

# Case Series Drug Analysis Print

**Name: HPV**

Report Run Date: 19-Feb-2014  
Data Lock Date: 18-Feb-2014 01:01:22  
Earliest Reaction Date: 29-Nov-2006  
MedDRA Version: MedDRA 16.1  
HPV: Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i><b>Anaemia deficiencies</b></i>		
Anaemia vitamin B12 deficiency	1	0
<i><b>Anaemias NEC</b></i>		
Anaemia	7	0
<i><b>Anaemias haemolytic mechanical factor</b></i>		
Haemolytic uraemic syndrome	1	0
<i><b>Bleeding tendencies</b></i>		
Increased tendency to bruise	1	0
<i><b>Coagulopathies</b></i>		
Coagulopathy	1	0
<i><b>Eosinophilic disorders</b></i>		
Eosinophilia	1	0
<i><b>Haematological disorders</b></i>		
Mastocytosis	1	0
<i><b>Lymphatic system disorders NEC</b></i>		
Lymphadenopathy	31	0
<i><b>Marrow depression and hypoplastic anaemias</b></i>		
Aplastic anaemia	1	0
Pancytopenia	1	0
<i><b>Neutropenias</b></i>		
Neutropenia	1	0
<i><b>Spleen disorders</b></i>		
Splenomegaly	1	0
<i><b>Thrombocytopenias</b></i>		
Idiopathic thrombocytopenic purpura	3	0
Thrombocytopenia	1	0
<b>Blood disorders SOC TOTAL</b>	<b>52</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cyanosis	24	0
Palpitations	16	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	5	0
Postural orthostatic tachycardia syndrome	3	0
Tachycardia	29	0
<i>Supraventricular arrhythmias</i>		
Sinus arrhythmia	1	0
Sinus tachycardia	3	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>87</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Anorectal disorders congenital</i>		
Preternatural anus	2	0
<i>Cardiac septal defects congenital</i>		
Atrioventricular septal defect	2	0
<i>Cerebral disorders congenital</i>		
Cerebral palsy	1	0
<i>Congenital disorders NEC</i>		
Congenital anomaly	1	0
VACTERL syndrome	2	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>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
<b>Congenital disorders SOC TOTAL</b>	<b>34</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear discomfort	2	0
Ear pain	14	0
<i>Hearing losses</i>		
Deafness	12	0
Deafness bilateral	1	0
Deafness transitory	3	0
Hearing impaired	8	0
Hypoacusis	6	0
<i>Hyperacusia</i>		
Hyperacusis	3	0
<i>Inner ear disorders NEC</i>		
Inner ear disorder	1	0
Vestibular disorder	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	11	0
Vertigo	11	0
<b>Ear disorders SOC TOTAL</b>	<b>73</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	2	0
<i>Adrenal cortical hypofunctions</i>		
Adrenocortical insufficiency acute	2	0
<i>Posterior pituitary disorders</i>		
Diabetes insipidus	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	2	0
<b>Endocrine disorders SOC TOTAL</b>	<b>7</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i>Blindness (excl colour blindness)</i>		
Blindness	9	0
Blindness transient	10	0
Blindness unilateral	1	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous floaters	4	0
<i>Colour blindness (incl acquired)</i>		
Colour blindness acquired	2	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	2	0
Conjunctivitis	1	0
<i>Eyelid movement disorders</i>		
Excessive eye blinking	2	0
Eyelid ptosis	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
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	13	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	2	0
Eye disorder	3	0
Eye pain	12	0
Eye swelling	30	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	1	0
Eye pruritus	4	0
Ocular hyperaemia	5	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	20	0
Gaze palsy	2	0
Ocular myasthenia	1	0
<i>Ocular sensation disorders</i>		
Asthenopia	3	0
Photophobia	24	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	4	0
<i>Pupil disorders</i>		
Mydriasis	16	0
Pupil fixed	2	0
Pupillary disorder	1	0

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<b>Eye disorders</b> Eye disorders cont'd		
Pupillary reflex impaired	1	0
<b><i>Refractive and accommodative disorders</i></b>		
Accommodation disorder	1	0
Altered visual depth perception	1	0
<b><i>Retinal, choroid and vitreous infections and inflammations</i></b>		
Choroiditis	1	0
Retinal vasculitis	1	0
<b><i>Visual disorders NEC</i></b>		
Diplopia	10	0
Metamorphopsia	1	0
Photopsia	3	0
Vision blurred	116	0
Visual impairment	41	0
<b>Eye disorders SOC TOTAL</b>	<b>363</b>	<b>0</b>



