

Case Series Drug Analysis Print
Name: Shingrix Product Analysis Print

Report Run Date: 04-Feb-2023
Data Lock Date: 31-Jan-2023 18:30:05
Earliest Reaction Date: 30-Nov-2018
MedDRA Version: MedDRA 25.1

Shingrix Product Analysis Print: All UK, spontaneous suspected reports associated with the Shingrix vaccination, received up to and including the 20th January 2023. Date of extraction: 4th February 2023

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Reaction Name	Total	Fatal
Blood disorders		
<i>Leukytoses NEC</i>		
Lymphocytosis	1	0
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	2	0
<i>Thrombocytopenias</i>		
Thrombocytopenia	1	0
Blood disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Inner ear signs and symptoms</i>		
Tinnitus	1	0
Vertigo	3	0
Ear disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Ocular disorders NEC</i>		
Eye disorder	1	0
Eye swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye inflammation	1	0
<i>Ocular sensation disorders</i>		
Asthenopia	1	0
<i>Visual disorders NEC</i>		
Vision blurred	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Visual impairment	3	0
Eye disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	7	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	2	0
Abdominal pain upper	4	0
Gastrointestinal pain	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	2	0
<i>Nausea and vomiting symptoms</i>		
Nausea	17	0
Vomiting	8	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	2	0
<i>Stomatitis and ulceration</i>		
Stomatitis	1	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	1	0
Gastrointestinal disorders SOC TOTAL	47	0

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Reaction Name	Total	Fatal
General disorders		
<i>Asthenic conditions</i>		
Asthenia	3	0
Fatigue	20	0
Malaise	18	0
<i>Febrile disorders</i>		
Pyrexia	20	0
<i>Feelings and sensations NEC</i>		
Chills	9	0
Feeling abnormal	2	0
Feeling cold	3	0
Feeling hot	1	0
Feeling of body temperature change	1	0
<i>Gait disturbances</i>		
Gait disturbance	1	0
<i>General signs and symptoms NEC</i>		
Illness	3	0
Influenza like illness	1	0
Local reaction	1	0
Peripheral swelling	6	0
Swelling	4	0
Swelling face	3	0
<i>Inflammations</i>		
Inflammation	3	0
<i>Injection site reactions</i>		
Injection site erythema	3	0
Injection site joint pain	1	0
Injection site pain	7	0
Injection site swelling	3	0
Injection site warmth	1	0
<i>Mass conditions NEC</i>		
Mass	1	0
<i>Pain and discomfort NEC</i>		
Axillary pain	1	0
Chest pain	1	0
Facial pain	1	0
Pain	24	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	26	0
Therapeutic response unexpected	1	0
Vaccination failure	16	0
<i>Vaccination site reactions</i>		
Vaccination site bruising	1	0
Vaccination site discolouration	1	0
Vaccination site erythema	7	0
Vaccination site joint pain	1	0
Vaccination site pain	6	0
Vaccination site rash	1	0
Vaccination site swelling	3	0
Vaccination site warmth	2	0
General disorders SOC TOTAL	207	0

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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 shock	1	0
<i>Immune and associated conditions NEC</i>		
Immune system disorder	1	0
Immune system disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Cellulitis	2	0
<i>Dental and oral soft tissue infections</i>		
Gingival abscess	1	0
<i>Herpes viral infections</i>		
Herpes simplex	1	0
Herpes zoster	22	0
Ophthalmic herpes zoster	1	0
Oral herpes	1	0
Varicella	1	0
<i>Influenza viral infections</i>		
Influenza	4	0
Infections SOC TOTAL	33	0

