

# Case Series Drug Analysis Print

**Name: MMR**

Report Run Date: 19-Feb-2014  
Data Lock Date: 18-Feb-2014 01:01:22  
Earliest Reaction Date: 14-May-1987  
MedDRA Version: MedDRA 16.1  
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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<b>Anaemias NEC</b>		
Anaemia	2	0
<b>Anaemias haemolytic mechanical factor</b>		
Haemolytic uraemic syndrome	2	0
<b>Bleeding tendencies</b>		
Increased tendency to bruise	2	0
<b>Coagulopathies</b>		
Antiphospholipid syndrome	1	0
Coagulopathy	1	0
Disseminated intravascular coagulation	1	0
<b>Haematological disorders</b>		
Histiocytosis haematophagic	1	1
<b>Leukocytoses NEC</b>		
Leukocytosis	1	0
Monocytosis	1	0
<b>Leukopenias NEC</b>		
Leukopenia	1	0
<b>Lymphatic system disorders NEC</b>		
Lymphadenitis	1	0
Lymphadenopathy	158	0
Lymphoid tissue hyperplasia	1	0
<b>Marrow depression and hypoplastic anaemias</b>		
Aplasia pure red cell	1	0
Aplastic anaemia	1	0
Bone marrow failure	1	0
Pancytopenia	1	0
<b>Neutropenias</b>		
Neutropenia	3	0
<b>Polycythaemia (excl rubra vera)</b>		
Polycythaemia	1	0
<b>Spleen disorders</b>		
Splenomegaly	2	0
<b>Thrombocytopenias</b>		
Autoimmune thrombocytopenia	3	0
Idiopathic thrombocytopenic purpura	53	0
Thrombocytopenia	43	0
Thrombocytopenic purpura	6	0
Thrombotic thrombocytopenic purpura	8	0
<b>Blood disorders SOC TOTAL</b>	<b>296</b>	<b>1</b>

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<b>Cardiac disorders</b>		
<i>Cardiac disorders NEC</i>		
Cardiac disorder	2	0
<i>Cardiac signs and symptoms NEC</i>		
Cyanosis	44	0
Palpitations	4	0
<i>Heart failures NEC</i>		
Cardiac failure	1	1
Cardiopulmonary failure	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	5	2
<i>Noninfectious pericarditis</i>		
Pericarditis	1	0
<i>Pulmonary valvular disorders</i>		
Pulmonary valve stenosis	2	0
<i>Rate and rhythm disorders NEC</i>		
Bradycardia	15	0
Tachycardia	8	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	0
Cardio-respiratory arrest	1	1
Ventricular fibrillation	1	0
Ventricular tachycardia	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>87</b>	<b>4</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Anorectal disorders congenital</i>		
Preternatural anus	2	0
<i>Cardiac septal defects congenital</i>		
Atrioventricular septal defect	2	0
<i>Cerebral disorders congenital</i>		
Congenital hydrocephalus	1	0
<i>Chromosomal abnormalities NEC</i>		
Gene mutation	1	0
Mutagenic effect	2	0
<i>Congenital disorders NEC</i>		
Congenital anomaly	1	0
VACTERL syndrome	2	0
<i>Gastric disorders congenital</i>		
Pyloric stenosis	1	0
<i>Great vessel disorders congenital</i>		
Double outlet right ventricle	2	0
<i>Inborn errors of amino acid metabolism</i>		
Phenylketonuria	1	0
<i>Male reproductive tract disorders congenital</i>		
Hydrocele	1	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	2	0
<i>Musculoskeletal and connective tissue disorders of skull congenital</i>		
Plagiocephaly	1	0
<i>Musculoskeletal and connective tissue disorders of spine congenital</i>		
Spine malformation	2	0
<i>Ocular disorders congenital NEC</i>		
Congenital eye disorder	1	0
<i>Pulmonary and bronchial disorders congenital</i>		
Congenital pneumonia	1	0
Pulmonary aplasia	2	0
Pulmonary hypoplasia	2	0
<i>Renal disorders congenital</i>		
Congenital cystic kidney disease	2	0
<i>Skin and subcutaneous tissue disorders congenital NEC</i>		
Congenital skin dimples	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>39</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear discomfort	2	0
Ear pain	12	0
Otorrhoea	1	0
Ototoxicity	1	0
<i>External ear disorders NEC</i>		
Auricular swelling	1	0
<i>Hearing losses</i>		
Deafness	8	0
Deafness bilateral	1	0
Deafness neurosensory	18	0
Deafness transitory	1	0
Deafness unilateral	1	0
Hearing impaired	3	0
Hypoacusis	5	0
Sudden hearing loss	1	0
<i>Inner ear disorders NEC</i>		
Inner ear disorder	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	1	0
Vertigo	4	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane disorder	1	0
<b>Ear disorders SOC TOTAL</b>	<b>62</b>	<b>0</b>

