia	1	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Pulmonary alveolar haemorrhage	1	0
Pulmonary fibrosis	1	0
Pharyngeal disorders (excl infections and neoplasms)		
Pharyngeal disorder	1	0
Pharyngeal erythema	8	0
Pharyngeal inflammation	2	0
Pharyngeal paraesthesia	1	0
Pharyngeal swelling	10	0
Pharyngeal ulceration	1	0
Tonsillar hypertrophy	6	0
Tonsillar inflammation	2	0
Velopharyngeal incompetence	2	0
Pleural conditions NEC		
Pleural adhesion	1	0
Pneumothorax and pleural effusions NEC		
Pleural effusion	3	0
Pulmonary oedemas		
Acute lung injury	1	0
Acute pulmonary oedema	1	0
Acute respiratory distress syndrome	4	1
Pulmonary congestion	1	0
Pulmonary oedema	2	0
Pulmonary thrombotic and embolic conditions		
Pulmonary embolism	1	0
Respiratory failures (excl neonatal)		
Acute respiratory failure	1	0
Respiratory failure	6	2
Respiratory tract disorders NEC		
Aspiration	1	1
Respiratory disorder	3	0
Respiratory tract irritation	1	0
Respiratory tract oedema	1	0
Upper respiratory tract signs and symptoms		
Aphonia	3	0
Catarrh	4	0
Choking	1	0
Dry throat	1	0
Dysphonia	1	0
Increased viscosity of upper respiratory secretion	1	0
Nasal discharge discolouration	1	0
Oropharyngeal discomfort	2	0
Oropharyngeal pain	56	0
Rhinorrhoea	59	0
Sinus pain	1	0
Sneezing	3	0
Snoring	2	0
Throat irritation	1	0
Throat tightness	3	0
Upper-airway cough syndrome	2	0
Yawning	1	0
Vascular pulmonary disorders NEC		
Pulmonary arteriopathy	2	0
Respiratory disorders SOC TOTAL	571	7

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	2	0
<i>Angioedemas</i>		
Angioedema	23	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	25	0
Hyperhidrosis	30	0
Miliaria	1	0
Night sweats	4	0
<i>Bullous conditions</i>		
Blister	25	0
Blood blister	2	0
Dermatitis bullous	13	0
Erythema multiforme	68	0
Stevens-Johnson syndrome	3	0
Toxic epidermal necrolysis	1	0
<i>Connective tissue disorders</i>		
Dermatomyositis	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	5	0
Pain of skin	2	0
Papule	16	0
Scab	4	0
Skin burning sensation	2	0
Skin discolouration	13	0
Skin disorder	2	0
Skin fissures	1	0
Skin induration	5	0
Skin lesion	5	0
Skin necrosis	1	0
Skin reaction	3	0
Skin tightness	4	0
Skin warm	25	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	21	0
Dermatitis atopic	3	0
Dermatitis contact	1	0
Dermatitis diaper	7	0
Eczema	34	0
Eczema infantile	3	0
Eczema weeping	1	0
Seborrhoeic dermatitis	1	0
<i>Dermatitis ascribed to specific agent</i>		
Drug reaction with eosinophilia and systemic symptoms	1	0
Toxic skin eruption	1	0
<i>Erythemas</i>		
Erythema	133	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	1	0
Skin exfoliation	10	0
<i>Hyperkeratoses</i>		
Hyperkeratosis	2	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Hypopigmentation disorders</i>		
Vitiligo	2	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail discolouration	1	0
<i>Panniculitides</i>		
Erythema nodosum	1	0
<i>Papulosquamous conditions</i>		
Erythema annulare	1	0
Lichen sclerosus	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	1	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	1	0
<i>Pilar disorders NEC</i>		
Hair disorder	1	0
<i>Pruritus NEC</i>		
Pruritus	64	0
<i>Psoriatic conditions</i>		
Guttate psoriasis	1	0
<i>Purpura and related conditions</i>		
Ecchymosis	1	0
Henoch-Schonlein purpura	12	0
Petechiae	25	0
Purpura	14	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	574	0
Rash erythematous	48	0
Rash macular	50	0
Rash maculo-papular	46	0
Rash morbilliform	163	0
Rash papular	23	0
Rash pruritic	19	0
Rash rubelliform	11	0
Rash scarlatiniform	1	0
Rash vesicular	8	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Skin ulcer	1	0
<i>Skin injuries and mechanical dermatoses</i>		
Decubitus ulcer	1	0
<i>Skin vasculitides</i>		
Nodular vasculitis	1	0
Vasculitic rash	2	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	4	0
<i>Urticarias</i>		
Urticaria	105	0
Skin disorders SOC TOTAL	1690	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Bedridden	1	0
Immobile	5	0
Impaired work ability	2	0
Mental disability	2	0
Physical disability	1	0
Walking disability	2	0
<i>Educational issues</i>		
Educational problem	1	0
<i>Family and partner issues</i>		
Multiple birth sibling	2	0
<i>Social issues NEC</i>		
Contraindication to vaccination	5	0
Social circumstances SOC TOTAL	21	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Blood and blood product treatment</i>		
Transfusion	1	0
<i>Induced abortions</i>		
Abortion induced	6	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	20	0
Episiotomy	1	0
Forceps delivery	1	0
Labour induction	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
Surgical & medical procedures SOC TOTAL	36	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Accelerated hypertension	1	0
<i>Arterial infections and inflammations</i>		
Arteritis	1	0
Giant cell arteritis	1	0
Kawasaki's disease	9	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	17	0
Peripheral circulatory failure	1	0
Shock	6	0
<i>Haemorrhages NEC</i>		
Haemorrhage	8	0
<i>Non-site specific vascular disorders NEC</i>		
Vasodilatation	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	57	0
Flushing	10	0
Hot flush	4	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	8	0
Poor peripheral circulation	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	118	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	7	0
<i>Vascular hypotensive disorders</i>		
Hypotension	7	0
<i>Vasculitides NEC</i>		
Vasculitis	2	0
Vascular disorders SOC TOTAL	260	0
TOTAL REACTIONS FOR DRUG	12880	53
TOTAL REPORTS	4526	
TOTAL FATAL OUTCOME REPORTS		53