

Case Series Drug Analysis Print

Name: VARIVAX FOI 21/1063

Report Run Date: 07-Oct-2021
Data Lock Date: 30-Sep-2021 18:30:04
Earliest Reaction Date: 14-Jan-2005
MedDRA Version: MedDRA 24.0

VARIVAX FOI
21/1063:

All UK spontaneous reports received up until 30-Sep-2021 for the Varivax 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
<i>Spleen disorders</i>		
Splenomegaly	1	0
Blood disorders SOC TOTAL	3	0

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

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Skin and subcutaneous tissue disorders congenital NEC</i>		
Aplasia cutis congenita	1	0
Congenital disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	2	0
Ear swelling	1	0
<i>Inner ear signs and symptoms</i>		
Vertigo	1	0
Ear disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Lacrimation disorders</i>		
Lacrimation increased	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	2	0
<i>Ocular disorders NEC</i>		
Eye swelling	2	0
<i>Ocular nerve and muscle disorders</i>		
Ophthalmoplegia	1	0
<i>Ocular sensation disorders</i>		
Photophobia	2	0
<i>Visual disorders NEC</i>		
Vision blurred	1	0
Eye disorders SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Dental disorders NEC</i>		
Tooth disorder	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	2	0
<i>Flatulence, bloating and distension</i>		
Flatulence	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	1	0
Abdominal pain upper	2	0
<i>Gastrointestinal dyskinetic disorders</i>		
Dyschezia	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	7	0
Retching	2	0
Vomiting	10	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	1	0
<i>Rectal inflammations NEC</i>		
Proctitis	1	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	1	0
Gastrointestinal disorders SOC TOTAL	30	0

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General disorders		
<i>Asthenic conditions</i>		
Asthenia	3	0
Fatigue	4	0
Malaise	16	0
<i>Febrile disorders</i>		
Pyrexia	26	0
<i>Feelings and sensations NEC</i>		
Chills	2	0
Feeling abnormal	1	0
Feeling cold	1	0
Feeling drunk	1	0
Feeling hot	3	0
Feeling of body temperature change	1	0
<i>Gait disturbances</i>		
Gait disturbance	1	0
<i>General signs and symptoms NEC</i>		
Crying	1	0
Disease progression	1	0
Illness	3	0
Influenza like illness	1	0
Peripheral swelling	6	0
Swelling	1	0
Swelling face	1	0
<i>Injection site reactions</i>		
Injection site erythema	8	0
Injection site hypersensitivity	1	0
Injection site inflammation	2	0
Injection site mass	1	0
Injection site pain	2	0
Injection site papule	1	0
Injection site pruritus	2	0
Injection site rash	2	0
Injection site reaction	1	0
Injection site swelling	4	0
Injection site urticaria	2	0
Injection site vesicles	1	0
<i>Oedema NEC</i>		
Localised oedema	1	0
<i>Pain and discomfort NEC</i>		
Chest discomfort	1	0
Discomfort	2	0
Pain	2	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	1	0
Drug ineffective	2	0
Therapy non-responder	5	0
Vaccination failure	4	0
<i>Vaccination site reactions</i>		
Vaccination site erythema	2	0
Vaccination site irritation	1	0
Vaccination site pain	1	0
Vaccination site pruritus	1	0
Vaccination site rash	1	0

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General disorders General disorders cont'd		
Vaccination site reaction	1	0
Vaccination site swelling	1	0
General disorders SOC TOTAL	126	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactoid reaction	1	0
Immune system disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Gastroenteritis	1	0
<i>Bacterial infections NEC</i>		
Skin bacterial infection	1	0
<i>Herpes viral infections</i>		
Herpes zoster	2	0
Herpes zoster oticus	1	0
Varicella	20	0
Varicella post vaccine	1	0
Varicella zoster virus 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>Streptococcal infections</i>		
Beta haemolytic streptococcal infection	1	0
<i>Upper respiratory tract infections</i>		
Croup infectious	2	0
<i>Viral infections NEC</i>		
Bronchiolitis	1	0
Meningoencephalitis viral	1	0
Post viral fatigue syndrome	1	0
Infections SOC TOTAL	37	0

