

Case Series Drug Analysis Print

Name: Human Papilloma Virus (HPV)

Report Run Date: 23-Jun-2021

Data Lock Date: 22-Jun-2021 18:30:04

Earliest Reaction Date: 20-May-2008

MedDRA Version: MedDRA 24.0

Human Papilloma Virus (HPV): UK Spontaneous ADR reports for Human Papilloma Virus until from 01/01/2018-31/12/2018

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Reaction Name	Total	Fatal
Blood disorders		
<i>Haematological disorders</i>		
Mast cell activation syndrome	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	5	0
Blood disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac disorders NEC</i>		
Cardiac disorder	1	0
<i>Rate and rhythm disorders NEC</i>		
Postural orthostatic tachycardia syndrome	11	0
Tachycardia	1	0
Cardiac disorders SOC TOTAL	13	0

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

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Reaction Name	Total	Fatal
Ear disorders		
<i>Hearing losses</i>		
Deafness	1	0
Hypoacusis	2	0
<i>Hyperacusia</i>		
Hyperacusis	2	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	2	0
Ear disorders SOC TOTAL	7	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>Eyelid movement disorders</i>		
Blepharospasm	1	0
<i>Lacrimation disorders</i>		
Lacrimation increased	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	1	0
<i>Ocular disorders NEC</i>		
Eye pain	1	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	3	0
Gaze palsy	1	0
<i>Ocular sensation disorders</i>		
Photophobia	4	0
<i>Pupil disorders</i>		
Miosis	1	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal aneurysm	1	0
<i>Visual disorders NEC</i>		
Diplopia	1	0
Vision blurred	4	0
<i>Visual field disorders</i>		
Visual field defect	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	1	0
Blindness transient	2	0
Visual impairment	4	0
Eye disorders SOC TOTAL	27	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	5	0
Diarrhoea haemorrhagic	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	3	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	5	0
Abdominal pain lower	1	0
Abdominal pain upper	12	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	3	0
<i>Gastrointestinal disorders NEC</i>		
Gastric disorder	2	0
Gastrointestinal disorder	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
Dyschezia	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	4	0
Dysphagia	2	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Irritable bowel syndrome	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival ulceration	1	0
<i>Malabsorption syndromes</i>		
Coeliac disease	2	0
Malabsorption	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	40	0
Vomiting	18	0
<i>Oral dryness and saliva altered</i>		
Lip dry	1	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	1	0
Lip blister	1	0
<i>Oral soft tissue signs and symptoms</i>		
Lip erythema	1	0
Oral mucosal blistering	1	0
Paraesthesia oral	2	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	4	0
<i>Stomatitis and ulceration</i>		
Lip ulceration	1	0
Mouth ulceration	2	0
<i>Tongue disorders</i>		
Tongue ulceration	1	0
Gastrointestinal disorders SOC TOTAL	119	0

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General disorders		
<i>Asthenic conditions</i>		
Asthenia	9	0
Chronic fatigue syndrome	11	0
Fatigue	39	0
Malaise	33	0
<i>Body temperature altered</i>		
Temperature regulation disorder	2	0
<i>Death and sudden death</i>		
Death	1	1
<i>Febrile disorders</i>		
Pyrexia	25	0
<i>Feelings and sensations NEC</i>		
Chills	8	0
Feeling abnormal	9	0
Feeling cold	2	0
Feeling hot	2	0
Feeling of body temperature change	2	0
Sensation of foreign body	1	0
Temperature intolerance	1	0
<i>Gait disturbances</i>		
Gait disturbance	2	0
Gait inability	3	0
Loss of control of legs	3	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	1	0
Crying	1	0
Glassy eyes	1	0
Illness	4	0
Influenza like illness	4	0
Peripheral swelling	6	0
Secretion discharge	1	0
Swelling	1	0
Swelling face	4	0
<i>Hernias NEC</i>		
Hernia	1	0
<i>Injection site reactions</i>		
Injection site inflammation	1	0
Injection site mass	1	0
Injection site pain	1	0
Injection site swelling	1	0
<i>Mucosal findings abnormal</i>		
Mucosal ulceration	1	0
<i>Pain and discomfort NEC</i>		
Chest discomfort	4	0
Chest pain	11	0
Discomfort	1	0
Facial pain	1	0
Pain	22	0
Tenderness	1	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse event	1	0
Adverse reaction	1	0
Drug ineffective	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Therapeutic response unexpected	1	0
Ulcers NEC		
Ulcer	1	0
Vaccination site reactions		
Vaccination site bruising	1	0
Vaccination site discolouration	2	0
Vaccination site erythema	3	0
Vaccination site induration	1	0
Vaccination site inflammation	1	0
Vaccination site mass	2	0
Vaccination site nodule	1	0
Vaccination site pain	7	0
Vaccination site paraesthesia	1	0
Vaccination site pruritus	2	0
Vaccination site rash	1	0
Vaccination site swelling	6	0
General disorders SOC TOTAL	255	1