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Reaction Name	Total	Fatal
Injuries		
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	3	0
<i>Nerve injuries NEC</i>		
Nerve injury	1	0
<i>Non-site specific procedural complications</i>		
Infusion related reaction	1	0
<i>Product administration errors and issues</i>		
Incomplete course of vaccination	1	0
<i>Site specific injuries NEC</i>		
Limb injury	1	0
<i>Skin injuries NEC</i>		
Contusion	1	0
Scar	1	0
Injuries SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Investigations		
<i>Physical examination procedures and organ system status</i>		
Body temperature decreased	1	0
Body temperature increased	3	0
Investigations SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	2	0
Hypophagia	1	0
Metabolic disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Bone related signs and symptoms</i>		
Bone pain	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	11	0
Joint swelling	1	0
<i>Muscle pains</i>		
Myalgia	25	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle fatigue	1	0
Muscle tightness	1	0
Muscle twitching	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	1	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Limb mass	1	0
Mobility decreased	1	0
Musculoskeletal stiffness	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	6	0
Pain in extremity	13	0
<i>Soft tissue disorders NEC</i>		
Soft tissue disorder	1	0
<i>Spondyloarthropathies</i>		
Spondyloarthropathy	1	0
Muscle & tissue disorders SOC TOTAL	66	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Coordination and balance disturbances</i>		
Balance disorder	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	3	0
Somnolence	1	0
Syncope	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	1	0
<i>Headaches NEC</i>		
Headache	26	0
Tension headache	1	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	1	0
<i>Muscle tone abnormal</i>		
Hypotonia	1	0
<i>Nervous system disorders NEC</i>		
Cerebral disorder	1	0
Nervous system disorder	3	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	9	0
Head discomfort	2	0
<i>Paraesthesias and dysaesthesias</i>		
Hypoaesthesia	2	0
Paraesthesia	2	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Monoplegia	1	0
<i>Peripheral neuropathies NEC</i>		
Neuropathy peripheral	1	0
<i>Sensory abnormalities NEC</i>		
Dysgeusia	1	0
Neuralgia	3	0
<i>Tremor (excl congenital)</i>		
Tremor	3	0
Nervous system disorders SOC TOTAL	64	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Anxiety symptoms</i>		
Stress	1	0
<i>Confusion and disorientation</i>		
Confusional state	1	0
Disorientation	1	0
<i>Deliria</i>		
Delirium	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	4	0
<i>Emotional and mood disturbances NEC</i>		
Anger	1	0
<i>Perception disturbances NEC</i>		
Near death experience	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	1	0
Psychiatric disorders SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Renal disorders NEC</i>		
Renal disorder	1	0
<i>Urinary abnormalities</i>		
Chromaturia	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	1	0
Renal & urinary disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	1	0
Hypopnoea	1	0
Respiratory arrest	1	0
<i>Coughing and associated symptoms</i>		
Cough	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal paraesthesia	1	0
Pharyngeal swelling	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Choking sensation	1	0
Oropharyngeal pain	1	0
Respiratory disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Apocrine and eccrine gland disorders</i>		
Night sweats	3	0
<i>Bullous conditions</i>		
Blister	3	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	1	0
Pain of skin	2	0
Scab	1	0
Skin reaction	2	0
Skin warm	2	0
<i>Dermatitis and eczema</i>		
Dermatitis	1	0
Dermatitis allergic	1	0
Skin irritation	1	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	2	0
<i>Erythemas</i>		
Erythema	10	0
<i>Exfoliative conditions</i>		
Skin exfoliation	1	0
<i>Papulosquamous conditions</i>		
Lichen planus	1	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	1	0
<i>Pruritus NEC</i>		
Pruritus	11	0
<i>Pustular conditions</i>		
Acute generalised exanthematous pustulosis	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Nodular rash	1	0
Rash	11	0
Rash erythematous	2	0
Rash macular	1	0
Rash papular	3	0
Rash pruritic	3	0
Rash vesicular	3	0
<i>Urticarias</i>		
Urticaria	5	0
Skin disorders SOC TOTAL	73	0

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Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Loss of personal independence in daily activities	2	0
Social circumstances SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Therapeutic procedures NEC</i>		
Bed rest	1	0
Surgical & medical procedures SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	2	0
Flushing	1	0
Hot flush	1	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
Vascular disorders SOC TOTAL	6	0
TOTAL REACTIONS FOR DRUG	558	0
TOTAL REPORTS	198	