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<b>Gastrointestinal disorders</b>		
<b><i>Anal and rectal disorders NEC</i></b>		
Anal fissure	1	0
<b><i>Colitis (excl infective)</i></b>		
Colitis	1	0
Colitis ulcerative	4	0
<b><i>Dental disorders NEC</i></b>		
Tooth erosion	1	0
<b><i>Diarrhoea (excl infective)</i></b>		
Diarrhoea	94	0
Diarrhoea haemorrhagic	1	0
<b><i>Dyspeptic signs and symptoms</i></b>		
Dyspepsia	5	0
Eructation	1	0
<b><i>Faecal abnormalities NEC</i></b>		
Abnormal faeces	1	0
<b><i>Flatulence, bloating and distension</i></b>		
Abdominal distension	6	0
Flatulence	1	0
<b><i>Gastritis (excl infective)</i></b>		
Gastritis	4	0
<b><i>Gastrointestinal and abdominal pains (excl oral and throat)</i></b>		
Abdominal migraine	1	0
Abdominal pain	146	0
Abdominal pain lower	9	0
Abdominal pain upper	137	0
Abdominal tenderness	1	0
Gastrointestinal pain	1	0
<b><i>Gastrointestinal atonic and hypomotility disorders NEC</i></b>		
Constipation	3	0
Gastric dilatation	1	0
Gastrooesophageal reflux disease	6	0
Impaired gastric emptying	1	0
<b><i>Gastrointestinal disorders NEC</i></b>		
Functional gastrointestinal disorder	1	0
Gastric disorder	1	0
Gastrointestinal disorder	4	0
<b><i>Gastrointestinal dyskinetic disorders</i></b>		
Gastrointestinal motility disorder	1	0
<b><i>Gastrointestinal inflammatory disorders NEC</i></b>		
Duodenitis	1	0
<b><i>Gastrointestinal mucosal dystrophies and secretion disorders</i></b>		
Oesophageal mucosal hyperplasia	1	0
<b><i>Gastrointestinal signs and symptoms NEC</i></b>		
Abdominal discomfort	40	0
Aphagia	1	0
Dysphagia	14	0
Oesophageal discomfort	1	0
<b><i>Gastrointestinal spastic and hypermotility disorders</i></b>		
Frequent bowel movements	2	0
Irritable bowel syndrome	6	0
<b><i>Gastrointestinal ulcers and perforation, site unspecified</i></b>		
Gastrointestinal ulcer	1	0
<b><i>Gingival disorders NEC</i></b>		

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<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Gingival disorder	1	0
<b>Haemorrhoids and gastrointestinal varices (excl oesophageal)</b>		
Haemorrhoids	1	0
<b>Inguinal hernias</b>		
Inguinal hernia	1	0
<b>Intestinal haemorrhages</b>		
Rectal haemorrhage	1	0
<b>Nausea and vomiting symptoms</b>		
Nausea	1338	0
Regurgitation	1	0
Retching	5	0
Vomiting	584	0
Vomiting projectile	1	0
<b>Non-site specific gastrointestinal haemorrhages</b>		
Gastrointestinal haemorrhage	1	0
Haematemesis	5	0
<b>Oral dryness and saliva altered</b>		
Dry mouth	5	0
Saliva altered	1	0
Salivary hypersecretion	3	0
<b>Oral soft tissue disorders NEC</b>		
Cheilitis	1	0
Lip blister	2	0
Lip ulceration	1	0
<b>Oral soft tissue pain and paraesthesia</b>		
Lip pain	1	0
Odynophagia	2	0
Oral pain	3	0
Paraesthesia oral	30	0
<b>Oral soft tissue signs and symptoms</b>		
Hypoaesthesia oral	9	0
Oral discomfort	2	0
Oral mucosal blistering	1	0
Oral pruritus	2	0
<b>Oral soft tissue swelling and oedema</b>		
Gingival swelling	1	0
Lip swelling	51	0
Oedema mouth	8	0
<b>Pancreatic disorders NEC</b>		
Pancreatic disorder	1	0
<b>Stomatitis and ulceration</b>		
Mouth ulceration	5	0
<b>Tongue signs and symptoms</b>		
Swollen tongue	24	0
Tongue coated	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>2593</b>	<b>0</b>

