

Case Series Drug Analysis Print

Name: Influenza DAP

Report Run Date: 21-Feb-2014
Data Lock Date: 19-Feb-2014 23:39:39
Earliest Reaction Date: 09-Oct-1963
MedDRA Version: MedDRA 16.1
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Reaction Name	Total	Fatal
Blood disorders		
Anaemias NEC		
Anaemia	8	0
Anaemias haemolytic NEC		
Haemolytic anaemia	5	1
Anaemias haemolytic immune		
Autoimmune haemolytic anaemia	4	0
Anaemias haemolytic mechanical factor		
Microangiopathic haemolytic anaemia	2	0
Bleeding tendencies		
Increased tendency to bruise	2	0
Coagulopathies		
Disseminated intravascular coagulation	3	0
Eosinophilic disorders		
Eosinophilia	5	0
Leukocytoses NEC		
Monocytosis	1	0
Neutrophilia	1	0
Leukopenias NEC		
Lymphopenia	1	0
Lymphatic system disorders NEC		
Lymph node pain	4	0
Lymphadenitis	1	0
Lymphadenopathy	73	0
Marrow depression and hypoplastic anaemias		
Aplastic anaemia	5	2
Pancytopenia	1	0
Neutropenias		
Agranulocytosis	1	1
Autoimmune neutropenia	1	0
Neutropenia	9	0
Spleen disorders		
Splenomegaly	1	0
Thrombocytopenias		
Autoimmune thrombocytopenia	2	0
Idiopathic thrombocytopenic purpura	14	0
Thrombocytopenia	18	0
Thrombocytopenic purpura	3	0
Thrombotic thrombocytopenic purpura	6	0
Thrombocytoses		
Thrombocytosis	2	0
Blood disorders SOC TOTAL	173	4

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block first degree	1	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	1	0
Cardiovascular disorder	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cyanosis	15	0
Palpitations	31	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	1	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	1	0
Coronary artery disease	1	0
Coronary artery thrombosis	5	4
<i>Heart failures NEC</i>		
Cardiac failure	8	2
Cardiac failure congestive	1	0
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	4	3
Angina pectoris	4	0
Myocardial infarction	29	13
Myocardial ischaemia	9	7
<i>Left ventricular failures</i>		
Left ventricular failure	9	2
<i>Myocardial disorders NEC</i>		
Left ventricular hypertrophy	1	1
Ventricular hypertrophy	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	2	0
<i>Noninfectious pericarditis</i>		
Pericarditis	9	0
<i>Pericardial disorders NEC</i>		
Cardiac tamponade	1	0
Pericardial effusion	1	0
Pericardial haemorrhage	1	1
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	3	0
Bradycardia	9	0
Bradycardia foetal	1	0
Extrasystoles	2	0
Tachycardia	40	0
Tachycardia foetal	1	0
Tachycardia paroxysmal	2	0
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	2	0
Atrial fibrillation	16	0
Atrial flutter	1	0
Sinus tachycardia	3	0
Supraventricular tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	12	7
Cardio-respiratory arrest	1	1

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Ventricular fibrillation	2	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	235	42

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Congenital disorders NEC</i>		
Congenital anomaly	1	0
Multiple congenital abnormalities	1	0
<i>Haemoglobinopathies congenital</i>		
Sickle cell anaemia with crisis	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Polydactyly	1	0
Talipes	1	0
<i>Musculoskeletal and connective tissue disorders of skull congenital</i>		
Plagiocephaly	1	0
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital musculoskeletal anomaly	1	0
Dysmorphism	1	0
<i>Neurological disorders congenital NEC</i>		
Spinal muscular atrophy	1	0
<i>Renal and urinary tract disorders congenital NEC</i>		
Urinary tract malformation	1	0
<i>Sex chromosomal abnormalities</i>		
Turner's syndrome	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
Congenital disorders SOC TOTAL	12	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	3	0
Ear pain	19	0
Ear pruritus	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube obstruction	1	0
<i>Hearing losses</i>		
Deafness	9	0
Deafness neurosensory	6	0
Deafness transitory	2	0
Deafness unilateral	4	0
Hearing impaired	5	0
Hypacusis	2	0
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear disorders NEC</i>		
Inner ear disorder	2	0
Meniere's disease	2	0
Vestibular disorder	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	10	0
Vertigo	32	0
Vertigo positional	1	0
Ear disorders SOC TOTAL	101	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Adrenal cortical hypofunctions</i>		
Adrenocortical insufficiency acute	1	0
<i>Adrenal gland disorders NEC</i>		
Adrenal haemorrhage	1	0
<i>Posterior pituitary disorders</i>		
Diabetes insipidus	1	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	1	0
Endocrine disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Blindness (excl colour blindness)</i>		
Blindness	2	0
Blindness transient	3	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Choroidal effusion	1	0
Vitreous floaters	3	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	3	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	4	0
Conjunctival oedema	2	0
Conjunctivitis	17	0
Conjunctivitis allergic	1	0
<i>Corneal infections, oedemas and inflammations</i>		
Corneal oedema	1	0
<i>Corneal structural change, deposit and degeneration</i>		
Corneal deposits	1	0
<i>Glaucomas (excl congenital)</i>		
Glaucoma	2	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iritis	1	0
<i>Lacrimation disorders</i>		
Dry eye	3	0
Lacrimation increased	10	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Erythema of eyelid	1	0
Eyelid oedema	17	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haemorrhage	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	4	0
Eye pain	20	0
Eye swelling	26	0
Ocular icterus	1	0
Periorbital oedema	9	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	2	0
Eye inflammation	1	0
Eye irritation	5	0
Eye pruritus	11	0
Ocular hyperaemia	14	0
<i>Ocular nerve and muscle disorders</i>		
Extraocular muscle disorder	2	0
Eye movement disorder	3	0
Ophthalmoplegia	1	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	1	0
Asthenopia	2	0
Foreign body sensation in eyes	2	0
Photophobia	16	0
<i>Pupil disorders</i>		
Mydriasis	1	0
Pupil fixed	1	0

