Report Run Date: 23-Jun-2021

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Earliest Reaction Date: 17-Mar-2010 MedDRA Version: MedDRA 24.0

UK Spontaneous ADR reports for Human Papilloma Virus until from 01/01/2020-31/12/2020 Human Papilloma

Virus (HPV):

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Reaction Name	Total	Fatal
Blood disorders		
Lymphatic system disorders NEC		
Lymphadenopathy	1	0
Thrombocytopenias		
Immune thrombocytopenia	1	0
Blood disorders SOC TOTAL	2	0

Reaction Name	Total	Fatal
Cardiac disorders		
Cardiac signs and symptoms NEC		
Palpitations	1	ı 0
Rate and rhythm disorders NEC		
Arrhythmia	1	ı o
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	1	ı o
Cardiac disorders SOC TOTAL		3 0

Reaction Name	Total	Fatal
Ear disorders		
Hearing disorders NEC		
Auditory disorder	1	0
Hearing losses		
Deafness	1	0
Hypoacusis	1	0
Inner ear signs and symptoms		
Vertigo	1	0
Ear disorders SOC TOTAL	4	0

Reaction Name	Total	Fatal
Eve disorders		
Ocular disorders NEC		
Eye swelling	1	0
Ocular infections, inflammations and associated manifestations		
Eye pruritus	1	0
Ocular hyperaemia	1	0
Ocular nerve and muscle disorders		
Eye movement disorder	3	0
Visual disorders NEC		
Vision blurred	4	0
Visual impairment and blindness (excl colour blindness)		
Blindness transient	1	0
Visual impairment	1	0
Eve disorders SOC TOTAL	12	0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Colitis (excl infective)		
Colitis	1	0
Diarrhoea (excl infective)		
Diarrhoea	3	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	3	0
Abdominal pain upper	4	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	2	0
Dysphagia	1	0
Intestinal haemorrhages		
Rectal haemorrhage	1	0
Nausea and vomiting symptoms		
Nausea	15	0
Vomiting	11	0
Oral soft tissue signs and symptoms		
Paraesthesia oral	2	0
Oral soft tissue swelling and oedema		
Lip swelling	1	0
Gastrointestinal disorders SOC TOTAL	44	l o

Earliest Reaction Date: 17-Mar-2010	MedDRA Version: MedDRA 24.0	
Reaction Name	Total	<u> Fatal</u>
General disorders		
Asthenic conditions		
Asthenia		4 O
Chronic fatigue syndrome	,	۱ 0
Fatigue	15	5 0
Malaise		el o
Febrile disorders		
Pyrexia	16	0
Feelings and sensations NEC		
Chills		0
Feeling abnormal		
Feeling cold		i ő
Feeling hot		0
Gait disturbances		1
Gait inability		1 0
General signs and symptoms NEC		
Illness		1 0
Peripheral swelling		
Swelling		2 0
		1
Swelling face	,	0
Injection site reactions		
Injection site bruising		0
Injection site discomfort		0
Injection site erythema		0
Injection site mass		0
Injection site pain		0
Injection site pruritus	· ·	1 0
Pain and discomfort NEC		
Axillary pain	·	0
Chest discomfort		0
Chest pain	· · · · · · · · · · · · · · · · · · ·	1 0
Pain	2	2 0
Therapeutic and nontherapeutic responses		
Drug ineffective	,	1 0
Vaccination site reactions		
Extensive swelling of vaccinated limb	•	1 0
Vaccination site bruising	•	1 0
Vaccination site discomfort	•	1 0
Vaccination site erythema	•	1 0
Vaccination site haemorrhage	2	2 0
Vaccination site inflammation		1 0
Vaccination site joint movement impairment	nt ´	1 0
Vaccination site joint pain	,	1 0
Vaccination site mass		1 0
Vaccination site movement impairment		1 0
Vaccination site pain		3 0
Vaccination site swelling		2 0
Vaccination site warmth		i ő
General disorders SOC TOTAL	10 ⁻	