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<b>General disorders</b>		
<b>Administration site reactions NEC</b>		
Puncture site reaction	1	0
<b>Asthenic conditions</b>		
Asthenia	111	0
Chronic fatigue syndrome	27	0
Fatigue	502	0
Malaise	637	0
<b>Body temperature altered</b>		
Temperature regulation disorder	1	0
<b>Febrile disorders</b>		
Hyperpyrexia	1	0
Pyrexia	386	0
<b>Feelings and sensations NEC</b>		
Chills	67	0
Feeling abnormal	34	0
Feeling cold	61	0
Feeling drunk	3	0
Feeling hot	183	0
Feeling jittery	3	0
Feeling of body temperature change	17	0
Sensation of foreign body	2	0
Sensation of pressure	2	0
Temperature intolerance	1	0
Thirst	4	0
<b>Gait disturbances</b>		
Abasia	14	0
Gait disturbance	22	0
<b>General signs and symptoms NEC</b>		
Condition aggravated	10	0
Crying	8	0
Exercise tolerance decreased	1	0
Foaming at mouth	2	0
General physical health deterioration	1	0
Ill-defined disorder	2	0
Induration	2	0
Influenza like illness	104	0
Irritability	2	0
Local reaction	31	0
Local swelling	312	0
Swelling	30	0
<b>Inflammations</b>		
Inflammation	18	0
Systemic inflammatory response syndrome	1	0
<b>Infusion site reactions</b>		
Infusion site anaesthesia	1	0
<b>Injection site reactions</b>		
Injected limb mobility decreased	4	0
Injection site anaesthesia	13	0
Injection site bruising	27	0
Injection site coldness	4	0
Injection site discharge	3	0
Injection site discolouration	6	0
Injection site discomfort	2	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Injection site erythema	123	0
Injection site granuloma	1	0
Injection site haemorrhage	3	0
Injection site induration	10	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	61	0
Injection site movement impairment	3	0
Injection site nerve damage	1	0
Injection site nodule	8	0
Injection site pain	127	0
Injection site papule	1	0
Injection site paraesthesia	1	0
Injection site pruritus	22	0
Injection site rash	52	0
Injection site reaction	35	0
Injection site scab	2	0
Injection site scar	1	0
Injection site swelling	167	0
Injection site urticaria	5	0
Injection site vesicles	5	0
Injection site warmth	27	0
<b>Mass conditions NEC</b>		
Mass	4	0
Nodule	1	0
<b>Oedema NEC</b>		
Extensive swelling of vaccinated limb	2	0
Face oedema	5	0
Localised oedema	1	0
Oedema peripheral	10	0
<b>Pain and discomfort NEC</b>		
Axillary pain	1	0
Chest discomfort	51	0
Chest pain	52	0
Discomfort	6	0
Facial pain	1	0
Pain	162	0
Tenderness	15	0
<b>Therapeutic and nontherapeutic responses</b>		
Drug ineffective	1	0
<b>Trophic disorders</b>		
Atrophy	1	0
<b>Ulcers NEC</b>		
Ulcer	1	0
<b>Vaccination site reactions</b>		
Vaccination site hypersensitivity	1	0
<b>General disorders SOC TOTAL</b>	<b>3669</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Cholestasis and jaundice</i>		
Jaundice	2	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Hepatic cyst	1	0
Liver disorder	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Allergic oedema	1	0
Allergy to animal	2	0
Hypersensitivity	55	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><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Drug hypersensitivity	1	0
Food allergy	2	0
Reaction to preservatives	1	0
Rubber sensitivity	1	0
<i><b>Anaphylactic responses</b></i>		
Anaphylactic reaction	65	0
Anaphylactic shock	5	0
Anaphylactoid reaction	3	0
<i><b>Autoimmune disorders NEC</b></i>		
Autoimmune disorder	3	0
<i><b>Immune and associated conditions NEC</b></i>		
Immune system disorder	2	0
Immunisation reaction	2	0
<b>Immune system disorders SOC TOTAL</b>	<b>151</b>	<b>0</b>

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<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Appendicitis	2	0
Gastrointestinal infection	1	0
Peritonitis	1	0
<b><i>Bacterial infections NEC</i></b>		
Cellulitis	2	0
Folliculitis	1	0
Injection site cellulitis	2	0
Small intestinal bacterial overgrowth	1	0
<b><i>Breast infections</i></b>		
Mastitis	1	0
<b><i>Candida infections</i></b>		
Candida infection	2	0
Vulvovaginal candidiasis	1	0
<b><i>Central nervous system and spinal infections</i></b>		
Encephalitis lethargica	1	0
<b><i>Dental and oral soft tissue infections</i></b>		
Gingivitis	1	0
<b><i>Ear infections</i></b>		
Labyrinthitis	2	0
Otitis media	1	0
<b><i>Ectoparasitic infestations</i></b>		
Acarodermatitis	1	0
<b><i>Epstein-Barr viral infections</i></b>		
Infectious mononucleosis	7	0
<b><i>Eye and eyelid infections</i></b>		
Hordeolum	4	0
<b><i>Female reproductive tract infections</i></b>		
Amniotic cavity infection	1	0
<b><i>Herpes viral infections</i></b>		
Herpes zoster	8	0
Oral herpes	1	0
Varicella	1	0
<b><i>Infections NEC</i></b>		
Infection	4	0
Infection susceptibility increased	1	0
Injection site abscess	1	0
Injection site infection	4	0
Respiratory tract infection	2	0
<b><i>Influenza viral infections</i></b>		
Influenza	3	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Bronchitis	2	0
Lower respiratory tract infection	12	0
<b><i>Molluscum contagiosum viral infections</i></b>		
Molluscum contagiosum	1	0
<b><i>Papilloma viral infections</i></b>		
Papilloma viral infection	1	0
<b><i>Respiratory syncytial viral infections</i></b>		
Respiratory syncytial virus infection	1	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Sepsis	1	0
Septic rash	1	0

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<b>Infections</b> Infections cont'd		
Viraemia	1	0
<b><i>Skin structures and soft tissue infections</i></b>		
Application site pustules	1	0
Furuncle	3	0
Impetigo	1	0
Skin infection	1	0
<b><i>Staphylococcal infections</i></b>		
Staphylococcal infection	1	0
<b><i>Streptococcal infections</i></b>		
Beta haemolytic streptococcal infection	2	0
Streptococcal sepsis	1	1
<b><i>Upper respiratory tract infections</i></b>		
Epiglottitis	1	0
Laryngitis	1	0
Nasopharyngitis	31	0
Pharyngitis	4	0
Tonsillitis	3	0
Upper respiratory tract infection	3	0
<b><i>Urinary tract infections</i></b>		
Kidney infection	1	0
Urinary tract infection	3	0
<b><i>Viral infections NEC</i></b>		
Gastroenteritis viral	1	0
Hepatitis viral	1	0
Pneumonia viral	1	0
Post viral fatigue syndrome	27	0
Severe acute respiratory syndrome	1	0
Viral infection	13	0
<b>Infections SOC TOTAL</b>	<b>178</b>	<b>1</b>