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Eye disorders Eye disorders cont'd		
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal haemorrhage	1	0
<i>Retinal structural change, deposit and degeneration</i>		
Retinal detachment	1	0
Retinal tear	1	0
<i>Scleral infections, irritations and inflammations</i>		
Scleritis	1	0
<i>Visual disorders NEC</i>		
Diplopia	10	0
Metamorphopsia	1	0
Photopsia	3	0
Vision blurred	28	0
Visual impairment	7	0
Eye disorders SOC TOTAL	248	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	1	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	0
Pancreatitis acute	3	0
Pancreatitis haemorrhagic	1	1
<i>Anal and rectal pains</i>		
Painful defaecation	1	0
<i>Anal and rectal signs and symptoms</i>		
Anorectal discomfort	1	0
<i>Colitis (excl infective)</i>		
Colitis ulcerative	2	0
<i>Dental disorders NEC</i>		
Tooth disorder	1	0
<i>Dental pain and sensation disorders</i>		
Toothache	3	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	121	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	6	0
Eructation	1	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	3	0
Mucous stools	3	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	8	0
Flatulence	5	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	38	0
Abdominal pain lower	7	0
Abdominal pain upper	35	0
Abdominal rigidity	2	0
Abdominal tenderness	2	0
Gastrointestinal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	3	0
Gastrooesophageal reflux disease	1	0
Infrequent bowel movements	1	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	3	0
Gastric disorder	1	0
Gastrointestinal disorder	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
Gastrointestinal motility disorder	3	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	17	0
Aphagia	2	0

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Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Breath odour	1	0
Dysphagia	19	0
Faecal incontinence	2	0
Gastrointestinal spastic and hypermotility disorders		
Defaecation urgency	1	0
Irritable bowel syndrome	3	0
Gastrointestinal stenosis and obstruction NEC		
Intussusception	1	0
Gingival disorders NEC		
Gingival erythema	1	0
Gingival haemorrhages		
Gingival bleeding	1	0
Gingival pains		
Gingival pain	3	0
Intestinal haemorrhages		
Rectal haemorrhage	3	0
Nausea and vomiting symptoms		
Nausea	218	0
Retching	4	0
Vomiting	276	0
Vomiting projectile	4	0
Non-site specific gastrointestinal haemorrhages		
Gastrointestinal haemorrhage	1	0
Haematemesis	3	0
Haematochezia	1	0
Melaena	2	0
Oral dryness and saliva altered		
Dry mouth	12	0
Salivary hypersecretion	3	0
Oral soft tissue disorders NEC		
Cheilitis	2	0
Oral disorder	1	0
Pigmentation lip	1	0
Oral soft tissue haemorrhages		
Mouth haemorrhage	2	0
Oral soft tissue pain and paraesthesia		
Oral pain	6	0
Paraesthesia oral	31	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	8	0
Lip discolouration	1	0
Oral discomfort	1	0
Oral mucosal blistering	3	0
Oral mucosal erythema	2	0
Oral pruritus	3	0
Oral soft tissue swelling and oedema		
Lip oedema	1	0
Lip swelling	48	0
Oedema mouth	4	0
Salivary gland enlargements		
Parotid gland enlargement	1	0
Submaxillary gland enlargement	1	0
Salivary gland infections and inflammations		

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Salivary duct inflammation	1	0
<i>Stomatitis and ulceration</i>		
Aphthous stomatitis	1	0
Mouth ulceration	14	0
Stomatitis	6	0
<i>Tongue disorders</i>		
Glossitis	2	0
Tongue disorder	2	0
Tongue ulceration	1	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	37	0
Tongue blistering	1	0
Tongue discolouration	1	0
Tongue oedema	2	0
Gastrointestinal disorders SOC TOTAL	1025	1

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Reaction Name	Total	Fatal
General disorders		
<i>Adverse effect absent</i>		
No adverse event	7	0
<i>Application and instillation site reactions</i>		
Application site erythema	2	0
Application site pain	2	0
Application site pruritus	1	0
Application site swelling	1	0
Application site vesicles	1	0
<i>Asthenic conditions</i>		
Asthenia	88	0
Chronic fatigue syndrome	6	0
Fatigue	146	0
Malaise	423	0
<i>Body temperature altered</i>		
Hypothermia	3	0
<i>Death and sudden death</i>		
Death	13	13
Sudden death	33	33
<i>Device issues NEC</i>		
Device dislocation	1	0
<i>Device physical property and chemical issues</i>		
Device component issue	1	0
<i>Febrile disorders</i>		
Hyperpyrexia	3	0
Pyrexia	507	0
<i>Feelings and sensations NEC</i>		
Chills	137	0
Feeling abnormal	40	0
Feeling cold	29	0
Feeling drunk	2	0
Feeling hot	90	0
Feeling jittery	2	0
Feeling of body temperature change	20	0
Sensation of foreign body	3	0
Thirst	4	0
<i>Gait disturbances</i>		
Abasia	6	0
Gait disturbance	19	0
Loss of control of legs	1	0
<i>General signs and symptoms NEC</i>		
Apparent death	1	0
Condition aggravated	26	1
Crepitations	2	0
Crying	5	0
Deformity	1	0
Disease progression	1	0
Disease recurrence	1	0
Effusion	1	0
Exercise tolerance decreased	3	0
Ill-defined disorder	2	0
Induration	7	0
Influenza like illness	281	0
Irritability	6	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Local reaction	92	0
Local swelling	213	0
Multi-organ failure	7	2
Swelling	57	0
Unevaluable event	1	0
Inflammations		
Granuloma	25	0
Inflammation	37	0
Soft tissue inflammation	1	0
Infusion site reactions		
Infusion site pain	1	0
Injection site reactions		
Injected limb mobility decreased	4	0
Injection site abscess sterile	1	0
Injection site anaesthesia	3	0
Injection site atrophy	2	0
Injection site bruising	14	0
Injection site discharge	1	0
Injection site discolouration	2	0
Injection site discomfort	7	0
Injection site dryness	1	0
Injection site erythema	125	0
Injection site fibrosis	1	0
Injection site haematoma	1	0
Injection site haemorrhage	3	0
Injection site induration	15	0
Injection site inflammation	69	0
Injection site irritation	3	0
Injection site joint pain	1	0
Injection site joint redness	1	0
Injection site joint warmth	1	0
Injection site mass	26	0
Injection site movement impairment	5	0
Injection site necrosis	2	0
Injection site oedema	1	0
Injection site pain	159	0
Injection site pruritus	31	0
Injection site rash	32	0
Injection site reaction	233	0
Injection site scab	2	0
Injection site scar	2	0
Injection site swelling	82	0
Injection site ulcer	2	0
Injection site urticaria	7	0
Injection site vesicles	4	0
Injection site warmth	39	0
Interactions		
Drug interaction	27	0
Food interaction	1	0
Inhibitory drug interaction	2	0
Potentiating drug interaction	4	0
Mass conditions NEC		
Mass	2	0

