

Case Series Drug Analysis Print

Name: Gardasil

Report Run Date: 26-Jun-2015
Data Lock Date: 24-Jun-2015 19:00:15
Earliest Reaction Date: 29-Nov-2006
MedDRA Version: MedDRA 18.0
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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	3	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	1	0
<i>Coagulopathies</i>		
Coagulopathy	1	0
<i>Haematological disorders</i>		
Blood disorder	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	1	0
Lymphadenopathy	9	0
Blood disorders SOC TOTAL	16	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Cyanosis	6	0
Palpitations	3	0
<i>Rate and rhythm disorders NEC</i>		
Postural orthostatic tachycardia syndrome	4	0
Tachycardia	5	0
<i>Supraventricular arrhythmias</i>		
Sinus arrhythmia	1	0
Cardiac disorders SOC TOTAL	19	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	2	0
<i>Hearing losses</i>		
Deafness	2	0
Deafness transitory	1	0
Hearing impaired	2	0
Hypoacusis	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	2	0
Vertigo	3	0
Ear disorders SOC TOTAL	13	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	1	0
Endocrine disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Blindness (excl colour blindness)</i>		
Blindness	2	0
Blindness transient	3	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous floaters	2	0
<i>Eyelid movement disorders</i>		
Eyelid ptosis	1	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	1	0
Eye swelling	4	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye irritation	1	0
Ocular hyperaemia	1	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	8	0
<i>Ocular sensation disorders</i>		
Asthenopia	1	0
Photophobia	4	0
<i>Partial vision loss</i>		
Visual acuity reduced	1	0
<i>Pupil disorders</i>		
Mydriasis	3	0
Pupillary disorder	1	0
<i>Visual disorders NEC</i>		
Diplopia	4	0
Halo vision	1	0
Photopsia	1	0
Vision blurred	32	0
Visual impairment	10	0
Eye disorders SOC TOTAL	89	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 ulcerative	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	14	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	2	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	26	0
Abdominal pain lower	3	0
Abdominal pain upper	28	0
Abdominal tenderness	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
Gastrointestinal hypomotility	1	0
Gastrooesophageal reflux disease	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastrointestinal disorder	2	0
<i>Gastrointestinal dyskinetic disorders</i>		
Gastrointestinal motility disorder	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
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	9	0
Dysphagia	2	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Irritable bowel syndrome	2	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	1	0
<i>Inguinal hernias</i>		
Inguinal hernia	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	269	0
Retching	3	0
Vomiting	107	0
Vomiting projectile	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	2	0
<i>Oral soft tissue pain and paraesthesia</i>		
Paraesthesia oral	7	0
<i>Oral soft tissue signs and symptoms</i>		
Oral mucosal eruption	1	0
<i>Oral soft tissue swelling and oedema</i>		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Lip swelling	4	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	1	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	2	0
Gastrointestinal disorders SOC TOTAL	502	0

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Reaction Name	Total	Fatal
General disorders		
<i>Asthenic conditions</i>		
Asthenia	30	0
Chronic fatigue syndrome	1	0
Fatigue	87	0
Malaise	137	0
<i>Body temperature altered</i>		
Temperature regulation disorder	1	0
<i>Febrile disorders</i>		
Pyrexia	73	0
<i>Feelings and sensations NEC</i>		
Chills	12	0
Feeling abnormal	12	0
Feeling cold	9	0
Feeling drunk	1	0
Feeling hot	38	0
Feeling jittery	1	0
Feeling of body temperature change	4	0
<i>Gait disturbances</i>		
Abasia	3	0
Gait disturbance	7	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	2	0
Crying	5	0
Foaming at mouth	1	0
Influenza like illness	7	0
Local reaction	5	0
Local swelling	6	0
Peripheral swelling	57	0
Swelling	4	0
<i>Inflammations</i>		
Inflammation	5	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	2	0
Injection site bruising	3	0
Injection site erythema	10	0
Injection site haemorrhage	1	0
Injection site hypoaesthesia	4	0
Injection site induration	2	0
Injection site mass	10	0
Injection site movement impairment	1	0
Injection site nerve damage	1	0
Injection site oedema	1	0
Injection site pain	23	0
Injection site pruritus	6	0
Injection site rash	1	0
Injection site reaction	1	0
Injection site swelling	20	0
Injection site warmth	2	0
<i>Mass conditions NEC</i>		
Mass	1	0
<i>Oedema NEC</i>		
Face oedema	1	0
Localised oedema	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Oedema peripheral	4	0
Pain and discomfort NEC		
Chest discomfort	9	0
Chest pain	8	0
Discomfort	8	0
Pain	28	0
Tenderness	3	0
Product quality issues NEC		
Product substitution issue	1	0
Therapeutic and nontherapeutic responses		
Drug ineffective	1	0
Immediate post-injection reaction	1	0
Trophic disorders		
Atrophy	1	0
General disorders SOC TOTAL	663	0

