

Case Series Drug Analysis Print

Name: Human Papillomavirus

Report Run Date: 02-Jun-2016
Data Lock Date: 01-Jun-2016 19:00:04
Earliest Reaction Date: 29-Nov-2006
MedDRA Version: MedDRA 19.0

Human Papillomavirus: Human Papillomavirus Drug Analysis Print up to and including 01/06/2016

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia vitamin B12 deficiency	1	0
<i>Anaemias NEC</i>		
Anaemia	10	0
<i>Anaemias haemolytic mechanical factor</i>		
Haemolytic uraemic syndrome	1	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	2	0
<i>Coagulopathies</i>		
Coagulopathy	2	0
<i>Eosinophilic disorders</i>		
Eosinophilia	1	0
<i>Haematological disorders</i>		
Blood disorder	1	0
Mast cell activation syndrome	3	0
Mastocytosis	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	2	0
Lymphadenopathy	41	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplastic anaemia	1	0
Pancytopenia	1	0
<i>Neutropenias</i>		
Autoimmune neutropenia	1	0
Neutropenia	3	0
<i>Spleen disorders</i>		
Splenomegaly	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenic purpura	6	0
Thrombocytopenia	2	0
Blood disorders SOC TOTAL	80	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	1	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	3	0
<i>Cardiac signs and symptoms NEC</i>		
Cyanosis	31	0
Palpitations	32	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	3	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	1	0
<i>Pulmonary valvular disorders</i>		
Pulmonary valve stenosis	2	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	1	0
Bradycardia	6	0
Postural orthostatic tachycardia syndrome	40	0
Tachycardia	35	0
<i>Supraventricular arrhythmias</i>		
Sinus arrhythmia	1	0
Sinus tachycardia	5	0
Supraventricular tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	2	1
Cardiac disorders SOC TOTAL	164	1

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Reaction Name	Total	Fatal
Congenital disorders		
<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>		
Cerebral palsy	1	0
<i>Congenital disorders NEC</i>		
Congenital anomaly	1	0
VACTERL syndrome	2	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	4	0
<i>Great vessel disorders congenital</i>		
Double outlet right ventricle	2	0
<i>Male reproductive tract disorders congenital</i>		
Hypospadias	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Limb hypoplasia congenital	2	0
Limb reduction defect	2	0
Talipes	1	0
<i>Musculoskeletal and connective tissue disorders of spine congenital</i>		
Spine malformation	2	0
<i>Non-site specific bone disorders congenital</i>		
Osteopetrosis	1	0
<i>Palate disorders congenital</i>		
Cleft palate	1	0
High arched palate	1	0
<i>Pulmonary and bronchial disorders congenital</i>		
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>		
Birth mark	1	0
Congenital skin dimples	2	0
Ichthyosis	1	0
Sebaceous naevus	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	2	0
<i>Vascular anomalies congenital NEC</i>		
Arteriovenous malformation	1	0
Congenital disorders SOC TOTAL	39	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear discomfort	2	0
Ear pain	15	0
<i>Hearing losses</i>		
Deafness	14	0
Deafness bilateral	1	0
Deafness transitory	3	0
Hypoacusis	15	0
<i>Hyperacusia</i>		
Hyperacusis	10	0
<i>Inner ear disorders NEC</i>		
Inner ear disorder	1	0
Vestibular disorder	1	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	1	0
Tinnitus	11	0
Vertigo	14	0
Ear disorders SOC TOTAL	88	0

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Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	3	0
<i>Adrenal cortical hypofunctions</i>		
Adrenocortical insufficiency acute	2	0
<i>Endocrine abnormalities of puberty</i>		
Delayed puberty	1	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Lymphocytic hypophysitis	1	0
<i>Posterior pituitary disorders</i>		
Diabetes insipidus	1	0
<i>Thyroid disorders NEC</i>		
Thyroid disorder	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	6	0
Endocrine disorders SOC TOTAL	15	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Blindness (excl colour blindness)</i>		
Blindness	12	0
Blindness transient	13	0
Blindness unilateral	1	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous floaters	4	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	2	0
<i>Eyelid movement disorders</i>		
Excessive eye blinking	2	0
Eyelid ptosis	2	0
<i>Glaucomas (excl congenital)</i>		
Glaucoma	1	0
<i>Iris and ciliary body structural change, deposit and degeneration</i>		
Iris adhesions	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iritis	1	0
Uveitis	1	0
<i>Lacrimation disorders</i>		
Dry eye	1	0
Lacrimation increased	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid oedema	16	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	2	0
Eye disorder	4	0
Eye pain	16	0
Eye swelling	34	0
Eyelid disorder	1	0
Eyelids pruritus	1	0
Ocular discomfort	1	0
Periorbital oedema	2	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	1	0
Eye inflammation	1	0
Eye irritation	2	0
Eye pruritus	6	0
Ocular hyperaemia	5	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	28	0
Gaze palsy	2	0
Ocular myasthenia	1	0
Strabismus	1	0
<i>Ocular sensation disorders</i>		
Asthenopia	3	0
Photophobia	37	0
<i>Optic disc abnormalities NEC</i>		
Optic disc disorder	1	0
<i>Orbital structural change, deposit and degeneration</i>		
Lid sulcus deepened	1	0
<i>Partial vision loss</i>		
Visual acuity reduced	5	0
<i>Pupil disorders</i>		

