

**Case Series Drug Analysis Print**  
**Name: Gardasil Product Analysis Print**

Report Run Date:	14-Aug-2017
Data Lock Date:	11-Aug-2017 19:00:04
Earliest Reaction Date:	17-Nov-2008
MedDRA Version:	MedDRA 20.0
Gardasil Product Analysis Print:	All UK spontaneous cases concerning Gardasil received between 01/09/2012 and 07/08/2017

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Anaemia deficiencies</i>		
Iron deficiency anaemia	1	0
Pernicious anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	3	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	2	0
<i>Haematological disorders</i>		
Blood disorder	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	1	0
Lymphadenopathy	14	0
<i>Neutropenias</i>		
Autoimmune neutropenia	1	0
Neutropenia	2	0
<i>Spleen disorders</i>		
Splenomegaly	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenic purpura	3	0
<b>Blood disorders SOC TOTAL</b>	<b>30</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac signs and symptoms NEC</i>		
Cyanosis	8	0
Palpitations	17	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	1	0
<i>Rate and rhythm disorders NEC</i>		
Postural orthostatic tachycardia syndrome	27	0
Tachycardia	10	0
<i>Supraventricular arrhythmias</i>		
Sinus arrhythmia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	1
Pulseless electrical activity	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>66</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	2	0
<b>Congenital disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear pain	6	0
<i>Hearing losses</i>		
Deafness	3	0
Deafness transitory	1	0
Hypoacusis	4	0
<i>Hyperacusia</i>		
Hyperacusis	6	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	1	0
Tinnitus	2	0
Vertigo	3	0
<b>Ear disorders SOC TOTAL</b>	<b>26</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
<i>Hypothalamic and pituitary disorders NEC</i>		
Lymphocytic hypophysitis	1	0
<i>Thyroid disorders NEC</i>		
Goitre	1	0
<i>Thyroid hypofunction disorders</i>		
Autoimmune hypothyroidism	1	0
Hypothyroidism	3	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	2	0
Blindness transient	5	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous floaters	2	0
<i>Eyelid movement disorders</i>		
Blepharospasm	1	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
<i>Lacrimation disorders</i>		
Lacrimation increased	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid oedema	4	0
<i>Ocular disorders NEC</i>		
Eye pain	6	0
Eye swelling	4	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye irritation	1	0
Eye pruritus	2	0
Ocular hyperaemia	2	0
<i>Ocular nerve and muscle disorders</i>		
Extraocular muscle paresis	1	0
Eye movement disorder	12	0
Ophthalmoplegia	1	0
Strabismus	1	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	1	0
Asthenopia	1	0
Photophobia	14	0
<i>Partial vision loss</i>		
Visual acuity reduced	1	0
<i>Pupil disorders</i>		
Mydriasis	4	0
Pupillary disorder	1	0
<i>Visual disorders NEC</i>		
Diplopia	6	0
Halo vision	1	0
Photopsia	2	0
Vision blurred	41	0
Visual impairment	22	0
<b>Eye disorders SOC TOTAL</b>	<b>144</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	1	0
<i>Anal and rectal disorders NEC</i>		
Anal fissure	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	19	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	3	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	9	0
Flatulence	1	0
<i>Gastric and oesophageal haemorrhages</i>		
Oesophageal haemorrhage	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	2	0
Reflux gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	45	0
Abdominal pain lower	5	0
Abdominal pain upper	41	0
Abdominal rigidity	1	0
Abdominal tenderness	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	7	0
Gastrointestinal hypomotility	1	0
Gastrooesophageal reflux disease	5	0
<i>Gastrointestinal disorders NEC</i>		
Gastric disorder	2	0
Gastrointestinal disorder	2	0
<i>Gastrointestinal dyskinetic disorders</i>		
Gastrointestinal motility disorder	2	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Gastrointestinal inflammation	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	12	0
Dysphagia	6	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	1	0
Irritable bowel syndrome	6	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	1	0
<i>Inguinal hernias</i>		
Inguinal hernia	1	0
<i>Malabsorption syndromes</i>		
Bile acid malabsorption	1	0
Coeliac disease	2	0
Malabsorption	1	0
<i>Nausea and vomiting symptoms</i>		
Cyclic vomiting syndrome	1	0
Nausea	349	0
Retching	3	0
Vomiting	136	0
<i>Non-site specific gastrointestinal haemorrhages</i>		