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	1	0
Hepatic disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	1	0
Hypersensitivity	12	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Rubber sensitivity	1	0
<i>Anaphylactic responses</i>		
Anaphylactic reaction	7	0
Anaphylactic shock	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	3	0
<i>Immune and associated conditions NEC</i>		
Immune system disorder	3	0
Immune system disorders SOC TOTAL	28	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Gastrointestinal infection	1	0
<i>Bacterial infections NEC</i>		
Cellulitis	1	0
<i>Candida infections</i>		
Candida infection	1	0
Vulvovaginal candidiasis	1	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	1	0
<i>Dental and oral soft tissue infections</i>		
Gingivitis	1	0
<i>Ear infections</i>		
Otitis media	1	0
<i>Female reproductive tract infections</i>		
Amniotic cavity infection	1	0
Pelvic inflammatory disease	1	0
<i>Herpes viral infections</i>		
Herpes zoster	3	0
Oral herpes	1	0
<i>Infections NEC</i>		
Infection	1	0
Injection site infection	1	0
<i>Influenza viral infections</i>		
Influenza	1	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	1	0
<i>Papilloma viral infections</i>		
Papilloma viral infection	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Septic rash	1	0
<i>Streptococcal infections</i>		
Beta haemolytic streptococcal infection	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	6	0
Pharyngitis	1	0
Sinusitis	1	0
<i>Urinary tract infections</i>		
Urinary tract infection	1	0
<i>Viral infections NEC</i>		
Post viral fatigue syndrome	2	0
Viral infection	1	0
Infections SOC TOTAL	32	0

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	2	0
Foetal exposure during pregnancy	2	0
<i>Non-site specific injuries NEC</i>		
Fall	3	0
<i>Poisoning and toxicity</i>		
Poisoning	1	0
<i>Site specific injuries NEC</i>		
Head injury	1	0
<i>Skin injuries NEC</i>		
Contusion	4	0
<i>Thermal burns</i>		
Thermal burn	1	0
<i>Vaccination related complications</i>		
Vaccination complication	1	0
Injuries SOC TOTAL	15	0