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General disorders General disorders cont'd		
<i>Mucosal findings abnormal</i>		
Mucosal discolouration	1	0
Mucosal inflammation	2	0
<i>Necrosis NEC</i>		
Necrosis	2	0
<i>Oedema NEC</i>		
Face oedema	8	0
Generalised oedema	2	0
Gravitational oedema	1	0
Localised oedema	4	0
Oedema	17	0
Oedema peripheral	17	0
<i>Pain and discomfort NEC</i>		
Axillary pain	9	0
Chest discomfort	49	0
Chest pain	73	0
Discomfort	7	0
Facial pain	6	0
Non-cardiac chest pain	2	0
Pain	211	0
Tenderness	20	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse event	2	0
Adverse reaction	3	0
Drug ineffective	7	0
Immediate post-injection reaction	1	0
Therapeutic response unexpected	3	0
<i>Ulcers NEC</i>		
Ulcer	1	0
<i>Vaccination site reactions</i>		
Vaccination site erythema	4	0
Vaccination site inflammation	3	0
Vaccination site pain	11	0
Vaccination site rash	4	0
Vaccination site reaction	5	0
Vaccination site swelling	6	0
Vaccination site warmth	3	0
General disorders SOC TOTAL	3764	49

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	1	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	2	0
Cholelithiasis	2	0
<i>Cholestasis and jaundice</i>		
Hepatitis cholestatic	1	0
Hyperbilirubinaemia neonatal	1	0
Jaundice	14	0
Jaundice cholestatic	2	0
<i>Gallbladder disorders NEC</i>		
Gallbladder disorder	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	2	0
Liver injury	1	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	6	0
<i>Hepatic failure and associated disorders</i>		
Hepatic failure	1	0
Hepatorenal failure	1	0
Hepatorenal syndrome	2	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatomegaly	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Drug-induced liver injury	1	0
Hepatitis	8	0
Hepatitis acute	1	0
Hepatic disorders SOC TOTAL	48	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	101	0
Serum sickness	2	0
Serum sickness-like reaction	2	0
Type I hypersensitivity	2	0
Type III immune complex mediated reaction	2	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to chemicals	1	0
Drug hypersensitivity	1	0
Food allergy	2	0
Reaction to drug excipients	1	0
<i>Anaphylactic responses</i>		
Anaphylactic reaction	116	1
Anaphylactic shock	16	1
Anaphylactoid reaction	14	0
<i>Atopic disorders</i>		
Seasonal allergy	2	0
<i>Immune and associated conditions NEC</i>		
Immune system disorder	4	0
Sensitisation	1	0
<i>Transplant rejections</i>		
Corneal graft rejection	4	0
Kidney transplant rejection	1	0
<i>Vasculitides</i>		
Allergic granulomatous angiitis	3	0
Immune system disorders SOC TOTAL	275	2

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Diarrhoea infectious	1	0
Gastroenteritis	4	0
<i>Bacterial infections NEC</i>		
Arthritis bacterial	1	0
Cellulitis	39	0
Folliculitis	1	0
Gangrene	3	1
Injection site cellulitis	12	0
Vaccination site cellulitis	2	0
<i>Bone and joint infections</i>		
Arthritis infective	1	0
<i>Borrelial infections</i>		
Lyme disease	1	0
<i>Candida infections</i>		
Candida infection	3	0
Oral candidiasis	1	0
<i>Cardiac infections</i>		
Endocarditis	1	0
<i>Central nervous system and spinal infections</i>		
Meningitis	5	1
Myelitis	3	0
Panencephalitis	1	0
<i>Clostridia infections</i>		
Gas gangrene	1	1
<i>Cytomegaloviral infections</i>		
Cytomegalovirus infection	2	0
<i>Dental and oral soft tissue infections</i>		
Gingivitis	1	0
Parotitis	2	0
<i>Ear infections</i>		
Ear infection	2	0
Labyrinthitis	8	0
Otitis media	2	0
<i>Female reproductive tract infections</i>		
Amniotic cavity infection	2	0
<i>Haemophilus infections</i>		
Haemophilus infection	1	0
Haemophilus sepsis	1	0
Pneumonia haemophilus	1	0
Septic arthritis haemophilus	1	0
<i>Herpes viral infections</i>		
Herpes simplex	6	0
Herpes zoster	33	0
Herpes zoster meningitis	1	0
Herpes zoster oticus	1	0
Ophthalmic herpes zoster	4	0
Oral herpes	10	0
Varicella	2	0
<i>Infections NEC</i>		
Abscess	7	0
Device related infection	1	0
Infection	10	0

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Earliest Reaction Date: 09-Oct-1963

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Reaction Name	Total	Fatal
Infections Infections cont'd		
Injection site abscess	8	0
Injection site infection	5	0
Localised infection	3	0
Purulent discharge	1	0
Respiratory tract infection	3	0
Toxic shock syndrome	1	0
Vaccination site infection	1	0
Infectious transmissions		
Infection via vaccinee	1	0
Nosocomial infection	1	0
Influenza viral infections		
H1N1 influenza	5	0
Influenza	44	0
Pneumonia influenzal	3	0
Lower respiratory tract and lung infections		
Atypical pneumonia	1	0
Bronchitis	31	0
Bronchopneumonia	10	5
Infective exacerbation of chronic obstructive airways disease	4	0
Lobar pneumonia	4	0
Lower respiratory tract infection	56	0
Pneumonia	35	9
Sputum purulent	1	0
Male reproductive tract infections		
Orchitis	1	0
Neisseria infections		
Meningococcal sepsis	1	1
Parainfluenzae viral infections		
Croup infectious	2	0
Pneumocystis infections		
Pneumocystis jirovecii pneumonia	2	1
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Bacteraemia	1	0
Sepsis	13	4
Septic shock	1	0
Viraemia	1	0
Skin structures and soft tissue infections		
Eczema infected	1	0
Furuncle	1	0
Impetigo	1	0
Rash pustular	1	0
Soft tissue infection	1	0
Staphylococcal infections		
Staphylococcal infection	1	0
Streptococcal infections		
Streptococcal abscess	1	0
Streptococcal infection	3	0
Tinea infections		
Tinea pedis	1	0
Tinea versicolour	1	0
Tuberculous infections		
Erythema induratum	10	0
Upper respiratory tract infections		