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<b>Injuries</b>		
<i><b>Exposures associated with pregnancy, delivery and lactation</b></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><b>Maladministrations</b></i>		
Inappropriate schedule of drug administration	4	0
Incorrect dose administered	1	0
Wrong technique in drug usage process	1	0
<i><b>Muscle, tendon and ligament injuries</b></i>		
Muscle injury	1	0
<i><b>Nerve injuries NEC</b></i>		
Nerve injury	2	0
<i><b>Neurological and psychiatric procedural complications</b></i>		
Procedural dizziness	2	0
<i><b>Non-site specific injuries NEC</b></i>		
Fall	11	0
Wound	1	0
<i><b>Overdoses</b></i>		
Intentional overdose	1	0
<i><b>Peripheral nerve injuries</b></i>		
Axillary nerve injury	1	0
<i><b>Site specific injuries NEC</b></i>		
Face injury	1	0
Head injury	1	0
Mouth injury	1	0
<i><b>Skin injuries NEC</b></i>		
Contusion	43	0
Dermatitis artefacta	1	0
Excoriation	1	0
Scar	1	0
<i><b>Vaccination related complications</b></i>		
Vaccination complication	1	0
<b>Injuries SOC TOTAL</b>	<b>118</b>	<b>0</b>

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

Reaction Name	Total	Fatal
<b>Investigations</b>		
<b>Adrenal cortex tests</b>		
Blood cortisol decreased	1	0
<b>Autoimmunity analyses</b>		
Antinuclear antibody increased	1	0
<b>Blood counts NEC</b>		
Blood count abnormal	1	0
<b>Blood gas and acid base analyses</b>		
Blood pH increased	1	0
Oxygen saturation decreased	1	0
<b>Carbohydrate tolerance analyses (incl diabetes)</b>		
Blood glucose decreased	2	0
Blood glucose increased	6	0
<b>Cell marker analyses</b>		
Cell marker increased	1	0
<b>Cerebrospinal fluid tests (excl microbiology)</b>		
CSF cell count increased	1	0
<b>ECG investigations</b>		
Electrocardiogram QT prolonged	1	0
Electrocardiogram T wave inversion	1	0
Electrocardiogram abnormal	1	0
<b>Endocrine analyses and imaging NEC</b>		
Hormone level abnormal	2	0
<b>Foetal and neonatal diagnostic procedures</b>		
Foetal heart rate abnormal	1	0
<b>Heart rate and pulse investigations</b>		
Heart rate decreased	6	0
Heart rate increased	24	0
Heart rate irregular	7	0
Pulse abnormal	5	0
Pulse absent	1	0
Pulse pressure decreased	3	0
<b>Investigations NEC</b>		
Quality of life decreased	3	0
<b>Liver function analyses</b>		
Alanine aminotransferase increased	1	0
Liver function test abnormal	1	0
<b>Mineral and electrolyte analyses</b>		
Blood iron decreased	2	0
Serum ferritin decreased	2	0
<b>Ophthalmic function diagnostic procedures</b>		
Corneal reflex decreased	1	0
<b>Physical examination procedures and organ system status</b>		
Body temperature decreased	4	0
Body temperature fluctuation	3	0
Body temperature increased	91	0
Breath sounds abnormal	1	0
Grip strength decreased	3	0
Respiratory rate decreased	1	0
Respiratory rate increased	6	0
Weight decreased	21	0
Weight increased	4	0
<b>Platelet analyses</b>		
Platelet count decreased	3	0

# Case Series Drug Analysis Print

Name: HPV

Report Run Date: 19-Feb-2014  
 Earliest Reaction Date: 29-Nov-2006

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

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
<i><b>Protein analyses NEC</b></i>		
Blood albumin abnormal	1	0
Protein total abnormal	1	0
<i><b>Reproductive organ and breast histopathology procedures</b></i>		
Smear cervix abnormal	1	0
<i><b>Respiratory and pulmonary function diagnostic procedures</b></i>		
Peak expiratory flow rate decreased	1	0
<i><b>Urinary tract function analyses NEC</b></i>		
Urine output decreased	1	0
<i><b>Vascular tests NEC (incl blood pressure)</b></i>		
Blood pressure abnormal	1	0
Blood pressure decreased	7	0
Blood pressure immeasurable	1	0
Blood pressure increased	7	0
Blood pressure systolic decreased	1	0
<i><b>Vitamin analyses</b></i>		
Vitamin B12 increased	1	0
<i><b>White blood cell analyses</b></i>		
Neutrophil count decreased	1	0
White blood cell count decreased	1	0
<b>Investigations SOC TOTAL</b>	<b>239</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: HPV

Report Run Date: 19-Feb-2014  
Earliest Reaction Date: 29-Nov-2006

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

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Appetite disorder	1	0
Decreased appetite	51	0
Increased appetite	1	0
<i><b>Calcium metabolism disorders</b></i>		
Tetany	2	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Diabetes mellitus inadequate control	2	0
Type 1 diabetes mellitus	6	0
<i><b>Diabetic complications NEC</b></i>		
Diabetic ketoacidosis	2	0
<i><b>Fat soluble vitamin deficiencies and disorders</b></i>		
Vitamin D deficiency	1	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Food intolerance	3	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	1	0
<i><b>Hyperglycaemic conditions NEC</b></i>		
Hyperglycaemia	3	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	1	0
<i><b>Iron deficiencies</b></i>		
Iron deficiency	2	0
<i><b>Metabolic disorders NEC</b></i>		
Metabolic disorder	1	0
<i><b>Sugar intolerance (excl glucose intolerance)</b></i>		
Lactose intolerance	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	5	0
<i><b>Water soluble vitamin deficiencies</b></i>		
Vitamin B12 deficiency	2	0
Vitamin C deficiency	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>86</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: HPV

