

Case Series Drug Analysis Print

Name: FOI 21/1254 Human Papillomavirus Vaccine (brand not specified) VAP

Report Run Date: 13-Dec-2021

Data Lock Date: 09-Dec-2021 18:30:07

Earliest Reaction Date: 07-Feb-2007

MedDRA Version: MedDRA 24.1

FOI 21/1254 Human Papillomavirus Vaccine (brand not specified) VAP: All UK Spontaneously received Adverse Drug Reaction (ADR) reports associated with the Human Papillomavirus Vaccine (brand not specified)

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| Reaction Name | Total | Fatal |
|---------------------------------------|-----------|----------|
| Blood disorders | | |
| <i>Anaemia deficiencies</i> | | |
| Anaemia vitamin B12 deficiency | 1 | 0 |
| <i>Anaemias NEC</i> | | |
| Anaemia | 2 | 0 |
| <i>Bleeding tendencies</i> | | |
| Increased tendency to bruise | 1 | 0 |
| <i>Coagulopathies</i> | | |
| Coagulopathy | 1 | 0 |
| <i>Haematological disorders</i> | | |
| Mast cell activation syndrome | 3 | 0 |
| <i>Lymphatic system disorders NEC</i> | | |
| Lymph node pain | 1 | 0 |
| Lymphadenopathy | 11 | 0 |
| <i>Thrombocytopenias</i> | | |
| Immune thrombocytopenia | 1 | 0 |
| Blood disorders SOC TOTAL | 21 | 0 |

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|---|-----------|----------|
| Cardiac disorders | | |
| <i>Cardiac disorders NEC</i> | | |
| Cardiac disorder | 2 | 0 |
| <i>Cardiac signs and symptoms NEC</i> | | |
| Palpitations | 14 | 0 |
| <i>Rate and rhythm disorders NEC</i> | | |
| Arrhythmia | 1 | 0 |
| Postural orthostatic tachycardia syndrome | 20 | 0 |
| Tachycardia | 8 | 0 |
| <i>Supraventricular arrhythmias</i> | | |
| Atrial tachycardia | 1 | 0 |
| Sinus tachycardia | 1 | 0 |
| Cardiac disorders SOC TOTAL | 47 | 0 |

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| Reaction Name | Total | Fatal |
|---|----------|----------|
| Congenital disorders | | |
| <i>Connective tissue disorders congenital</i> | | |
| Ehlers-Danlos syndrome | 3 | 0 |
| Congenital disorders SOC TOTAL | 3 | 0 |

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| Reaction Name | Total | Fatal |
|-------------------------------------|-----------|----------|
| Ear disorders | | |
| <i>Ear disorders NEC</i> | | |
| Ear pain | 3 | 0 |
| <i>Hearing losses</i> | | |
| Deafness | 3 | 0 |
| Hypoacusis | 1 | 0 |
| <i>Hyperacusia</i> | | |
| Hyperacusis | 5 | 0 |
| <i>Inner ear signs and symptoms</i> | | |
| Tinnitus | 1 | 0 |
| Vertigo | 2 | 0 |
| Ear disorders SOC TOTAL | 15 | 0 |

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|---|----------|----------|
| Endocrine disorders | | |
| <i>Acute and chronic thyroiditis</i> | | |
| Autoimmune thyroiditis | 1 | 0 |
| <i>Adrenal cortical hypofunctions</i> | | |
| Adrenocortical insufficiency acute | 1 | 0 |
| <i>Endocrine abnormalities of puberty</i> | | |
| Delayed puberty | 1 | 0 |
| <i>Endocrine disorders NEC</i> | | |
| Endocrine disorder | 1 | 0 |
| <i>Thyroid disorders NEC</i> | | |
| Thyroid disorder | 1 | 0 |
| <i>Thyroid hypofunction disorders</i> | | |
| Hypothyroidism | 1 | 0 |
| Endocrine disorders SOC TOTAL | 6 | 0 |

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|--|-----------|----------|
| Eye disorders | | |
| <i>Choroid and vitreous structural change, deposit and degeneration</i> | | |
| Vitreous floaters | 1 | 0 |
| <i>Eyelid movement disorders</i> | | |
| Blepharospasm | 1 | 0 |
| <i>Iris and uveal tract infections, irritations and inflammations</i> | | |
| Uveitis | 1 | 0 |
| <i>Lacrimation disorders</i> | | |
| Lacrimation increased | 1 | 0 |
| <i>Lid, lash and lacrimal infections, irritations and inflammations</i> | | |
| Eyelid oedema | 1 | 0 |
| Swelling of eyelid | 4 | 0 |
| <i>Ocular disorders NEC</i> | | |
| Dark circles under eyes | 1 | 0 |
| Eye disorder | 3 | 0 |
| Eye pain | 7 | 0 |
| Eye swelling | 4 | 0 |
| Ocular discomfort | 1 | 0 |
| Periorbital swelling | 2 | 0 |
| <i>Ocular infections, inflammations and associated manifestations</i> | | |
| Eye discharge | 1 | 0 |
| Eye inflammation | 1 | 0 |
| Eye pruritus | 1 | 0 |
| Ocular hyperaemia | 2 | 0 |
| <i>Ocular nerve and muscle disorders</i> | | |
| Eye movement disorder | 5 | 0 |
| Gaze palsy | 1 | 0 |
| Ocular myasthenia | 1 | 0 |
| Oculogyric crisis | 1 | 0 |
| <i>Ocular sensation disorders</i> | | |
| Asthenopia | 1 | 0 |
| Photophobia | 11 | 0 |
| <i>Optic disc abnormalities NEC</i> | | |
| Optic disc disorder | 1 | 0 |
| <i>Pupil disorders</i> | | |
| Pupillary reflex impaired | 1 | 0 |
| <i>Retinal, choroid and vitreous infections and inflammations</i> | | |
| Retinal vasculitis | 1 | 0 |
| <i>Visual disorders NEC</i> | | |
| Photopsia | 1 | 0 |
| Vision blurred | 18 | 0 |
| <i>Visual field disorders</i> | | |
| Visual field defect | 2 | 0 |
| <i>Visual impairment and blindness (excl colour blindness)</i> | | |
| Blindness | 5 | 0 |
| Blindness transient | 1 | 0 |
| Visual impairment | 13 | 0 |
| Eye disorders SOC TOTAL | 95 | 0 |