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Laryngitis	7	0
Nasopharyngitis	43	0
Pharyngitis	8	0
Rhinitis	16	0
Sinusitis	12	0
Tonsillitis	1	0
Upper respiratory tract infection	30	0
Urinary tract infections		
Cystitis	3	0
Pyelonephritis	2	0
Urinary tract infection	8	0
Vascular infections		
Lymphangitis	2	0
Viral infections NEC		
Encephalitis viral	4	0
Gastroenteritis viral	1	0
Meningitis viral	1	0
Post viral fatigue syndrome	10	0
Sweating fever	1	0
Vestibular neuronitis	6	0
Viral infection	11	0
Viral myocarditis	1	0
Viral rash	5	0
Viral upper respiratory tract infection	12	0
Infections SOC TOTAL	624	23

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Reaction Name	Total	Fatal
Injuries		
<i>Accidental exposures to product</i>		
Accidental exposure to product	1	0
<i>Chest and lung injuries NEC</i>		
Chest crushing	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	10	0
Foetal exposure during pregnancy	7	0
Maternal exposure during pregnancy	1	0
Maternal exposure timing unspecified	1	0
<i>Eye injuries NEC</i>		
Retinal injury	2	0
<i>Maladministrations</i>		
Drug administered at inappropriate site	3	0
Drug administered to patient of inappropriate age	20	0
Drug administration error	6	0
Expired drug administered	7	0
Inappropriate schedule of drug administration	3	0
Incorrect dose administered	7	0
Wrong drug administered	4	0
<i>Medication errors NEC</i>		
Drug prescribing error	2	0
Medication error	2	0
<i>Medication monitoring errors</i>		
Labelled drug-drug interaction medication error	1	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	2	0
Muscle injury	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	4	0
<i>Non-site specific injuries NEC</i>		
Eschar	1	0
Fall	10	0
Injury	3	0
Wound haemorrhage	1	0
Wound secretion	2	0
<i>Non-site specific procedural complications</i>		
Wound decomposition	1	0
Wound dehiscence	1	0
<i>Occupational exposures</i>		
Occupational exposure to product	7	0
<i>Overdoses</i>		
Accidental overdose	1	0
Overdose	1	0
<i>Pathways and sources of exposure</i>		
Exposure via direct contact	1	0
<i>Poisoning and toxicity</i>		
Toxicity to various agents	1	1
<i>Site specific injuries NEC</i>		
Tooth injury	1	0
<i>Skin injuries NEC</i>		
Contusion	29	0
Excoriation	1	0
Laceration	4	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Scar	1	0
Thermal burns		
Thermal burn	1	0
Vaccination related complications		
Vaccination complication	2	0
Vaccination failure	5	0
Injuries SOC TOTAL	159	1

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Reaction Name	Total	Fatal
Investigations		
<i>Autoimmunity analyses</i>		
Antinuclear antibody increased	1	0
Antinuclear antibody positive	1	0
Antiphospholipid antibodies positive	1	0
DNA antibody positive	1	0
Rheumatoid factor increased	1	0
<i>Blood gas and acid base analyses</i>		
Blood gases abnormal	1	0
Oxygen saturation decreased	6	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose abnormal	1	0
Blood glucose decreased	2	0
Blood glucose fluctuation	2	0
Blood glucose increased	1	0
<i>Cerebrospinal fluid tests (excl microbiology)</i>		
CSF protein increased	3	0
<i>Chemistry analyses NEC</i>		
Inflammatory marker increased	1	0
<i>Cholesterol analyses</i>		
High density lipoprotein decreased	1	0
<i>Coagulation and bleeding analyses</i>		
Activated partial thromboplastin time prolonged	1	0
Bleeding time prolonged	1	0
Coagulation time prolonged	3	0
International normalised ratio abnormal	2	0
International normalised ratio decreased	4	0
International normalised ratio increased	27	0
Prothrombin time shortened	1	0
<i>Digestive enzymes</i>		
Amylase increased	1	0
<i>ECG investigations</i>		
Electrocardiogram ST segment depression	1	0
Electrocardiogram change	1	0
<i>Haematological analyses NEC</i>		
Red blood cell sedimentation rate increased	17	0
<i>Heart rate and pulse investigations</i>		
Heart rate abnormal	1	0
Heart rate increased	15	0
Heart rate irregular	2	0
Pulse pressure decreased	1	0
<i>Imaging procedures NEC</i>		
Positron emission tomogram abnormal	1	0
<i>Investigations NEC</i>		
False positive investigation result	1	0
Quality of life decreased	1	0
<i>Liver function analyses</i>		
Alanine aminotransferase increased	6	0
Aspartate aminotransferase increased	1	0
Blood bilirubin increased	2	0
Gamma-glutamyltransferase increased	4	0
Liver function test abnormal	17	0
<i>Microbiology and serology tests NEC</i>		
Blood culture negative	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Mineral and electrolyte analyses		
Blood iron decreased	1	0
Blood sodium abnormal	1	0
Blood sodium decreased	1	0
Neurologic diagnostic procedures		
Electroencephalogram abnormal	2	0
Nerve conduction studies abnormal	1	0
Romberg test positive	1	0
Sensory level abnormal	1	0
Ophthalmic function diagnostic procedures		
Corneal reflex decreased	1	0
Intraocular pressure increased	1	0
Physical examination procedures and organ system status		
Body temperature fluctuation	1	0
Body temperature increased	53	0
Grip strength decreased	2	0
Respiratory rate increased	2	0
Weight decreased	10	0
Weight increased	1	0
Platelet analyses		
Platelet count decreased	8	0
Protein analyses NEC		
C-reactive protein abnormal	1	0
C-reactive protein increased	10	0
Globulins increased	1	0
Red blood cell analyses		
Haemoglobin abnormal	1	0
Haemoglobin decreased	1	0
Mean cell volume increased	1	0
Renal function analyses		
Blood creatinine increased	3	0
Blood urea increased	2	0
Creatinine renal clearance decreased	1	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume increased	1	0
Peak expiratory flow rate decreased	3	0
Pulmonary function test decreased	1	0
Respiratory tract and thoracic imaging procedures		
Chest X-ray abnormal	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	4	0
Thyroid analyses		
Thyroid function test abnormal	1	0
Thyroxine increased	1	0
Tissue enzyme analyses NEC		
Blood alkaline phosphatase increased	2	0
Urinalysis NEC		
Blood urine present	3	0
Protein urine present	1	0
Urine analysis	2	0
Urine analysis abnormal	1	0
Urinary tract function analyses NEC		
Urine output decreased	1	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	10	0
Blood pressure diastolic increased	1	0
Blood pressure increased	19	0
Blood pressure systolic increased	1	0
<i>Virus identification and serology</i>		
Cytomegalovirus test positive	1	0
Epstein-Barr virus antibody positive	2	0
<i>White blood cell analyses</i>		
Lymphocyte morphology abnormal	1	0
Neutrophil count increased	1	0
White blood cell count decreased	2	0
White blood cell count increased	4	0
Investigations SOC TOTAL	307	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	57	0
Hypophagia	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	3	0
Diabetes mellitus inadequate control	5	0
Type 1 diabetes mellitus	3	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	1	0
<i>Disorders of purine metabolism</i>		
Gout	2	0
<i>Electrolyte imbalance NEC</i>		
Fluid imbalance	1	0
<i>Fluid intake increased</i>		
Polydipsia	2	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	1	0
Food intolerance	1	0
<i>General nutritional disorders NEC</i>		
Feeding disorder neonatal	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	8	1
Hypoglycaemia neonatal	2	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Hyperlactacidaemia	1	0
Ketoacidosis	1	0
Metabolic acidosis	2	0
<i>Mixed acid-base disorders</i>		
Acidosis	1	0
<i>Potassium imbalance</i>		
Hyperkalaemia	2	0
<i>Sodium imbalance</i>		
Hyponatraemia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	7	0
<i>Total fluid volume increased</i>		
Fluid retention	2	0
Metabolic disorders SOC TOTAL	106	1