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<b>Endocrine disorders</b>		
<i>Adrenal cortical hyperfunctions</i>		
Cushingoid	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
<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
<i>Cataract conditions</i>		
Cataract	1	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctivitis	43	0
<i>Corneal structural change, deposit and degeneration</i>		
Xerophthalmia	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iridocyclitis	3	0
<i>Lacrimation disorders</i>		
Lacrimation increased	5	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	2	0
Erythema of eyelid	1	0
Eyelid oedema	8	0
<i>Lid, lash and lacrimal structural disorders</i>		
Dacryostenosis acquired	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye pain	10	0
Eye swelling	14	0
Periorbital oedema	13	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	6	0
Eye irritation	1	0
Eye pruritus	2	0
Ocular hyperaemia	9	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	16	0
Ophthalmoplegia	1	0
Strabismus	3	0
<i>Ocular sensation disorders</i>		
Asthenopia	1	0
Photophobia	15	0
<i>Pupil disorders</i>		
Mydriasis	1	0
Pupil fixed	1	0
<i>Retinal, choroid and vitreous infections and inflammations</i>		
Retinitis	1	0
<i>Visual disorders NEC</i>		
Diplopia	2	0
Vision blurred	3	0
Visual impairment	7	0
<b>Eye disorders SOC TOTAL</b>	<b>174</b>	<b>0</b>

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<b>Gastrointestinal disorders</b>		
<i>Acute and chronic pancreatitis</i>		
Pancreatitis acute	1	0
Pancreatitis haemorrhagic	1	0
Pancreatitis necrotising	1	0
<i>Anal and rectal signs and symptoms</i>		
Anal inflammation	1	0
<i>Colitis (excl infective)</i>		
Colitis	2	0
Colitis ulcerative	1	0
Crohn's disease	4	0
Inflammatory bowel disease	3	0
<i>Dental disorders NEC</i>		
Tooth disorder	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	146	0
Diarrhoea haemorrhagic	2	0
Diarrhoea neonatal	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	1	0
<i>Faecal abnormalities NEC</i>		
Faecaloma	2	0
Faeces discoloured	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	5	0
Flatulence	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	36	0
Abdominal pain lower	1	0
Abdominal pain upper	7	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	11	0
Gastrooesophageal reflux disease	2	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	2	0
Gastrointestinal disorder	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Enteritis	1	0
<i>Gastrointestinal necrosis and gangrene (excl gangrenous hernia)</i>		
Gastrointestinal necrosis	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	3	0
Aphagia	2	0
Dysphagia	2	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	1	0
Frequent bowel movements	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intussusception	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	3	0
<i>Gingival pains</i>		

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<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Gingival pain	1	0
<b>Intestinal haemorrhages</b>		
Rectal haemorrhage	1	0
<b>Nausea and vomiting symptoms</b>		
Nausea	45	0
Retching	1	0
Vomiting	271	0
Vomiting projectile	3	0
<b>Non-site specific gastrointestinal haemorrhages</b>		
Gastrointestinal haemorrhage	1	0
Haematemesis	2	0
<b>Oesophagitis (excl infective)</b>		
Oesophagitis	2	0
<b>Oral dryness and saliva altered</b>		
Salivary hypersecretion	2	0
<b>Oral soft tissue disorders NEC</b>		
Chapped lips	3	0
Lip ulceration	1	0
Oral disorder	1	0
<b>Oral soft tissue haemorrhages</b>		
Lip haemorrhage	1	0
Mouth haemorrhage	1	0
<b>Oral soft tissue pain and paraesthesia</b>		
Oral pain	3	0
Paraesthesia oral	9	0
<b>Oral soft tissue signs and symptoms</b>		
Hypoaesthesia oral	3	0
Oral mucosal blistering	2	0
<b>Oral soft tissue swelling and oedema</b>		
Gingival swelling	2	0
Lip swelling	13	0
Oedema mouth	5	0
<b>Salivary gland disorders NEC</b>		
Salivary gland mass	2	0
<b>Salivary gland enlargements</b>		
Parotid gland enlargement	63	0
Salivary gland enlargement	10	0
<b>Stomatitis and ulceration</b>		
Aphthous stomatitis	3	0
Mouth ulceration	13	0
Stomatitis	4	0
<b>Tongue disorders</b>		
Tongue disorder	1	0
Tongue ulceration	4	0
<b>Tongue signs and symptoms</b>		
Glossodynia	1	0
Swollen tongue	4	0
Tongue coated	1	0
Tongue discolouration	2	0
<b>Umbilical hernias</b>		
Umbilical hernia	2	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>733</b>	<b>0</b>