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|--|-------|-------|
| Gastrointestinal disorders | | |
| <i>Colitis (excl infective)</i> | | |
| Crohn's disease | 1 | 0 |
| <i>Diaphragmatic hernias</i> | | |
| Hiatus hernia | 1 | 0 |
| <i>Diarrhoea (excl infective)</i> | | |
| Diarrhoea | 21 | 0 |
| <i>Dyspeptic signs and symptoms</i> | | |
| Dyspepsia | 1 | 0 |
| Eructation | 1 | 0 |
| <i>Flatulence, bloating and distension</i> | | |
| Abdominal distension | 1 | 0 |
| <i>Gastric ulcers and perforation</i> | | |
| Gastric ulcer | 1 | 0 |
| Gastritis erosive | 1 | 0 |
| <i>Gastritis (excl infective)</i> | | |
| Gastritis | 1 | 0 |
| <i>Gastrointestinal and abdominal pains (excl oral and throat)</i> | | |
| Abdominal pain | 29 | 0 |
| Abdominal pain lower | 3 | 0 |
| Abdominal pain upper | 33 | 0 |
| <i>Gastrointestinal atonic and hypomotility disorders NEC</i> | | |
| Constipation | 2 | 0 |
| Gastrooesophageal reflux disease | 2 | 0 |
| <i>Gastrointestinal disorders NEC</i> | | |
| Gastric disorder | 1 | 0 |
| Gastrointestinal disorder | 5 | 0 |
| <i>Gastrointestinal signs and symptoms NEC</i> | | |
| Abdominal discomfort | 7 | 0 |
| Dysphagia | 5 | 0 |
| Odynophagia | 1 | 0 |
| <i>Gastrointestinal spastic and hypermotility disorders</i> | | |
| Irritable bowel syndrome | 4 | 0 |
| <i>Gingival disorders, signs and symptoms NEC</i> | | |
| Gingival disorder | 1 | 0 |
| <i>Malabsorption syndromes</i> | | |
| Coeliac disease | 2 | 0 |
| <i>Nausea and vomiting symptoms</i> | | |
| Nausea | 141 | 0 |
| Vomiting | 83 | 0 |
| <i>Non-site specific gastrointestinal haemorrhages</i> | | |
| Haematemesis | 1 | 0 |
| <i>Oral dryness and saliva altered</i> | | |
| Dry mouth | 1 | 0 |
| <i>Oral soft tissue signs and symptoms</i> | | |
| Hypoaesthesia oral | 1 | 0 |
| Oral pain | 1 | 0 |
| Paraesthesia oral | 2 | 0 |
| <i>Oral soft tissue swelling and oedema</i> | | |
| Lip swelling | 4 | 0 |
| Mouth swelling | 1 | 0 |
| <i>Stomatitis and ulceration</i> | | |
| Mouth ulceration | 2 | 0 |

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|---|------------|----------|
| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| <i>Tongue disorders</i> | | |
| Glossitis | 1 | 0 |
| <i>Tongue signs and symptoms</i> | | |
| Glossodynia | 2 | 0 |
| Swollen tongue | 6 | 0 |
| Tongue discomfort | 1 | 0 |
| <i>Tooth missing</i> | | |
| Tooth loss | 1 | 0 |
| Gastrointestinal disorders SOC TOTAL | 372 | 0 |

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|--|-------|-------|
| General disorders | | |
| <i>Asthenic conditions</i> | | |
| Asthenia | 36 | 0 |
| Chronic fatigue syndrome | 27 | 0 |
| Decreased activity | 1 | 0 |
| Fatigue | 140 | 0 |
| Malaise | 101 | 0 |
| <i>Body temperature altered</i> | | |
| Temperature regulation disorder | 2 | 0 |
| <i>Febrile disorders</i> | | |
| Hyperpyrexia | 1 | 0 |
| Pyrexia | 117 | 0 |
| <i>Feelings and sensations NEC</i> | | |
| Chills | 18 | 0 |
| Feeling abnormal | 14 | 0 |
| Feeling cold | 9 | 0 |
| Feeling hot | 11 | 0 |
| Feeling jittery | 1 | 0 |
| Feeling of body temperature change | 5 | 0 |
| Temperature intolerance | 1 | 0 |
| Thirst | 2 | 0 |
| <i>Gait disturbances</i> | | |
| Gait disturbance | 8 | 0 |
| Gait inability | 5 | 0 |
| Loss of control of legs | 1 | 0 |
| <i>General signs and symptoms NEC</i> | | |
| Condition aggravated | 4 | 0 |
| Crying | 2 | 0 |
| Disease recurrence | 1 | 0 |
| Exercise tolerance decreased | 1 | 0 |
| Foaming at mouth | 1 | 0 |
| General physical health deterioration | 1 | 0 |
| Glassy eyes | 1 | 0 |
| Illness | 26 | 0 |
| Induration | 1 | 0 |
| Influenza like illness | 19 | 0 |
| Local reaction | 2 | 0 |
| Peripheral swelling | 28 | 0 |
| Swelling | 13 | 0 |
| Swelling face | 8 | 0 |
| <i>Hernias NEC</i> | | |
| Hernia | 1 | 0 |
| <i>Injection site reactions</i> | | |
| Injection site bruising | 1 | 0 |
| Injection site coldness | 3 | 0 |
| Injection site discolouration | 2 | 0 |
| Injection site erythema | 11 | 0 |
| Injection site granuloma | 1 | 0 |
| Injection site haemorrhage | 1 | 0 |
| Injection site hypoaesthesia | 3 | 0 |
| Injection site injury | 1 | 0 |
| Injection site mass | 5 | 0 |
| Injection site movement impairment | 1 | 0 |