Report Run Date: 19-Feb-2014  
Earliest Reaction Date: 29-Nov-2006

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

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<b><i>Arthropathies NEC</i></b>		
Arthritis	2	0
Arthritis reactive	4	0
Arthropathy	4	0
Palindromic rheumatism	1	0
<b><i>Bone disorders NEC</i></b>		
Osteitis	1	0
<b><i>Bone related signs and symptoms</i></b>		
Bone pain	1	0
Pain in jaw	3	0
<b><i>Cartilage disorders</i></b>		
Costochondritis	1	0
<b><i>Connective tissue disorders (excl LE)</i></b>		
Mixed connective tissue disease	1	0
<b><i>Extremity deformities</i></b>		
Foot deformity	1	0
<b><i>Joint related disorders NEC</i></b>		
Hypermobility syndrome	1	0
Joint contracture	1	0
<b><i>Joint related signs and symptoms</i></b>		
Arthralgia	119	0
Joint effusion	1	0
Joint stiffness	7	0
Joint swelling	19	0
<b><i>Lupus erythematosus (incl subtypes)</i></b>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	2	0
<b><i>Metabolic bone disorders</i></b>		
Osteoporosis	1	0
<b><i>Muscle pains</i></b>		
Fibromyalgia	1	0
Myalgia	107	0
Myalgia intercostal	1	0
<b><i>Muscle related signs and symptoms NEC</i></b>		
Muscle fatigue	5	0
Muscle spasms	16	0
Muscle swelling	1	0
Muscle tightness	5	0
Muscle twitching	27	0
<b><i>Muscle tone abnormalities</i></b>		
Muscle rigidity	21	0
<b><i>Muscle weakness conditions</i></b>		
Muscular weakness	55	0
<b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>		
Back pain	45	0
Flank pain	2	0
Growing pains	1	0
Limb discomfort	123	0
Musculoskeletal chest pain	2	0
Musculoskeletal discomfort	5	0
Musculoskeletal pain	17	0
Neck pain	38	0
Pain in extremity	921	0

# Case Series Drug Analysis Print

Name: HPV

Report Run Date: 19-Feb-2014  
 Earliest Reaction Date: 29-Nov-2006

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

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
<b><i>Musculoskeletal and connective tissue signs and symptoms NEC</i></b>		
Back disorder	2	0
Growth retardation	1	0
Mastication disorder	1	0
Mobility decreased	10	0
Muscle contracture	1	0
Musculoskeletal stiffness	77	0
Posture abnormal	1	0
Sensation of heaviness	50	0
Spinal pain	1	0
Weight bearing difficulty	4	0
<b><i>Rheumatoid arthropathies</i></b>		
Juvenile idiopathic arthritis	3	0
Rheumatoid arthritis	3	0
<b><i>Soft tissue disorders NEC</i></b>		
Axillary mass	1	0
Groin pain	4	0
Neck mass	1	0
Soft tissue disorder	1	0
<b><i>Synovial disorders</i></b>		
Synovitis	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>1726</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: HPV

Report Run Date: 19-Feb-2014  
Earliest Reaction Date: 29-Nov-2006

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

Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Endocrine neoplasms malignant and unspecified NEC</i>		
Pituitary tumour	1	0
<i>Glial tumours malignant</i>		
Medulloblastoma	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>Neoplasms malignant site unspecified NEC</i>		
Neoplasm malignant	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
Skin papilloma	2	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
<b>Neoplasms SOC TOTAL</b>	<b>15</b>	<b>2</b>

# Case Series Drug Analysis Print

Name: HPV

Report Run Date: 19-Feb-2014  
Earliest Reaction Date: 29-Nov-2006

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

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Abnormal reflexes</i>		
Areflexia	2	0
<i>Absence seizures</i>		
Petit mal epilepsy	3	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	5	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	2	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Basal ganglia stroke	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>Coordination and balance disturbances</i>		
Ataxia	2	0
Balance disorder	14	0
Cerebellar ataxia	1	0
Coordination abnormal	2	0
Dysstasia	12	0
<i>Cortical dysfunction NEC</i>		
Agnosia	1	0
Aphasia	4	0
Dyslexia	1	0
Dyspraxia	1	0
<i>Demyelinating disorders NEC</i>		
Demyelination	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	3	0
Consciousness fluctuating	4	0
Depressed level of consciousness	3	0
Lethargy	158	0
Loss of consciousness	67	0
Sedation	1	0
Somnolence	116	0
Syncope	658	0
<i>Dyskinesias and movement disorders NEC</i>		
Clumsiness	1	0
Dyskinesia	39	0
Hypokinesia	11	0
Movement disorder	5	0
Psychomotor hyperactivity	4	0
<i>Dystonias</i>		
Dystonia	1	0
<i>Encephalitis NEC</i>		
Encephalitis	5	0
Encephalitis autoimmune	4	0
<i>Encephalopathies NEC</i>		
Hashimoto's encephalopathy	1	0
<i>Eye movement disorders</i>		
IVth nerve paralysis	1	0
VIth nerve paralysis	1	0



