## 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:	: 08-Sep-2008
MedDRA Version:	MedDRA 24.0
Human Danillama	LIK Spontaneous ADP reports for Human Papillon

Human Papilloma Virus (HPV): UK Spontaneous ADR reports for Human Papilloma Virus until from 01/01/2019-31/12/2019

## Name: Human Papilloma Virus (HPV)

Report Run Date: 23-Jun-2021 Earliest Reaction Date: 08-Sep-2008

Total	Fatal
1	0
2	0
1	0
1	0
5	0
	1 2 1 1

## Name: Human Papilloma Virus (HPV)

Report Run Date: 23-Jun-2021 Earliest Reaction Date: 08-Sep-2008

21.0	
Total	Fatal
5	0
4	0
2	0
11	0

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 Reaction Name
 Total Fatal

 Congenital disorders
 Image: Connective tissue disorders congenital

 Ehlers-Danlos syndrome
 1
 0

 Congenital disorders SOC TOTAL
 1
 0

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 Reaction Name
 Total Fatal

 Ear disorders
 Inner ear signs and symptoms

 Tinnitus
 1

 Ear disorders SOC TOTAL
 1

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Reaction Name	Total	Fatal
Eve disorders		
Eyelid movement disorders		
Eyelid ptosis	1	0
Lid, lash and lacrimal infections, irritations and inflammations		
Swelling of eyelid	3	0
Ocular disorders NEC		
Eye pain	1	0
Periorbital pain	1	0
Ocular infections, inflammations and associated manifestations		
Eye allergy	1	0
Ocular sensation disorders		
Photophobia	3	0
Pupil disorders		
Miosis	1	0
Mydriasis	1	0
Visual disorders NEC		
Photopsia	1	0
Vision blurred	7	0
Visual impairment and blindness (excl colour blindness)		
Visual impairment	2	0
Eye disorders SOC TOTAL	22	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Diarrhoea (excl infective)		
Diarrhoea	3	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	5	0
Abdominal pain lower	1	0
Abdominal pain upper	3	0
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	1	0
Gastrooesophageal reflux disease	2	0
Gastrointestinal disorders NEC		
Gastrointestinal disorder	2	0
Gastrointestinal inflammatory disorders NEC		
Gastrointestinal inflammation	1	0
Gastrointestinal signs and symptoms NEC		
Dysphagia	2	0
Gastrointestinal spastic and hypermotility disorders		
Irritable bowel syndrome	1	0
Gingival haemorrhages		
Gingival bleeding	1	0
Malabsorption syndromes		
Coeliac disease	1	0
Nausea and vomiting symptoms		
Nausea	30	0
Retching	1	0
Vomiting	18	0
Oesophagitis (excl infective)		
Eosinophilic oesophagitis	1	0
Oral soft tissue signs and symptoms		
Oral pain	2	0
Tongue disorders		
Glossitis	1	0
Tongue signs and symptoms		
Glossodynia	1	0
Tongue discomfort	1	0
Gastrointestinal disorders SOC TOTAL	78	0

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Earliest Reaction Date: 08-Sep-2008 MedDRA Version: MedDRA 24.0

Earliest Reaction Date: 08-Sep-2008 MedDRA Version: MedDRA 24.0 Reaction Name Total Fatal General disorders Administration site reactions NEC Administration site pain 0 1 Administration site swelling 0 1 Asthenic conditions 0 Asthenia 8 0 3 Chronic fatigue syndrome 20 0 Fatigue Malaise 7 0 Febrile disorders 21 0 **Pyrexia** Feelings and sensations NEC 0 Chills 7 0 Feeling abnormal 6 Feeling cold 3 0 0 Feeling hot 3 Feeling of body temperature change 0 1 General signs and symptoms NEC 0 Condition aggravated **Disease recurrence** 0 1 0 Illness 5 0 Induration 1 0 Influenza like illness Δ 0 Peripheral swelling 13 0 Swelling 1 0 Swelling face 1 Inflammations 0 Inflammation 1 Injection site reactions Injected limb mobility decreased 0 0 Injection site haemorrhage 1 Injection site swelling 0 1 Mass conditions NEC 0 Cyst Nodule 0 Oedema NEC 0 Oedema peripheral Pain and discomfort NEC Chest discomfort 0 Chest pain 6 0 0 8 Pain Vaccination site reactions Vaccination site bruising 0 2 0 Vaccination site coldness 1 0 Vaccination site erythema 3 0 Vaccination site hypoaesthesia 1 0 Vaccination site mass 4 0 2 Vaccination site movement impairment 0 Vaccination site nerve damage 1 Vaccination site pain 8 0 0 Vaccination site pruritus 1 0 2 Vaccination site rash 0 8 Vaccination site swelling General disorders SOC TOTAL 163 0