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Mydriasis	18	0
Pupil fixed	3	0
Pupillary disorder	1	0
Pupillary reflex impaired	1	0
Refractive and accommodative disorders		
Accommodation disorder	1	0
Altered visual depth perception	1	0
Retinal, choroid and vitreous infections and inflammations		
Choroiditis	1	0
Retinal vasculitis	1	0
Visual colour distortions		
Chromatopsia	2	0
Visual disorders NEC		
Diplopia	12	0
Halo vision	1	0
Metamorphopsia	1	0
Photopsia	3	0
Vision blurred	136	0
Visual impairment	49	0
Eye disorders SOC TOTAL	444	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	0
<i>Anal and rectal disorders NEC</i>		
Anal fissure	1	0
<i>Colitis (excl infective)</i>		
Colitis	1	0
Colitis ulcerative	4	0
Crohn's disease	1	0
<i>Dental disorders NEC</i>		
Tooth erosion	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	107	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	7	0
Eructation	1	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	8	0
Flatulence	1	0
<i>Gastric ulcers and perforation</i>		
Gastritis erosive	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	6	0
Reflux gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	1	0
Abdominal pain	177	0
Abdominal pain lower	10	0
Abdominal pain upper	158	0
Abdominal tenderness	1	0
Gastrointestinal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	6	0
Gastric dilatation	1	0
Gastrointestinal hypomotility	1	0
Gastrooesophageal reflux disease	9	0
Impaired gastric emptying	1	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	1	0
Gastric disorder	3	0
Gastrointestinal disorder	12	0
<i>Gastrointestinal dyskinetic disorders</i>		
Gastrointestinal motility disorder	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Duodenitis	1	0
Gastrointestinal inflammation	1	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Oesophageal mucosal hyperplasia	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	44	0
Dysphagia	15	0

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Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Oesophageal discomfort	1	0
Gastrointestinal spastic and hypermotility disorders		
Frequent bowel movements	2	0
Irritable bowel syndrome	13	0
Gastrointestinal ulcers and perforation, site unspecified		
Gastrointestinal ulcer	1	0
Gingival disorders NEC		
Gingival disorder	1	0
Gingival pains		
Gingival pain	1	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)		
Haemorrhoids	1	0
Inguinal hernias		
Inguinal hernia	1	0
Intestinal haemorrhages		
Rectal haemorrhage	1	0
Malabsorption syndromes		
Coeliac disease	1	0
Nausea and vomiting symptoms		
Cyclic vomiting syndrome	2	0
Nausea	1542	0
Regurgitation	1	0
Retching	6	0
Vomiting	649	0
Vomiting projectile	1	0
Non-site specific gastrointestinal haemorrhages		
Gastrointestinal haemorrhage	1	0
Haematemesis	6	0
Oral dryness and saliva altered		
Dry mouth	5	0
Saliva altered	1	0
Salivary hypersecretion	3	0
Oral soft tissue disorders NEC		
Cheilitis	1	0
Lip blister	2	0
Lip ulceration	1	0
Oral soft tissue pain and paraesthesia		
Lip pain	1	0
Odynophagia	2	0
Oral pain	3	0
Paraesthesia oral	33	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	9	0
Oral discomfort	2	0
Oral mucosal blistering	1	0
Oral mucosal eruption	1	0
Oral pruritus	2	0
Oral soft tissue swelling and oedema		
Gingival swelling	1	0
Lip swelling	53	0
Mouth swelling	8	0
Pancreatic disorders NEC		
Pancreatic disorder	1	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Stomatitis and ulceration</i>		
Mouth ulceration	6	0
<i>Tongue signs and symptoms</i>		
Glossodynia	1	0
Swollen tongue	25	0
Tongue coated	1	0
Gastrointestinal disorders SOC TOTAL	2982	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Puncture site reaction	1	0
<i>Asthenic conditions</i>		
Asthenia	141	0
Chronic fatigue syndrome	64	0
Decreased activity	1	0
Fatigue	612	0
Malaise	741	0
<i>Body temperature altered</i>		
Temperature regulation disorder	6	0
<i>Death and sudden death</i>		
Death	2	2
<i>Febrile disorders</i>		
Hyperpyrexia	1	0
Pyrexia	447	0
<i>Feelings and sensations NEC</i>		
Chills	79	0
Feeling abnormal	57	0
Feeling cold	66	0
Feeling drunk	4	0
Feeling hot	199	0
Feeling jittery	3	0
Feeling of body temperature change	19	0
Sensation of foreign body	2	0
Temperature intolerance	4	0
Thirst	6	0
<i>Gait disturbances</i>		
Abasia	20	0
Gait disturbance	26	0
Loss of control of legs	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	12	0
Crying	11	0
Exercise tolerance decreased	1	0
Foaming at mouth	3	0
General physical health deterioration	2	0
Glassy eyes	1	0
Ill-defined disorder	2	0
Induration	3	0
Influenza like illness	111	0
Local reaction	31	0
Local swelling	36	0
Organ failure	1	0
Peripheral swelling	307	0
Swelling	34	0
<i>Healing abnormal NEC</i>		
Impaired healing	1	0
<i>Inflammations</i>		
Inflammation	19	0
Systemic inflammatory response syndrome	1	0
<i>Infusion site reactions</i>		
Infusion site hypoaesthesia	1	0
<i>Injection site reactions</i>		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injected limb mobility decreased	4	0
Injection site bruising	28	0
Injection site coldness	4	0
Injection site discharge	3	0
Injection site discolouration	6	0
Injection site discomfort	2	0
Injection site erythema	126	0
Injection site granuloma	1	0
Injection site haemorrhage	4	0
Injection site hypoaesthesia	15	0
Injection site induration	11	0
Injection site inflammation	27	0
Injection site injury	1	0
Injection site irritation	6	0
Injection site joint movement impairment	1	0
Injection site joint pain	1	0
Injection site mass	63	0
Injection site movement impairment	3	0
Injection site nerve damage	1	0
Injection site nodule	8	0
Injection site oedema	1	0
Injection site pain	140	0
Injection site papule	1	0
Injection site paraesthesia	2	0
Injection site pruritus	27	0
Injection site rash	52	0
Injection site reaction	36	0
Injection site scab	2	0
Injection site scar	1	0
Injection site swelling	174	0
Injection site urticaria	5	0
Injection site vesicles	5	0
Injection site warmth	28	0
Mass conditions NEC		
Mass	5	0
Nodule	1	0
Oedema NEC		
Face oedema	5	0
Localised oedema	1	0
Oedema peripheral	11	0
Pain and discomfort NEC		
Axillary pain	1	0
Chest discomfort	55	0
Chest pain	72	0
Discomfort	24	0
Facial pain	1	0
Pain	202	0
Tenderness	17	0
Therapeutic and nontherapeutic responses		
Drug ineffective	1	0
Immediate post-injection reaction	1	0
Trophic disorders		
Atrophy	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Hyperplasia	1	0
Ulcers NEC		
Ulcer	2	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	2	0
Vaccination site erythema	2	0
Vaccination site hypersensitivity	1	0
Vaccination site inflammation	1	0
Vaccination site irritation	1	0
Vaccination site mass	1	0
Vaccination site pain	5	0
Vaccination site pruritus	1	0
Vaccination site swelling	2	0
Vaccination site warmth	1	0
General disorders SOC TOTAL	4286	2