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<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Haematemesis	2	0
Haematochezia	1	0
<b>Oral soft tissue disorders NEC</b>		
Uvulitis	1	0
<b>Oral soft tissue pain and paraesthesia</b>		
Paraesthesia oral	7	0
<b>Oral soft tissue signs and symptoms</b>		
Oral discomfort	1	0
Oral mucosal eruption	1	0
<b>Oral soft tissue swelling and oedema</b>		
Lip swelling	7	0
<b>Peritoneal and retroperitoneal disorders</b>		
Intra-abdominal fluid collection	1	0
<b>Stomatitis and ulceration</b>		
Mouth ulceration	2	0
<b>Tongue signs and symptoms</b>		
Swollen tongue	2	0
Tongue coated	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>698</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Asthenic conditions</b></i>		
Asthenia	48	0
Chronic fatigue syndrome	24	0
Fatigue	155	0
Malaise	191	0
<i><b>Body temperature altered</b></i>		
Temperature regulation disorder	4	0
<i><b>Death and sudden death</b></i>		
Death	2	2
<i><b>Febrile disorders</b></i>		
Pyrexia	99	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	14	0
Feeling abnormal	25	0
Feeling cold	12	0
Feeling drunk	1	0
Feeling hot	49	0
Feeling jittery	2	0
Feeling of body temperature change	3	0
Temperature intolerance	5	0
Thirst	2	0
<i><b>Gait disturbances</b></i>		
Abasia	6	0
Gait disturbance	11	0
<i><b>General signs and symptoms NEC</b></i>		
Condition aggravated	3	0
Crying	4	0
Exercise tolerance decreased	4	0
Foaming at mouth	2	0
General physical health deterioration	1	0
Glassy eyes	1	0
Induration	1	0
Influenza like illness	13	0
Local reaction	4	0
Local swelling	8	0
Peripheral swelling	75	0
Swelling	5	0
<i><b>Healing abnormal NEC</b></i>		
Impaired healing	2	0
<i><b>Inflammations</b></i>		
Inflammation	4	0
Serositis	1	0
<i><b>Injection site reactions</b></i>		
Injected limb mobility decreased	2	0
Injection site bruising	3	0
Injection site erythema	9	0
Injection site haemorrhage	1	0
Injection site hypoaesthesia	5	0
Injection site induration	2	0
Injection site joint pain	1	0
Injection site mass	10	0
Injection site movement impairment	1	0
Injection site nerve damage	1	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Injection site oedema	1	0
Injection site pain	26	0
Injection site paraesthesia	1	0
Injection site pruritus	7	0
Injection site rash	1	0
Injection site reaction	1	0
Injection site swelling	18	0
Injection site warmth	2	0
<b>Mass conditions NEC</b>		
Mass	2	0
<b>Oedema NEC</b>		
Face oedema	1	0
Localised oedema	1	0
Oedema peripheral	3	0
<b>Pain and discomfort NEC</b>		
Chest discomfort	13	0
Chest pain	22	0
Discomfort	8	0
Non-cardiac chest pain	1	0
Pain	47	0
Tenderness	3	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse event	3	0
Immediate post-injection reaction	1	0
<b>Trophic disorders</b>		
Atrophy	1	0
Hyperplasia	1	0
<b>Vaccination site reactions</b>		
Vaccination site erythema	4	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	4	0
Vaccination site warmth	2	0
<b>General disorders SOC TOTAL</b>	<b>999</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis acute	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i><b>Allergic conditions NEC</b></i>		
Allergic oedema	1	0
Hypersensitivity	20	0
Multiple allergies	2	0
<i><b>Allergies to foods, food additives, drugs and other chemicals</b></i>		
Food allergy	1	0
Rubber sensitivity	1	0
<i><b>Anaphylactic and anaphylactoid responses</b></i>		
Anaphylactic reaction	15	0
Anaphylactic shock	1	0
<i><b>Autoimmune disorders NEC</b></i>		
Autoimmune disorder	5	0
<i><b>Immune and associated conditions NEC</b></i>		
Decreased immune responsiveness	1	0
Immune system disorder	6	0
<b>Immune system disorders SOC TOTAL</b>	<b>53</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Abdominal and gastrointestinal infections</b></i>		