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|---|------------|----------|
| General disorders General disorders cont'd | | |
| Injection site pain | 13 | 0 |
| Injection site pruritus | 5 | 0 |
| Injection site rash | 2 | 0 |
| Injection site reaction | 5 | 0 |
| Injection site swelling | 15 | 0 |
| Injection site warmth | 2 | 0 |
| Mass conditions NEC | | |
| Cyst | 1 | 0 |
| Mass | 2 | 0 |
| Nodule | 1 | 0 |
| Pain and discomfort NEC | | |
| Axillary pain | 1 | 0 |
| Chest discomfort | 6 | 0 |
| Chest pain | 21 | 0 |
| Discomfort | 4 | 0 |
| Facial pain | 1 | 0 |
| Pain | 66 | 0 |
| Tenderness | 4 | 0 |
| Therapeutic and nontherapeutic responses | | |
| Adverse drug reaction | 15 | 0 |
| Ulcers NEC | | |
| Ulcer | 1 | 0 |
| Vaccination site reactions | | |
| Vaccination site atrophy | 1 | 0 |
| Vaccination site bruising | 2 | 0 |
| Vaccination site discomfort | 1 | 0 |
| Vaccination site erythema | 1 | 0 |
| Vaccination site haemorrhage | 1 | 0 |
| Vaccination site inflammation | 1 | 0 |
| Vaccination site mass | 3 | 0 |
| Vaccination site pain | 5 | 0 |
| Vaccination site swelling | 2 | 0 |
| Vaccination site warmth | 1 | 0 |
| General disorders SOC TOTAL | 821 | 0 |

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|--|----------|----------|
| Hepatic disorders | | |
| <i>Cholestasis and jaundice</i> | | |
| Jaundice | 1 | 0 |
| <i>Hepatocellular damage and hepatitis NEC</i> | | |
| Autoimmune hepatitis | 1 | 0 |
| Hepatic disorders SOC TOTAL | 2 | 0 |

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|---|-----------|----------|
| Immune system disorders | | |
| <i>Allergic conditions NEC</i> | | |
| Allergy to animal | 2 | 0 |
| Hypersensitivity | 10 | 0 |
| Multiple allergies | 2 | 0 |
| Type IV hypersensitivity reaction | 1 | 0 |
| <i>Allergies to foods, food additives, drugs and other chemicals</i> | | |
| Drug hypersensitivity | 1 | 0 |
| Food allergy | 1 | 0 |
| Rubber sensitivity | 1 | 0 |
| <i>Anaphylactic and anaphylactoid responses</i> | | |
| Anaphylactic reaction | 11 | 0 |
| <i>Autoimmune disorders NEC</i> | | |
| Autoimmune disorder | 1 | 0 |
| <i>Immune and associated conditions NEC</i> | | |
| Immune system disorder | 2 | 0 |
| Immunisation reaction | 1 | 0 |
| <i>Immunodeficiency disorders NEC</i> | | |
| Immunodeficiency | 1 | 0 |
| Immune system disorders SOC TOTAL | 34 | 0 |

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|--|-----------|----------|
| Infections | | |
| <i>Abdominal and gastrointestinal infections</i> | | |
| Appendicitis | 1 | 0 |
| <i>Bacterial infections NEC</i> | | |
| Cellulitis | 1 | 0 |
| <i>Bone and joint infections</i> | | |
| Osteomyelitis | 1 | 0 |
| <i>Central nervous system and spinal infections</i> | | |
| Encephalitis | 2 | 0 |
| <i>Ear infections</i> | | |
| Ear infection | 2 | 0 |
| Labyrinthitis | 1 | 0 |
| <i>Epstein-Barr viral infections</i> | | |
| Infectious mononucleosis | 1 | 0 |
| <i>Eye and eyelid infections</i> | | |
| Hordeolum | 1 | 0 |
| <i>Herpes viral infections</i> | | |
| Genital herpes | 1 | 0 |
| Herpes zoster | 5 | 0 |
| Oral herpes | 1 | 0 |
| <i>Infections NEC</i> | | |
| Infection | 2 | 0 |
| Infection susceptibility increased | 3 | 0 |
| Respiratory tract infection | 1 | 0 |
| <i>Influenza viral infections</i> | | |
| Influenza | 1 | 0 |
| <i>Lower respiratory tract and lung infections</i> | | |
| Lower respiratory tract infection | 2 | 0 |
| Pneumonia | 1 | 0 |
| <i>Retroviral infections</i> | | |
| Acquired immunodeficiency syndrome | 1 | 0 |
| <i>Skin structures and soft tissue infections</i> | | |
| Skin infection | 2 | 0 |
| <i>Upper respiratory tract infections</i> | | |
| Epiglottitis | 1 | 0 |
| Nasopharyngitis | 6 | 0 |
| Upper respiratory tract infection | 1 | 0 |
| <i>Viral infections NEC</i> | | |
| Gastroenteritis viral | 1 | 0 |
| Post viral fatigue syndrome | 18 | 0 |
| Viral infection | 2 | 0 |
| Infections SOC TOTAL | 59 | 0 |