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Reaction Name	Total	Fatal
Investigations		
<i>Blood gas and acid base analyses</i>		
Oxygen saturation decreased	1	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose decreased	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	1	0
<i>ECG investigations</i>		
Electrocardiogram QT prolonged	1	0
Electrocardiogram T wave inversion	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate decreased	4	0
Heart rate increased	5	0
Pulse abnormal	1	0
Pulse pressure decreased	1	0
<i>Mineral and electrolyte analyses</i>		
Blood iron decreased	2	0
<i>Ophthalmic function diagnostic procedures</i>		
Corneal reflex decreased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature fluctuation	1	0
Body temperature increased	10	0
Respiratory rate increased	1	0
Weight decreased	2	0
Weight increased	1	0
<i>Platelet analyses</i>		
Platelet count decreased	1	0
<i>Protein analyses NEC</i>		
Blood albumin abnormal	1	0
Protein total abnormal	1	0
<i>Reproductive organ and breast histopathology procedures</i>		
Smear cervix abnormal	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	2	0
Blood pressure immeasurable	1	0
Blood pressure increased	1	0
<i>Vitamin analyses</i>		
Vitamin B12 increased	1	0
Investigations SOC TOTAL	43	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	1	0
Decreased appetite	13	0
<i>Calcium metabolism disorders</i>		
Tetany	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Type 1 diabetes mellitus	3	0
<i>Diabetic complications NEC</i>		
Diabetic ketoacidosis	1	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	1	0
<i>General nutritional disorders NEC</i>		
Feeding disorder	1	0
Weight gain poor	1	0
<i>Metabolic disorders NEC</i>		
Metabolic disorder	1	0
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	1	0
<i>Total fluid volume decreased</i>		
Dehydration	1	0
<i>Water soluble vitamin deficiencies</i>		
Vitamin B12 deficiency	1	0
Metabolic disorders SOC TOTAL	26	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis reactive	2	0
Arthropathy	1	0
<i>Bone related signs and symptoms</i>		
Pain in jaw	2	0
<i>Extremity deformities</i>		
Foot deformity	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	33	0
Joint stiffness	2	0
Joint swelling	4	0
<i>Muscle pains</i>		
Myalgia	12	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	1	0
Muscle spasms	6	0
Muscle tightness	2	0
Muscle twitching	6	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	8	0
<i>Muscle weakness conditions</i>		
Muscular weakness	13	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	6	0
Limb discomfort	9	0
Musculoskeletal discomfort	1	0
Musculoskeletal pain	5	0
Neck pain	7	0
Pain in extremity	78	0
<i>Musculoskeletal and connective tissue signs and symptoms NEC</i>		
Back disorder	1	0
Mobility decreased	3	0
Musculoskeletal stiffness	15	0
Posture abnormal	1	0
Weight bearing difficulty	2	0
<i>Rheumatoid arthropathies</i>		
Juvenile idiopathic arthritis	1	0
<i>Synovial disorders</i>		
Synovitis	1	0
Muscle & tissue disorders SOC TOTAL	223	0

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Reaction Name	Total	Fatal
Neoplasms		
<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>Leukaemias acute lymphocytic</i>		
T-cell type acute leukaemia	1	1
<i>Metastases to specified sites</i>		
Metastases to liver	1	0
<i>Skin neoplasms benign</i>		
Anogenital warts	1	0
Skin papilloma	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	1	0
Neoplasms SOC TOTAL	7	1

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	2	0
<i>Absence seizures</i>		
Petit mal epilepsy	1	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral thrombosis	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	1	0
Balance disorder	2	0
Coordination abnormal	1	0
Dysstasia	4	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	1	0
Depressed level of consciousness	2	0
Lethargy	38	0
Loss of consciousness	7	0
Somnolence	21	0
Syncope	181	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	17	0
Hypokinesia	2	0
Movement disorder	4	0
<i>Facial cranial nerve disorders</i>		
VIIIth nerve paralysis	2	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	3	0
<i>Headaches NEC</i>		
Cluster headache	2	0
Headache	257	0
Sinus headache	1	0
Tension headache	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	2	0
Memory impairment	3	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Disturbance in attention	6	0
Mental impairment	1	0
<i>Migraine headaches</i>		
Migraine	10	0
<i>Mononeuropathies</i>		
Peroneal nerve palsy	1	0
<i>Muscle tone abnormal</i>		
Hypotonia	5	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	4	0
<i>Nervous system disorders NEC</i>		
Motor dysfunction	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Nervous system disorder	1	0
Neurological signs and symptoms NEC		
Dizziness	471	0
Dizziness postural	1	0
Hyporesponsive to stimuli	1	0
Myoclonus	1	0
Presyncope	9	0
Slow response to stimuli	2	0
Unresponsive to stimuli	11	0
Paraesthesias and dysaesthesias		
Burning sensation	2	0
Hypoaesthesia	35	0
Paraesthesia	48	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	1	0
Monoplegia	2	0
Peripheral neuropathies NEC		
Peripheral sensory neuropathy	1	0
Seizures and seizure disorders NEC		
Epilepsy	3	0
Seizure	18	0
Seizure anoxic	1	0
Seizure like phenomena	2	0
Tonic clonic movements	2	0
Sensory abnormalities NEC		
Complex regional pain syndrome	2	0
Neuralgia	1	0
Sensory disturbance	4	0
Sensory loss	3	0
Speech and language abnormalities		
Dysarthria	2	0
Slow speech	1	0
Speech disorder	1	0
Spinal cord and nerve root disorders NEC		
Spinal cord oedema	1	0
Tremor (excl congenital)		
Tremor	36	0
Nervous system disorders SOC TOTAL	1251	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	1	0
Abortion threatened	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	1	1
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	1	0
<i>Labour onset and length abnormalities</i>		
Premature labour	1	0
<i>Maternal complications of pregnancy NEC</i>		
Cervical incompetence	1	0
Pregnancy conditions SOC TOTAL	6	1