Abdominal abscess	1	0
Appendicitis	1	0
Appendicitis perforated	1	0
Gastroenteritis	1	0
<i><b>Bacterial infections NEC</b></i>		
Cellulitis	1	0
<i><b>Central nervous system and spinal infections</b></i>		
Encephalitis	3	0
<i><b>Coxsackie viral infections</b></i>		
Hand-foot-and-mouth disease	1	0
<i><b>Ear infections</b></i>		
Otitis media	1	0
<i><b>Epstein-Barr viral infections</b></i>		
Epstein-Barr virus infection	1	0
Infectious mononucleosis	1	0
<i><b>Eye and eyelid infections</b></i>		
Conjunctivitis	2	0
<i><b>Female reproductive tract infections</b></i>		
Pelvic inflammatory disease	1	0
Vulvovaginitis	1	0
<i><b>Haemophilus infections</b></i>		
Haemophilus infection	1	0
<i><b>Herpes viral infections</b></i>		
Herpes zoster	2	0
<i><b>Infections NEC</b></i>		
Infection	2	0
Infection susceptibility increased	1	0
Injection site infection	1	0
<i><b>Lower respiratory tract and lung infections</b></i>		
Bronchitis	1	0
Lower respiratory tract infection	1	0
<i><b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b></i>		
Sepsis	1	0
Septic rash	1	0
<i><b>Upper respiratory tract infections</b></i>		
Pharyngitis	2	0
Sinusitis	1	0
Tonsillitis	2	0
<i><b>Urinary tract infections</b></i>		
Urinary tract infection	1	0
<i><b>Viral infections NEC</b></i>		
Post viral fatigue syndrome	8	0
Viral infection	2	0
Viral upper respiratory tract infection	6	0
<b>Infections SOC TOTAL</b>	<b>49</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	2	0
Foetal exposure during pregnancy	1	0
<i>Fractures and dislocations NEC</i>		
Joint dislocation	1	0
<i>Non-site specific injuries NEC</i>		
Fall	7	0
Wound haemorrhage	1	0
<i>Poisoning and toxicity</i>		
Poisoning	1	0
<i>Product administration errors and issues</i>		
Drug administered at inappropriate site	1	0
Expired product administered	1	0
Inappropriate schedule of drug administration	1	0
<i>Site specific injuries NEC</i>		
Head injury	1	0
<i>Skin injuries NEC</i>		
Contusion	6	0
<i>Thermal burns</i>		
Thermal burn	1	0
<i>Vaccination related complications</i>		
Vaccination complication	6	0
Vaccination failure	1	0
<b>Injuries SOC TOTAL</b>	<b>31</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Blood gas and acid base analyses</b></i>		
Oxygen saturation decreased	1	0
<i><b>Carbohydrate tolerance analyses (incl diabetes)</b></i>		
Blood glucose decreased	1	0
<i><b>Cardiac auscultatory investigations</b></i>		
Cardiac murmur	1	0
<i><b>ECG investigations</b></i>		
Electrocardiogram QT prolonged	1	0
Electrocardiogram T wave inversion	1	0
<i><b>Endocrine analyses and imaging NEC</b></i>		
Hormone level abnormal	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate abnormal	1	0
Heart rate decreased	5	0
Heart rate increased	10	0
Heart rate irregular	2	0
Pulse abnormal	3	0
<i><b>Liver function analyses</b></i>		
Hepatic enzyme increased	1	0
<i><b>Mineral and electrolyte analyses</b></i>		
Blood iron decreased	2	0
<i><b>Ophthalmic function diagnostic procedures</b></i>		
Corneal reflex decreased	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature abnormal	1	0
Body temperature fluctuation	3	0
Body temperature increased	13	0
Respiratory rate increased	4	0
Weight decreased	1	0
Weight increased	1	0
<i><b>Pituitary analyses anterior</b></i>		
Blood growth hormone abnormal	1	0
Blood thyroid stimulating hormone abnormal	1	0
<i><b>Platelet analyses</b></i>		
Platelet count decreased	1	0
<i><b>Protein analyses NEC</b></i>		
C-reactive protein increased	2	0
<i><b>Tissue enzyme analyses NEC</b></i>		
Blood lactate dehydrogenase increased	1	0
<i><b>Vascular tests NEC (incl blood pressure)</b></i>		
Blood pressure decreased	4	0
<i><b>Vitamin analyses</b></i>		
Vitamin D decreased	2	0
<b>Investigations SOC TOTAL</b>	<b>66</b>	<b>0</b>