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<b>General disorders</b>		
<i>Adverse effect absent</i>		
No adverse event	1	0
<i>Asthenic conditions</i>		
Asthenia	17	0
Chronic fatigue syndrome	1	0
Fatigue	36	0
Malaise	225	0
<i>Death and sudden death</i>		
Death	5	5
Sudden death	1	1
Sudden infant death syndrome	3	3
<i>Febrile disorders</i>		
Pyrexia	882	0
<i>Feelings and sensations NEC</i>		
Chills	21	0
Feeling abnormal	18	0
Feeling cold	1	0
Feeling hot	31	0
Feeling jittery	1	0
Feeling of body temperature change	3	0
Sensation of pressure	1	0
Thirst	1	0
Thirst decreased	1	0
<i>Gait disturbances</i>		
Abasia	5	0
Gait disturbance	19	0
<i>General signs and symptoms NEC</i>		
Crying	39	0
Developmental delay	22	0
Foaming at mouth	1	0
Glassy eyes	1	0
Ill-defined disorder	1	0
Induration	2	0
Influenza like illness	21	0
Irritability	102	0
Local reaction	74	0
Local swelling	116	0
Swelling	26	0
<i>Inflammations</i>		
Granuloma	1	0
Inflammation	18	0
Vestibulitis	1	0
<i>Injection site reactions</i>		
Injection site abscess sterile	2	0
Injection site bruising	3	0
Injection site cyst	1	0
Injection site discolouration	2	0
Injection site erythema	41	0
Injection site induration	6	0
Injection site inflammation	49	0
Injection site irritation	1	0
Injection site mass	8	0
Injection site oedema	2	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Injection site pain	35	0
Injection site pruritus	5	0
Injection site rash	15	0
Injection site reaction	200	0
Injection site swelling	35	0
Injection site urticaria	1	0
Injection site vesicles	4	0
Injection site warmth	4	0
<b>Interactions</b>		
Drug interaction	2	0
Potentiating drug interaction	1	0
<b>Mass conditions NEC</b>		
Cyst	1	0
Nodule	1	0
<b>Mucosal findings abnormal</b>		
Mucosal haemorrhage	1	0
Mucous membrane disorder	1	0
<b>Oedema NEC</b>		
Face oedema	19	0
Generalised oedema	1	0
Gravitational oedema	1	0
Oedema	14	0
Oedema peripheral	23	0
<b>Pain and discomfort NEC</b>		
Chest discomfort	6	0
Chest pain	7	0
Discomfort	9	0
Pain	36	0
Tenderness	12	0
<b>Product quality issues NEC</b>		
Product quality issue	2	0
<b>Therapeutic and nontherapeutic responses</b>		
Drug ineffective	17	0
No therapeutic response	12	0
<b>Vaccination site reactions</b>		
Vaccination site erythema	1	0
Vaccination site pain	1	0
Vaccination site swelling	1	0
Vaccination site warmth	1	0
<b>General disorders SOC TOTAL</b>	<b>2282</b>	<b>9</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i><b>Cholecystitis and cholelithiasis</b></i>		
Cholecystitis	1	0
<i><b>Cholestasis and jaundice</b></i>		
Jaundice	5	0
<i><b>Hepatic enzymes and function abnormalities</b></i>		
Hepatic function abnormal	2	0
<i><b>Hepatic failure and associated disorders</b></i>		
Hepatic failure	1	0
<i><b>Hepatobiliary signs and symptoms</b></i>		
Hepatomegaly	1	0
Hepatosplenomegaly	1	0
<i><b>Hepatocellular damage and hepatitis NEC</b></i>		
Hepatitis acute	1	0
Reye's syndrome	1	1
<b>Hepatic disorders SOC TOTAL</b>	<b>13</b>	<b>1</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	36	0
Multiple allergies	1	0
Serum sickness-like reaction	1	0
<i><b>Anaphylactic responses</b></i>		
Anaphylactic reaction	71	1
Anaphylactic shock	6	0
Anaphylactoid reaction	11	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
<i><b>Immunodeficiency disorders NEC</b></i>		
Immunodeficiency	1	0
<i><b>Primary immunodeficiency syndromes</b></i>		
Selective IgG subclass deficiency	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>132</b>	<b>1</b>

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<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Diarrhoea infectious	1	0
Gastroenteritis	3	0
<b><i>Bacterial infections NEC</i></b>		
Cellulitis	41	0
Injection site cellulitis	14	0
Meningitis bacterial	3	0
Vaccination site cellulitis	1	0
<b><i>Bone and joint infections</i></b>		
Intervertebral discitis	3	0
<b><i>Borrelial infections</i></b>		
Relapsing fever	2	0
<b><i>Candida infections</i></b>		
Oral candidiasis	2	0
Vulvovaginal candidiasis	1	0
<b><i>Cardiac infections</i></b>		
Pericarditis infective	1	0
<b><i>Central nervous system and spinal infections</i></b>		
Meningitis	49	0
Meningitis aseptic	7	0
Myelitis	1	0
<b><i>Dental and oral soft tissue infections</i></b>		
Parotitis	870	0
Sialoadenitis	2	0
<b><i>Ear infections</i></b>		
Ear infection	12	0
Mastoiditis	1	0
Otitis media	25	0
Otitis media acute	1	0
Otitis media chronic	1	0
<b><i>Epstein-Barr viral infections</i></b>		
Infectious mononucleosis	1	0
<b><i>Eye and eyelid infections</i></b>		
Eye infection	2	0
<b><i>Fungal infections NEC</i></b>		
Fungal skin infection	1	0
<b><i>Haemophilus infections</i></b>		
Haemophilus sepsis	1	0
<b><i>Hepatitis viral infections</i></b>		
Gianotti-Crosti syndrome	2	0
<b><i>Herpes viral infections</i></b>		
Herpes zoster	5	0
Human herpesvirus 6 infection	1	0
Human herpesvirus 7 infection	1	0
Oral herpes	2	0
Varicella	5	0
<b><i>Infections NEC</i></b>		
Abscess	5	0
Infection	5	0
Infection susceptibility increased	1	0
Injection site abscess	5	0
Injection site infection	1	0
Respiratory tract infection	1	0