# Case Series Drug Analysis Print

Name: HPV

Report Run Date: 19-Feb-2014  
Earliest Reaction Date: 29-Nov-2006

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

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
<b>Facial cranial nerve disorders</b>		
Facial paresis	1	0
Facial spasm	1	0
VIIth nerve paralysis	10	0
<b>Generalised tonic-clonic seizures</b>		
Grand mal convulsion	14	0
<b>Headaches NEC</b>		
Cluster headache	3	0
Headache	1377	0
Sinus headache	1	0
Tension headache	2	0
<b>Memory loss (excl dementia)</b>		
Amnesia	9	0
Memory impairment	8	0
<b>Mental impairment (excl dementia and memory loss)</b>		
Cognitive disorder	1	0
Disturbance in attention	16	0
Mental impairment	2	0
<b>Migraine headaches</b>		
Basilar migraine	1	0
Migraine	43	0
Migraine with aura	1	0
<b>Mononeuropathies</b>		
Peroneal nerve palsy	1	0
<b>Muscle tone abnormal</b>		
Hypertonia	1	0
Hypotonia	5	0
<b>Myelitis (incl infective)</b>		
Myelitis transverse	1	0
<b>Narcolepsy and hypersomnia</b>		
Cataplexy	1	0
Hypersomnia	8	0
Narcolepsy	3	0
<b>Nervous system disorders NEC</b>		
Motor dysfunction	1	0
Nervous system disorder	2	0
<b>Neurologic visual problems NEC</b>		
Visual field defect	5	0
<b>Neurological signs and symptoms NEC</b>		
Clonus	1	0
Dizziness	1780	0
Dizziness postural	20	0
Drooling	1	0
Head discomfort	7	0
Hyporesponsive to stimuli	1	0
Meningism	1	0
Myoclonus	3	0
Neurological symptom	1	0
Presyncope	41	0
Slow response to stimuli	5	0
Unresponsive to stimuli	30	0
<b>Neuromuscular disorders NEC</b>		
Muscle contractions involuntary	1	0

# Case Series Drug Analysis Print

Name: HPV

Report Run Date: 19-Feb-2014  
Earliest Reaction Date: 29-Nov-2006

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

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
<b>Neuromuscular junction dysfunction</b>		
Myasthenia gravis	1	0
<b>Olfactory nerve disorders</b>		
Parosmia	1	0
<b>Optic nerve disorders NEC</b>		
Optic neuritis	3	0
<b>Paraesthesias and dysaesthesias</b>		
Burning sensation	5	0
Hyperaesthesia	3	0
Paraesthesia	200	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Diplegia	2	0
Hemiparesis	6	0
Monoparesis	1	0
Monoplegia	4	0
Paralysis	4	0
Paralysis flaccid	1	0
Quadriparesis	1	0
<b>Parkinson's disease and parkinsonism</b>		
Masked facies	1	0
<b>Peripheral neuropathies NEC</b>		
Lumbosacral plexus lesion	1	0
Neuritis	1	0
Peripheral sensory neuropathy	1	0
<b>Seizures and seizure disorders NEC</b>		
Clonic convulsion	1	0
Convulsion	90	0
Epilepsy	14	0
Myoclonic epilepsy	1	0
Partial seizures	3	0
Seizure anoxic	5	0
Seizure like phenomena	2	0
Status epilepticus	2	0
Tonic clonic movements	2	0
<b>Sensory abnormalities NEC</b>		
Ageusia	1	0
Complex regional pain syndrome	8	0
Dysgeusia	11	0
Hypoaesthesia	289	0
Neuralgia	2	0
Sensory disturbance	15	0
Sensory loss	20	0
<b>Sleep disturbances NEC</b>		
Poor quality sleep	1	0
Sudden onset of sleep	2	0
<b>Speech and language abnormalities</b>		
Aphonia	6	0
Dysarthria	11	0
Incoherent	2	0
Slow speech	1	0
Speech disorder	6	0
<b>Spinal cord and nerve root disorders NEC</b>		
Radiculitis brachial	1	0

# Case Series Drug Analysis Print

Name: HPV

Report Run Date: 19-Feb-2014  
Earliest Reaction Date: 29-Nov-2006

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

Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
<i>Tremor (excl congenital)</i>		
Tremor	143	0
<b>Nervous system disorders SOC TOTAL</b>	<b>5423</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: HPV