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|--|-----------|----------|
| Injuries | | |
| <i>Chemical injuries</i> | | |
| Chemical burn | 1 | 0 |
| <i>Fractures and dislocations NEC</i> | | |
| Joint dislocation | 2 | 0 |
| <i>Medication errors, product use errors and issues NEC</i> | | |
| Medication error | 1 | 0 |
| <i>Muscle, tendon and ligament injuries</i> | | |
| Muscle injury | 1 | 0 |
| <i>Nerve injuries NEC</i> | | |
| Nerve injury | 1 | 0 |
| <i>Non-site specific injuries NEC</i> | | |
| Fall | 1 | 0 |
| Injury | 2 | 0 |
| <i>Overdoses NEC</i> | | |
| Intentional overdose | 1 | 0 |
| <i>Peripheral nerve injuries</i> | | |
| Axillary nerve injury | 1 | 0 |
| <i>Product administration errors and issues</i> | | |
| Expired product administered | 1 | 0 |
| Extra dose administered | 1 | 0 |
| Inappropriate schedule of product administration | 1 | 0 |
| Product administered at inappropriate site | 1 | 0 |
| <i>Skin injuries NEC</i> | | |
| Contusion | 7 | 0 |
| Injuries SOC TOTAL | 22 | 0 |

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| Investigations | | |
| <i>Central nervous system imaging procedures</i> | | |
| Magnetic resonance imaging head abnormal | 1 | 0 |
| <i>Chemistry analyses NEC</i> | | |
| Histamine level increased | 1 | 0 |
| <i>Endocrine analyses and imaging NEC</i> | | |
| Hormone level abnormal | 2 | 0 |
| <i>Heart rate and pulse investigations</i> | | |
| Heart rate abnormal | 3 | 0 |
| Heart rate increased | 11 | 0 |
| Heart rate irregular | 2 | 0 |
| Pulse abnormal | 1 | 0 |
| <i>Investigations NEC</i> | | |
| Quality of life decreased | 1 | 0 |
| <i>Liver function analyses</i> | | |
| Liver function test abnormal | 1 | 0 |
| <i>Mineral and electrolyte analyses</i> | | |
| Blood iron decreased | 2 | 0 |
| Blood sodium abnormal | 1 | 0 |
| Serum ferritin decreased | 1 | 0 |
| <i>Physical examination procedures and organ system status</i> | | |
| Body temperature abnormal | 1 | 0 |
| Body temperature decreased | 2 | 0 |
| Body temperature fluctuation | 4 | 0 |
| Body temperature increased | 16 | 0 |
| Respiratory rate increased | 1 | 0 |
| Weight decreased | 5 | 0 |
| <i>Reproductive hormone analyses</i> | | |
| Oestradiol decreased | 1 | 0 |
| <i>Vascular tests NEC (incl blood pressure)</i> | | |
| Blood pressure increased | 2 | 0 |
| <i>Vitamin analyses</i> | | |
| Vitamin D decreased | 1 | 0 |
| Investigations SOC TOTAL | 60 | 0 |

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| Metabolic disorders | | |
| <i>Appetite disorders</i> | | |
| Decreased appetite | 20 | 0 |
| Hypophagia | 2 | 0 |
| <i>Calcium metabolism disorders</i> | | |
| Tetany | 1 | 0 |
| <i>Diabetes mellitus (incl subtypes)</i> | | |
| Diabetes mellitus inadequate control | 1 | 0 |
| Type 1 diabetes mellitus | 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 | 9 | 0 |
| Feeding disorder | 1 | 0 |
| Malnutrition | 1 | 0 |
| Weight fluctuation | 1 | 0 |
| <i>Hyperglycaemic conditions NEC</i> | | |
| Hyperglycaemia | 1 | 0 |
| <i>Iron deficiencies</i> | | |
| Iron deficiency | 2 | 0 |
| <i>Water soluble vitamin deficiencies</i> | | |
| Vitamin B12 deficiency | 2 | 0 |
| Vitamin C deficiency | 1 | 0 |
| Metabolic disorders SOC TOTAL | 47 | 0 |

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| Muscle & tissue disorders | | |
| <i>Arthropathies NEC</i> | | |
| Arthritis | 3 | 0 |
| <i>Bone related signs and symptoms</i> | | |
| Bone pain | 4 | 0 |
| Spinal pain | 3 | 0 |
| <i>Connective tissue disorders NEC</i> | | |
| Morphoea | 1 | 0 |
| <i>Joint related disorders NEC</i> | | |
| Hypermobility syndrome | 3 | 0 |
| <i>Joint related signs and symptoms</i> | | |
| Arthralgia | 47 | 0 |
| Joint effusion | 1 | 0 |
| Joint stiffness | 4 | 0 |
| Joint swelling | 2 | 0 |
| <i>Muscle infections and inflammations</i> | | |
| Myositis | 1 | 0 |
| <i>Muscle pains</i> | | |
| Fibromyalgia | 2 | 0 |
| Myalgia | 27 | 0 |
| <i>Muscle related signs and symptoms NEC</i> | | |
| Muscle fatigue | 1 | 0 |
| Muscle spasms | 6 | 0 |
| Muscle tightness | 1 | 0 |
| Muscle twitching | 7 | 0 |
| <i>Muscle tone abnormalities</i> | | |
| Muscle rigidity | 2 | 0 |
| <i>Muscle weakness conditions</i> | | |
| Muscular weakness | 19 | 0 |
| <i>Musculoskeletal and connective tissue conditions NEC</i> | | |
| Back disorder | 1 | 0 |
| Mastication disorder | 1 | 0 |
| Mobility decreased | 7 | 0 |
| Musculoskeletal stiffness | 15 | 0 |
| Weight bearing difficulty | 2 | 0 |
| <i>Musculoskeletal and connective tissue pain and discomfort</i> | | |
| Back pain | 19 | 0 |
| Limb discomfort | 11 | 0 |
| Musculoskeletal chest pain | 3 | 0 |
| Musculoskeletal discomfort | 1 | 0 |
| Musculoskeletal pain | 1 | 0 |
| Neck pain | 11 | 0 |
| Pain in extremity | 81 | 0 |
| <i>Soft tissue disorders NEC</i> | | |
| Groin pain | 1 | 0 |
| <i>Spine and neck deformities</i> | | |
| Scoliosis | 1 | 0 |
| <i>Spondyloarthropathies</i> | | |
| Arthritis reactive | 1 | 0 |
| Muscle & tissue disorders SOC TOTAL | 290 | 0 |