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<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Appetite disorder	2	0
Decreased appetite	18	0
Salt craving	2	0
<i><b>Calcium metabolism disorders</b></i>		
Tetany	1	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Type 1 diabetes mellitus	5	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	4	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Cow's milk intolerance	1	0
Food intolerance	1	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	7	0
Abnormal weight gain	1	0
Feeding disorder	2	0
Weight gain poor	1	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	1	0
<i><b>Metabolic acidoses (excl diabetic acidoses)</b></i>		
Lactic acidosis	1	0
<i><b>Mineral related disorders NEC</b></i>		
Mineral deficiency	1	0
<i><b>Vitamin deficiencies NEC</b></i>		
Multi-vitamin deficiency	1	0
<i><b>Water soluble vitamin deficiencies</b></i>		
Vitamin B12 deficiency	3	0
<b>Metabolic disorders SOC TOTAL</b>	<b>54</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthropathy	2	0
Seronegative arthritis	1	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	5	0
Pain in jaw	3	0
Spinal pain	2	0
<i><b>Extremity deformities</b></i>		
Finger deformity	1	0
<i><b>Joint related disorders NEC</b></i>		
Hypermobility syndrome	1	0
Periarthritis	2	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	59	0
Joint crepitation	2	0
Joint stiffness	3	0
Joint swelling	4	0
<i><b>Muscle pains</b></i>		
Fibromyalgia	1	0
Myalgia	29	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle fatigue	1	0
Muscle spasms	21	0
Muscle tightness	2	0
Muscle twitching	16	0
<i><b>Muscle tone abnormalities</b></i>		
Muscle rigidity	12	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	42	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Back pain	20	0
Growing pains	1	0
Limb discomfort	15	0
Musculoskeletal chest pain	4	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	10	0
Neck pain	21	0
Pain in extremity	119	0
<i><b>Musculoskeletal and connective tissue signs and symptoms NEC</b></i>		
Back disorder	1	0
Mobility decreased	4	0
Muscle contracture	1	0
Musculoskeletal stiffness	23	0
Posture abnormal	1	0
Weight bearing difficulty	4	0
<i><b>Rheumatoid arthropathies</b></i>		
Rheumatoid arthritis	1	0
<i><b>Soft tissue disorders NEC</b></i>		
Axillary mass	1	0
<i><b>Synovial disorders</b></i>		
Synovitis	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>437</b>	<b>0</b>