Reaction Name	Total	Fatal
Hepatic disorders		
Hepatocellular damage and hepatitis NEC		
Autoimmune hepatitis	1	0
Hepatic disorders SOC TOTAL	1	l o

Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		
Hypersensitivity	3	0
Allergies to foods, food additives, drugs and other chemicals		
Drug hypersensitivity	1	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	8	0
Immune and associated conditions NEC		
Immune system disorder	1	0
Immune system disorders SOC TOTAL	13	0

Reaction Name	Total	Fatal
Infections		
Central nervous system and spinal infections		
Subdural abscess	1	0
Herpes viral infections		
Herpes zoster	1	0
Oral herpes	1	0
Upper respiratory tract infections		
Nasopharyngitis	1	0
Sinusitis	1	0
Infections SOC TOTAL	5	0

Reaction Name	Total	Fatal
Injuries		
Exposures associated with pregnancy, delivery and lactation		
Exposure during pregnancy	1	0
Maternal exposure during pregnancy	1	0
Product administration errors and issues		
Expired product administered	1	0
Skin injuries NEC		
Contusion	1	0
Injuries SOC TOTAL	4	0

Reaction Name	Total	Fatal
Investigations		
Heart rate and pulse investigations		
Heart rate increased	2	0
Heart rate irregular	1	0
Physical examination procedures and organ system status		
Body temperature decreased	1	0
Urinalysis NEC		
Blood urine present	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure decreased	1	0
Investigations SOC TOTAL	6	0

Reaction Name	Total	Fatal
Metabolic disorders		
Appetite disorders		
Decreased appetite	2	. 0
Metabolic disorders SOC TOTAL	2	l o

Earliest Reaction Date: 17-Mar-2010 MedDRA Version: MedDRA 24.0		
Reaction Name	Total	Fatal
Muscle & tissue disorders		
Joint related signs and symptoms		
Arthralgia	3	0
Joint range of motion decreased	1	0
Muscle pains		
Myalgia	3	0
Muscle related signs and symptoms NEC		
Muscle fatigue	1	0
Muscle spasms	1	0
Muscle twitching	1	0
Muscle tone abnormalities		
Muscle rigidity	1	0
Muscle weakness conditions		
Muscular weakness	3	0
Musculoskeletal and connective tissue conditions NEC		
Musculoskeletal stiffness	4	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	4	0
Limb discomfort	1	0
Neck pain	3	0
Pain in extremity	14	0
Soft tissue disorders NEC		
Groin pain	1	0
Muscle & tissue disorders SOC TOTAL	41	l o

Reaction Name	Total	Fatal
Neoplasms		
Neoplasms unspecified malignancy and site unspecified NEC		
Neoplasm	1	1
Reproductive neoplasms male benign NEC		
Penile wart	1	0
Neoplasms SOC TOTAL	2	1

	/ersion: MedDRA 24.0	
Reaction Name	Total	Fatal
Nervous system disorders		
Central nervous system haemorrhages and cerebrova	scular accidents	
Cerebrovascular accident	1	0
Coordination and balance disturbances		
Ataxia	1	0
Coordination abnormal		0
Nystagmus	1	0
Cortical dysfunction NEC		
Aphasia	1	0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	1	0
Disturbances in consciousness NEC		
Lethargy	3	0
Loss of consciousness	2	. 0
Somnolence	2	. 0
Syncope	21	0
Dyskinesias and movement disorders NEC		
Dyskinesia	3	0
Motor dysfunction	1	0
Headaches NEC		
Headache	26	0
Memory loss (excl dementia)		
Amnesia	1	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	1	0
Disturbance in attention	2	. 0
Migraine headaches		
Migraine	1	0
Muscle tone abnormal		
Hypotonia	1	0
Narcolepsy and hypersomnia		
Hypersomnia	1	0
Neurological signs and symptoms NEC		
Dizziness	20	0
Dizziness postural	1	0
Head discomfort	1	0
Presyncope	3	0
Unresponsive to stimuli	1	0
Neuromuscular disorders NEC		
Muscle contractions involuntary		0
Olfactory nerve disorders		
Anosmia		0
Paraesthesias and dysaesthesias		
Hypoaesthesia	4	. 0
Paraesthesia	5	0
Seizures and seizure disorders NEC		
Epilepsy	1	0
Febrile convulsion	1	0
Partial seizures	1	0
Seizure	6	0
Seizure like phenomena		0
Tonic convulsion	1	0
Sensory abnormalities NEC		
Ageusia	1	0