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Name: FOI 21/1254 Human Papillomavirus Vaccine (brand not specified) VAP

Report Run Date: 13-Dec-2021

Data Lock Date: 09-Dec-2021 18:30:07

Earliest Reaction Date: 07-Feb-2007

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|----------|----------|
| Neoplasms | | |
| <i>Kaposi's sarcomas</i> | | |
| Kaposi's sarcoma | 1 | 0 |
| <i>Pharyngeal and laryngeal neoplasms benign</i> | | |
| Laryngeal papilloma | 1 | 0 |
| <i>Skin neoplasms benign</i> | | |
| Anogenital warts | 1 | 0 |
| Skin papilloma | 3 | 0 |
| Neoplasms SOC TOTAL | 6 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

| 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 | 2 | 0 |
| <i>Autonomic nervous system disorders</i> | | |
| Autonomic nervous system imbalance | 3 | 0 |
| <i>Central nervous system haemorrhages and cerebrovascular accidents</i> | | |
| Basal ganglia stroke | 1 | 0 |
| Cerebrovascular accident | 1 | 0 |
| <i>Central nervous system vascular disorders NEC</i> | | |
| Central nervous system vasculitis | 1 | 0 |
| <i>Choreiform movements</i> | | |
| Chorea | 1 | 0 |
| <i>Coordination and balance disturbances</i> | | |
| Ataxia | 1 | 0 |
| Balance disorder | 3 | 0 |
| Cerebellar ataxia | 1 | 0 |
| Coordination abnormal | 3 | 0 |
| Dysstasia | 2 | 0 |
| <i>Cortical dysfunction NEC</i> | | |
| Aphasia | 4 | 0 |
| <i>Demyelinating disorders NEC</i> | | |
| Acute disseminated encephalomyelitis | 1 | 0 |
| Demyelination | 1 | 0 |
| <i>Disturbances in consciousness NEC</i> | | |
| Altered state of consciousness | 1 | 0 |
| Lethargy | 35 | 0 |
| Loss of consciousness | 15 | 0 |
| Somnolence | 23 | 0 |
| Syncope | 87 | 0 |
| <i>Dyskinesias and movement disorders NEC</i> | | |
| Dyskinesia | 4 | 0 |
| Hypokinesia | 3 | 0 |
| <i>Dystonias</i> | | |
| Opisthotonus | 1 | 0 |
| <i>Encephalitis NEC</i> | | |
| Encephalitis autoimmune | 1 | 0 |
| <i>Encephalopathies NEC</i> | | |
| Encephalopathy | 1 | 0 |
| Hashimoto's encephalopathy | 1 | 0 |
| <i>Facial cranial nerve disorders</i> | | |
| Bell's palsy | 2 | 0 |
| <i>Generalised tonic-clonic seizures</i> | | |
| Generalised tonic-clonic seizure | 5 | 0 |
| <i>Headaches NEC</i> | | |
| Headache | 208 | 0 |
| <i>Intellectual disabilities</i> | | |
| Intellectual disability | 1 | 0 |
| <i>Memory loss (excl dementia)</i> | | |
| Amnesia | 6 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Memory impairment | 8 | 0 |
| <i>Mental impairment (excl dementia and memory loss)</i> | | |
| Cognitive disorder | 2 | 0 |
| Disturbance in attention | 18 | 0 |
| <i>Migraine headaches</i> | | |
| Basilar migraine | 1 | 0 |
| Hemiplegic migraine | 1 | 0 |
| Migraine | 12 | 0 |
| Migraine with aura | 1 | 0 |
| Typical aura without headache | 1 | 0 |
| <i>Mononeuropathies</i> | | |
| Peroneal nerve palsy | 1 | 0 |
| <i>Multiple sclerosis acute and progressive</i> | | |
| Multiple sclerosis | 1 | 0 |
| <i>Muscle tone abnormal</i> | | |
| Hypotonia | 1 | 0 |
| <i>Myelitis (incl infective)</i> | | |
| Myelitis transverse | 2 | 0 |
| <i>Narcolepsy and hypersomnia</i> | | |
| Cataplexy | 2 | 0 |
| Hypersomnia | 10 | 0 |
| Narcolepsy | 2 | 0 |
| <i>Nervous system disorders NEC</i> | | |
| Nervous system disorder | 2 | 0 |
| <i>Neurological signs and symptoms NEC</i> | | |
| Clonus | 1 | 0 |
| Dizziness | 170 | 0 |
| Dizziness postural | 13 | 0 |
| Drooling | 1 | 0 |
| Meningism | 1 | 0 |
| Presyncope | 8 | 0 |
| Unresponsive to stimuli | 4 | 0 |
| <i>Neuromuscular junction dysfunction</i> | | |
| Myasthenia gravis | 1 | 0 |
| <i>Olfactory nerve disorders</i> | | |
| Parosmia | 1 | 0 |
| <i>Optic nerve disorders NEC</i> | | |
| Optic neuritis | 1 | 0 |
| <i>Paraesthesias and dysaesthesias</i> | | |
| Burning sensation | 2 | 0 |
| Dysaesthesia | 1 | 0 |
| Formication | 1 | 0 |
| Hyperaesthesia | 5 | 0 |
| Hypoaesthesia | 42 | 0 |
| Paraesthesia | 32 | 0 |
| <i>Paralysis and paresis (excl cranial nerve)</i> | | |
| Hemiparesis | 1 | 0 |
| Hemiplegia | 1 | 0 |
| Monoplegia | 1 | 0 |
| Paralysis | 4 | 0 |
| Paraplegia | 1 | 0 |
| <i>Peripheral neuropathies NEC</i> | | |