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<b>Infections</b>		
Infections cont'd		
Toxic shock syndrome	1	0
Vaccination site infection	2	0
<b><i>Influenza viral infections</i></b>		
Influenza	2	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Bronchitis	4	0
Bronchopneumonia	2	1
Lobar pneumonia	1	0
Lower respiratory tract infection	2	0
Pneumonia	8	0
<b><i>Male reproductive tract infections</i></b>		
Orchitis	26	0
<b><i>Molluscum contagiosum viral infections</i></b>		
Molluscum contagiosum	2	0
<b><i>Mumps viral infections</i></b>		
Meningitis mumps	5	0
Mumps	86	0
Orchitis mumps	1	0
<b><i>Neisseria infections</i></b>		
Meningitis meningococcal	3	0
Meningococcal sepsis	3	1
<b><i>Parainfluenzae viral infections</i></b>		
Croup infectious	4	0
<b><i>Parvoviral infections</i></b>		
Erythema infectiosum	1	0
<b><i>Rubella viral infections</i></b>		
Rubella	50	0
<b><i>Rubeola viral infections</i></b>		
Measles	181	0
Measles post vaccine	2	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Sepsis	5	0
Septic shock	1	0
Viraemia	1	0
<b><i>Skin structures and soft tissue infections</i></b>		
Eczema infected	2	0
Pyoderma	1	0
Rash pustular	2	0
Skin infection	2	0
Subcutaneous abscess	1	0
<b><i>Staphylococcal infections</i></b>		
Staphylococcal abscess	1	0
<b><i>Streptococcal infections</i></b>		
Pneumonia pneumococcal	1	0
<b><i>Tuberculous infections</i></b>		
Erythema induratum	7	0
<b><i>Upper respiratory tract infections</i></b>		
Acute tonsillitis	1	0
Laryngitis	1	0
Nasopharyngitis	17	0
Pharyngitis	16	0
Rhinitis	25	0
Tonsillitis	9	0

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<b>Infections</b>		
Infections cont'd		
Upper respiratory tract infection	12	0
<b>Urinary tract infections</b>		
Urinary tract infection	4	0
<b>Viral infections NEC</b>		
Bronchiolitis	2	0
Ear infection viral	1	0
Encephalitis viral	1	0
Gastroenteritis viral	2	0
Meningitis viral	15	0
Pneumonia viral	1	0
Post viral fatigue syndrome	3	0
Viral infection	10	0
Viral myocarditis	2	1
Viral rash	7	0
Viral tonsillitis	1	0
<b>Infections SOC TOTAL</b>	<b>1620</b>	<b>3</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i><b>Exposures associated with pregnancy, delivery and lactation</b></i>		
Exposure during pregnancy	46	0
Foetal exposure during pregnancy	25	0
Maternal exposure before pregnancy	9	0
Maternal exposure timing unspecified	3	0
<i><b>Lower limb fractures and dislocations</b></i>		
Foot fracture	1	0
<i><b>Maladministrations</b></i>		
Expired drug administered	1	0
Inappropriate schedule of drug administration	5	0
Incorrect dose administered	1	0
Wrong drug administered	3	0
<i><b>Medication errors NEC</b></i>		
Vaccination error	1	0
<i><b>Medication monitoring errors</b></i>		
Labelled drug-drug interaction medication error	1	0
<i><b>Nerve injuries NEC</b></i>		
Nerve injury	1	0
<i><b>Non-site specific injuries NEC</b></i>		
Fall	8	0
<i><b>Site specific injuries NEC</b></i>		
Head injury	1	0
<i><b>Skin injuries NEC</b></i>		
Contusion	21	0
Laceration	1	0
<i><b>Vaccination related complications</b></i>		
Vaccination complication	2	0
Vaccination failure	18	0
<b>Injuries SOC TOTAL</b>	<b>148</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	3	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose fluctuation	1	0
Blood glucose increased	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	4	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	2	0
<i>Haematological analyses NEC</i>		
Red blood cell sedimentation rate increased	2	0
<i>Heart rate and pulse investigations</i>		
Heart rate decreased	7	0
Heart rate increased	5	0
Heart rate irregular	5	0
Pulse abnormal	1	0
Pulse pressure decreased	5	0
Radial pulse abnormal	1	0
<i>Immunoglobulin analyses</i>		
Blood immunoglobulin G increased	1	0
<i>Immunology analyses NEC</i>		
Immunology test abnormal	1	0
<i>Immunology skin tests NEC</i>		
Skin test positive	2	0
<i>Investigations NEC</i>		
Blood test abnormal	1	0
Quality of life decreased	1	0
<i>Liver function analyses</i>		
Liver function test abnormal	2	0
<i>Neurologic diagnostic procedures</i>		
Electroencephalogram abnormal	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	1	0
Body temperature decreased	1	0
Body temperature fluctuation	2	0
Body temperature increased	77	0
Breath sounds abnormal	1	0
Grip strength decreased	1	0
Lymph node palpable	1	0
Respiratory rate increased	2	0
Weight decreased	6	0
Weight increased	1	0
<i>Platelet analyses</i>		
Platelet count abnormal	1	0
Platelet count decreased	5	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	5	0