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Reaction Name	Total	Fatal
Immune system disorders		
Allergic conditions NEC		
Hypersensitivity	4	0
Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	1	0
Immune and associated conditions NEC		
Immune system disorder	1	0
Immune system disorders SOC TOTAL	6	0

## Name: Human Papilloma Virus (HPV)

Report Run Date: 23-Jun-2021 Earliest Reaction Date: 08-Sep-2008

Edited Reddion Bate. 00 Cep 2000			
Reaction Name		Total	Fatal
Infections			
Bone and joint infections			
Osteomyelitis		1	0
Ear infections			
Ear infection		1	0
Herpes viral infections			
Herpes zoster		1	0
Infections NEC			
Localised infection		1	0
Sepsis, bacteraemia, viraemia and fu	ngaemia NEC		
Neutropenic sepsis		1	0
Skin structures and soft tissue infection	ons		
Pustule		1	0
Upper respiratory tract infections			
Nasopharyngitis		2	0
Infections SOC TOTAL		8	0

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Report Run Date: 23-Jun-2021 Earliest Reaction Date: 08-Sep-2008

Reaction Name	Total	Fatal
Injuries		
Bone and joint injuries NEC		
Joint injury	1	0
Medication errors, product use errors and issues NEC		
Wrong technique in product usage process	1	0
Peripheral nerve injuries		
Peripheral nerve injury	1	0
Product administration errors and issues		
Inappropriate schedule of product administration	2	0
Product administered at inappropriate site	1	0
Skin injuries NEC		
Contusion	2	0
Vaccination related complications		
Vaccination complication	1	0
Injuries SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Investigations		
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose decreased	1	0
Central nervous system imaging procedures		
Magnetic resonance imaging head abnormal	1	0
Chemistry analyses NEC		
Histamine level increased	1	0
Heart rate and pulse investigations		
Heart rate increased	2	0
Heart rate irregular	2	0
Physical examination procedures and organ system status		
Body temperature abnormal	1	0
Body temperature increased	1	0
Respiratory rate increased	1	0
Investigations SOC TOTAL	10	0

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Reaction Name	<u>Total</u>	Fatal
Metabolic disorders		
Appetite disorders		
Decreased appetite	3	0
Hypophagia	1	0
Food malabsorption and intolerance syndromes (excl sugar intolerance)		
Histamine intolerance	1	0
General nutritional disorders NEC		
Abnormal loss of weight	3	0
Malnutrition	1	0
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	1	0
Metabolic disorders SOC TOTAL	10	0

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Report Run Date: 23-Jun-2021 Earliest Reaction Date: 08-Sep-2008

Earliest Reaction Date: 08-Sep-2008 MedDRA Version: MedDRA	24.0	
Reaction Name	Total	Fatal
Muscle & tissue disorders		
Bone related signs and symptoms		
Bone pain	1	0
Joint related signs and symptoms		
Arthralgia	10	0
Joint stiffness	2	0
Joint swelling	1	0
Muscle pains		
Myalgia	8	0
Muscle related signs and symptoms NEC		
Muscle atrophy	1	0
Muscle spasms	3	0
Muscle twitching	1	0
Muscle weakness conditions		
Muscular weakness	7	0
Musculoskeletal and connective tissue conditions NEC		
Mobility decreased	1	0
Musculoskeletal stiffness	2	0
Musculoskeletal and connective tissue pain and discomfort		
Limb discomfort	3	0
Musculoskeletal discomfort	1	0
Neck pain	4	0
Pain in extremity	15	0
Muscle & tissue disorders SOC TOTAL	60	0