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Jaundice	2	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Hepatic cyst	1	0
Liver disorder	2	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	1	0
<i>Obstructive bile duct disorders (excl neoplasms)</i>		
Sphincter of Oddi dysfunction	1	0
Hepatic disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	1	0
Allergy to animal	2	0
Hypersensitivity	64	0
Multiple allergies	1	0
Type I hypersensitivity	2	0
Type III immune complex mediated reaction	3	0
Type IV hypersensitivity reaction	2	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Drug hypersensitivity	1	0
Food allergy	4	0
Reaction to drug excipients	1	0
Reaction to preservatives	1	0
Rubber sensitivity	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	71	0
Anaphylactic shock	5	0
Anaphylactoid reaction	3	0
<i>Atopic disorders</i>		
Seasonal allergy	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	8	0
Overlap syndrome	1	0
<i>Immune and associated conditions NEC</i>		
Immune system disorder	7	0
Immunisation reaction	2	0
Immune system disorders SOC TOTAL	182	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Abdominal abscess	1	0
Appendicitis	3	0
Gastrointestinal infection	1	0
Peritonitis	1	0
<i>Bacterial infections NEC</i>		
Cellulitis	3	0
Injection site cellulitis	2	0
Small intestinal bacterial overgrowth	1	0
<i>Breast infections</i>		
Mastitis	1	0
<i>Candida infections</i>		
Candida infection	2	0
Vulvovaginal candidiasis	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	5	0
Encephalitis lethargica	1	0
<i>Dental and oral soft tissue infections</i>		
Gingivitis	1	0
<i>Ear infections</i>		
Labyrinthitis	3	0
Otitis media	2	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	1	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	10	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	2	0
Hordeolum	4	0
<i>Female reproductive tract infections</i>		
Amniotic cavity infection	1	0
Pelvic inflammatory disease	1	0
<i>Herpes viral infections</i>		
Genital herpes	1	0
Herpes virus infection	1	0
Herpes zoster	11	0
Oral herpes	2	0
Varicella	1	0
<i>Infections NEC</i>		
Infection	8	0
Infection susceptibility increased	4	0
Injection site abscess	1	0
Injection site infection	5	0
Respiratory tract infection	2	0
<i>Influenza viral infections</i>		
Influenza	3	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	2	0
Lower respiratory tract infection	15	0
Pneumonia	1	0
<i>Molluscum contagiosum viral infections</i>		
Molluscum contagiosum	1	0
<i>Papilloma viral infections</i>		

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Infections		
<i>Infections cont'd</i>		
Papilloma viral infection	2	0
Vulvovaginal human papilloma virus infection	1	0
<i>Respiratory syncytial viral infections</i>		
Respiratory syncytial virus infection	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
Septic rash	1	0
Viraemia	1	0
<i>Skin structures and soft tissue infections</i>		
Application site pustules	1	0
Folliculitis	1	0
Impetigo	1	0
Skin infection	2	0
<i>Staphylococcal infections</i>		
Furuncle	3	0
Staphylococcal infection	1	0
<i>Streptococcal infections</i>		
Beta haemolytic streptococcal infection	2	0
Streptococcal sepsis	1	1
<i>Upper respiratory tract infections</i>		
Epiglottitis	1	0
Laryngitis	1	0
Nasopharyngitis	34	0
Pharyngitis	6	0
Sinusitis	1	0
Tonsillitis	5	0
Upper respiratory tract infection	3	0
<i>Urinary tract infections</i>		
Kidney infection	1	0
Urinary tract infection	3	0
<i>Viral infections NEC</i>		
Gastroenteritis viral	2	0
Hepatitis viral	1	0
Meningitis viral	1	0
Pneumonia viral	1	0
Post viral fatigue syndrome	41	0
Severe acute respiratory syndrome	1	0
Viral infection	16	0
Infections SOC TOTAL	242	1

