

Case Series Drug Analysis Print

Name: FOI 21/1254 Gardasil 9 Vaccine VAP

Report Run Date: 10-Dec-2021

Data Lock Date: 09-Dec-2021 18:30:03

Earliest Reaction Date: 27-Jan-2017

MedDRA Version: MedDRA 24.1

FOI 21/1254 Gardasil 9 Vaccine VAP: All UK Spontaneously received Adverse Drug Reaction (ADR) reports associated with the Gardasil 9 Vaccine

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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>		
Lymph node pain	1	0
Lymphadenitis	1	0
Lymphadenopathy	4	0
Blood disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	1	0
<i>Rate and rhythm disorders NEC</i>		
Tachycardia	1	0
Cardiac disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Hearing losses</i>		
Hypoacusis	1	0
Ear disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	1	0
<i>Ocular sensation disorders</i>		
Photophobia	1	0
<i>Pupil disorders</i>		
Miosis	1	0
Mydriasis	1	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal aneurysm	1	0
<i>Visual disorders NEC</i>		
Vision blurred	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Visual impairment	1	0
Eye disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	3	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	4	0
Abdominal pain lower	1	0
Abdominal pain upper	2	0
Gastrointestinal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
Gastrooesophageal reflux disease	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Gastrointestinal inflammation	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	2	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	1	0
<i>Malabsorption syndromes</i>		
Coeliac disease	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	11	0
Vomiting	5	0
<i>Oesophagitis (excl infective)</i>		
Eosinophilic oesophagitis	1	0
<i>Oral soft tissue signs and symptoms</i>		
Oral mucosal blistering	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	1	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	1	0
Gastrointestinal disorders SOC TOTAL	39	0

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General disorders		
<i>Administration site reactions NEC</i>		
Administration site pain	1	0
<i>Asthenic conditions</i>		
Asthenia	2	0
Fatigue	8	0
Malaise	7	0
<i>Death and sudden death</i>		
Death	1	1
<i>Febrile disorders</i>		
Pyrexia	9	0
<i>Feelings and sensations NEC</i>		
Chills	1	0
Feeling abnormal	1	0
Feeling cold	1	0
Feeling hot	1	0
Feeling of body temperature change	1	0
<i>Gait disturbances</i>		
Gait inability	1	0
<i>General signs and symptoms NEC</i>		
Ill-defined disorder	1	0
Illness	2	0
Influenza like illness	2	0
Peripheral swelling	6	0
Swelling	1	0
Swelling face	1	0
<i>Inflammations</i>		
Inflammation	1	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	1	0
Injection site mass	2	0
Injection site pain	2	0
Injection site swelling	1	0
<i>Pain and discomfort NEC</i>		
Chest discomfort	2	0
Chest pain	2	0
Pain	4	0
Tenderness	1	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	2	0
Adverse reaction	1	0
<i>Ulcers NEC</i>		
Ulcer	1	0
<i>Vaccination site reactions</i>		
Vaccination site bruising	2	0
Vaccination site coldness	1	0
Vaccination site discolouration	2	0
Vaccination site erythema	2	0
Vaccination site haemorrhage	1	0
Vaccination site hypoaesthesia	1	0
Vaccination site induration	1	0
Vaccination site mass	5	0
Vaccination site movement impairment	1	0
Vaccination site nodule	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site pain	10	0
Vaccination site pruritus	1	0
Vaccination site swelling	9	0
General disorders SOC TOTAL	104	1