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	8	0
Multiple allergies	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Food allergy	2	0
Reaction to excipient	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	2	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
Immune system disorders SOC TOTAL	17	0

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Reaction Name	Total	Fatal
Infections		
<i>Central nervous system and spinal infections</i>		
Encephalitis	1	0
<i>Herpes viral infections</i>		
Herpes zoster	2	0
<i>Influenza viral infections</i>		
Influenza	1	0
<i>Papilloma viral infections</i>		
Papilloma viral infection	2	0
<i>Staphylococcal infections</i>		
Staphylococcal infection	1	0
<i>Upper respiratory tract infections</i>		
Pharyngitis	1	0
Tonsillitis	1	0
<i>Urinary tract infections</i>		
Urinary tract infection	2	0
<i>Viral infections NEC</i>		
Gastroenteritis viral	1	0
Post viral fatigue syndrome	5	0
Viral infection	2	0
Infections SOC TOTAL	19	0

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	1	0
<i>Non-site specific injuries NEC</i>		
Fall	1	0
Injury	1	0
<i>Overdoses NEC</i>		
Overdose	1	0
<i>Product administration errors and issues</i>		
Product administered at inappropriate site	1	0
Product administered to patient of inappropriate age	1	0
Wrong product administered	1	0
<i>Skin injuries NEC</i>		
Contusion	2	0
<i>Vaccination related complications</i>		
Vaccination complication	1	0
Injuries SOC TOTAL	10	0

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Reaction Name	Total	Fatal
Investigations		
<i>Cardiac auscultatory investigations</i>		
Heart sounds abnormal	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate abnormal	2	0
Heart rate increased	2	0
Heart rate irregular	3	0
Pulse absent	2	0
<i>Mineral and electrolyte analyses</i>		
Blood iron decreased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature increased	2	0
Weight decreased	2	0
<i>Reproductive hormone analyses</i>		
Anti-Muellerian hormone level decreased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	1	0
Investigations SOC TOTAL	17	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	5	0
<i>Diabetes mellitus (incl subtypes)</i>		
Type 1 diabetes mellitus	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Gluten sensitivity	2	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	1	0
Metabolic disorders SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	1	0
Arthropathy	2	0
<i>Bone related signs and symptoms</i>		
Bone pain	1	0
Coccydynia	1	0
<i>Joint related disorders NEC</i>		
Hypermobility syndrome	2	0
<i>Joint related signs and symptoms</i>		
Arthralgia	16	0
Joint stiffness	1	0
Joint swelling	4	0
<i>Ligament disorders</i>		
Ligament pain	1	0
<i>Muscle pains</i>		
Fibromyalgia	1	0
Myalgia	9	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	1	0
Muscle fatigue	3	0
Muscle spasms	1	0
Muscle twitching	3	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	3	0
Trismus	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	7	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Growth retardation	1	0
Mobility decreased	1	0
Musculoskeletal stiffness	6	0
Weight bearing difficulty	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	6	0
Limb discomfort	1	0
Musculoskeletal chest pain	1	0
Musculoskeletal pain	2	0
Neck pain	6	0
Pain in extremity	29	0
<i>Spine and neck deformities</i>		
Scoliosis	2	0
<i>Tendon disorders</i>		
Tendonitis	1	0
Muscle & tissue disorders SOC TOTAL	115	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Cervix neoplasms malignant</i>		
Cervix carcinoma	1	0
Neoplasms SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal sleep-related events</i>		
Sleep paralysis	1	0
<i>Absence seizures</i>		
Petit mal epilepsy	1	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<i>Autonomic nervous system disorders</i>		
Autonomic neuropathy	1	0
<i>Coordination and balance disturbances</i>		
Dysstasia	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	2	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	2	0
Lethargy	10	0
Loss of consciousness	6	0
Somnolence	5	0
Syncope	29	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	3	0
<i>Encephalitis NEC</i>		
Encephalitis autoimmune	1	0
<i>Facial cranial nerve disorders</i>		
Facial paralysis	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	1	0
<i>Headaches NEC</i>		
Headache	44	0
Tension headache	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	4	0
Memory impairment	3	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	2	0
Disturbance in attention	3	0
<i>Migraine headaches</i>		
Migraine	4	0
<i>Muscle tone abnormal</i>		
Hypotonia	1	0
<i>Narcolepsy and hypersomnia</i>		
Cataplexy	1	0
Hypersomnia	1	0
Narcolepsy	2	0
<i>Nervous system cysts and polyps</i>		
Pineal gland cyst	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	48	0
Dizziness postural	3	0
Drooling	1	0
Head discomfort	1	0
Presyncope	3	0
Slow response to stimuli	1	0
Unresponsive to stimuli	6	0