Report Run Date: 19-Feb-2014  
Earliest Reaction Date: 29-Nov-2006

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

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

# Case Series Drug Analysis Print

Name: HPV

Report Run Date: 19-Feb-2014  
Earliest Reaction Date: 29-Nov-2006

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

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	6	0
<b><i>Anxiety symptoms</i></b>		
Agitation	6	0
Anxiety	24	0
Nervousness	17	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	6	0
Disinhibition	1	0
Disturbance in social behaviour	1	0
Paranoia	1	0
Personality change	4	0
Social avoidant behaviour	2	0
<b><i>Bipolar disorders</i></b>		
Bipolar disorder	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	21	0
Disorientation	18	0
<b><i>Decreased physical activity levels</i></b>		
Decreased activity	1	0
<b><i>Deliria</i></b>		
Delirium	1	0
<b><i>Delusional symptoms</i></b>		
Delusion	2	0
<b><i>Depressive disorders</i></b>		
Depression	10	0
<b><i>Dissociative states</i></b>		
Dissociation	3	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	19	0
Middle insomnia	1	0
<b><i>Eating disorders NEC</i></b>		
Eating disorder	2	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Emotional disorder	8	0
Emotional distress	8	0
Emotional poverty	1	0
Euphoric mood	1	0
Mood altered	2	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Autophobia	1	0
Fear	3	0
Fear of crowded places	1	0
Social phobia	1	0
<b><i>Fluctuating mood symptoms</i></b>		
Mood swings	2	0
<b><i>Impulse control disorders</i></b>		
Impulse-control disorder	1	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	3	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Decreased interest	2	0
Depressed mood	7	0

# Case Series Drug Analysis Print

Name: HPV

Report Run Date: 19-Feb-2014  
Earliest Reaction Date: 29-Nov-2006

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

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Depressive symptom	2	0
Feeling guilty	1	0
Feeling of despair	1	0
Negative thoughts	1	0
Tearfulness	19	0
<b>Mood alterations with manic symptoms</b>		
Hypomania	1	0
<b>Mood disorders NEC</b>		
Listless	5	0
<b>Narcolepsy and associated conditions</b>		
Sleep attacks	1	0
<b>Obsessive-compulsive disorders and symptoms</b>		
Obsessive thoughts	1	0
<b>Panic attacks and disorders</b>		
Panic attack	20	0
Panic reaction	6	0
<b>Parasomnias</b>		
Abnormal sleep-related event	1	0
<b>Perception disturbances</b>		
Hallucination	8	0
Hallucination, auditory	2	0
Hallucination, visual	2	0
<b>Personality disorders NEC</b>		
Self esteem decreased	2	0
<b>Psychiatric symptoms NEC</b>		
Psychiatric symptom	1	0
<b>Psychotic disorder NEC</b>		
Acute psychosis	1	0
Psychotic disorder	2	0
<b>Sleep disorders NEC</b>		
Sleep disorder	6	0
<b>Somatoform disorders</b>		
Somatisation disorder	2	0
<b>Speech articulation and rhythm disturbances</b>		
Dysphemia	2	0
Screaming	2	0
<b>Stereotypies and automatisms</b>		
Bruxism	1	0
Head banging	2	0
<b>Stress disorders</b>		
Burnout syndrome	1	0
<b>Suicidal and self-injurious behaviour</b>		
Intentional self-injury	2	0
Self-injurious ideation	1	0
Suicidal ideation	4	0
Suicide attempt	1	0
<b>Thinking disturbances</b>		
Bradyphrenia	2	0
Thinking abnormal	2	0
Thought blocking	2	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>295</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: HPV

Report Run Date: 19-Feb-2014  
Earliest Reaction Date: 29-Nov-2006

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

Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Bladder pain	1	0
Bladder spasm	1	0
Dysuria	1	0
Incontinence	1	0
Micturition urgency	1	0
Pollakiuria	4	0
Urinary incontinence	10	0
Urinary retention	2	0
<i>Bladder disorders NEC</i>		
Bladder fibrosis	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 failure and impairment</i>		
Renal failure	1	0
<i>Urinary abnormalities</i>		
Proteinuria	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>29</b>	<b>0</b>

# Case Series Drug Analysis Print

Name: HPV

Report Run Date: 19-Feb-2014  
Earliest Reaction Date: 29-Nov-2006

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

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Breast disorders NEC</b></i>		
Breast enlargement	1	0
<i><b>Breast signs and symptoms</b></i>		
Breast pain	1	0
Breast swelling	1	0
Breast tenderness	2	0
<i><b>Cervix disorders NEC</b></i>		
Cervical dysplasia	1	0
<i><b>Cervix infections and inflammations</b></i>		
Cervix inflammation	1	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Dysmenorrhoea	5	0
Menstrual disorder	7	0
Menstruation irregular	17	0
Metrorrhagia	1	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	14	0
Menstruation delayed	7	0
Oligomenorrhoea	2	0
<i><b>Menstruation with increased bleeding</b></i>		
Menorrhagia	14	0
<i><b>Ovarian and fallopian tube cysts and neoplasms</b></i>		
Ovarian cyst	2	0
<i><b>Reproductive tract signs and symptoms NEC</b></i>		
Genital pain	1	0
Pelvic pain	2	0
<i><b>Vulvovaginal disorders NEC</b></i>		
Vaginal haemorrhage	9	0
Vaginal mucosal blistering	1	0
Vaginal ulceration	1	0
Vulval ulceration	2	0
<i><b>Vulvovaginal signs and symptoms</b></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
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>100</b>	<b>0</b>



# Case Series Drug Analysis Print

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Earliest Reaction Date: 29-Nov-2006