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
<i><b>Skeletal and cardiac muscle analyses</b></i>		
Blood creatine phosphokinase increased	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	9	0
<i><b>Virus identification and serology</b></i>		
Measles antibody negative	2	0
Measles antibody positive	1	0
Mumps antibody test negative	1	0
Rubella antibody negative	5	0
Rubella antibody positive	1	0
<i><b>White blood cell analyses</b></i>		
Lymphocyte morphology abnormal	1	0
<b>Investigations SOC TOTAL</b>	<b>180</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<b><i>Appetite disorders</i></b>		
Decreased appetite	110	0
Diet refusal	1	0
Hyperphagia	1	0
Hypophagia	1	0
<b><i>Cell metabolism disorders NEC</i></b>		
Mitochondrial cytopathy	1	0
<b><i>Diabetes mellitus (incl subtypes)</i></b>		
Diabetes mellitus	9	0
Type 1 diabetes mellitus	3	0
<b><i>Fat soluble vitamin deficiencies and disorders</i></b>		
Vitamin D deficiency	1	0
<b><i>Fluid intake decreased</i></b>		
Fluid intake reduced	5	0
<b><i>Fluid intake increased</i></b>		
Polydipsia	1	0
<b><i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i></b>		
Food intolerance	3	0
<b><i>General nutritional disorders NEC</i></b>		
Failure to thrive	1	0
Feeding disorder	1	0
Feeding disorder of infancy or early childhood	2	0
Weight gain poor	1	0
<b><i>Hypoglycaemic conditions NEC</i></b>		
Hypoglycaemia	1	0
<b><i>Iron deficiencies</i></b>		
Iron deficiency	1	0
<b><i>Metabolic acidoses (excl diabetic acidoses)</i></b>		
Metabolic acidosis	1	0
<b><i>Sodium imbalance</i></b>		
Hyponatraemia	2	0
<b><i>Total fluid volume decreased</i></b>		
Dehydration	6	0
<b><i>Total fluid volume increased</i></b>		
Fluid retention	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>153</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<b><i>Arthropathies NEC</i></b>		
Arthritis	16	0
Arthritis reactive	2	0
Arthropathy	7	0
Monarthritis	1	0
<b><i>Bone disorders NEC</i></b>		
Exostosis	1	0
<b><i>Bone related signs and symptoms</i></b>		
Bone pain	1	0
Pain in jaw	3	0
<b><i>Connective tissue disorders (excl LE)</i></b>		
Myofascitis	1	0
<b><i>Joint related signs and symptoms</i></b>		
Arthralgia	69	0
Joint effusion	1	0
Joint stiffness	2	0
Joint swelling	14	0
<b><i>Lupus erythematosus (incl subtypes)</i></b>		
Systemic lupus erythematosus	1	0
<b><i>Muscle pains</i></b>		
Myalgia	21	0
<b><i>Muscle related signs and symptoms NEC</i></b>		
Diastasis recti abdominis	1	0
Muscle spasms	4	0
Muscle tightness	2	0
Muscle twitching	12	0
<b><i>Muscle tone abnormalities</i></b>		
Floppy infant	1	0
Muscle rigidity	5	0
Torticollis	1	0
Trismus	1	0
<b><i>Muscle weakness conditions</i></b>		
Muscular weakness	8	0
<b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>		
Back pain	15	0
Limb discomfort	3	0
Musculoskeletal chest pain	1	0
Musculoskeletal pain	5	0
Neck pain	15	0
Pain in extremity	35	0
<b><i>Musculoskeletal and connective tissue signs and symptoms NEC</i></b>		
Mobility decreased	1	0
Musculoskeletal stiffness	13	0
Posture abnormal	2	0
Sensation of heaviness	1	0
Weight bearing difficulty	1	0
<b><i>Osteoarthropathies</i></b>		
Osteoarthritis	2	0
<b><i>Rheumatoid arthropathies</i></b>		
Juvenile idiopathic arthritis	4	0
Rheumatoid arthritis	1	0
<b><i>Soft tissue disorders NEC</i></b>		
Neck mass	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders cont'd		
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>275</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Cardiovascular neoplasms benign</i>		
Haemangioma	1	0
<i>Hepatoblastomas</i>		
Hepatoblastoma	1	0
<i>Leukaemias acute lymphocytic</i>		
Acute lymphocytic leukaemia	1	0
<b>Neoplasms SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<b>Absence seizures</b>		
Petit mal epilepsy	4	0
<b>Acute polyneuropathies</b>		
Guillain-Barre syndrome	5	1
Polyneuropathy	2	0
<b>Central nervous system haemorrhages and cerebrovascular accidents</b>		
Cerebrovascular accident	1	0
<b>Choreiform movements</b>		
Chorea	1	0
<b>Coma states</b>		
Coma	1	0
<b>Coordination and balance disturbances</b>		
Ataxia	23	0
Balance disorder	16	0
Cerebellar ataxia	1	0
Cerebellar syndrome	1	0
Coordination abnormal	5	0
Dysstasia	1	0
Nystagmus	1	0
<b>Cortical dysfunction NEC</b>		
Aphasia	5	0
Dyslexia	1	0
Dyspraxia	1	0
<b>Developmental disorders cognitive</b>		
Autism	89	0
<b>Disturbances in consciousness NEC</b>		
Altered state of consciousness	2	0
Depressed level of consciousness	8	0
Lethargy	65	0
Loss of consciousness	24	0
Somnolence	60	0
Syncope	87	0
<b>Dyskinesias and movement disorders NEC</b>		
Akinesia	1	0
Clumsiness	2	0
Dyskinesia	7	0
Hyperkinesia	3	0
Hypokinesia	1	0
Psychomotor hyperactivity	13	0
<b>Dystonias</b>		
Opisthotonus	3	0
<b>Encephalitis NEC</b>		
