

**Case Series Drug Analysis Print**  
**Name: GARDASIL 9 - Product Analysis Print**

Report Run Date: 02-Aug-2021  
Data Lock Date: 31-Jul-2021 19:00:04  
Earliest Reaction Date: 27-Jan-2017  
MedDRA Version: MedDRA 24.0

GARDASIL 9 - Product All UK Spontaneous ADR reports for Gardasil 9 until  
Analysis Print: 31/07/2021

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Blood disorders</b>		
<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
<b>Blood disorders SOC TOTAL</b>	<b>7</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Rate and rhythm disorders NEC</i>		
Tachycardia	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<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
<b>Eye disorders SOC TOTAL</b>	<b>8</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<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	3	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	10	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
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>37</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<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	1	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
<b>General disorders</b> General disorders cont'd		
Vaccination site pain	10	0
Vaccination site pruritus	1	0
Vaccination site swelling	9	0
<b>General disorders SOC TOTAL</b>	<b>103</b>	<b>1</b>



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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Allergic conditions NEC</i>		
Hypersensitivity	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	2	0
<b>Immune system disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Infections</b>		
<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
<b>Infections SOC TOTAL</b>	<b>6</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<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
<b>Injuries SOC TOTAL</b>	<b>8</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<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>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
<b>Investigations SOC TOTAL</b>	<b>6</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<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
<b>Metabolic disorders SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<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
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>46</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<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	20	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	1	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	7	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
<b>Nervous system disorders SOC TOTAL</b>	<b>81</b>	<b>0</b>

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



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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i><b>Anxiety symptoms</b></i>		
Anxiety	1	0
<i><b>Behaviour and socialisation disturbances</b></i>		
Impatience	1	0
<i><b>Confusion and disorientation</b></i>		
Confusional state	2	0
Disorientation	1	0
<i><b>Depressive disorders</b></i>		
Depression	1	0
Depression suicidal	1	0
<i><b>Disturbances in initiating and maintaining sleep</b></i>		
Insomnia	1	0
<i><b>Emotional and mood disturbances NEC</b></i>		
Irritability	1	0
<i><b>Pervasive developmental disorders NEC</b></i>		
Autism spectrum disorder	1	0
<i><b>Sleep disorders NEC</b></i>		
Sleep disorder	1	0
<i><b>Somatic symptom disorders</b></i>		
Conversion disorder	1	0
<i><b>Suicidal and self-injurious behaviour</b></i>		
Suicide attempt	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>13</b>	<b>0</b>

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

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Breast signs and symptoms</b></i>		
Breast pain	1	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Dysmenorrhoea	1	0
Intermenstrual bleeding	2	0
Menstrual discomfort	1	0
Menstruation irregular	3	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	3	0
Menstruation delayed	15	0
<i><b>Menstruation with increased bleeding</b></i>		
Heavy menstrual bleeding	2	0
Polymenorrhoea	1	0
<i><b>Pelvis and broad ligament disorders NEC</b></i>		
Adnexa uteri pain	1	0
<i><b>Vulvovaginal disorders NEC</b></i>		
Vaginal haemorrhage	2	0
<i><b>Vulvovaginal signs and symptoms</b></i>		
Vaginal discharge	5	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>37</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<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
<b>Respiratory disorders SOC TOTAL</b>	<b>13</b>	<b>1</b>

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

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

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>441</b>	<b>2</b>
<b>TOTAL REPORTS</b>	<b>186</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>2</b>