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MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|--|------------|----------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| Autoimmune neuropathy | 1 | 0 |
| Brachial plexopathy | 1 | 0 |
| Lumbosacral plexus lesion | 1 | 0 |
| Neuritis | 1 | 0 |
| <i>Seizures and seizure disorders NEC</i> | | |
| Epilepsy | 8 | 0 |
| Partial seizures | 2 | 0 |
| Psychogenic seizure | 1 | 0 |
| Seizure | 33 | 0 |
| Tonic clonic movements | 1 | 0 |
| Tonic convulsion | 1 | 0 |
| <i>Sensory abnormalities NEC</i> | | |
| Allodynia | 1 | 0 |
| Complex regional pain syndrome | 9 | 0 |
| Dysgeusia | 1 | 0 |
| Neuralgia | 3 | 0 |
| Post herpetic neuralgia | 1 | 0 |
| Restless legs syndrome | 1 | 0 |
| Sensory disturbance | 4 | 0 |
| Sensory loss | 10 | 0 |
| <i>Sleep disturbances NEC</i> | | |
| Sudden onset of sleep | 1 | 0 |
| <i>Speech and language abnormalities</i> | | |
| Dysarthria | 3 | 0 |
| Speech disorder | 1 | 0 |
| <i>Transient cerebrovascular events</i> | | |
| Transient ischaemic attack | 1 | 0 |
| <i>Tremor (excl congenital)</i> | | |
| Tremor | 23 | 0 |
| Nervous system disorders SOC TOTAL | 887 | 0 |

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MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|----------|----------|
| Pregnancy conditions | | |
| <i>Maternal complications of labour NEC</i> | | |
| Labour complication | 1 | 0 |
| Pregnancy conditions SOC TOTAL | 1 | 0 |

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Earliest Reaction Date: 07-Feb-2007

MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|-----------------------------------|----------|----------|
| <i>Product quality issues NEC</i> | | |
| Product origin unknown | 4 | 0 |
| null SOC TOTAL | 4 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Psychiatric disorders | | |
| <i>Abnormal behaviour NEC</i> | | |
| Abnormal behaviour | 2 | 0 |
| <i>Adjustment disorders</i> | | |
| Adjustment disorder with mixed anxiety and depressed mood | 2 | 0 |
| <i>Affect alterations NEC</i> | | |
| Affect lability | 1 | 0 |
| <i>Anxiety symptoms</i> | | |
| Agitation | 2 | 0 |
| Anxiety | 19 | 0 |
| Stress | 1 | 0 |
| <i>Behaviour and socialisation disturbances</i> | | |
| Aggression | 2 | 0 |
| Disinhibition | 1 | 0 |
| Paranoia | 2 | 0 |
| Personality change | 1 | 0 |
| Social avoidant behaviour | 1 | 0 |
| <i>Bipolar disorders</i> | | |
| Bipolar I disorder | 1 | 0 |
| Bipolar disorder | 1 | 0 |
| <i>Confusion and disorientation</i> | | |
| Confusional state | 7 | 0 |
| Disorientation | 1 | 0 |
| <i>Depressive disorders</i> | | |
| Depression | 15 | 0 |
| <i>Dissociative states</i> | | |
| Dissociation | 1 | 0 |
| <i>Disturbances in initiating and maintaining sleep</i> | | |
| Insomnia | 18 | 0 |
| <i>Eating disorders NEC</i> | | |
| Mercism | 1 | 0 |
| <i>Emotional and mood disturbances NEC</i> | | |
| Emotional disorder | 3 | 0 |
| Emotional distress | 1 | 0 |
| Irritability | 5 | 0 |
| Mood altered | 3 | 0 |
| <i>Fear symptoms and phobic disorders (incl social phobia)</i> | | |
| Fear of death | 1 | 0 |
| Social anxiety disorder | 2 | 0 |
| <i>Fluctuating mood symptoms</i> | | |
| Mood swings | 2 | 0 |
| <i>Hallucinations (excl sleep-related)</i> | | |
| Hallucination | 5 | 0 |
| Hallucination, visual | 1 | 0 |
| Hallucinations, mixed | 1 | 0 |
| <i>Impulse control disorders</i> | | |
| Impulsive behaviour | 1 | 0 |
| <i>Increased physical activity levels</i> | | |
| Restlessness | 3 | 0 |
| <i>Mental disorders NEC</i> | | |
| Mental disorder | 1 | 0 |
| <i>Mood alterations with depressive symptoms</i> | | |
| Decreased interest | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|------------|----------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| Depressed mood | 6 | 0 |
| Depressive symptom | 1 | 0 |
| Mood disorders NEC | | |
| Affective disorder | 1 | 0 |
| Listless | 2 | 0 |
| Obsessive-compulsive disorders and symptoms | | |
| Trichotillomania | 1 | 0 |
| Panic attacks and disorders | | |
| Panic attack | 3 | 0 |
| Parasomnias | | |
| Sleep terror | 1 | 0 |
| Pervasive developmental disorders NEC | | |
| Autism spectrum disorder | 2 | 0 |
| Psychiatric symptoms NEC | | |
| Psychiatric symptom | 1 | 0 |
| Psychotic disorder NEC | | |
| Psychotic disorder | 1 | 0 |
| Sexual desire disorders | | |
| Loss of libido | 1 | 0 |
| Sleep disorders NEC | | |
| Sleep disorder | 8 | 0 |
| Somatic symptom disorders | | |
| Conversion disorder | 1 | 0 |
| Stereotypies and automatisms | | |
| Head banging | 1 | 0 |
| Stress disorders | | |
| Post-traumatic stress disorder | 1 | 0 |
| Suicidal and self-injurious behaviour | | |
| Intentional self-injury | 1 | 0 |
| Suicidal ideation | 1 | 0 |
| Suicide attempt | 1 | 0 |
| Thinking disturbances | | |
| Intrusive thoughts | 1 | 0 |
| Thinking abnormal | 1 | 0 |
| Psychiatric disorders SOC TOTAL | 145 | 0 |