Encephalitis	29	2
Encephalitis post measles	1	0
Encephalomyelitis	1	0
<b>Encephalopathies NEC</b>		
Encephalopathy	26	0
Hypoxic-ischaemic encephalopathy	1	0
<b>Eye movement disorders</b>		
VIth nerve paralysis	3	0
<b>Facial cranial nerve disorders</b>		
Facial spasm	1	0
VIIth nerve paralysis	11	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
<b>Generalised tonic-clonic seizures</b>		
Grand mal convulsion	24	0
<b>Headaches NEC</b>		
Headache	81	0
<b>Hydrocephalic conditions</b>		
Hydrocephalus	2	0
<b>Increased intracranial pressure disorders</b>		
Brain oedema	1	1
<b>Lumbar spinal cord and nerve root disorders</b>		
Sciatica	1	0
<b>Memory loss (excl dementia)</b>		
Amnesia	1	0
<b>Mental impairment (excl dementia and memory loss)</b>		
Cognitive disorder	3	0
Disturbance in attention	5	0
Mental impairment	1	0
<b>Migraine headaches</b>		
Migraine	3	0
<b>Mixed cranial nerve disorders</b>		
Bulbar palsy	1	0
<b>Mononeuropathies</b>		
Mononeuropathy multiplex	1	0
<b>Muscle tone abnormal</b>		
Hypotonia	31	0
<b>Myelitis (incl infective)</b>		
Myelitis transverse	3	0
<b>Narcolepsy and hypersomnia</b>		
Hypersomnia	2	0
<b>Nervous system disorders NEC</b>		
Cerebral disorder	1	0
Motor dysfunction	1	0
Nervous system disorder	1	0
<b>Neurologic visual problems NEC</b>		
Visual field defect	1	0
<b>Neurological signs and symptoms NEC</b>		
Decorticate posture	1	0
Dizziness	40	0
Dizziness postural	1	0
Drooling	1	0
Head discomfort	1	0
Meningism	8	0
Myoclonus	5	0
Neurological symptom	2	0
Presyncope	21	0
Slow response to stimuli	1	0
Unresponsive to stimuli	18	0
<b>Neuromuscular disorders NEC</b>		
Hypotonic-hyporesponsive episode	1	0
<b>Optic nerve disorders NEC</b>		
Optic neuritis	1	0
<b>Paraesthesias and dysaesthesias</b>		
Dysaesthesia	1	0
Hyperaesthesia	4	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Paraesthesia	24	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Hemiparesis	9	0
Hemiplegia	2	0
Paralysis	2	0
Paralysis flaccid	1	0
Paresis	2	0
<b><i>Partial complex seizures</i></b>		
Complex partial seizures	3	0
Temporal lobe epilepsy	1	0
<b><i>Peripheral neuropathies NEC</i></b>		
Neuralgic amyotrophy	1	0
Neuropathy peripheral	3	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Convulsion	254	0
Convulsion neonatal	1	0
Epilepsy	24	0
Febrile convulsion	160	0
Frontal lobe epilepsy	1	0
Partial seizures	5	0
Seizure anoxic	1	0
Status epilepticus	7	0
Tonic convulsion	1	0
<b><i>Sensory abnormalities NEC</i></b>		
Dysgeusia	2	0
Hypoaesthesia	11	0
Hypogeusia	1	0
Neuralgia	1	0
Sensory disturbance	2	0
Sensory loss	2	0
<b><i>Sleep disturbances NEC</i></b>		
Poor quality sleep	2	0
<b><i>Speech and language abnormalities</i></b>		
Aphonia	2	0
Dysarthria	2	0
Speech disorder	8	0
Speech disorder developmental	11	0
<b><i>Structural brain disorders NEC</i></b>		
Brain injury	3	0
<b><i>Tremor (excl congenital)</i></b>		
Tremor	30	0
<b>Nervous system disorders SOC TOTAL</b>	<b>1356</b>	<b>4</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 not specified as induced or spontaneous</i>		
Abortion missed	2	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	29	0
Abortion threatened	2	0
Imminent abortion	1	0
<i>Foetal complications NEC</i>		
Foetal hypokinesia	1	0
<i>Foetal growth complications</i>		
Foetal growth restriction	5	0
<i>Foetal position and presentation abnormalities</i>		
Breech presentation	2	0
<i>Gestational age and weight conditions</i>		
Low birth weight baby	1	0
Premature baby	6	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	2	0
<i>Labour onset and length abnormalities</i>		
Premature delivery	2	0
Premature labour	2	0
Premature rupture of membranes	1	0
Prolonged labour	6	0
<i>Maternal complications of labour NEC</i>		
Labour complication	5	0
<i>Maternal complications of pregnancy NEC</i>		
Complication of pregnancy	1	0
Vomiting in pregnancy	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>Stillbirth and foetal death</i>		
Foetal death	2	1
Stillbirth	1	1
<i>Unintended pregnancies</i>		
Unintended pregnancy	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>89</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	21	0
Breath holding	2	0
Staring	3	0
<b><i>Affect alterations NEC</i></b>		
Affect lability	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	8	0
Anxiety	12	0
Nervousness	8	0
Stress	1	0
<b><i>Attention deficit and disruptive behaviour disorders</i></b>		
Attention deficit/hyperactivity disorder	2	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	8	0
Antisocial behaviour	1	0
Personality change	2	0
Social avoidant behaviour	2	0
<b><i>Communications disorders</i></b>		
Communication disorder	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	6	0
Disorientation	6	0