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	21	0
Arthritis reactive	8	0
Arthropathy	17	0
Haemarthrosis	2	0
Monarthritis	1	0
Palindromic rheumatism	1	0
Polyarthritis	8	0
Seronegative arthritis	1	0
<i>Bone disorders NEC</i>		
Bone disorder	1	0
Jaw disorder	1	0
Osteitis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	3	0
Pain in jaw	8	0
<i>Bursal disorders</i>		
Bursitis	3	0
<i>Connective tissue disorders (excl LE)</i>		
Myofascitis	1	0
Polymyalgia rheumatica	22	0
<i>Intervertebral disc disorders NEC</i>		
Intervertebral disc disorder	3	0
<i>Joint related disorders NEC</i>		
Periarthritis	12	0
Rotator cuff syndrome	3	0
<i>Joint related signs and symptoms</i>		
Arthralgia	178	0
Joint crepitation	1	0
Joint effusion	4	0
Joint range of motion decreased	2	0
Joint stiffness	9	0
Joint swelling	32	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	1	0
<i>Muscle infections and inflammations</i>		
Myositis	13	0
Myositis-like syndrome	1	0
<i>Muscle pains</i>		
Fibromyalgia	1	0
Myalgia	260	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	5	0
Muscle disorder	2	0
Muscle spasms	34	0
Muscle swelling	2	0
Muscle tightness	2	0
Muscle twitching	10	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	2	0
<i>Muscle weakness conditions</i>		
Muscular weakness	68	0
<i>Musculoskeletal and connective tissue infections and inflammations NEC</i>		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Dupuytren's contracture	1	0
Fasciitis	1	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	45	0
Limb discomfort	12	0
Musculoskeletal chest pain	2	0
Musculoskeletal discomfort	3	0
Musculoskeletal pain	66	0
Neck pain	52	0
Pain in extremity	239	0
Musculoskeletal and connective tissue signs and symptoms NEC		
Mobility decreased	13	0
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	52	0
Sensation of heaviness	16	0
Spinal pain	1	0
Upper extremity mass	2	0
Weight bearing difficulty	1	0
Myopathies		
Diabetic amyotrophy	1	0
Muscle necrosis	1	0
Myopathy	4	0
Rhabdomyolysis	14	0
Osteoarthropathies		
Osteoarthritis	3	0
Psoriatic arthropathies		
Psoriatic arthropathy	1	0
Rheumatoid arthropathies		
Rheumatoid arthritis	25	0
Soft tissue disorders NEC		
Groin pain	2	0
Neck mass	1	0
Synovial disorders		
Synovitis	2	0
Tendon disorders		
Enthesopathy	1	0
Tendon disorder	3	0
Tendonitis	3	0
Tenosynovitis	1	0
Trigger finger	1	0
Muscle & tissue disorders SOC TOTAL	1314	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Leukaemias acute NEC</i>		
Acute leukaemia	1	1
<i>Leukaemias acute lymphocytic</i>		
Acute lymphocytic leukaemia	1	0
<i>Leukaemias acute myeloid</i>		
Acute myeloid leukaemia	1	1
<i>Neoplasms malignant site unspecified NEC</i>		
Neoplasm malignant	1	0
<i>Ovarian neoplasms malignant (excl germ cell)</i>		
Ovarian cancer	1	1
<i>Paranasal sinus and nasal cavity neoplasms malignant and unspecified</i>		
Nasal sinus cancer	1	0
<i>Reproductive neoplasms female benign NEC</i>		
Placental chorioangioma	1	0
<i>Respiratory tract and pleural neoplasms malignancy unspecified NEC</i>		
Lung neoplasm	1	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Lung neoplasm malignant	1	0
<i>Skin melanomas (excl ocular)</i>		
Malignant melanoma	1	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Basal cell carcinoma	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	3	0
<i>Soft tissue sarcomas histology unspecified</i>		
Sarcoma	1	0
Neoplasms SOC TOTAL	15	3

