

Case Series Drug Analysis Print

Name: Cervarix Product Analysis Print

Report Run Date: 01-Jul-2015
Data Lock Date: 30-Jun-2015 19:00:15
Earliest Reaction Date: 17-Nov-2008
MedDRA Version: MedDRA 18.0
Cervarix PAP: All Cervarix cases after 31/07/2012

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Reaction Name	Total	Fatal
Blood disorders		
<i>Haematological disorders</i>		
Mast cell activation syndrome	1	0
Mastocytosis	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	3	0
<i>Spleen disorders</i>		
Splenomegaly	1	0
<i>Thrombocytopenias</i>		
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cyanosis	1	0
Palpitations	3	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	1	0
<i>Rate and rhythm disorders NEC</i>		
Postural orthostatic tachycardia syndrome	3	0
Cardiac disorders SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Non-site specific bone disorders congenital</i>		
Osteopetrosis	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
Congenital disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Hearing losses</i>		
Deafness	1	0
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	1	0
Vertigo	2	0
Ear disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Posterior pituitary disorders</i>		
Diabetes insipidus	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	1	0
Endocrine disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Blindness (excl colour blindness)</i>		
Blindness transient	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye irritation	1	0
<i>Ocular sensation disorders</i>		
Photophobia	3	0
<i>Partial vision loss</i>		
Visual acuity reduced	1	0
<i>Pupil disorders</i>		
Pupil fixed	1	0
<i>Refractive and accommodative disorders</i>		
Altered visual depth perception	1	0
<i>Visual disorders NEC</i>		
Vision blurred	3	0
Visual impairment	5	0
Eye disorders SOC TOTAL	17	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Colitis (excl infective)</i>		
Colitis ulcerative	1	0
<i>Dental disorders NEC</i>		
Tooth erosion	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	7	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	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	1	0
Abdominal pain	5	0
Abdominal pain lower	2	0
Abdominal pain upper	9	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	2	0
Gastrooesophageal reflux disease	2	0
Impaired gastric emptying	1	0
<i>Gastrointestinal disorders NEC</i>		
Gastric disorder	1	0
Gastrointestinal disorder	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	3	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Irritable bowel syndrome	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	84	0
Regurgitation	1	0
Vomiting	17	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	1	0
Haematemesis	1	0
<i>Oral soft tissue disorders NEC</i>		
Cheilitis	1	0
<i>Pancreatic disorders NEC</i>		
Pancreatic disorder	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	1	0
Gastrointestinal disorders SOC TOTAL	150	0

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Reaction Name	Total	Fatal
General disorders		
<i>Asthenic conditions</i>		
Asthenia	10	0
Chronic fatigue syndrome	11	0
Decreased activity	1	0
Fatigue	60	0
Malaise	25	0
<i>Febrile disorders</i>		
Pyrexia	7	0
<i>Feelings and sensations NEC</i>		
Chills	1	0
Feeling abnormal	2	0
Feeling cold	3	0
Feeling hot	6	0
Feeling of body temperature change	2	0
Thirst	1	0
<i>Gait disturbances</i>		
Gait disturbance	2	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	1	0
Ill-defined disorder	1	0
Influenza like illness	5	0
Local swelling	1	0
Peripheral swelling	7	0
Swelling	1	0
<i>Injection site reactions</i>		
Injection site bruising	3	0
Injection site erythema	2	0
Injection site haemorrhage	1	0
Injection site hypoaesthesia	2	0
Injection site irritation	1	0
Injection site mass	4	0
Injection site pain	3	0
Injection site rash	2	0
Injection site scar	1	0
Injection site swelling	4	0
<i>Pain and discomfort NEC</i>		
Chest discomfort	1	0
Chest pain	3	0
Discomfort	1	0
Pain	12	0
<i>Ulcers NEC</i>		
Ulcer	1	0
General disorders SOC TOTAL	188	0