Reaction Name	Total	Fatal
Nervous system disorders us system disorders cont'd		
Neuralgia	1	0
Sensory disturbance	1	0
Sensory loss	1	0
Taste disorder	1	0
Speech and language abnormalities		
Slow speech	1	0
Tremor (excl congenital)		
Tremor	4	0
Nervous system disorders SOC TOTAL	129	0

Reaction Name	Total	Fatal
Pregnancy conditions		
Normal pregnancy, labour and delivery		
Live birth	1	0
Unintended pregnancies		
Pregnancy with injectable contraceptive	1	0
Pregnancy conditions SOC TOTAL	2	0

Reaction Name	Total	Fatal
Product quality issues NEC		
Product origin unknown	1	0
null SOC TOTAL	1	l o

Reaction Name	Total	Fatal
Psychiatric disorders		
Behaviour and socialisation disturbances		
Impatience	1	0
Confusion and disorientation		
Confusional state	1	0
Emotional and mood disturbances NEC		
Emotional distress	1	0
Irritability	1	0
Sexual desire disorders		
Loss of libido	1	0
Sleep disorders NEC		
Sleep disorder	3	0
Psychiatric disorders SOC TOTAL	8	o l

Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Urinary incontinence	2	0
Renal & urinary disorders SOC TOTAL	2	0

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Breast signs and symptoms		
Breast pain	2	2 0
Menstruation and uterine bleeding NEC		
Dysmenorrhoea	2	2 0
Menstruation irregular	2	2 0
Menstruation with decreased bleeding		
Amenorrhoea	2	2 0
Ovarian and fallopian tube cysts and neoplasms		
Polycystic ovaries	1	0
Vulvovaginal signs and symptoms		
Vaginal discharge	2	2 0
Reproductive & breast disorders SOC TOTAL	11	0

Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	4	1 0
Respiratory arrest		0
Coughing and associated symptoms		
Cough	3	3 0
Upper respiratory tract signs and symptoms		
Oropharyngeal pain	2	2 0
Throat irritation	2	2 0
Throat tightness	1	0
Respiratory disorders SOC TOTAL	13	3 0

Reaction Name	Tota	al	Fatal
Skin disorders			
Acnes			
Acne		1	0
Alopecias			
Alopecia		1	0
Alopecia areata		1	0
Apocrine and eccrine gland disorders			
Hyperhidrosis		2	0
Dermal and epidermal conditions NEC			
Scab		1	0
Sensitive skin		2	O
Skin discolouration		2	C
Dermatitis and eczema			
Dermatitis allergic		1	C
Eczema		1	O
Erythemas			
Erythema		3	0
Exfoliative conditions			
Skin exfoliation		1	0
Pruritus NEC			
Pruritus		7	0
Purpura and related conditions			
Petechiae		1	C
Rashes, eruptions and exanthems NEC			
Rash		7	0
Rash erythematous		1	C
Rash macular		1	C
Rash pruritic		2	0
Skin vasomotor conditions			
Livedo reticularis		2	C
Urticarias			
Urticaria		9	C
Skin disorders SOC TOTAL		46	C

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Reaction Name	<u> Total</u>	<u>Fatal</u>
Vascular disorders		
Circulatory collapse and shock		
Circulatory collapse	1	0
Peripheral vascular disorders NEC		
Cyanosis	2	0
Flushing	1	0
Hot flush	1	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Peripheral coldness	4	0
Site specific vascular disorders NEC		
Pallor	6	0
Vascular disorders SOC TOTAL	15	0
TOTAL REACTIONS FOR DRUG	467	1
TOTAL REPORTS	147	
TOTAL FATAL OUTCOME REPORTS		1