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	4	0
Hyperreflexia	1	0
Hyporeflexia	1	0
<i>Absence seizures</i>		
Petit mal epilepsy	5	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	125	9
Polyneuropathy	1	0
<i>Autonomic nervous system disorders</i>		
Autonomic failure syndrome	1	0
Horner's syndrome	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem haemorrhage	1	0
Cerebellar infarction	1	1
Cerebral haemorrhage	2	2
Cerebral infarction	3	1
Cerebrovascular accident	25	4
Subarachnoid haemorrhage	2	0
<i>Central nervous system vascular disorders NEC</i>		
Cerebrovascular disorder	3	0
<i>Cervical spinal cord and nerve root disorders</i>		
Cervical myelopathy	1	0
<i>Choreiform movements</i>		
Chorea	1	0
<i>Chronic polyneuropathies</i>		
Chronic inflammatory demyelinating polyradiculoneuropathy	4	0
Demyelinating polyneuropathy	3	0
Diabetic neuropathy	1	0
<i>Coma states</i>		
Coma	5	0
<i>Coordination and balance disturbances</i>		
Ataxia	10	0
Balance disorder	22	0
Coordination abnormal	3	0
Dysstasia	7	0
Nystagmus	5	0
<i>Cortical dysfunction NEC</i>		
Aphasia	11	0
Dyspraxia	1	0
<i>Cranial nerve disorders NEC</i>		
Cranial nerve disorder	1	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	1	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	9	1
Demyelination	3	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	3	0
Depressed level of consciousness	3	0
Lethargy	72	0
Loss of consciousness	33	0
Postictal state	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Sedation	1	0
Somnolence	38	0
Stupor	2	0
Syncope	91	0
Dyskinesias and movement disorders NEC		
Akathisia	1	0
Clumsiness	4	0
Dyskinesia	7	0
Extrapyramidal disorder	1	0
Hypokinesia	6	0
Movement disorder	6	0
Up and down phenomenon	1	0
Dystonias		
Dystonia	2	0
Encephalitis NEC		
Encephalitis	17	3
Encephalomyelitis	8	1
Encephalopathies NEC		
Encephalopathy	9	0
Eye movement disorders		
IIIrd nerve paralysis	1	0
IVth nerve paralysis	1	0
Facial cranial nerve disorders		
Facial paresis	6	0
VIIth nerve paralysis	37	0
Generalised tonic-clonic seizures		
Grand mal convulsion	22	0
Headaches NEC		
Headache	405	0
Sinus headache	5	0
Tension headache	2	0
Hypoglossal nerve disorders		
Tongue paralysis	1	0
Increased intracranial pressure disorders		
Intracranial pressure increased	2	1
Lumbar spinal cord and nerve root disorders		
Sciatica	3	0
Memory loss (excl dementia)		
Amnesia	10	0
Memory impairment	7	0
Transient global amnesia	4	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	1	0
Disturbance in attention	11	0
Mental impairment	2	0
Mental retardations		
Mental retardation	1	0
Migraine headaches		
Hemiplegic migraine	1	0
Migraine	20	0
Migraine with aura	2	0
Mononeuropathies		
Mononeuropathy multiplex	4	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Nerve compression	1	0
Radial nerve palsy	1	0
Ulnar neurapraxia	1	0
Ulnar neuritis	1	0
Multiple sclerosis acute and progressive		
Multiple sclerosis	7	0
Muscle tone abnormal		
Hypertonia	1	0
Hypotonia	7	0
Myelitis (incl infective)		
Myelitis transverse	16	1
Narcolepsy and hypersomnia		
Cataplexy	3	0
Hypersomnia	3	0
Narcolepsy	8	0
Nervous system disorders NEC		
Nervous system disorder	7	0
Neurologic visual problems NEC		
Hemianopia	1	0
Hemianopia homonymous	1	0
Visual field defect	5	0
Neurological signs and symptoms NEC		
Clonus	1	0
Dizziness	231	0
Dizziness postural	3	0
Head discomfort	4	0
Meningism	11	0
Myoclonus	1	0
Neurological symptom	2	0
Presyncope	7	0
Slow response to stimuli	1	0
Unresponsive to stimuli	7	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	1	0
Muscle spasticity	2	0
Olfactory nerve disorders		
Anosmia	5	0
Parosmia	1	0
Optic nerve disorders NEC		
Optic neuritis	6	0
Paraesthesias and dysaesthesias		
Burning sensation	27	0
Dysaesthesia	1	0
Formication	1	0
Hyperaesthesia	5	0
Paraesthesia	192	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	7	0
Hemiplegia	9	1
Monoparesis	1	0
Monoplegia	5	0
Paralysis	15	0
Paraparesis	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Paraplegia	3	0
Spastic paralysis	1	0
Parkinson's disease and parkinsonism		
Cogwheel rigidity	1	0
Freezing phenomenon	1	0
Parkinson's disease	1	0
Partial complex seizures		
Complex partial seizures	1	0
Peripheral neuropathies NEC		
Axonal neuropathy	4	0
Brachial plexopathy	3	0
Neuralgic amyotrophy	9	0
Neuritis	7	0
Neuropathy peripheral	34	0
Peripheral motor neuropathy	2	0
Peripheral sensorimotor neuropathy	2	0
Peripheral sensory neuropathy	3	0
Seizures and seizure disorders NEC		
Convulsion	37	0
Convulsion neonatal	1	0
Convulsive threshold lowered	1	0
Epilepsy	23	2
Epileptic aura	1	0
Febrile convulsion	11	0
Hypoglycaemic seizure	1	0
Partial seizures	4	0
Seizure cluster	1	0
Seizure like phenomena	1	0
Status epilepticus	2	0
Tonic convulsion	1	0
Sensory abnormalities NEC		
Ageusia	7	0
Dysgeusia	17	0
Hypoaesthesia	83	0
Neuralgia	16	0
Post herpetic neuralgia	1	0
Restless legs syndrome	2	0
Sensory disturbance	9	0
Sensory loss	8	0
Sleep disturbances NEC		
Poor quality sleep	1	0
Speech and language abnormalities		
Aphonia	10	0
Dysarthria	10	0
Incoherent	2	0
Speech disorder	6	0
Spinal cord and nerve root disorders NEC		
Brown-Sequard syndrome	1	0
Myelopathy	2	0
Radiculitis brachial	13	0
Radiculopathy	1	0
Spinal cord disorder	1	0
Structural brain disorders NEC		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Brain injury	2	1
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	5	0
<i>Tremor (excl congenital)</i>		
Tremor	65	0
<i>Trigeminal disorders</i>		
Facial neuralgia	1	0
<i>Vagus nerve disorders</i>		
Vocal cord paralysis	1	0
Nervous system disorders SOC TOTAL	2149	28

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Report Run Date: 21-Feb-2014
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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	23	0
<i>Foetal complications NEC</i>		
Foetal distress syndrome	1	0
Foetal hypokinesia	2	0
<i>Foetal growth complications</i>		
Foetal growth restriction	3	0
<i>Gestational age and weight conditions</i>		
Premature baby	3	0
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	2	0
Premature separation of placenta	1	0
<i>Labour onset and length abnormalities</i>		
Premature delivery	1	0
Premature labour	2	0
Premature rupture of membranes	1	0
Prolonged labour	2	0
<i>Maternal complications of delivery NEC</i>		
Breech delivery	1	0
<i>Maternal complications of pregnancy NEC</i>		
Hyperemesis gravidarum	1	0
<i>Normal newborn status</i>		
Normal newborn	2	0
<i>Normal pregnancy, labour and delivery</i>		
Delivery	1	0
<i>Stillbirth and foetal death</i>		
Foetal death	1	0
Stillbirth	4	3
Pregnancy conditions SOC TOTAL	51	3