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Hepatic and hepatobiliary disorders NEC</i>		
Hepatic cyst	1	0
Liver disorder	1	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	1	0
Hepatic disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	2	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Food allergy	2	0
Reaction to preservatives	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
Overlap syndrome	1	0
<i>Immune and associated conditions NEC</i>		
Immune system disorder	1	0
Immune system disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Small intestinal bacterial overgrowth	1	0
<i>Candida infections</i>		
Candida infection	1	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	4	0
<i>Eye and eyelid infections</i>		
Hordeolum	1	0
<i>Herpes viral infections</i>		
Herpes virus infection	1	0
Herpes zoster	1	0
<i>Infections NEC</i>		
Infection	1	0
Infection susceptibility increased	1	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	1	0
<i>Papilloma viral infections</i>		
Vulvovaginal human papilloma virus infection	1	0
<i>Staphylococcal infections</i>		
Furuncle	2	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	3	0
Pharyngitis	1	0
Tonsillitis	2	0
<i>Viral infections NEC</i>		
Post viral fatigue syndrome	6	0
Viral infection	4	0
Infections SOC TOTAL	31	0

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Foetal exposure during pregnancy	1	0
<i>Maladministrations</i>		
Inappropriate schedule of drug administration	1	0
<i>Non-site specific injuries NEC</i>		
Wound	1	0
<i>Skin injuries NEC</i>		
Contusion	5	0
Dermatitis artefacta	1	0
Injuries SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Investigations		
<i>Autoimmunity analyses</i>		
Antinuclear antibody increased	1	0
<i>Blood counts NEC</i>		
Blood count abnormal	1	0
<i>Blood gas and acid base analyses</i>		
Blood pH increased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate increased	2	0
<i>Investigations NEC</i>		
Quality of life decreased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature decreased	1	0
Body temperature increased	1	0
Weight decreased	4	0
Weight increased	1	0
<i>Platelet analyses</i>		
Platelet count decreased	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output decreased	1	0
<i>White blood cell analyses</i>		
White blood cell count decreased	1	0
Investigations SOC TOTAL	16	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	2	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Food intolerance	2	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	1	0
Feeding disorder	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	1	0
<i>Iron deficiencies</i>		
Iron deficiency	1	0
<i>Total fluid volume decreased</i>		
Dehydration	1	0
Metabolic disorders SOC TOTAL	10	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	1	0
Arthropathy	1	0
<i>Cartilage disorders</i>		
Costochondritis	1	0
<i>Connective tissue disorders NEC</i>		
Mixed connective tissue disease	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	16	0
Joint swelling	4	0
<i>Lupus erythematosus (incl subtypes)</i>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	3	0
<i>Metabolic bone disorders</i>		
Osteoporosis	1	0
<i>Muscle infections and inflammations</i>		
Myositis	1	0
<i>Muscle pains</i>		
Fibromyalgia	1	0
Myalgia	5	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	1	0
Muscle spasms	2	0
Muscle twitching	2	0
<i>Muscle weakness conditions</i>		
Muscular weakness	2	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	4	0
Growing pains	1	0
Pain in extremity	42	0
<i>Musculoskeletal and connective tissue signs and symptoms NEC</i>		
Growth retardation	2	0
Musculoskeletal stiffness	1	0
<i>Rheumatoid arthropathies</i>		
Juvenile idiopathic arthritis	2	0
Muscle & tissue disorders SOC TOTAL	95	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Endocrine neoplasms malignant and unspecified NEC</i>		
Pituitary tumour	1	0
<i>Non-Hodgkin's lymphomas NEC</i>		
Non-Hodgkin's lymphoma	1	1
Neoplasms SOC TOTAL	2	1

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	1	0
<i>Autonomic nervous system disorders</i>		
Autonomic nervous system imbalance	1	0
<i>Central nervous system vascular disorders NEC</i>		
Cerebrovascular disorder	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	2	0
Dysstasia	2	0
<i>Cortical dysfunction NEC</i>		
Aphasia	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	5	0
Loss of consciousness	5	0
Somnolence	9	0
Syncope	10	0
<i>Dyskinesias and movement disorders NEC</i>		
Clumsiness	1	0
<i>Encephalitis NEC</i>		
Encephalitis autoimmune	2	0
<i>Facial cranial nerve disorders</i>		
VIIth nerve paralysis	1	0
<i>Headaches NEC</i>		
Cluster headache	1	0
Headache	77	0
Tension headache	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	1	0
Memory impairment	4	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	2	0
Disturbance in attention	4	0
<i>Migraine headaches</i>		
Migraine	5	0
Migraine without aura	1	0
<i>Narcolepsy and hypersomnia</i>		
Cataplexy	2	0
Hypersomnia	3	0
Narcolepsy	2	0
<i>Neurologic visual problems NEC</i>		
Visual field defect	2	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	138	0
Dizziness postural	1	0
Head discomfort	1	0
Neurological symptom	1	0
Presyncope	1	0
<i>Neuromuscular disorders NEC</i>		
Muscle contractions involuntary	1	0
<i>Paraesthesias and dysaesthesias</i>		
Hypoaesthesia	9	0
Paraesthesia	3	0
<i>Paralysis and paresis (excl cranial nerve)</i>		