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	22	0
Foetal exposure during pregnancy	8	0
Maternal exposure before pregnancy	2	0
Maternal exposure timing unspecified	11	0
<i>Fractures and dislocations NEC</i>		
Joint dislocation	1	0
<i>Maladministrations</i>		
Drug administered at inappropriate site	1	0
Extra dose administered	2	0
Inappropriate schedule of drug administration	4	0
Wrong technique in product usage process	1	0
<i>Muscle, tendon and ligament injuries</i>		
Muscle injury	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	2	0
<i>Neurological and psychiatric procedural complications</i>		
Procedural dizziness	2	0
<i>Non-site specific injuries NEC</i>		
Fall	15	0
Wound	1	0
Wound haemorrhage	2	0
<i>Off label uses</i>		
Off label use	1	0
<i>Overdoses NEC</i>		
Intentional overdose	1	0
<i>Peripheral nerve injuries</i>		
Axillary nerve injury	1	0
<i>Poisoning and toxicity</i>		
Poisoning	1	0
<i>Site specific injuries NEC</i>		
Face injury	1	0
Head injury	1	0
Mouth injury	1	0
<i>Skin injuries NEC</i>		
Contusion	45	0
Dermatitis artefacta	1	0
Excoriation	1	0
Scar	1	0
<i>Thermal burns</i>		
Thermal burn	1	0
<i>Vaccination related complications</i>		
Vaccination complication	3	0
Vaccination failure	1	0
Injuries SOC TOTAL	135	0

Case Series Drug Analysis Print

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Report Run Date: 02-Jun-2016
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Reaction Name	Total	Fatal
Investigations		
Adrenal cortex tests		
Blood cortisol decreased	1	0
Autoimmunity analyses		
Antinuclear antibody increased	1	0
Antinuclear antibody positive	1	0
Blood counts NEC		
Blood count abnormal	1	0
Blood gas and acid base analyses		
Blood pH increased	1	0
Oxygen saturation decreased	1	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose decreased	2	0
Blood glucose increased	6	0
Cardiac auscultatory investigations		
Cardiac murmur	1	0
Cell marker analyses		
Cell marker increased	1	0
Cerebrospinal fluid tests (excl microbiology)		
CSF cell count increased	1	0
Chemistry analyses NEC		
Histamine level increased	1	0
ECG investigations		
Electrocardiogram QT prolonged	1	0
Electrocardiogram T wave inversion	1	0
Electrocardiogram abnormal	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	4	0
Foetal and neonatal diagnostic procedures		
Foetal heart rate abnormal	1	0
Heart rate and pulse investigations		
Heart rate abnormal	3	0
Heart rate decreased	9	0
Heart rate increased	39	0
Heart rate irregular	8	0
Pulse abnormal	9	0
Pulse absent	2	0
Pulse pressure decreased	1	0
Investigations NEC		
Precancerous cells present	1	0
Quality of life decreased	3	0
Liver function analyses		
Alanine aminotransferase increased	1	0
Liver function test abnormal	1	0
Liver function test increased	1	0
Mineral and electrolyte analyses		
Blood iron decreased	3	0
Blood sodium abnormal	1	0
Serum ferritin decreased	2	0
Ophthalmic function diagnostic procedures		
Corneal reflex decreased	1	0
Physical examination procedures and organ system status		
Body temperature	1	0
Body temperature abnormal	2	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Body temperature decreased	5	0
Body temperature fluctuation	5	0
Body temperature increased	97	0
Breath sounds abnormal	1	0
Grip strength decreased	3	0
Respiratory rate decreased	1	0
Respiratory rate increased	9	0
Weight decreased	21	0
Weight increased	4	0
<i>Pituitary analyses anterior</i>		
Blood growth hormone abnormal	1	0
Blood thyroid stimulating hormone abnormal	1	0
<i>Platelet analyses</i>		
Platelet count decreased	3	0
<i>Protein analyses NEC</i>		
Blood albumin abnormal	1	0
Protein total abnormal	1	0
<i>Reproductive hormone analyses</i>		
Oestradiol decreased	1	0
<i>Reproductive organ and breast histopathology procedures</i>		
Smear cervix abnormal	1	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Peak expiratory flow rate decreased	1	0
<i>Tissue enzyme analyses NEC</i>		
Blood lactate dehydrogenase increased	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output decreased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	1	0
Blood pressure decreased	10	0
Blood pressure immeasurable	1	0
Blood pressure increased	7	0
Blood pressure systolic decreased	1	0
<i>Vitamin analyses</i>		
Vitamin B12 decreased	1	0
Vitamin B12 increased	1	0
Vitamin D decreased	1	0
<i>White blood cell analyses</i>		
Neutrophil count decreased	1	0
White blood cell count decreased	1	0
Investigations SOC TOTAL	297	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	2	0
Decreased appetite	63	0
Increased appetite	1	0
Salt craving	2	0
<i>Calcium metabolism disorders</i>		
Tetany	2	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus inadequate control	2	0
Type 1 diabetes mellitus	8	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	2	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	6	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Cow's milk intolerance	1	0
Food intolerance	5	0
Gluten sensitivity	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	10	0
Feeding disorder	3	0
Underweight	1	0
Weight gain poor	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	3	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	2	0
<i>Iron deficiencies</i>		
Iron deficiency	3	0
<i>Metabolic disorders NEC</i>		
Metabolic disorder	1	0
<i>Mineral related disorders NEC</i>		
Mineral deficiency	1	0
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	1	0
<i>Total fluid volume decreased</i>		
Dehydration	5	0
<i>Vitamin deficiencies NEC</i>		
Multi-vitamin deficiency	1	0
<i>Water soluble vitamin deficiencies</i>		
Vitamin B12 deficiency	5	0
Vitamin C deficiency	1	0
Metabolic disorders SOC TOTAL	133	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	4	0
Arthritis reactive	4	0
Arthropathy	5	0
Palindromic rheumatism	1	0
Seronegative arthritis	1	0
<i>Bone disorders NEC</i>		
Osteitis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	4	0
Pain in jaw	5	0
Spinal pain	3	0
<i>Cartilage disorders</i>		
Costochondritis	1	0
<i>Connective tissue disorders NEC</i>		
Mixed connective tissue disease	1	0
Reynold's syndrome	1	0
<i>Extremity deformities</i>		
Finger deformity	1	0
Foot deformity	1	0
<i>Joint related disorders NEC</i>		
Hypermobility syndrome	2	0
Joint contracture	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	156	0
Joint effusion	1	0
Joint stiffness	8	0
Joint swelling	22	0
<i>Lupus erythematosus (incl subtypes)</i>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	3	0
<i>Metabolic bone disorders</i>		
Osteoporosis	1	0
<i>Muscle infections and inflammations</i>		
Myositis	1	0
<i>Muscle pains</i>		
Fibromyalgia	7	0
Myalgia	129	0
Myalgia intercostal	1	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	6	0
Muscle spasms	30	0
Muscle swelling	1	0
Muscle tightness	5	0
Muscle twitching	38	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	28	0
<i>Muscle weakness conditions</i>		
Muscular weakness	68	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	58	0
Flank pain	2	0
Growing pains	2	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Limb discomfort	168	0
Musculoskeletal chest pain	5	0
Musculoskeletal discomfort	5	0
Musculoskeletal pain	22	0
Neck pain	49	0
Pain in extremity	987	0
Musculoskeletal and connective tissue signs and symptoms NEC		
Back disorder	2	0
Growth retardation	2	0
Mastication disorder	1	0
Mobility decreased	12	0
Muscle contracture	2	0
Musculoskeletal stiffness	86	0
Posture abnormal	1	0
Weight bearing difficulty	5	0
Rheumatoid arthropathies		
Juvenile idiopathic arthritis	3	0
Rheumatoid arthritis	3	0
Soft tissue disorders NEC		
Axillary mass	1	0
Groin pain	4	0
Neck mass	1	0
Soft tissue disorder	1	0
Spine and neck deformities		
Scoliosis	1	0
Synovial disorders		
Synovitis	1	0
Muscle & tissue disorders SOC TOTAL	1966	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Bone neoplasms malignant (excl sarcomas)</i>		
Bone cancer	1	0
<i>Endocrine neoplasms malignant and unspecified NEC</i>		
Pituitary tumour	1	0
<i>Glial tumours malignant</i>		
Medulloblastoma	1	0
<i>Hepatobiliary neoplasms benign</i>		
Focal nodular hyperplasia	1	0
<i>Islet cell neoplasms and APUDoma NEC</i>		
Pancreatic neuroendocrine tumour metastatic	1	0
<i>Leukaemias acute lymphocytic</i>		
Acute lymphocytic leukaemia	1	0
T-cell type acute leukaemia	1	1
<i>Leukaemias acute myeloid</i>		
Acute myeloid leukaemia	1	0
<i>Leukaemias chronic myeloid</i>		
Chronic myeloid leukaemia	1	0
<i>Metastases to specified sites</i>		
Metastases to liver	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Neoplasm malignant	1	1
<i>Non-Hodgkin's lymphomas NEC</i>		
Non-Hodgkin's lymphoma	1	1
<i>Pharyngeal and laryngeal neoplasms benign</i>		
Laryngeal papilloma	1	0
<i>Reproductive neoplasms female benign NEC</i>		
Benign hydatidiform mole	1	0
<i>Salivary gland neoplasms malignant</i>		
Salivary gland cancer stage I	1	0
<i>Skin neoplasms benign</i>		
Anogenital warts	2	0
Melanocytic naevus	1	0
Skin papilloma	4	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	23	3