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<b>Neoplasms</b>		
<i>Bone neoplasms malignant (excl sarcomas)</i>		
Bone cancer	1	0
<i>Islet cell neoplasms and APUDoma NEC</i>		
Pancreatic neuroendocrine tumour metastatic	1	0
<i>Metastases to specified sites</i>		
Metastases to liver	1	0
<i>Skin neoplasms benign</i>		
Anogenital warts	1	0
Skin papilloma	1	0
<b>Neoplasms SOC TOTAL</b>	<b>5</b>	<b>0</b>

# Case Series Drug Analysis Print

## Name: Gardasil Product Analysis Print

Report Run Date: 14-Aug-2017

Data Lock Date: 11-Aug-2017 19:00:04

Earliest Reaction Date: 17-Nov-2008

MedDRA Version: MedDRA 20.0

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>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	2	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem stroke	1	0
Cerebral thrombosis	1	0
Cerebrovascular accident	1	0
Lacunar infarction	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	2	0
Balance disorder	5	0
Coordination abnormal	2	0
Dysstasia	5	0
<i>Cortical dysfunction NEC</i>		
Dyslexia	1	0
Dyspraxia	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	1	0
Consciousness fluctuating	2	0
Depressed level of consciousness	4	0
Lethargy	49	0
Loss of consciousness	18	0
Somnolence	36	0
Syncope	216	0
<i>Disturbances in sleep phase rhythm</i>		
Sleep phase rhythm disturbance	2	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	24	0
Fine motor skill dysfunction	1	0
Hypokinesia	3	0
Motor dysfunction	1	0
Movement disorder	5	0
<i>Encephalitis NEC</i>		
Noninfective encephalitis	1	0
<i>Facial cranial nerve disorders</i>		
Facial paralysis	4	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	7	0
<i>Headaches NEC</i>		
Cluster headache	3	0
Headache	351	0
Tension headache	1	0
<i>Increased intracranial pressure disorders</i>		
Idiopathic intracranial hypertension	1	0
Intracranial pressure increased	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	6	0
Memory impairment	7	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	3	0

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Earliest Reaction Date: 17-Nov-2008