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	2	0
Immune system disorders SOC TOTAL	5	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
Oral herpes	1	0
<i>Papilloma viral infections</i>		
Papilloma viral infection	1	0
<i>Skin structures and soft tissue infections</i>		
Pustule	1	0
Infections SOC TOTAL	6	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>Medication errors, product use errors and issues NEC</i>		
Medication error	1	0
Wrong technique in product usage process	1	0
<i>Non-site specific injuries NEC</i>		
Injury	1	0
<i>Peripheral nerve injuries</i>		
Peripheral nerve injury	1	0
<i>Product administration errors and issues</i>		
Inappropriate schedule of product administration	1	0
Product administered to patient of inappropriate age	1	0
<i>Skin injuries NEC</i>		
Scar	1	0
Injuries SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Investigations		
<i>Chemistry analyses NEC</i>		
Histamine level increased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate increased	2	0
Heart rate irregular	1	0
<i>Imaging procedures NEC</i>		
Positron emission tomogram abnormal	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature abnormal	1	0
<i>Reproductive hormone analyses</i>		
Anti-Muellerian hormone level decreased	1	0
Investigations SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	2	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Histamine intolerance	1	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	1	0
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	1	0
Metabolic disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Joint related disorders NEC</i>		
Periarthritis	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	4	0
Joint swelling	1	0
<i>Muscle pains</i>		
Myalgia	6	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	1	0
Muscle fatigue	1	0
Muscle spasms	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	5	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal disorder	1	0
Musculoskeletal stiffness	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	1	0
Limb discomfort	4	0
Neck pain	1	0
Pain in extremity	19	0
Muscle & tissue disorders SOC TOTAL	47	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<i>Autonomic nervous system disorders</i>		
Autonomic neuropathy	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	1	0
Lethargy	1	0
Somnolence	2	0
Syncope	21	0
<i>Dyskinesias and movement disorders NEC</i>		
Hypokinesia	1	0
<i>Headaches NEC</i>		
Headache	11	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	2	0
Disturbance in attention	1	0
<i>Mononeuropathies</i>		
Carpal tunnel syndrome	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	15	0
Dizziness postural	1	0
Presyncope	2	0
Unresponsive to stimuli	3	0
<i>Neuromuscular disorders NEC</i>		
Muscle contractions involuntary	1	0
<i>Paraesthesias and dysaesthesias</i>		
Hypoaesthesia	3	0
Paraesthesia	8	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Paralysis	3	0
<i>Seizures and seizure disorders NEC</i>		
Seizure	1	0
<i>Sensory abnormalities NEC</i>		
Neuralgia	1	0
Sensory loss	1	0
<i>Tremor (excl congenital)</i>		
Tremor	2	0
Nervous system disorders SOC TOTAL	84	0

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Reaction Name	Total	Fatal
<i>Product label issues</i>		
Product lot number issue	1	0
<i>Product quality issues NEC</i>		
Product origin unknown	4	0
null SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Anxiety symptoms</i>		
Anxiety	1	0
<i>Behaviour and socialisation disturbances</i>		
Impatience	1	0
<i>Confusion and disorientation</i>		
Confusional state	2	0
Disorientation	1	0
<i>Depressive disorders</i>		
Depression	1	0
Depression suicidal	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	1	0
<i>Emotional and mood disturbances NEC</i>		
Irritability	1	0
<i>Panic attacks and disorders</i>		
Panic attack	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	1	0
<i>Somatic symptom disorders</i>		
Conversion disorder	1	0
<i>Suicidal and self-injurious behaviour</i>		
Suicide attempt	1	0
Psychiatric disorders SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Pollakiuria	1	0
<i>Renal vascular and ischaemic conditions</i>		
Renal vasculitis	1	0
Renal & urinary disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast pain	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	1	0
Intermenstrual bleeding	2	0
Menstrual discomfort	1	0
Menstruation irregular	5	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	3	0
Menstruation delayed	15	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	3	0
Polymenorrhoea	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	2	0
<i>Vulvovaginal signs and symptoms</i>		
Vaginal discharge	5	0
Reproductive & breast disorders SOC TOTAL	40	0

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Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	3	0
<i>Bronchospasm and obstruction</i>		
Bronchospasm	1	0
<i>Coughing and associated symptoms</i>		
Cough	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	2	0
Nasal oedema	1	0
<i>Respiratory tract disorders NEC</i>		
Respiratory disorder	1	1
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	2	0
Throat tightness	2	0
Respiratory disorders SOC TOTAL	13	1

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	1	0
Hyperhidrosis	2	0
<i>Bullous conditions</i>		
Erythema multiforme	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	2	0
Papule	1	0
Sensitive skin	1	0
Skin disorder	1	0
Skin fissures	1	0
Skin induration	1	0
Skin texture abnormal	1	0
Skin warm	1	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	4	0
<i>Erythemas</i>		
Erythema	7	0
<i>Exfoliative conditions</i>		
Skin exfoliation	1	0
<i>Papulosquamous conditions</i>		
Lichen planus	1	0
<i>Pilar disorders NEC</i>		
Hair growth abnormal	1	0
<i>Pruritus NEC</i>		
Pruritus	7	0
<i>Purpura and related conditions</i>		
Purpura	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	9	0
Rash macular	1	0
Rash papular	2	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	1	0
<i>Urticarias</i>		
Mechanical urticaria	1	0
Urticaria	5	0
Skin disorders SOC TOTAL	55	0

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

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Vascular disorders		
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	1	0
Vascular disorders SOC TOTAL	1	0
TOTAL REACTIONS FOR DRUG	454	2
TOTAL REPORTS	191	
TOTAL FATAL OUTCOME REPORTS		2