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	5	0
<i>Absence seizures</i>		
Petit mal epilepsy	6	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	5	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	5	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Basal ganglia stroke	1	0
Cerebral thrombosis	1	0
<i>Central nervous system vascular disorders NEC</i>		
Cerebrovascular disorder	1	0
Vasculitis cerebral	1	0
<i>Choreiform movements</i>		
Chorea	1	0
<i>Chronic polyneuropathies</i>		
Demyelinating polyneuropathy	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	2	0
Balance disorder	17	0
Cerebellar ataxia	1	0
Coordination abnormal	5	0
Dysstasia	18	0
<i>Cortical dysfunction NEC</i>		
Agnosia	1	0
Aphasia	6	0
Dyslexia	1	0
Dyspraxia	1	0
<i>Demyelinating disorders NEC</i>		
Demyelination	1	0
<i>Developmental disorders cognitive</i>		
Autism	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	5	0
Consciousness fluctuating	5	0
Depressed level of consciousness	5	0
Lethargy	183	0
Loss of consciousness	81	0
Sedation	1	0
Somnolence	144	0
Syncope	745	0
<i>Disturbances in sleep phase rhythm</i>		
Sleep phase rhythm disturbance	2	0
<i>Dyskinesias and movement disorders NEC</i>		
Clumsiness	1	0
Dyskinesia	44	0
Hypokinesia	12	0
Movement disorder	5	0
Psychomotor hyperactivity	4	0
<i>Dystonias</i>		
Dystonia	1	0
<i>Encephalitis NEC</i>		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Encephalitis autoimmune	5	0
Encephalopathies NEC		
Encephalopathy	1	0
Hashimoto's encephalopathy	1	0
Eye movement disorders		
IVth nerve paralysis	1	0
VIth nerve paralysis	1	0
Facial cranial nerve disorders		
Facial paralysis	15	0
Facial paresis	1	0
Facial spasm	1	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	19	0
Headaches NEC		
Cluster headache	3	0
Headache	1582	0
Sinus headache	1	0
Tension headache	2	0
Typical aura without headache	1	0
Increased intracranial pressure disorders		
Benign intracranial hypertension	1	0
Intracranial pressure increased	1	0
Intellectual disabilities		
Intellectual disability	1	0
Memory loss (excl dementia)		
Amnesia	15	0
Memory impairment	18	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	5	0
Disturbance in attention	41	0
Mental impairment	2	0
Migraine headaches		
Basilar migraine	1	0
Migraine	62	0
Migraine with aura	1	0
Migraine without aura	3	0
Mononeuropathies		
Peroneal nerve palsy	2	0
Multiple sclerosis acute and progressive		
Multiple sclerosis	1	0
Muscle tone abnormal		
Hypertonia	1	0
Hypotonia	7	0
Myelitis (incl infective)		
Myelitis transverse	1	0
Narcolepsy and hypersomnia		
Cataplexy	3	0
Hypersomnia	21	0
Narcolepsy	5	0
Nervous system disorders NEC		
Motor dysfunction	1	0
Nervous system disorder	4	0
Neurologic visual problems NEC		

