

Case Series Drug Analysis Print

Name: VARILRIX® FOI 21/1063

Report Run Date: 07-Oct-2021
Data Lock Date: 30-Sep-2021 18:30:04
Earliest Reaction Date: 09-Dec-1999
MedDRA Version: MedDRA 24.0

VARILRIX® FOI
21/1063:

All UK spontaneous reports received up until 30-Sep-2021 for the VARILRIX Vaccine analysis print. A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

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Reaction Name	Total	Fatal
Blood disorders		
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	2	0
Blood disorders SOC TOTAL	2	0

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

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Reaction Name	Total	Fatal
Ear disorders		
<i>Hearing losses</i>		
Deafness neurosensory	1	0
Deafness unilateral	1	0
Ear disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Lacrimation disorders</i>		
Dry eye	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	2	0
<i>Ocular disorders NEC</i>		
Eye pain	1	0
Eye swelling	1	0
Periorbital swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	1	0
Ocular hyperaemia	1	0
<i>Optic disc abnormalities NEC</i>		
Optic discs blurred	1	0
<i>Visual disorders NEC</i>		
Vision blurred	1	0
Eye disorders SOC TOTAL	10	0

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Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	9	0
<i>Faecal abnormalities NEC</i>		
Faeces discoloured	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	2	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intussusception	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	4	0
Vomiting	12	0
Vomiting projectile	1	0
<i>Oral soft tissue signs and symptoms</i>		
Paraesthesia oral	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	2	0
Gastrointestinal disorders SOC TOTAL	34	0

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Reaction Name	Total	Fatal
General disorders		
<i>Asthenic conditions</i>		
Asthenia	1	0
Fatigue	4	0
Malaise	3	0
<i>Febrile disorders</i>		
Pyrexia	23	0
<i>Feelings and sensations NEC</i>		
Feeling abnormal	1	0
Feeling cold	1	0
Feeling hot	2	0
<i>General signs and symptoms NEC</i>		
Crying	1	0
Influenza like illness	5	0
Local reaction	1	0
Swelling	3	0
<i>Injection site reactions</i>		
Injection site erythema	1	0
Injection site inflammation	2	0
Injection site pain	2	0
Injection site reaction	4	0
Injection site swelling	1	0
<i>Pain and discomfort NEC</i>		
Discomfort	1	0
Pain	4	0
Tenderness	1	0
<i>Therapeutic and nontherapeutic responses</i>		
Drug ineffective	4	0
Therapeutic response decreased	1	0
Vaccination failure	28	0
<i>Vaccination site reactions</i>		
Vaccination site discolouration	1	0
Vaccination site erythema	1	0
Vaccination site pain	2	0
Vaccination site papule	1	0
Vaccination site rash	1	0
Vaccination site vesicles	1	0
General disorders SOC TOTAL	101	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 reaction	1	0
Immune system disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Infections		
<i>Candida infections</i>		
Oral candidiasis	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	1	0
<i>Fungal infections NEC</i>		
Genital infection fungal	1	0
<i>Herpes viral infections</i>		
Eczema herpeticum	1	0
Varicella	37	0
Varicella post vaccine	2	0
Varicella zoster virus infection	1	0
<i>Infections NEC</i>		
Abscess limb	1	0
Infection	1	0
<i>Infectious transmissions</i>		
Infection via vaccinee	2	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Pustule	1	0
Skin infection	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	1	0
<i>Viral infections NEC</i>		
Conjunctivitis viral	1	0
Infections SOC TOTAL	53	0

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure timing unspecified	1	0
<i>Off label uses</i>		
Off label use	2	0
<i>Product administration errors and issues</i>		
Contraindicated product administered	1	0
Incorrect dose administered	1	0
<i>Skin injuries NEC</i>		
Contusion	1	0
Skin abrasion	1	0
<i>Vaccination related complications</i>		
Vaccination complication	1	0
Injuries SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Investigations		
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose decreased	1	0
<i>Microbiology and serology tests NEC</i>		
Seroconversion test negative	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature increased	3	0
Investigations SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Fluid intake decreased</i>		
Fluid intake reduced	1	0
<i>Total fluid volume decreased</i>		
Dehydration	1	0
Metabolic disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	1	0
Musculoskeletal chest pain	1	0
Pain in extremity	1	0
<i>Spondyloarthropathies</i>		
Arthritis reactive	1	0
Muscle & tissue disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Leukaemias acute lymphocytic</i>		
Acute lymphocytic leukaemia	1	0
<i>Leukaemias acute myeloid</i>		
Acute myeloid leukaemia	1	0
Neoplasms SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Disturbances in consciousness NEC</i>		
Lethargy	3	0
Loss of consciousness	1	0
Somnolence	1	0
Syncope	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	1	0
<i>Headaches NEC</i>		
Headache	6	0
<i>Increased intracranial pressure disorders</i>		
Intracranial pressure increased	1	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	5	0
Slow response to stimuli	1	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	1	0
Hypoaesthesia	1	0
Paraesthesia	2	0
<i>Seizures and seizure disorders NEC</i>		
Seizure	1	0
<i>Sensory abnormalities NEC</i>		
Neuralgia	1	0
Sensory disturbance	1	0
<i>Speech and language abnormalities</i>		
Dysarthria	1	0
Speech disorder	1	0
<i>Tremor (excl congenital)</i>		
Tremor	3	0
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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	2	0
Pregnancy conditions SOC TOTAL	2	0

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Reaction Name	Total	Fatal
<i>Product quality issues NEC</i>		
Product complaint	1	0
null SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Orgasmic disorders and disturbances</i>		
Orgasm abnormal	1	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	2	0
Psychiatric disorders SOC TOTAL	3	0

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Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	3	0
<i>Coughing and associated symptoms</i>		
Cough	4	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	2	0
Rhinorrhoea	2	0
Yawning	1	0
Respiratory disorders SOC TOTAL	12	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Alopecias</i>		
Alopecia	1	0
<i>Bullous conditions</i>		
Blister	5	0
Erythema multiforme	1	0
<i>Dermal and epidermal conditions NEC</i>		
Papule	1	0
Skin disorder	1	0
Skin induration	1	0
Skin lesion	2	0
Skin plaque	1	0
Skin reaction	1	0
<i>Dermatitis and eczema</i>		
Dermatitis	1	0
Eczema	3	0
<i>Dermatitis ascribed to specific agent</i>		
Fixed eruption	1	0
<i>Erythemas</i>		
Erythema	4	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	1	0
<i>Pruritus NEC</i>		
Pruritus	5	0
<i>Psoriatic conditions</i>		
Psoriasis	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	25	0
Rash erythematous	2	0
Rash macular	2	0
Rash maculo-papular	2	0
Rash papular	5	0
Rash pruritic	3	0
Rash vesicular	12	0
<i>Urticarias</i>		
Urticaria	4	0
Skin disorders SOC TOTAL	86	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Peripheral vascular disorders NEC</i>		
Flushing	1	0
Vascular disorders SOC TOTAL	1	0
TOTAL REACTIONS FOR DRUG	369	0
TOTAL REPORTS	152	