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Reaction Name		Total	Fatal
Neoplasms			
Kaposi's sarcomas			
Kaposi's sarcoma		1	0
Neoplasms SOC TOTAL		1	0

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Reaction Name		Total	Fatal
Nervous system disorders			
Acute polyneuropathies			
Guillain-Barre syndrome		1	(
Autonomic nervous system disorders			
Autonomic nervous system imbalance		2	(
Coordination and balance disturbances			
Ataxia		1	(
Balance disorder		2	(
Disturbances in consciousness NEC			
Depressed level of consciousness		1	(
Lethargy		4	C
Loss of consciousness		6	C
Somnolence		2	C
Syncope		27	C
Dyskinesias and movement disorders NEC			
Dyskinesia		4	C
Hypokinesia		2	C
Motor dysfunction		1	C
Headaches NEC			
Headache		41	C
Memory loss (excl dementia)			
Memory impairment		2	C
Mental impairment (excl dementia and merr	ory loss)		
Cognitive disorder		1	C
Disturbance in attention		3	C
Migraine headaches			
Migraine		1	C
Migraine with aura		1	C
Mononeuropathies			
Carpal tunnel syndrome		1	C
Muscle tone abnormal			
Hypotonia		1	C
Narcolepsy and hypersomnia			
Hypersomnia		1	C
Neurologic visual problems NEC			
Tunnel vision		1	C
Neurological signs and symptoms NEC			
Dizziness		41	C
Dizziness postural		2	C
Presyncope		2	C
Unresponsive to stimuli		4	C
Paraesthesias and dysaesthesias			
Burning sensation		1	C
Dysaesthesia		1	C
Hypoaesthesia		6	C
Paraesthesia		12	C
Paralysis and paresis (excl cranial nerve)			
Hemiparesis		1	C
Paralysis		1	(
Peripheral neuropathies NEC			
Autoimmune neuropathy		1	(
Seizures and seizure disorders NEC			
Seizure		12	(
Sensory abnormalities NEC			

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Report Run Date: 23-Jun-2021 Earliest Reaction Date: 08-Sep-2008

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Reaction Name		Total	Fatal
Nervous system disordersus system disorders cont'd			
Complex regional pain syndrome		2	0
Neuralgia		2	0
Sensory loss		1	0
Speech and language abnormalities			
Dysarthria		1	0
Tremor (excl congenital)			
Tremor		3	0
Nervous system disorders SOC TOTAL		199	0
-			

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 MedDRA Version: MedDRA 24.0

 Reaction Name
 Total Fatal

 Product quality issues NEC
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Product quality issues NEC	
Product origin unknown	
null SOC TOTĂL	

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## Name: Human Papilloma Virus (HPV)

Report Run Date: 23-Jun-2021 Earliest Reaction Date: 08-Sep-2008

Reaction Name	Total	Fatal
Psychiatric disorders		
Anxiety symptoms		
Anxiety	6	0
Stress	1	0
Behaviour and socialisation disturbances		
Paranoia	1	0
Social avoidant behaviour	1	0
Confusion and disorientation		
Confusional state	5	0
Disorientation	3	0
Depressive disorders		
Depression	1	0
Depression suicidal	3	0
Disturbances in initiating and maintaining sleep		
Insomnia	4	0
Eating disorders NEC		
Merycism	1	0
Emotional and mood disturbances NEC		
Emotional disorder	2	0
Hallucinations (excl sleep-related)		
Hallucination	1	0
Hallucination, auditory	1	0
Hallucination, visual	1	0
Mental disorders NEC		
Mental disorder	1	0
Mood alterations with depressive symptoms		0
Depressed mood	1	0
Tearfulness	1	0
Psychiatric symptoms NEC		-
Psychiatric symptom	1	0
Sleep disorders NEC		0
Sleep disorder	1	0
Somatic symptom disorders	0	0
Conversion disorder	2	0
Speech articulation and rhythm disturbances		0
Dysphemia	1	0
Suicidal and self-injurious behaviour		0
Intentional self-injury	1	0
Suicide attempt	1	0
Thinking disturbances		
Thinking abnormal	1	0
Psychiatric disorders SOC TOTAL	42	0