MedDRA Version: MedDRA 20.0

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Disturbance in attention	16	0
Mental impairment	1	0
<b>Migraine headaches</b>		
Migraine	20	0
Migraine with aura	1	0
<b>Mononeuropathies</b>		
Peroneal nerve palsy	1	0
<b>Multiple sclerosis acute and progressive</b>		
Multiple sclerosis	1	0
<b>Muscle tone abnormal</b>		
Hypotonia	7	0
<b>Narcolepsy and hypersomnia</b>		
Hypersomnia	9	0
Narcolepsy	1	0
<b>Nervous system cysts and polyps</b>		
Colloid brain cyst	1	0
<b>Nervous system disorders NEC</b>		
Nervous system disorder	4	0
<b>Neurological signs and symptoms NEC</b>		
Dizziness	590	0
Dizziness exertional	1	0
Dizziness postural	7	0
Head discomfort	2	0
Hyporesponsive to stimuli	1	0
Presyncope	14	0
Slow response to stimuli	2	0
Unresponsive to stimuli	18	0
<b>Paraesthesias and dysaesthesias</b>		
Burning sensation	6	0
Hyperaesthesia	3	0
Hypoaesthesia	52	0
Paraesthesia	64	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Diplegia	1	0
Hemiparesis	3	0
Monoplegia	8	0
Paralysis	7	0
Peripheral paralysis	1	0
Quadriplegia	1	0
<b>Seizures and seizure disorders NEC</b>		
Change in seizure presentation	1	0
Epilepsy	6	0
Seizure	34	0
Seizure anoxic	1	0
Seizure like phenomena	2	0
Tonic clonic movements	5	0
<b>Sensory abnormalities NEC</b>		
Complex regional pain syndrome	4	0
Dysgeusia	1	0
Neuralgia	2	0
Sensory disturbance	6	0
Sensory loss	5	0
<b>Speech and language abnormalities</b>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Dysarthria	4	0
Slow speech	2	0
Speech disorder	4	0
<b>Spinal cord and nerve root disorders NEC</b>		
Spinal cord oedema	1	0
<b>Structural brain disorders NEC</b>		
Brain injury	1	0
<b>Tremor (excl congenital)</b>		
Tremor	52	0
<b>Nervous system disorders SOC TOTAL</b>	<b>1748</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortions not specified as induced or spontaneous</i>		
Abortion	1	0
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<i>Product quality issues NEC</i>		
Product origin unknown	1	0
Product substitution issue	1	0
<b>null SOC TOTAL</b>	<b>2</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	7	0
Staring	1	0
<b><i>Affect alterations NEC</i></b>		
Inappropriate affect	1	0
<b><i>Anxiety disorders NEC</i></b>		
Generalised anxiety disorder	1	0
<b><i>Anxiety symptoms</i></b>		
Agitation	2	0
Anxiety	19	0
Stress	1	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	2	0
Disinhibition	1	0
Paranoia	3	0
Personality change	5	0
Social avoidant behaviour	1	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Mental fatigue	2	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	13	0
Disorientation	11	0
<b><i>Deliria</i></b>		
Delirium	1	0
<b><i>Delusional symptoms</i></b>		
Delusion	1	0
<b><i>Depressive disorders</i></b>		
Depression	7	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Insomnia	11	0
<b><i>Eating disorders NEC</i></b>		
Anorexia nervosa	1	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Anger	1	0
Emotional distress	4	0
Mood altered	2	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Fear of death	1	0
Phobia	1	0
Social anxiety disorder	1	0
<b><i>Fluctuating mood symptoms</i></b>		
Mood swings	3	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	1	0
<b><i>Mental disorders NEC</i></b>		
Mental disorder	2	0
Mental status changes	1	0
<b><i>Mood alterations with depressive symptoms</i></b>		
Decreased interest	1	0
Depressed mood	2	0
Tearfulness	8	0
<b><i>Mood disorders NEC</i></b>		
Apathy	3	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Listless	1	0
<b>Obsessive-compulsive disorders and symptoms</b>		
Obsessive-compulsive disorder	1	0
<b>Panic attacks and disorders</b>		
Panic attack	4	0
Panic reaction	2	0
<b>Parasomnias</b>		
Sleep terror	1	0
<b>Perception disturbances</b>		
Deja vu	1	0
Hallucination	2	0
Hallucination, auditory	2	0
<b>Personality disorders NEC</b>		
Self esteem decreased	1	0
<b>Personality disorders with anxious behaviour (Cluster C)</b>		
Dependent personality disorder	1	0
<b>Psychotic disorder NEC</b>		
Psychotic disorder	1	0
<b>Sleep disorders NEC</b>		
Sleep disorder	6	0
<b>Somatic symptom disorders</b>		
Psychogenic seizure	1	0
Somatic symptom disorder	1	0
<b>Speech articulation and rhythm disturbances</b>		
Screaming	1	0
<b>Suicidal and self-injurious behaviour</b>		
Intentional self-injury	3	0
Suicidal ideation	2	0
<b>Thinking disturbances</b>		
Thought blocking	1	0
<b>Tic disorders</b>		
Tic	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>155</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Bladder pain	1	0
Urinary incontinence	7	0
Urinary retention	2	0
<i>Bladder disorders NEC</i>		
Bladder disorder	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>		
Nephrotic syndrome	1	0
<i>Renal disorders NEC</i>		
Renal disorder	1	0
<i>Urinary abnormalities</i>		
Proteinuria	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Haemorrhage urinary tract	1	0
Renal pain	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>21</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Breast disorders NEC</b></i>		