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| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Renal & urinary disorders | | |
| <i>Bladder and urethral symptoms</i> | | |
| Dysuria | 1 | 0 |
| Incontinence | 1 | 0 |
| Micturition urgency | 1 | 0 |
| Pollakiuria | 3 | 0 |
| Urinary incontinence | 2 | 0 |
| <i>Bladder disorders NEC</i> | | |
| Bladder disorder | 1 | 0 |
| <i>Glomerulonephritis and nephrotic syndrome</i> | | |
| Focal segmental glomerulosclerosis | 1 | 0 |
| Henoch-Schonlein purpura nephritis | 1 | 0 |
| <i>Urinary tract signs and symptoms NEC</i> | | |
| Polyuria | 1 | 0 |
| Renal & urinary disorders SOC TOTAL | 12 | 0 |

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| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Reproductive & breast disorders | | |
| <i>Cervix disorders NEC</i> | | |
| Cervical dysplasia | 1 | 0 |
| Uterine cervix atrophy | 1 | 0 |
| <i>Menopausal effects NEC</i> | | |
| Premature menopause | 2 | 0 |
| <i>Menstruation and uterine bleeding NEC</i> | | |
| Dysmenorrhoea | 4 | 0 |
| Menstrual disorder | 6 | 0 |
| Menstruation irregular | 8 | 0 |
| <i>Menstruation with decreased bleeding</i> | | |
| Amenorrhoea | 10 | 0 |
| Menstruation delayed | 4 | 0 |
| <i>Menstruation with increased bleeding</i> | | |
| Heavy menstrual bleeding | 4 | 0 |
| <i>Ovarian and fallopian tube cysts and neoplasms</i> | | |
| Ovarian cyst | 2 | 0 |
| Polycystic ovaries | 5 | 0 |
| <i>Ovarian and fallopian tube disorders NEC</i> | | |
| Ovarian disorder | 1 | 0 |
| Ovarian failure | 2 | 0 |
| Ovulation disorder | 1 | 0 |
| <i>Reproductive tract signs and symptoms NEC</i> | | |
| Genital erythema | 1 | 0 |
| Genital pain | 1 | 0 |
| Genital rash | 1 | 0 |
| Genital swelling | 2 | 0 |
| Pelvic pain | 1 | 0 |
| <i>Sexual function and fertility disorders NEC</i> | | |
| Infertility | 1 | 0 |
| <i>Vulvovaginal disorders NEC</i> | | |
| Vaginal ulceration | 1 | 0 |
| Reproductive & breast disorders SOC TOTAL | 59 | 0 |