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## Name: Human Papilloma Virus (HPV)

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Cervix disorders NEC		
Cervical dysplasia	1	C
Menstruation and uterine bleeding NEC		
Dysmenorrhoea	1	C
Intermenstrual bleeding	1	C
Menstrual discomfort	1	C
Menstrual disorder	1	C
Menstruation irregular	4	C
Premenstrual pain	1	C
Premenstrual syndrome	1	C
Menstruation with decreased bleeding		
Amenorrhoea	2	C
Menstruation delayed	7	C
Oligomenorrhoea	1	C
Menstruation with increased bleeding		
Heavy menstrual bleeding	2	C
Polymenorrhoea	1	C
Ovarian and fallopian tube cysts and neoplasms		
Polycystic ovaries	1	C
Sexual function and fertility disorders NEC		
Dyspareunia	1	C
Uterine disorders NEC		
Endometriosis	1	C
Vulvovaginal disorders NEC		
Vaginal haemorrhage	1	C
Vulvovaginal signs and symptoms		
Coital bleeding	1	C
Reproductive & breast disorders SOC TOTAL	29	

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Reaction Name	Total	Fatal
Respiratory disorders		
Breathing abnormalities		
Dyspnoea	6	0
Grunting	1	0
Hyperventilation	1	0
Coughing and associated symptoms		
Cough	2	0
Nasal disorders NEC		
Epistaxis	2	0
Nasal oedema	1	0
Paranasal sinus disorders (excl infections and neoplasms)		
Sinonasal obstruction	1	0
Pharyngeal disorders (excl infections and neoplasms)		
Pharyngeal ulceration	1	0
Upper respiratory tract signs and symptoms		
Oropharyngeal pain	2	0
Throat tightness	1	0
Respiratory disorders SOC TOTAL	18	0

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Reaction Name	MedDRA Version: MedDRA 24.0	Fatal
Skin disorders	Total	<u>raiai</u>
Alopecias		
	1	0
Alopecia		
Apocrine and eccrine gland disorders		
Cold sweat		
Hyperhidrosis		
Night sweats		0
Bullous conditions		
Blister		
Erythema multiforme	1	0
Dermal and epidermal conditions NEC		
Dry skin	1	0
Skin burning sensation		0
Skin discolouration	1	0
Skin reaction	1	0
Skin warm	1	0
Dermatitis and eczema		
Dermatitis allergic	2	
Eczema	1	
Eczema nummular	1	0
Erythemas		
Erythema	8	3 0
Photosensitivity and photodermatosis cond		
Photosensitivity reaction	2	2 0
Pigmentation changes NEC		
Pigmentation disorder	1	0
Pruritus NEC		
Pruritus	14	4 O
Rashes, eruptions and exanthems NEC		
Rash	6	
Rash erythematous	2	
Rash macular	2	
Rash maculo-papular	1	0
Rash papular	Z	4 O
Rash pruritic		2 0
Skin vasomotor conditions		
Livedo reticularis	6	6 0
Urticarias		
Mechanical urticaria	1	
Urticaria	11	
Skin disorders SOC TOTAL	80	

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Reaction Name	Total	Fatal
Vascular disorders		
Circulatory collapse and shock		
Circulatory collapse	1	0
Peripheral vascular disorders NEC		
Cyanosis	1	0
Hot flush	1	0
Peripheral vascular disorder	1	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Peripheral coldness	7	0
Site specific vascular disorders NEC		
Pallor	6	0
Vascular hypotensive disorders		
Hypotension	2	0
Vascular disorders SOC TOTAL	19	0
TOTAL REACTIONS FOR DRUG	776	0
TOTAL REPORTS	234	