Nipple disorder	1	0
<i><b>Breast signs and symptoms</b></i>		
Nipple pain	1	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Dysmenorrhoea	4	0
Menstrual disorder	5	0
Menstruation irregular	7	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	5	0
Menstruation delayed	1	0
<i><b>Menstruation with increased bleeding</b></i>		
Menorrhagia	8	0
Polymenorrhoea	1	0
<i><b>Ovarian and fallopian tube cysts and neoplasms</b></i>		
Ovarian cyst	1	0
Polycystic ovaries	1	0
<i><b>Ovarian and fallopian tube disorders NEC</b></i>		
Ovarian disorder	1	0
Ovarian failure	1	0
<i><b>Reproductive tract signs and symptoms NEC</b></i>		
Pelvic pain	1	0
<i><b>Vulvovaginal disorders NEC</b></i>		
Vulval ulceration	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>39</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	45	0
Hyperventilation	10	0
Hypopnoea	6	0
Respiratory arrest	1	0
Tachypnoea	2	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	8	0
Bronchospasm	3	0
Obstructive airways disorder	1	0
Wheezing	4	0
<i><b>Coughing and associated symptoms</b></i>		
Allergic cough	1	0
Cough	7	0
Productive cough	2	0
<i><b>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</b></i>		
Vocal cord disorder	1	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Laryngospasm	1	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Pleuritic pain	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	2	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	9	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal oedema	2	0
<i><b>Pneumothorax and pleural effusions NEC</b></i>		
Pneumothorax	1	0
<i><b>Pulmonary oedemas</b></i>		
Pulmonary oedema	1	0
<i><b>Respiratory tract disorders NEC</b></i>		
Respiratory tract inflammation	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Choking sensation	1	0
Dry throat	1	0
Dysphonia	1	0
Oropharyngeal discomfort	1	0
Oropharyngeal pain	22	0
Rhinorrhoea	2	0
Sinus pain	2	0
Throat irritation	4	0
Throat tightness	6	0
<b>Respiratory disorders SOC TOTAL</b>	<b>149</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	4	0
Acne cystic	1	0
<b><i>Alopecias</i></b>		
Alopecia	11	0
Alopecia areata	1	0
Madarosis	1	0
<b><i>Angioedemas</i></b>		
Angioedema	2	0
Swelling face	15	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	33	0
Hyperhidrosis	24	0
Miliaria	1	0
<b><i>Bullous conditions</i></b>		
Blister	1	0
Erythema multiforme	1	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Dry skin	3	0
Pain of skin	2	0
Papule	3	0
Skin discolouration	26	0
Skin reaction	2	0
Skin tightness	3	0
Skin warm	14	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis allergic	6	0
Dermatitis contact	1	0
Eczema	4	0
Skin irritation	4	0
<b><i>Erythemas</i></b>		
Erythema	38	0
Generalised erythema	1	0
Palmar erythema	1	0
<b><i>Hyperpigmentation disorders</i></b>		
Melanoderma	1	0
<b><i>Nail and nail bed conditions (excl infections and infestations)</i></b>		
Nail discolouration	1	0
<b><i>Panniculitides</i></b>		
Erythema nodosum	1	0
<b><i>Photosensitivity and photodermatosis conditions</i></b>		
Photosensitivity reaction	3	0
<b><i>Pruritus NEC</i></b>		
Pruritus	35	0
Pruritus generalised	4	0
Rash pruritic	9	0
<b><i>Psoriatic conditions</i></b>		
Psoriasis	1	0
<b><i>Purpura and related conditions</i></b>		
Henoch-Schonlein purpura	3	0
Petechiae	3	0
Purpura	1	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Rash	67	0
Rash erythematous	17	0
Rash generalised	14	0
Rash macular	16	0
Rash papular	2	0
<b><i>Skin and subcutaneous conditions NEC</i></b>		
Skin mass	1	0
Umbilical discharge	1	0
<b><i>Skin hypoplasias and atrophies</i></b>		
Skin striae	2	0
<b><i>Skin preneoplastic conditions NEC</i></b>		
Precancerous skin lesion	1	0
<b><i>Urticarias</i></b>		
Urticaria	55	0
<b>Skin disorders SOC TOTAL</b>	<b>441</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Disability issues</i>		
Bedridden	2	0
Loss of personal independence in daily activities	6	0
Physical disability	1	0
<i>Educational issues</i>		
Educational problem	1	0
<b>Social circumstances SOC TOTAL</b>	<b>10</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	1	0
<i>Circulatory collapse and shock</i>		
Shock	1	0
<i>Haemorrhages NEC</i>		
Venous haemorrhage	1	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	1	0
<i>Non-site specific vascular disorders NEC</i>		
Vascular pain	1	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	21	0
Hot flush	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	21	0
Poor peripheral circulation	1	0
Raynaud's phenomenon	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	96	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
Orthostatic hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	8	0
Orthostatic hypotension	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>157</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>5395</b>	<b>3</b>
<b>TOTAL REPORTS</b>	<b>1830</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>3</b>