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	5	0
<i>Affect alterations NEC</i>		
Inappropriate affect	1	0
<i>Anxiety symptoms</i>		
Agitation	2	0
Anxiety	6	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	1	0
Disinhibition	1	0
Paranoia	2	0
Personality change	1	0
<i>Bipolar disorders</i>		
Bipolar disorder	1	0
<i>Confusion and disorientation</i>		
Confusional state	7	0
Disorientation	6	0
<i>Deliria</i>		
Delirium	1	0
<i>Delusional symptoms</i>		
Delusion	1	0
<i>Depressive disorders</i>		
Depression	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	1	0
<i>Emotional and mood disturbances NEC</i>		
Emotional distress	3	0
Mood altered	1	0
<i>Mood alterations with depressive symptoms</i>		
Tearfulness	5	0
<i>Mood disorders NEC</i>		
Apathy	1	0
Listless	1	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Obsessive-compulsive disorder	1	0
<i>Panic attacks and disorders</i>		
Panic attack	3	0
Panic reaction	2	0
<i>Parasomnias</i>		
Sleep terror	1	0
<i>Perception disturbances</i>		
Hallucination	2	0
Hallucination, auditory	2	0
<i>Sleep disorders NEC</i>		
Sleep disorder	1	0
<i>Somatoform disorders</i>		
Somatisation disorder	1	0
<i>Speech articulation and rhythm disturbances</i>		
Screaming	1	0
<i>Suicidal and self-injurious behaviour</i>		
Suicidal ideation	1	0
<i>Thinking disturbances</i>		
Thought blocking	1	0

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MedDRA Version: MedDRA 18.0

Reaction Name	Total	Fatal
Psychiatric disordersPsychiatric disorders cont'd		
Psychiatric disorders SOC TOTAL	64	0

Case Series Drug Analysis Print

Name: Gardasil

Report Run Date: 26-Jun-2015
Earliest Reaction Date: 29-Nov-2006

Data Lock Date: 24-Jun-2015 19:00:15
MedDRA Version: MedDRA 18.0

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Urinary incontinence	4	0
<i>Bladder infections and inflammations</i>		
Cystitis noninfective	1	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
Renal & urinary disorders SOC TOTAL	9	0

Case Series Drug Analysis Print

Name: Gardasil

Report Run Date: 26-Jun-2015
Earliest Reaction Date: 29-Nov-2006

Data Lock Date: 24-Jun-2015 19:00:15
MedDRA Version: MedDRA 18.0

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Cervix disorders NEC</i>		
Cervical dysplasia	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	1	0
Menstruation irregular	4	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	2	0
Oligomenorrhoea	1	0
<i>Menstruation with increased bleeding</i>		
Menorrhagia	8	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Polycystic ovaries	1	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovarian disorder	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Pelvic pain	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	1	0
Reproductive & breast disorders SOC TOTAL	21	0