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	119	0
Grunting	1	0
Hyperventilation	45	0
Hypopnoea	10	0
Respiratory arrest	1	0
Tachypnoea	4	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	16	0
Bronchospasm	2	0
Wheezing	18	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	34	0
Haemoptysis	2	0
Productive cough	1	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Laryngeal oedema	5	0
Stridor	1	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Increased bronchial secretion	1	0
Pleuritic pain	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	6	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	16	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal erythema	1	0
Pharyngeal oedema	13	0
Tonsillar hypertrophy	1	0
<i><b>Pneumothorax and pleural effusions NEC</b></i>		
Pneumothorax	1	0
<i><b>Respiratory failures (excl neonatal)</b></i>		
Acute respiratory failure	1	0
<i><b>Respiratory signs and symptoms NEC</b></i>		
Painful respiration	1	0
Respiration abnormal	1	0
<i><b>Respiratory tract disorders NEC</b></i>		
Respiratory disorder	2	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Choking sensation	2	0
Dry throat	6	0
Dysphonia	2	0
Increased upper airway secretion	1	0
Nasal obstruction	1	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	94	0
Rhinorrhoea	4	0
Sneezing	2	0
Throat irritation	18	0
Throat tightness	32	0
<i><b>Vascular pulmonary disorders NEC</b></i>		
Pulmonary arteriopathy	2	0
<b>Respiratory disorders SOC TOTAL</b>	<b>469</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	5	0
<b><i>Alopecias</i></b>		
Alopecia	25	0
Alopecia areata	6	0
Alopecia totalis	2	0
Diffuse alopecia	2	0
<b><i>Angioedemas</i></b>		
Angioedema	12	0
Circumoral oedema	1	0
Swelling face	74	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	81	0
Hyperhidrosis	68	0
Miliaria	4	0
Night sweats	2	0
<b><i>Bullous conditions</i></b>		
Blister	16	0
Erythema multiforme	8	0
Stevens-Johnson syndrome	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Dry skin	6	0
Pain of skin	4	0
Papule	2	0
Scab	1	0
Skin burning sensation	1	0
Skin discolouration	81	0
Skin disorder	3	0
Skin lesion	2	0
Skin reaction	13	0
Skin tightness	2	0
Skin warm	22	0
Yellow skin	1	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	1	0
Dermatitis allergic	19	0
Dermatitis contact	3	0
Eczema	12	0
Eczema vesicular	1	0
Seborrhoeic dermatitis	2	0
Skin irritation	7	0
<b><i>Erythemas</i></b>		
Erythema	186	0
Generalised erythema	4	0
Palmar erythema	1	0
Rash erythematous	29	0
<b><i>Exfoliative conditions</i></b>		
Skin exfoliation	4	0
<b><i>Hypopigmentation disorders</i></b>		
Skin depigmentation	1	0
Vitiligo	1	0
<b><i>Nail and nail bed conditions (excl infections and infestations)</i></b>		
Nail discolouration	2	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
<b><i>Panniculitides</i></b>		
Erythema nodosum	4	0
Panniculitis	1	0
<b><i>Papulosquamous conditions</i></b>		
Pityriasis lichenoides et varioliformis acuta	1	0
Rash papular	1	0
<b><i>Photosensitivity and photodermatosis conditions</i></b>		
Photosensitivity reaction	7	0
<b><i>Pilar disorders NEC</i></b>		
Piloerection	1	0
Trichorrhexis	1	0
<b><i>Pruritus NEC</i></b>		
Pruritus	128	0
Pruritus generalised	14	0
Rash pruritic	53	0
<b><i>Psoriatic conditions</i></b>		
Guttate psoriasis	1	0
Psoriasis	3	0
<b><i>Purpura and related conditions</i></b>		
Henoch-Schonlein purpura	3	0
Petechiae	6	0
Purpura	5	0
<b><i>Pustular conditions</i></b>		
Rash follicular	1	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Rash	323	0
Rash generalised	61	0
Rash macular	66	0
Rash maculo-papular	6	0
Rash vesicular	1	0
Systemic lupus erythematosus rash	1	0
<b><i>Skin and subcutaneous conditions NEC</i></b>		
Skin mass	2	0
<b><i>Skin haemorrhages</i></b>		
Skin haemorrhage	1	0
<b><i>Skin hyperplasias and hypertrophies</i></b>		
Skin hypertrophy	2	0
<b><i>Skin hypoplasias and atrophies</i></b>		
Skin striae	1	0
<b><i>Skin vasomotor conditions</i></b>		
Livedo reticularis	30	0
<b><i>Urticarias</i></b>		
Urticaria	179	0
Urticaria chronic	3	0
Urticaria pigmentosa	1	0
<b>Skin disorders SOC TOTAL</b>	<b>1625</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Age related issues</i>		
Puberty	1	0
<i>Disability issues</i>		
Activities of daily living impaired	5	0
Bedridden	2	0
Disability	1	0
Immobile	2	0
Impaired work ability	1	0
<i>Educational issues</i>		
Educational problem	1	0
<b>Social circumstances SOC TOTAL</b>	<b>13</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<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
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>13</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<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 necrosis and vascular insufficiency NEC</i>		
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Capillary disorder	3	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	1	0
Thrombophlebitis superficial	1	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	104	0
Hot flush	13	0
Peripheral vascular disorder	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	88	0
Poor peripheral circulation	4	0
Raynaud's phenomenon	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	295	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	5	0
<i>Vascular hypotensive disorders</i>		
Hypotension	22	0
Orthostatic hypotension	1	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>552</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>17952</b>	<b>4</b>
<b>TOTAL REPORTS</b>	<b>7685</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>4</b>