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Paralysis	1	0
Seizures and seizure disorders NEC		
Seizure	2	0
Seizure like phenomena	1	0
Status epilepticus	1	0
Speech and language abnormalities		
Dysarthria	1	0
Spinal cord and nerve root disorders NEC		
Spinal cord oedema	1	0
Tremor (excl congenital)		
Tremor	5	0
Nervous system disorders SOC TOTAL	313	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Anxiety symptoms</i>		
Anxiety	1	0
Nervousness	1	0
<i>Behaviour and socialisation disturbances</i>		
Disturbance in social behaviour	1	0
<i>Confusion and disorientation</i>		
Disorientation	2	0
<i>Depressive disorders</i>		
Depression	3	0
<i>Dissociative states</i>		
Dissociation	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	2	0
Middle insomnia	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	1	0
<i>Panic attacks and disorders</i>		
Panic attack	2	0
<i>Sleep disorders NEC</i>		
Sleep disorder	2	0
<i>Suicidal and self-injurious behaviour</i>		
Intentional self-injury	1	0
Psychiatric disorders SOC TOTAL	18	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder pain	1	0
Bladder spasm	1	0
Dysuria	1	0
Micturition urgency	1	0
Pollakiuria	3	0
<i>Myoneurogenic bladder disorders</i>		
Contracted bladder	1	0
Hypertonic bladder	1	0
Renal & urinary disorders SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Menstruation and uterine bleeding NEC</i>		
Menstrual disorder	2	0
Menstruation irregular	3	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	2	0
Oligomenorrhoea	1	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Polycystic ovaries	1	0
<i>Vulvovaginal disorders NEC</i>		
Vulval disorder	1	0
Vulvar dysplasia	1	0
Reproductive & breast disorders SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	5	0
Hypopnoea	1	0
<i>Coughing and associated symptoms</i>		
Cough	2	0
<i>Nasal disorders NEC</i>		
Epistaxis	2	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Tonsillar hypertrophy	1	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pneumothorax	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal discomfort	1	0
Oropharyngeal pain	8	0
Throat tightness	1	0
Respiratory disorders SOC TOTAL	22	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Alopecias</i>		
Alopecia	2	0
Alopecia totalis	1	0
Diffuse alopecia	1	0
<i>Apocrine and eccrine gland disorders</i>		
Hyperhidrosis	3	0
<i>Bullous conditions</i>		
Blister	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	1	0
Skin discolouration	3	0
Skin reaction	2	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	1	0
Dermatitis contact	1	0
Dyshidrotic eczema	1	0
<i>Erythemas</i>		
Erythema	1	0
Rash erythematous	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	3	0
Rash pruritic	1	0
<i>Psoriatic conditions</i>		
Psoriasis	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	12	0
Rash generalised	2	0
Rash macular	1	0
<i>Skin hypoplasias and atrophies</i>		
Skin striae	1	0
<i>Urticarias</i>		
Urticaria	1	0
Skin disorders SOC TOTAL	43	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Puberty	1	0
<i>Disability issues</i>		
Activities of daily living impaired	1	0
Bedridden	1	0
Immobile	1	0
Impaired work ability	1	0
<i>Educational issues</i>		
Educational problem	2	0
Social circumstances SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Vascular therapeutic procedures NEC</i>		
Vasodilation procedure	1	0
Surgical & medical procedures SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Peripheral vascular disorders NEC</i>		
Flushing	3	0
Hot flush	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	6	0
<i>Site specific vascular disorders NEC</i>		
Pallor	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	2	0
Vascular disorders SOC TOTAL	13	0
TOTAL REACTIONS FOR DRUG	991	1
TOTAL REPORTS	419	
TOTAL FATAL OUTCOME REPORTS		1