<b><i>Decreased physical activity levels</i></b>		
Catatonia	1	0
<b><i>Deliria</i></b>		
Delirium	6	0
<b><i>Depressive disorders</i></b>		
Depression	9	0
<b><i>Dissociative states</i></b>		
Depersonalisation	4	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Initial insomnia	1	0
Insomnia	21	0
Middle insomnia	2	0
<b><i>Eating disorders NEC</i></b>		
Eating disorder	1	0
Food aversion	1	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Emotional disorder	1	0
Emotional distress	6	0
Moaning	1	0
Mood altered	1	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Fear	1	0
<b><i>Fluctuating mood symptoms</i></b>		
Mood swings	1	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	2	0
<b><i>Learning disorders</i></b>		
Learning disorder	3	0
<b><i>Mental disorders NEC</i></b>		
Mental disorder	1	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
<b><i>Mood alterations with depressive symptoms</i></b>		
Decreased interest	1	0
Depressed mood	3	0
Tearfulness	6	0
<b><i>Mood disorders NEC</i></b>		
Apathy	3	0
Listless	7	0
<b><i>Panic attacks and disorders</i></b>		
Panic attack	2	0
<b><i>Parasomnias</i></b>		
Nightmare	1	0
<b><i>Perception disturbances</i></b>		
Hallucination	9	0
Hallucination, visual	2	0
<b><i>Pervasive developmental disorders NEC</i></b>		
Asperger's disorder	3	0
Autism spectrum disorder	1	0
Childhood disintegrative disorder	1	0
<b><i>Psychiatric symptoms NEC</i></b>		
Decreased eye contact	1	0
<b><i>Psychotic disorder NEC</i></b>		
Psychotic disorder	1	0
<b><i>Sleep disorders NEC</i></b>		
Sleep disorder	10	0
<b><i>Somatoform disorders</i></b>		
Conversion disorder	1	0
<b><i>Speech articulation and rhythm disturbances</i></b>		
Dysphemia	2	0
Screaming	51	0
<b><i>Stereotypies and automatisms</i></b>		
Head banging	3	0
Stereotypy	1	0
<b><i>Tic disorders</i></b>		
Tic	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>257</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Enuresis	2	0
Incontinence	3	0
Micturition urgency	1	0
Pollakiuria	2	0
Urinary incontinence	5	0
Urinary retention	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Nephrotic syndrome	6	0
<i>Nephritis NEC</i>		
Tubulointerstitial nephritis	1	0
<i>Renal vascular and ischaemic conditions</i>		
Renal tubular necrosis	1	0
<i>Urinary abnormalities</i>		
Haematuria	5	0
Proteinuria	2	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>30</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Breast disorders NEC</i>		
Breast enlargement	1	0
<i>Breast infections and inflammations</i>		
Thelitis	1	0
<i>Breast signs and symptoms</i>		
Breast swelling	1	0
<i>Cervix neoplasms</i>		
Cervical polyp	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>Penile and scrotal infections and inflammations</i>		
Balanitis	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital pain	1	0
Genital rash	1	0
Oedema genital	1	0
Pelvic pain	1	0
<i>Scrotal disorders NEC</i>		
Scrotal swelling	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	1	0
Testicular pain	5	0
Testicular swelling	14	0
<i>Testicular and epididymal infections and inflammations</i>		
Epididymitis	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	2	0
<i>Vulvovaginal signs and symptoms</i>		
Vulvovaginal discomfort	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>36</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i>Breathing abnormalities</i>		
Apnoea	2	0
Apnoeic attack	2	0
Dyspnoea	40	0
Hyperventilation	2	0
Hypopnoea	9	0
Respiratory arrest	6	0
Respiratory depression	1	0
Respiratory distress	4	0
<i>Bronchospasm and obstruction</i>		
Asthma	15	1
Bronchospasm	11	0
Wheezing	11	0
<i>Conditions associated with abnormal gas exchange</i>		
Cyanosis central	3	0
Respiratory gas exchange disorder	2	0
<i>Coughing and associated symptoms</i>		
Cough	98	0
Haemoptysis	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Stridor	7	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Lower respiratory tract inflammation	1	0
Pneumonitis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	2	0
<i>Nasal disorders NEC</i>		
Epistaxis	12	0
<i>Neonatal hypoxic conditions</i>		
Neonatal respiratory distress syndrome	2	0
<i>Newborn respiratory disorders NEC</i>		
Transient tachypnoea of the newborn	1	0
<i>Parenchymal lung disorders NEC</i>		
Interstitial lung disease	1	1
Pulmonary fibrosis	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	1	0
Pharyngeal oedema	8	0
Tonsillar hypertrophy	2	0
Tonsillar inflammation	1	0
<i>Pulmonary oedemas</i>		
Acute pulmonary oedema	1	0
Pulmonary oedema	1	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	1	1
Respiratory disorder	3	0
<i>Upper respiratory tract signs and symptoms</i>		
Choking	1	0
Dry throat	1	0
Dysphonia	3	0
Nasal discomfort	1	0