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Nervous system disorders		
Nervous system disorders cont'd		
<i>Paraesthesias and dysaesthesias</i>		
Hyperaesthesia	2	0
Hypoaesthesia	13	0
Paraesthesia	17	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	1	0
Paralysis	6	0
Paraplegia	1	0
<i>Seizures and seizure disorders NEC</i>		
Partial seizures	1	0
Psychogenic seizure	1	0
Seizure	8	0
Tonic clonic movements	1	0
Tonic convulsion	1	0
<i>Sensory abnormalities NEC</i>		
Complex regional pain syndrome	3	0
Neuralgia	1	0
Sensory loss	3	0
Taste disorder	1	0
<i>Speech and language abnormalities</i>		
Dysarthria	2	0
<i>Tremor (excl congenital)</i>		
Tremor	5	0
Nervous system disorders SOC TOTAL	262	0

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

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Anxiety symptoms</i>		
Anxiety	7	0
Nervousness	1	0
<i>Behaviour and socialisation disturbances</i>		
Personality change	2	0
<i>Confusion and disorientation</i>		
Confusional state	4	0
<i>Deliria</i>		
Delirium	1	0
<i>Depressive disorders</i>		
Depression	5	0
Depression suicidal	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	9	0
<i>Dyssomnias</i>		
Poor quality sleep	1	0
<i>Emotional and mood disturbances NEC</i>		
Emotional disorder	1	0
Emotional distress	1	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Claustrophobia	1	0
Social anxiety disorder	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	1	0
Hallucinations, mixed	1	0
<i>Mood alterations with depressive symptoms</i>		
Depressed mood	1	0
Tearfulness	2	0
<i>Panic attacks and disorders</i>		
Panic attack	1	0
<i>Parasomnias</i>		
Sleep terror	1	0
<i>Perception disturbances NEC</i>		
Near death experience	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	3	0
<i>Somatic symptom disorders</i>		
Conversion disorder	1	0
<i>Speech and language usage disturbances</i>		
Logorrhoea	1	0
<i>Suicidal and self-injurious behaviour</i>		
Suicidal ideation	1	0
<i>Tic disorders</i>		
Tic	1	0
Psychiatric disorders SOC TOTAL	51	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Urinary incontinence	1	0
<i>Urinary abnormalities</i>		
Proteinuria	1	0
Renal & urinary disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Menopausal effects NEC</i>		
Premature menopause	3	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	2	0
Intermenstrual bleeding	1	0
Menstrual disorder	1	0
Menstruation irregular	3	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	6	0
Menstruation delayed	4	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	3	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovarian failure	2	0
<i>Sexual function and fertility disorders NEC</i>		
Infertility	1	0
<i>Vulvovaginal signs and symptoms</i>		
Vaginal discharge	2	0
Reproductive & breast disorders SOC TOTAL	28	0

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Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	13	0
Hyperventilation	3	0
Hypopnoea	1	0
Respiration abnormal	2	0
Respiratory arrest	2	0
<i>Bronchospasm and obstruction</i>		
Asthma	2	0
Obstructive airways disorder	1	0
<i>Coughing and associated symptoms</i>		
Cough	4	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	2	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal paraesthesia	1	0
Tonsillar disorder	1	0
Tonsillar erythema	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Dysphonia	1	0
Oropharyngeal pain	8	0
Throat irritation	1	0
Throat tightness	1	0
Respiratory disorders SOC TOTAL	45	0

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Skin disorders		
Angioedemas		
Angioedema	1	0
Apocrine and eccrine gland disorders		
Cold sweat	9	0
Hyperhidrosis	2	0
Bullous conditions		
Blister	1	0
Erythema multiforme	1	0
Dermal and epidermal conditions NEC		
Dry skin	3	0
Papule	1	0
Skin burning sensation	1	0
Skin discolouration	3	0
Skin disorder	1	0
Skin fissures	1	0
Skin induration	1	0
Skin texture abnormal	1	0
Dermatitis and eczema		
Dermatitis allergic	2	0
Erythemas		
Erythema	7	0
Exfoliative conditions		
Skin exfoliation	2	0
Panniculitides		
Erythema nodosum	2	0
Papulosquamous conditions		
Lichen planus	1	0
Pityriasis rosea	1	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	2	0
Pilar disorders NEC		
Hair growth abnormal	1	0
Pruritus NEC		
Pruritus	4	0
Purpura and related conditions		
Henoch-Schonlein purpura	1	0
Rashes, eruptions and exanthems NEC		
Rash	12	0
Rash macular	2	0
Rash papular	1	0
Rash pruritic	4	0
Rash vesicular	1	0
Skin vasomotor conditions		
Livedo reticularis	2	0
Urticarias		
Urticaria	7	0
Skin disorders SOC TOTAL	78	0

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Data Lock Date: 22-Jun-2021 18:30:04

Earliest Reaction Date: 20-May-2008

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Bedridden	1	0
Loss of personal independence in daily activities	1	0
Social circumstances SOC TOTAL	2	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Induced abortions</i>		
Abortion induced	1	0
Surgical & medical procedures SOC TOTAL	1	0

Case Series Drug Analysis Print

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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	2	0
Poor peripheral circulation	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	12	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	2	0
Vascular disorders SOC TOTAL	22	0
TOTAL REACTIONS FOR DRUG	1111	1
TOTAL REPORTS	268	
TOTAL FATAL OUTCOME REPORTS		1