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Visual field defect	7	0
Neurological signs and symptoms NEC		
Clonus	1	0
Dizziness	2096	0
Dizziness exertional	1	0
Dizziness postural	26	0
Drooling	1	0
Head discomfort	10	0
Hyporesponsive to stimuli	1	0
Meningism	2	0
Myoclonus	3	0
Neurological symptom	1	0
Presyncope	53	0
Slow response to stimuli	5	0
Unresponsive to stimuli	37	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	2	0
Neuromuscular junction dysfunction		
Myasthenia gravis	1	0
Olfactory nerve disorders		
Parosmia	2	0
Optic nerve disorders NEC		
Optic neuritis	3	0
Paraesthesias and dysaesthesias		
Burning sensation	5	0
Formication	1	0
Hyperaesthesia	7	0
Hypoaesthesia	313	0
Paraesthesia	218	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	3	0
Hemiparesis	6	0
Monoparesis	1	0
Monoplegia	8	0
Paralysis	5	0
Quadriparesis	1	0
Parkinson's disease and parkinsonism		
Masked facies	1	0
Peripheral neuropathies NEC		
Lumbosacral plexus lesion	1	0
Neuritis	1	0
Peripheral sensory neuropathy	1	0
Seizures and seizure disorders NEC		
Clonic convulsion	1	0
Epilepsy	18	0
Myoclonic epilepsy	1	0
Partial seizures	3	0
Seizure	118	0
Seizure anoxic	5	0
Seizure like phenomena	4	0
Status epilepticus	2	0
Tonic clonic movements	2	0
Sensory abnormalities NEC		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Ageusia	1	0
Allodynia	1	0
Complex regional pain syndrome	15	0
Dysgeusia	11	0
Neuralgia	3	0
Post herpetic neuralgia	1	0
Sensory disturbance	18	0
Sensory loss	23	0
<i>Sleep disturbances NEC</i>		
Poor quality sleep	1	0
Sudden onset of sleep	3	0
<i>Speech and language abnormalities</i>		
Aphonia	7	0
Dysarthria	14	0
Incoherent	2	0
Slow speech	1	0
Speech disorder	7	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculitis brachial	1	0
Spinal cord oedema	1	0
<i>Tremor (excl congenital)</i>		
Tremor	167	0
Nervous system disorders SOC TOTAL	6405	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	15	0
Abortion threatened	1	0
<i>Foetal complications NEC</i>		
Foetal distress syndrome	1	0
<i>Foetal growth complications</i>		
Foetal growth restriction	2	0
<i>Gestational age and weight conditions</i>		
Premature baby	6	1
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	1	0
<i>Labour onset and length abnormalities</i>		
Premature labour	2	0
<i>Maternal complications of labour NEC</i>		
Labour complication	1	0
<i>Maternal complications of pregnancy NEC</i>		
Cervical incompetence	1	0
<i>Normal pregnancy, labour and delivery</i>		
Live birth	5	0
<i>Stillbirth and foetal death</i>		
Foetal death	1	0
<i>Unintended pregnancies</i>		
Pregnancy with injectable contraceptive	1	0
Pregnancy conditions SOC TOTAL	37	1