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	6	0
<i>Affect alterations NEC</i>		
Affect lability	1	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	2	0
<i>Anxiety symptoms</i>		
Agitation	13	0
Anxiety	17	0
Nervousness	2	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	2	0
Aversion	1	0
Personality change	1	0
Social avoidant behaviour	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Distractibility	1	0
<i>Confusion and disorientation</i>		
Confusional state	48	0
Disorientation	15	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	3	0
<i>Depressive disorders</i>		
Depression	17	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	27	0
<i>Eating disorders NEC</i>		
Binge eating	1	0
Eating disorder	1	0
Food aversion	3	0
<i>Emotional and mood disturbances NEC</i>		
Emotional disorder	1	0
Emotional distress	4	0
Moaning	1	0
Mood altered	3	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	3	0
Phonophobia	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	3	0
<i>Increased physical activity levels</i>		
Restlessness	3	0
<i>Learning disorders</i>		
Learning disorder	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	5	0
Feelings of worthlessness	1	0
Tearfulness	6	0
<i>Mood alterations with manic symptoms</i>		
Hypomania	1	0
<i>Mood disorders NEC</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Listless	4	0
<i>Panic attacks and disorders</i>		
Panic attack	5	0
Panic reaction	3	0
<i>Parasomnias</i>		
Abnormal dreams	2	0
Nightmare	6	0
<i>Perception disturbances</i>		
Hallucination	15	0
Hallucination, visual	1	0
Illusion	1	0
<i>Psychiatric symptoms NEC</i>		
Decreased eye contact	1	0
<i>Psychotic disorder NEC</i>		
Psychotic disorder	3	0
<i>Sexual desire disorders</i>		
Loss of libido	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	15	0
<i>Somatoform disorders</i>		
Conversion disorder	1	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	2	0
Screaming	4	0
<i>Stereotypies and automatisms</i>		
Head banging	1	0
<i>Substance-related disorders</i>		
Alcoholic hangover	1	0
<i>Suicidal and self-injurious behaviour</i>		
Completed suicide	2	2
Suicidal ideation	2	0
Suicide attempt	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	1	0
Thinking abnormal	2	0
Psychiatric disorders SOC TOTAL	270	2

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder pain	1	0
Dysuria	5	0
Incontinence	3	0
Micturition urgency	1	0
Pollakiuria	3	0
Urinary incontinence	5	0
Urinary retention	5	0
<i>Bladder disorders NEC</i>		
Bladder disorder	1	0
Bladder obstruction	1	0
Urinary bladder haemorrhage	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Glomerulonephritis acute	1	1
Nephrotic syndrome	4	0
<i>Myoneurogenic bladder disorders</i>		
Neurogenic bladder	1	0
<i>Nephropathies and tubular disorders NEC</i>		
Fanconi syndrome acquired	2	0
Renal tubular disorder	1	0
<i>Renal disorders NEC</i>		
Renal haemorrhage	1	0
<i>Renal failure and impairment</i>		
Anuria	2	0
Oliguria	2	0
Renal failure	7	0
Renal failure acute	22	0
Renal failure chronic	2	0
Renal impairment	5	0
<i>Renal lithiasis</i>		
Nephrolithiasis	1	0
<i>Renal neoplasms</i>		
Renal cyst	1	0
<i>Renal obstructive disorders</i>		
Hydronephrosis	1	0
<i>Renal vascular and ischaemic conditions</i>		
Renal vasculitis	2	0
<i>Urinary abnormalities</i>		
Chromaturia	2	0
Haematuria	4	1
Myoglobinuria	1	0
Proteinuria	2	0
Urine abnormality	3	0
<i>Urinary tract signs and symptoms NEC</i>		
Polyuria	2	0
Renal pain	6	0
Renal & urinary disorders SOC TOTAL	101	2

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast pain	1	0
Breast tenderness	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
Metrorrhagia	1	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	1	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penis disorder	1	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic disorder	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital discomfort	1	0
Genital rash	1	0
Oedema genital	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	3	0
Vulval ulceration	1	0
Reproductive & breast disorders SOC TOTAL	15	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	2	0
Dyspnoea	165	0
Dyspnoea exertional	4	0
Hyperventilation	2	0
Respiratory arrest	4	0
Respiratory depression	1	0
Respiratory distress	7	0
Sleep apnoea syndrome	1	0
Tachypnoea	2	0
<i>Bronchospasm and obstruction</i>		
Asthma	98	1
Asthma exercise induced	1	0
Bronchospasm	25	0
Chronic obstructive pulmonary disease	12	3
Obstructive airways disorder	1	0
Status asthmaticus	2	1
Wheezing	68	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	2	2
Cyanosis central	1	0
Hypoxia	3	0
Respiratory gas exchange disorder	1	0
<i>Coughing and associated symptoms</i>		
Cough	166	0
Haemoptysis	1	0
Productive cough	15	0
Sputum discoloured	2	0
Sputum increased	3	0
<i>Diaphragmatic disorders</i>		
Diaphragm muscle weakness	1	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Vocal cord disorder	2	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Laryngeal oedema	2	0
Stridor	5	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Alveolitis	1	0
Mendelson's syndrome	1	0
Pneumonia aspiration	3	2
Pneumonitis	5	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	1	0
Increased bronchial secretion	2	0
Pleuritic pain	4	0
Rales	2	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	20	0
Nasal inflammation	1	0
Rhinitis perennial	2	0
<i>Nasal disorders NEC</i>		
Epistaxis	45	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
<i>Newborn respiratory disorders NEC</i>		
Bronchopulmonary dysplasia	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	2	0
Sinus disorder	4	0
<i>Parenchymal lung disorders NEC</i>		
Idiopathic pulmonary fibrosis	2	0
Interstitial lung disease	1	0
Lung consolidation	1	0
Lung infiltration	1	0
Organising pneumonia	1	0
Pulmonary fibrosis	11	3
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	2	0
Pharyngeal oedema	21	0
Tonsillar disorder	3	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	1	0
Pneumothorax	1	0
<i>Pulmonary oedemas</i>		
Acute pulmonary oedema	1	0
Acute respiratory distress syndrome	1	0
Pulmonary oedema	4	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	9	5
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	2	0
Respiratory failure	12	3
<i>Respiratory signs and symptoms NEC</i>		
Painful respiration	2	0
<i>Respiratory tract disorders NEC</i>		
Lung disorder	1	0
Respiratory disorder	5	0
Respiratory tract congestion	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Choking	2	0
Choking sensation	2	0
Dry throat	6	0
Dysphonia	12	0
Increased upper airway secretion	11	0
Laryngeal pain	2	0
Nasal discomfort	8	0
Oropharyngeal pain	89	0
Rhinalgia	2	0
Rhinorrhoea	50	0
Sneezing	18	0
Throat irritation	8	0
Throat tightness	24	0
Yawning	1	0
Respiratory disorders SOC TOTAL	1011	20