Case Series Drug Analysis Print

Name: Gardasil

Report Run Date: 26-Jun-2015
Earliest Reaction Date: 29-Nov-2006

Data Lock Date: 24-Jun-2015 19:00:15
MedDRA Version: MedDRA 18.0

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	25	0
Hyperventilation	10	0
Hypopnoea	4	0
Tachypnoea	2	0
<i>Bronchospasm and obstruction</i>		
Asthma	4	0
Bronchospasm	2	0
Wheezing	2	0
<i>Coughing and associated symptoms</i>		
Cough	6	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	3	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	1	0
Pharyngeal oedema	1	0
<i>Respiratory tract disorders NEC</i>		
Respiratory tract inflammation	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Choking sensation	1	0
Dry throat	1	0
Dysphonia	1	0
Oropharyngeal pain	9	0
Throat irritation	2	0
Throat tightness	3	0
Respiratory disorders SOC TOTAL	79	0

Case Series Drug Analysis Print

Name: Gardasil

Report Run Date: 26-Jun-2015
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Data Lock Date: 24-Jun-2015 19:00:15
MedDRA Version: MedDRA 18.0

Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	2	0
<i>Alopecias</i>		
Alopecia	10	0
Diffuse alopecia	1	0
<i>Angioedemas</i>		
Angioedema	2	0
Swelling face	10	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	27	0
Hyperhidrosis	17	0
Miliaria	1	0
<i>Bullous conditions</i>		
Blister	1	0
Erythema multiforme	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	3	0
Pain of skin	2	0
Papule	2	0
Skin discolouration	20	0
Skin reaction	3	0
Skin tightness	2	0
Skin warm	11	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	2	0
Dermatitis contact	1	0
Eczema	5	0
Skin irritation	2	0
<i>Erythemas</i>		
Erythema	32	0
Generalised erythema	1	0
Palmar erythema	1	0
Rash erythematous	12	0
<i>Exfoliative conditions</i>		
Skin exfoliation	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail discolouration	1	0
<i>Panniculitides</i>		
Erythema nodosum	1	0
<i>Pruritus NEC</i>		
Pruritus	30	0
Pruritus generalised	3	0
Rash pruritic	9	0
<i>Purpura and related conditions</i>		
Petechiae	1	0
Purpura	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	56	0
Rash generalised	11	0
Rash macular	10	0
Rash maculo-papular	1	0
Rash papular	1	0
<i>Skin and subcutaneous conditions NEC</i>		

Case Series Drug Analysis Print

Name: Gardasil

Report Run Date: 26-Jun-2015

Data Lock Date: 24-Jun-2015 19:00:15

Earliest Reaction Date: 29-Nov-2006

MedDRA Version: MedDRA 18.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin mass	1	0
Umbilical discharge	1	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	1	0
Urticarias		
Urticaria	48	0
Skin disorders SOC TOTAL	348	0

Case Series Drug Analysis Print

Name: Gardasil

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Activities of daily living impaired	4	0
Physical disability	1	0
<i>Educational issues</i>		
Educational problem	1	0
Social circumstances SOC TOTAL	6	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Hernia repairs</i>		
Inguinal hernia repair	1	0
<i>Obstetric therapeutic procedures</i>		
Ventouse extraction	1	0
Surgical & medical procedures SOC TOTAL	2	0

Case Series Drug Analysis Print

Name: Gardasil

Report Run Date: 26-Jun-2015
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MedDRA Version: MedDRA 18.0

Reaction Name	Total	Fatal
Vascular disorders		
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	1	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	14	0
Hot flush	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	15	0
<i>Site specific vascular disorders NEC</i>		
Pallor	76	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	6	0
Orthostatic hypotension	1	0
Vascular disorders SOC TOTAL	115	0
TOTAL REACTIONS FOR DRUG	3579	2
TOTAL REPORTS	1483	
TOTAL FATAL OUTCOME REPORTS		2