# Case Series Drug Analysis Print

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Report Run Date: 19-Feb-2014  
Earliest Reaction Date: 14-May-1987

Data Lock Date: 18-Feb-2014 01:01:22  
MedDRA Version: MedDRA 16.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> Respiratory disorders cont'd		
Oropharyngeal pain	31	0
Rhinorrhoea	37	0
Sneezing	2	0
Throat irritation	1	0
Throat tightness	2	0
<b><i>Vascular pulmonary disorders NEC</i></b>		
Pulmonary arteriopathy	2	0
<b>Respiratory disorders SOC TOTAL</b>	<b>335</b>	<b>3</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	2	0
<b><i>Alopecias</i></b>		
Alopecia	6	0
Alopecia totalis	1	0
<b><i>Angioedemas</i></b>		
Angioedema	19	0
Swelling face	37	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	19	0
Hyperhidrosis	33	0
Miliaria	1	0
Sweat gland disorder	1	0
<b><i>Bullous conditions</i></b>		
Blister	24	0
Blood blister	1	0
Dermatitis bullous	11	0
Erythema multiforme	66	0
Stevens-Johnson syndrome	3	0
Toxic epidermal necrolysis	1	0
<b><i>Connective tissue disorders</i></b>		
Dermatomyositis	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Dry skin	3	0
Pain of skin	1	0
Scab	2	0
Skin discolouration	2	0
Skin disorder	3	0
Skin induration	4	0
Skin lesion	2	0
Skin necrosis	1	0
Skin reaction	16	0
Skin warm	2	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	2	0
Dermatitis allergic	8	0
Dermatitis atopic	3	0
Dermatitis contact	1	0
Dermatitis diaper	4	0
Eczema	52	0
Eczema infantile	2	0
Eczema weeping	1	0
Skin irritation	2	0
<b><i>Dermatitis ascribed to specific agent</i></b>		
Drug reaction with eosinophilia and systemic symptoms	1	0
Toxic skin eruption	1	0
<b><i>Erythemas</i></b>		
Erythema	142	0
Rash erythematous	61	0
<b><i>Exfoliative conditions</i></b>		
Dermatitis exfoliative	3	0
Skin exfoliation	8	0
<b><i>Hyperkeratoses</i></b>		

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Hyperkeratosis	2	0
Lichenoid keratosis	1	0
<b>Hypopigmentation disorders</b>		
Vitiligo	1	0
<b>Nail and nail bed conditions (excl infections and infestations)</b>		
Nail discolouration	1	0
<b>Panniculitides</b>		
Erythema nodosum	5	0
<b>Papulosquamous conditions</b>		
Erythema annulare	1	0
Erythema marginatum	1	0
Pityriasis rosea	1	0
Rash papular	13	0
<b>Photosensitivity and photodermatosis conditions</b>		
Photosensitivity reaction	1	0
<b>Pigmentation changes NEC</b>		
Pigmentation disorder	1	0
<b>Pilar disorders NEC</b>		
Hair disorder	1	0
<b>Pruritus NEC</b>		
Pruritus	49	0
Pruritus generalised	2	0
Rash pruritic	12	0
<b>Psoriatic conditions</b>		
Guttate psoriasis	1	0
<b>Purpura and related conditions</b>		
Ecchymosis	1	0
Henoch-Schonlein purpura	7	0
Petechiae	19	0
Purpura	18	0
<b>Pustular conditions</b>		
Rash follicular	1	0
<b>Rashes, eruptions and exanthems NEC</b>		
Rash	458	0
Rash generalised	66	0
Rash macular	84	0
Rash maculo-papular	108	0
Rash morbilliform	212	0
Rash rubelliform	13	0
Rash vesicular	10	0
<b>Skin and subcutaneous conditions NEC</b>		
Skin mass	1	0
<b>Skin injuries and mechanical dermatoses</b>		
Decubitus ulcer	1	0
<b>Skin vasculitides</b>		
Nodular vasculitis	1	0
Vasculitic rash	1	0
<b>Skin vasomotor conditions</b>		
Livedo reticularis	2	0
<b>Urticarias</b>		
Mechanical urticaria	1	0
Urticaria	270	0
<b>Skin disorders SOC TOTAL</b>	<b>1920</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Disability issues</i>		
Immobile	1	0
Impaired work ability	2	0
Learning disability	2	0
<i>Educational issues</i>		
Educational problem	1	0
<i>Family and partner issues</i>		
Multiple birth sibling	2	0
<b>Social circumstances SOC TOTAL</b>	<b>8</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	5	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	10	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
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>23</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Arterial inflammations</i>		
Arteritis	1	0
Kawasaki's disease	5	0
Temporal arteritis	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	16	0
Peripheral circulatory failure	1	0
Shock	5	0
<i>Haemorrhages NEC</i>		
Haemorrhage	7	0
<i>Non-site specific vascular disorders NEC</i>		
Superficial vein prominence	1	0
Vasodilatation	1	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	23	0
Hot flush	3	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	3	0
<i>Site specific vascular disorders NEC</i>		
Pallor	122	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	3	0
<i>Vascular hypotensive disorders</i>		
Hypotension	5	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>198</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>10453</b>	<b>28</b>
<b>TOTAL REPORTS</b>	<b>5241</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>28</b>