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Reaction Name	Total	Fatal
Skin disorders		
<i>Alopecias</i>		
Alopecia	3	0
Alopecia areata	2	0
Madarosis	1	0
<i>Angioedemas</i>		
Angioedema	28	0
Circumoral oedema	1	0
Swelling face	71	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	27	0
Hyperhidrosis	103	0
Night sweats	16	0
<i>Bullous conditions</i>		
Blister	22	0
Blood blister	3	0
Dermatitis bullous	1	0
Erythema multiforme	27	0
Pemphigoid	8	0
Pemphigus	1	0
Stevens-Johnson syndrome	5	0
Toxic epidermal necrolysis	1	0
<i>Connective tissue disorders</i>		
Dermatomyositis	2	0
<i>Dermal and epidermal conditions NEC</i>		
Dermatosis	1	0
Dry skin	6	0
Macule	2	0
Pain of skin	3	0
Papule	2	0
Scab	1	0
Skin burning sensation	3	0
Skin discolouration	6	0
Skin discomfort	1	0
Skin disorder	3	0
Skin fissures	1	0
Skin induration	6	0
Skin lesion	12	0
Skin necrosis	1	0
Skin reaction	24	0
Skin sensitisation	1	0
Skin swelling	2	0
Skin tightness	4	0
Skin warm	34	0
<i>Dermatitis and eczema</i>		
Dermatitis	11	0
Dermatitis allergic	10	0
Eczema	26	0
Seborrhoeic dermatitis	5	0
Skin irritation	6	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	3	0
Drug reaction with eosinophilia and systemic symptoms	1	0
Toxic skin eruption	3	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Erythemas</i>		
Erythema	226	0
Generalised erythema	2	0
Palmar erythema	2	0
Rash erythematous	75	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	6	0
Skin exfoliation	14	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Granuloma skin	1	0
<i>Hyperkeratoses</i>		
Hyperkeratosis	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Onychomadesis	1	0
<i>Panniculitides</i>		
Erythema nodosum	6	0
<i>Papulosquamous conditions</i>		
Erythema annulare	1	0
Parapsoriasis	1	0
Pityriasis rosea	3	0
Rash papular	8	0
Rash papulosquamous	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	5	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	1	0
<i>Pilar disorders NEC</i>		
Hair colour changes	1	0
Piloerection	1	0
<i>Pruritus NEC</i>		
Pruritus	152	0
Pruritus generalised	21	0
Rash pruritic	47	0
<i>Psoriatic conditions</i>		
Guttate psoriasis	3	0
Psoriasis	6	0
<i>Purpura and related conditions</i>		
Ecchymosis	1	0
Henoch-Schonlein purpura	10	0
Petechiae	10	0
Purpura	27	0
<i>Pustular conditions</i>		
Rash follicular	2	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	1	0
Rash	203	0
Rash generalised	57	0
Rash macular	36	0
Rash maculo-papular	33	0
Rash morbilliform	3	0
Rash vesicular	6	0
<i>Scaly conditions</i>		
Pityriasis	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Sebaceous gland disorders		
Seborrhoea	1	0
Skin and subcutaneous conditions NEC		
Skin mass	2	0
Skin and subcutaneous tissue ulcerations		
Pyoderma gangrenosum	1	0
Skin ulcer	2	0
Skin cysts and polyps		
Dermal cyst	1	0
Skin haemorrhages		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	1	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	1	0
Skin injuries and mechanical dermatoses		
Needle track marks	2	0
Skin vasculitides		
Cutaneous vasculitis	7	0
Leukocytoclastic vasculitis	12	0
Vasculitic rash	9	0
Skin vasomotor conditions		
Livedo reticularis	3	0
Urticarias		
Cold urticaria	1	0
Idiopathic urticaria	1	0
Mechanical urticaria	2	0
Urticaria	226	0
Urticaria chronic	1	0
Urticaria papular	2	0
Skin disorders SOC TOTAL	1751	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Activities of daily living impaired	8	0
Bedridden	5	0
Disability	1	0
Immobile	1	0
Impaired work ability	2	0
Physical disability	1	0
Walking aid user	1	0
Walking disability	1	0
Wheelchair user	1	0
Social circumstances SOC TOTAL	21	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Anaesthesia and allied procedures</i>		
Nerve block	1	0
<i>Large intestine therapeutic procedures</i>		
Colon operation	1	0
<i>Obstetric therapeutic procedures</i>		
Caesarean section	1	0
Vacuum extractor delivery	1	0
<i>Therapeutic procedures NEC</i>		
Bed rest	1	0
Off label use	1	0
<i>Urethral therapeutic procedures</i>		
Urethrotomy	1	0
Surgical & medical procedures SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Aortic aneurysms and dissections</i>		
Aortic aneurysm rupture	1	1
<i>Aortic inflammatory disorders</i>		
Aortitis	1	0
<i>Arterial inflammations</i>		
Temporal arteritis	4	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	23	2
Peripheral circulatory failure	1	0
Shock	1	0
<i>Haemorrhages NEC</i>		
Haematoma	2	0
Haemorrhage	9	0
<i>Lymphoedemas</i>		
Lymphoedema	1	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	4	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Infarction	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	1	0
Vasodilatation	2	0
<i>Peripheral aneurysms and dissections</i>		
Peripheral artery aneurysm	1	1
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	5	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	44	0
Hot flush	5	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Intermittent claudication	1	0
Peripheral coldness	7	0
Peripheral ischaemia	2	0
Poor peripheral circulation	1	0
Raynaud's phenomenon	1	0
<i>Phlebitis NEC</i>		
Phlebitis	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	49	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	21	0
<i>Vascular hypotensive disorders</i>		
Hypotension	18	0
<i>Vasculitides NEC</i>		
Behcet's syndrome	1	0
Granulomatosis with polyangiitis	2	0
Microscopic polyangiitis	1	0
Polyarteritis nodosa	1	1
Vasculitis	24	0
Vasculitis necrotising	1	0

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Vascular disorders SOC TOTAL	240	5
TOTAL REACTIONS FOR DRUG	14026	186
TOTAL REPORTS	5556	
TOTAL FATAL OUTCOME REPORTS		186