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Reaction Name	Total	Fatal
<i>Product quality issues NEC</i>		
Product substitution issue	1	0
null SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	12	0
<i>Adjustment disorders</i>		
Adjustment disorder with mixed anxiety and depressed mood	2	0
<i>Affect alterations NEC</i>		
Affect lability	1	0
Inappropriate affect	1	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	1	0
<i>Anxiety symptoms</i>		
Agitation	7	0
Anxiety	42	0
Nervousness	17	0
Stress	2	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	7	0
Disinhibition	2	0
Disturbance in social behaviour	1	0
Paranoia	5	0
Personality change	5	0
Social avoidant behaviour	3	0
<i>Bipolar disorders</i>		
Bipolar disorder	1	0
<i>Confusion and disorientation</i>		
Confusional state	26	0
Disorientation	24	0
<i>Deliria</i>		
Delirium	2	0
<i>Delusional symptoms</i>		
Delusion	2	0
<i>Depressive disorders</i>		
Depression	15	0
<i>Dissociative states</i>		
Dissociation	3	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	34	0
Middle insomnia	1	0
<i>Eating disorders NEC</i>		
Eating disorder	2	0
<i>Emotional and mood disturbances NEC</i>		
Emotional disorder	8	0
Emotional distress	10	0
Emotional poverty	1	0
Euphoric mood	1	0
Irritability	4	0
Mood altered	4	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Autophobia	1	0
Fear	3	0
Fear of crowded places	1	0
Fear of death	2	0
Social anxiety disorder	3	0
<i>Fluctuating mood symptoms</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
Mood swings	5	0
Impulse control disorders		
Impulse-control disorder	1	0
Impulsive behaviour	1	0
Increased physical activity levels		
Restlessness	4	0
Mood alterations with depressive symptoms		
Decreased interest	4	0
Depressed mood	10	0
Depressive symptom	2	0
Feeling guilty	1	0
Feeling of despair	1	0
Negative thoughts	1	0
Tearfulness	24	0
Mood alterations with manic symptoms		
Hypomania	1	0
Mood disorders NEC		
Affective disorder	1	0
Apathy	1	0
Listless	5	0
Narcolepsy and associated conditions		
Sleep attacks	1	0
Obsessive-compulsive disorders and symptoms		
Obsessive thoughts	1	0
Obsessive-compulsive disorder	1	0
Trichotillomania	1	0
Panic attacks and disorders		
Panic attack	23	0
Panic reaction	7	0
Parasomnias		
Abnormal dreams	1	0
Abnormal sleep-related event	1	0
Sleep terror	1	0
Perception disturbances		
Hallucination	12	0
Hallucination, auditory	4	0
Hallucination, visual	2	0
Personality disorders NEC		
Self esteem decreased	2	0
Personality disorders with anxious behaviour (Cluster C)		
Dependent personality disorder	1	0
Psychiatric symptoms NEC		
Psychiatric symptom	1	0
Psychotic disorder NEC		
Acute psychosis	1	0
Psychotic disorder	4	0
Sleep disorders NEC		
Sleep disorder	13	0
Somatic symptom disorders		
Somatic symptom disorder	2	0
Speech and language usage disturbances		
Disorganised speech	1	0
Speech articulation and rhythm disturbances		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Dysphemia	2	0
Screaming	2	0
<i>Stereotypies and automatisms</i>		
Bruxism	1	0
Head banging	2	0
<i>Stress disorders</i>		
Burnout syndrome	1	0
Post-traumatic stress disorder	1	0
<i>Suicidal and self-injurious behaviour</i>		
Intentional self-injury	2	0
Self-injurious ideation	1	0
Suicidal ideation	4	0
Suicide attempt	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	2	0
Thinking abnormal	2	0
Thought blocking	2	0
Psychiatric disorders SOC TOTAL	421	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder pain	1	0
Bladder spasm	1	0
Dysuria	1	0
Incontinence	1	0
Micturition urgency	2	0
Pollakiuria	7	0
Urinary incontinence	15	0
Urinary retention	2	0
<i>Bladder disorders NEC</i>		
Bladder disorder	3	0
Bladder fibrosis	1	0
<i>Bladder infections and inflammations</i>		
Cystitis noninfective	1	0
<i>Genital and urinary tract disorders NEC</i>		
Urinary tract disorder	3	0
<i>Genitourinary tract infections and inflammations NEC</i>		
Urinary tract inflammation	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Focal segmental glomerulosclerosis	1	0
Nephrotic syndrome	1	0
<i>Myoneurogenic bladder disorders</i>		
Contracted bladder	1	0
Hypertonic bladder	1	0
Neurogenic bladder	1	0
<i>Renal disorders NEC</i>		
Renal disorder	2	0
<i>Renal failure and impairment</i>		
Renal failure	1	0
<i>Urinary abnormalities</i>		
Proteinuria	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	2	0
Polyuria	1	0
Renal & urinary disorders SOC TOTAL	51	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast disorders NEC</i>		
Breast enlargement	1	0
<i>Breast signs and symptoms</i>		
Breast pain	1	0
Breast swelling	1	0
Breast tenderness	2	0
<i>Cervix disorders NEC</i>		
Cervical dysplasia	1	0
Uterine cervix atrophy	1	0
<i>Cervix infections and inflammations</i>		
Cervix inflammation	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	8	0
Menstrual disorder	12	0
Menstruation irregular	20	0
Metrorrhagia	1	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	21	0
Menstruation delayed	7	0
Oligomenorrhoea	2	0
<i>Menstruation with increased bleeding</i>		
Menorrhagia	20	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	2	0
Polycystic ovaries	3	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovarian disorder	1	0
Ovarian failure	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital erythema	1	0
Genital pain	2	0
Genital swelling	1	0
Pelvic pain	2	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	9	0
Vaginal mucosal blistering	1	0
Vaginal ulceration	1	0
Vulval disorder	1	0
Vulval ulceration	3	0
Vulvar dysplasia	1	0
Vulvovaginal disorder	1	0
<i>Vulvovaginal signs and symptoms</i>		
Vaginal discharge	1	0
Vaginal lesion	1	0
Vulval oedema	2	0
Vulvovaginal pain	1	0
Vulvovaginal pruritus	1	0
Vulvovaginal swelling	2	0
Reproductive & breast disorders SOC TOTAL	137	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	152	0
Grunting	1	0