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| Reaction Name | Total | Fatal |
|---|------------|----------|
| Respiratory disorders | | |
| <i>Breathing abnormalities</i> | | |
| Dyspnoea | 39 | 0 |
| Hyperventilation | 4 | 0 |
| Respiration abnormal | 1 | 0 |
| Respiratory arrest | 1 | 0 |
| Respiratory distress | 1 | 0 |
| <i>Bronchospasm and obstruction</i> | | |
| Asthma | 5 | 0 |
| Bronchospasm | 1 | 0 |
| Wheezing | 3 | 0 |
| <i>Coughing and associated symptoms</i> | | |
| Cough | 13 | 0 |
| <i>Laryngeal spasm, oedema and obstruction</i> | | |
| Laryngeal oedema | 1 | 0 |
| Stridor | 1 | 0 |
| <i>Lower respiratory tract signs and symptoms</i> | | |
| Pleuritic pain | 1 | 0 |
| <i>Nasal congestion and inflammations</i> | | |
| Nasal congestion | 3 | 0 |
| <i>Nasal disorders NEC</i> | | |
| Epistaxis | 3 | 0 |
| <i>Paranasal sinus disorders (excl infections and neoplasms)</i> | | |
| Sinonasal obstruction | 1 | 0 |
| <i>Pharyngeal disorders (excl infections and neoplasms)</i> | | |
| Pharyngeal paraesthesia | 1 | 0 |
| Pharyngeal swelling | 4 | 0 |
| Pharyngeal ulceration | 1 | 0 |
| Tonsillar disorder | 1 | 0 |
| Tonsillar erythema | 1 | 0 |
| <i>Respiratory tract disorders NEC</i> | | |
| Respiratory disorder | 1 | 0 |
| <i>Upper respiratory tract signs and symptoms</i> | | |
| Aphonia | 3 | 0 |
| Choking | 2 | 0 |
| Choking sensation | 1 | 0 |
| Dysphonia | 1 | 0 |
| Oropharyngeal pain | 28 | 0 |
| Rhinorrhoea | 1 | 0 |
| Sneezing | 1 | 0 |
| Throat irritation | 3 | 0 |
| Throat lesion | 1 | 0 |
| Throat tightness | 4 | 0 |
| Respiratory disorders SOC TOTAL | 132 | 0 |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Skin disorders | | |
| <i>Acnes</i> | | |
| Acne | 1 | 0 |
| <i>Alopecias</i> | | |
| Alopecia | 9 | 0 |
| Alopecia areata | 6 | 0 |
| Alopecia totalis | 1 | 0 |
| <i>Apocrine and eccrine gland disorders</i> | | |
| Cold sweat | 4 | 0 |
| Hyperhidrosis | 13 | 0 |
| Miliaria | 2 | 0 |
| <i>Bullous conditions</i> | | |
| Blister | 4 | 0 |
| Dermatitis bullous | 1 | 0 |
| Erythema multiforme | 2 | 0 |
| <i>Dermal and epidermal conditions NEC</i> | | |
| Dry skin | 3 | 0 |
| Pain of skin | 3 | 0 |
| Sensitive skin | 1 | 0 |
| Skin burning sensation | 3 | 0 |
| Skin discolouration | 10 | 0 |
| Skin disorder | 4 | 0 |
| Skin lesion | 2 | 0 |
| Skin reaction | 3 | 0 |
| Skin sensitisation | 1 | 0 |
| Skin warm | 2 | 0 |
| <i>Dermatitis and eczema</i> | | |
| Dermatitis allergic | 6 | 0 |
| Eczema | 2 | 0 |
| <i>Erythemas</i> | | |
| Erythema | 21 | 0 |
| <i>Hypopigmentation disorders</i> | | |
| Vitiligo | 1 | 0 |
| <i>Papulosquamous conditions</i> | | |
| Pityriasis rosea | 1 | 0 |
| <i>Photosensitivity and photodermatitis conditions</i> | | |
| Photosensitivity reaction | 6 | 0 |
| <i>Pruritus NEC</i> | | |
| Pruritus | 20 | 0 |
| <i>Psoriatic conditions</i> | | |
| Psoriasis | 2 | 0 |
| <i>Purpura and related conditions</i> | | |
| Henoch-Schonlein purpura | 3 | 0 |
| Petechiae | 2 | 0 |
| Purpura | 3 | 0 |
| <i>Rashes, eruptions and exanthems NEC</i> | | |
| Rash | 51 | 0 |
| Rash erythematous | 8 | 0 |
| Rash macular | 7 | 0 |
| Rash papular | 2 | 0 |
| Rash pruritic | 13 | 0 |
| <i>Skin hypoplasias and atrophies</i> | | |
| Skin striae | 1 | 0 |

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| Reaction Name | Total | Fatal |
|---|------------|----------|
| Skin disorders Skin disorders cont'd | | |
| <i>Skin vasomotor conditions</i> | | |
| Livedo reticularis | 5 | 0 |
| <i>Urticarias</i> | | |
| Chronic spontaneous urticaria | 1 | 0 |
| Urticaria | 27 | 0 |
| Urticaria pigmentosa | 1 | 0 |
| Skin disorders SOC TOTAL | 258 | 0 |

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| Reaction Name | Total | Fatal |
|---|----------|----------|
| Social circumstances | | |
| <i>Disability issues</i> | | |
| Bedridden | 1 | 0 |
| Disability | 1 | 0 |
| Loss of personal independence in daily activities | 4 | 0 |
| Wheelchair user | 1 | 0 |
| Social circumstances SOC TOTAL | 7 | 0 |

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| Reaction Name | Total | Fatal |
|--|----------|----------|
| Surgical & medical procedures | | |
| <i>Limb therapeutic procedures</i> | | |
| Limb immobilisation | 1 | 0 |
| Surgical & medical procedures SOC TOTAL | 1 | 0 |

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| Reaction Name | Total | Fatal |
|---|-------------|----------|
| Vascular disorders | | |
| <i>Lymphoedemas</i> | | |
| Lymphoedema | 1 | 0 |
| <i>Non-site specific embolism and thrombosis</i> | | |
| Thrombosis | 1 | 0 |
| <i>Non-site specific necrosis and vascular insufficiency NEC</i> | | |
| Peripheral venous disease | 2 | 0 |
| Vasospasm | 1 | 0 |
| <i>Peripheral embolism and thrombosis</i> | | |
| Superficial vein thrombosis | 1 | 0 |
| <i>Peripheral vascular disorders NEC</i> | | |
| Cyanosis | 2 | 0 |
| Flushing | 6 | 0 |
| Hot flush | 5 | 0 |
| <i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i> | | |
| Peripheral coldness | 18 | 0 |
| Raynaud's phenomenon | 4 | 0 |
| <i>Site specific vascular disorders NEC</i> | | |
| Pallor | 26 | 0 |
| <i>Vascular hypertensive disorders NEC</i> | | |
| Hypertension | 1 | 0 |
| <i>Vascular hypotensive disorders</i> | | |
| Hypotension | 5 | 0 |
| <i>Vasculitides NEC</i> | | |
| Behcet's syndrome | 1 | 0 |
| Vascular disorders SOC TOTAL | 74 | 0 |
| TOTAL REACTIONS FOR DRUG | 3480 | 0 |
| TOTAL REPORTS | 901 | |