Hyperventilation	47	0
Hypopnoea	11	0
Respiratory arrest	2	0
Respiratory distress	1	0
Tachypnoea	4	0
<i>Bronchospasm and obstruction</i>		
Asthma	20	0
Bronchospasm	3	0
Wheezing	22	0
<i>Coughing and associated symptoms</i>		
Allergic cough	1	0
Cough	36	0
Haemoptysis	2	0
Productive cough	2	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Laryngeal oedema	5	0
Laryngospasm	1	0
Stridor	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Increased bronchial secretion	1	0
Pleuritic pain	2	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	7	0
<i>Nasal disorders NEC</i>		
Epistaxis	18	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	1	0
Pharyngeal oedema	15	0
Tonsillar hypertrophy	2	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pneumothorax	1	0
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	1	0
<i>Respiratory signs and symptoms NEC</i>		
Painful respiration	1	0
Respiration abnormal	1	0
<i>Respiratory tract disorders NEC</i>		
Respiratory disorder	2	0
Respiratory tract inflammation	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Choking sensation	2	0
Dry throat	6	0
Dysphonia	2	0
Nasal obstruction	1	0
Oropharyngeal discomfort	2	0
Oropharyngeal pain	102	0
Rhinorrhoea	4	0
Sneezing	3	0
Throat irritation	21	0
Throat lesion	1	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Throat tightness	36	0
Vascular pulmonary disorders NEC		
Pulmonary arteriopathy	2	0
Respiratory disorders SOC TOTAL	546	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	5	0
Acne cystic	1	0
<i>Alopecias</i>		
Alopecia	36	0
Alopecia areata	7	0
Alopecia totalis	2	0
Diffuse alopecia	3	0
Madarosis	1	0
<i>Angioedemas</i>		
Angioedema	13	0
Circumoral oedema	1	0
Swelling face	78	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	93	0
Hyperhidrosis	78	0
Miliaria	4	0
Night sweats	2	0
<i>Bullous conditions</i>		
Blister	18	0
Erythema multiforme	8	0
Stevens-Johnson syndrome	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	8	0
Pain of skin	7	0
Papule	3	0
Scab	1	0
Skin burning sensation	1	0
Skin discolouration	119	0
Skin disorder	5	0
Skin lesion	3	0
Skin reaction	13	0
Skin tightness	2	0
Skin warm	26	0
Yellow skin	1	0
<i>Dermatitis and eczema</i>		
Dermatitis	1	0
Dermatitis allergic	21	0
Dermatitis contact	4	0
Dyshidrotic eczema	1	0
Eczema	13	0
Eczema vesicular	1	0
Seborrhoeic dermatitis	2	0
Skin irritation	9	0
<i>Erythemas</i>		
Erythema	202	0
Generalised erythema	4	0
Palmar erythema	1	0
Rash erythematous	33	0
<i>Exfoliative conditions</i>		
Skin exfoliation	4	0
<i>Hyperpigmentation disorders</i>		
Melanoderma	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Hypopigmentation disorders</i>		
Skin depigmentation	1	0
Vitiligo	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail discolouration	2	0
<i>Panniculitides</i>		
Erythema nodosum	4	0
Panniculitis	1	0
<i>Papulosquamous conditions</i>		
Pityriasis lichenoides et varioliformis acuta	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	12	0
<i>Pilar disorders NEC</i>		
Piloerection	1	0
Trichorrhexis	1	0
<i>Pruritus NEC</i>		
Pruritus	143	0
Pruritus generalised	16	0
Rash pruritic	59	0
<i>Psoriatic conditions</i>		
Guttate psoriasis	1	0
Psoriasis	3	0
<i>Purpura and related conditions</i>		
Henoch-Schonlein purpura	8	0
Petechiae	8	0
Purpura	5	0
<i>Pustular conditions</i>		
Rash follicular	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	344	0
Rash generalised	68	0
Rash macular	73	0
Rash maculo-papular	5	0
Rash papular	3	0
Rash vesicular	1	0
Systemic lupus erythematosus rash	1	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	3	0
Umbilical discharge	1	0
<i>Skin haemorrhages</i>		
Skin haemorrhage	1	0
<i>Skin hyperplasias and hypertrophies</i>		
Skin hypertrophy	2	0
<i>Skin hypoplasias and atrophies</i>		
Skin striae	2	0
<i>Skin preneoplastic conditions NEC</i>		
Precancerous skin lesion	1	0
<i>Urticarias</i>		
Urticaria	200	0
Urticaria chronic	3	0
Urticaria pigmentosa	1	0
Skin disorders SOC TOTAL	1814	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Puberty	1	0
<i>Disability issues</i>		
Activities of daily living impaired	11	0
Bedridden	4	0
Disability	1	0
Immobile	2	0
Impaired work ability	1	0
Physical disability	1	0
<i>Educational issues</i>		
Educational problem	2	0
Social circumstances SOC TOTAL	23	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Hernia repairs</i>		
Inguinal hernia repair	1	0
<i>Induced abortions</i>		
Abortion induced	5	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	5	0
<i>Obstetric therapeutic procedures</i>		
Ventouse extraction	1	0
<i>Vascular therapeutic procedures NEC</i>		
Vasodilation procedure	1	0
Surgical & medical procedures SOC TOTAL	13	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	1	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	5	0
Peripheral circulatory failure	1	0
Shock	2	0
<i>Haemorrhages NEC</i>		
Haemorrhage	2	0
<i>Lymphoedemas</i>		
Lymphoedema	1	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	2	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Peripheral venous disease	2	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Capillary disorder	3	0
Vascular pain	1	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	1	0
Thrombophlebitis superficial	1	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	113	0
Hot flush	16	0
Peripheral vascular disorder	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	99	0
Poor peripheral circulation	6	0
Raynaud's phenomenon	5	0
<i>Site specific vascular disorders NEC</i>		
Pallor	320	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	8	0
Orthostatic hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	28	0
Orthostatic hypotension	2	0
<i>Vasculitides NEC</i>		
Behcet's syndrome	1	0
Vasculitis	1	0
Vascular disorders SOC TOTAL	624	0
TOTAL REACTIONS FOR DRUG	21156	8
TOTAL REPORTS	8599	
TOTAL FATAL OUTCOME REPORTS		8