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	1	0
Foetal exposure during pregnancy	1	0
Maternal exposure before pregnancy	1	0
<i>Off label uses</i>		
Off label use	1	0
<i>Product administration errors and issues</i>		
Inappropriate schedule of product administration	2	0
Wrong product administered	1	0
<i>Skin injuries NEC</i>		
Scar	1	0
Skin laceration	1	0
<i>Underdoses NEC</i>		
Underdose	1	0
<i>Vaccination related complications</i>		
Post vaccination syndrome	1	0
Injuries SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Investigations		
<i>Heart rate and pulse investigations</i>		
Heart rate increased	2	0
Heart rate irregular	1	0
Pulse abnormal	1	0
<i>Immunology analyses NEC</i>		
Antibody test negative	2	0
<i>Liver function analyses</i>		
Liver function test abnormal	1	0
<i>Microbiology and serology tests NEC</i>		
Serology negative	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature fluctuation	1	0
Body temperature increased	2	0
Respiratory rate increased	1	0
Weight decreased	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output decreased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure increased	1	0
<i>Virus identification and serology</i>		
Varicella virus test negative	1	0
Investigations SOC TOTAL	16	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	3	0
<i>Total fluid volume decreased</i>		
Dehydration	1	0
Metabolic disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthropathy	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	2	0
Joint swelling	2	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	1	0
<i>Muscle pains</i>		
Myalgia	3	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	2	0
Muscle twitching	1	0
<i>Muscle tone abnormalities</i>		
Floppy infant	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	2	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Limb discomfort	1	0
Pain in extremity	3	0
Muscle & tissue disorders SOC TOTAL	19	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Absence seizures		
Petit mal epilepsy	1	0
Central nervous system inflammatory disorders NEC		
Central nervous system inflammation	1	0
Coordination and balance disturbances		
Balance disorder	1	0
Coordination abnormal	2	0
Cortical dysfunction NEC		
Aphasia	1	0
Disturbances in consciousness NEC		
Lethargy	2	0
Postictal state	1	0
Somnolence	5	0
Syncope	3	0
Dyskinesias and movement disorders NEC		
Dyskinesia	1	0
Psychomotor hyperactivity	1	0
Encephalitis NEC		
Encephalitis autoimmune	1	0
Encephalopathies NEC		
Encephalopathy	1	0
Eye movement disorders		
VIth nerve paralysis	1	0
Facial cranial nerve disorders		
Facial paralysis	2	0
Headaches NEC		
Headache	9	0
Mental impairment (excl dementia and memory loss)		
Disturbance in attention	1	0
Muscle tone abnormal		
Hypotonia	2	0
Narcolepsy and hypersomnia		
Hypersomnia	1	0
Neurological signs and symptoms NEC		
Dizziness	3	0
Presyncope	2	0
Unresponsive to stimuli	2	0
Paraesthesias and dysaesthesias		
Burning sensation	1	0
Hypoaesthesia	2	0
Paraesthesia	6	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	1	0
Seizures and seizure disorders NEC		
Epilepsy	1	0
Febrile convulsion	1	0
Seizure	3	0
Sensory abnormalities NEC		
Neuralgia	1	0
Speech and language abnormalities		
Dysarthria	2	0
Language disorder	1	0
Tremor (excl congenital)		

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Tremor	4	0
Nervous system disorders SOC TOTAL	67	0

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	1	0
<i>Labour onset and length abnormalities</i>		
Premature delivery	1	0
Premature rupture of membranes	1	0
Pregnancy conditions SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	1	0
Staring	2	0
<i>Anxiety symptoms</i>		
Agitation	1	0
Anxiety	1	0
<i>Behaviour and socialisation disturbances</i>		
Social avoidant behaviour	1	0
<i>Communications disorders</i>		
Communication disorder	1	0
<i>Confusion and disorientation</i>		
Confusional state	3	0
Disorientation	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	2	0
<i>Emotional and mood disturbances NEC</i>		
Irritability	2	0
<i>Mental disorders due to a general medical condition NEC</i>		
Neuropsychiatric symptoms	1	0
<i>Mood alterations with depressive symptoms</i>		
Tearfulness	1	0
<i>Mood disorders NEC</i>		
Listless	1	0
<i>Parasomnias</i>		
Nightmare	1	0
<i>Perception disturbances NEC</i>		
Illusion	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	3	0
<i>Tic disorders</i>		
Tic	1	0
Psychiatric disorders SOC TOTAL	25	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Urinary incontinence	1	0
Urinary retention	1	0
Renal & urinary disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	2	0
Grunting	1	0
Hypopnoea	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	1	0
<i>Coughing and associated symptoms</i>		
Cough	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	3	0
Throat tightness	1	0
Yawning	2	0
Respiratory disorders SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Skin disorders		
Acnes		
Dermatitis acneiform	1	0
Alopecias		
Alopecia	1	0
Angioedemas		
Angioedema	1	0
Apocrine and eccrine gland disorders		
Cold sweat	4	0
Hyperhidrosis	1	0
Night sweats	1	0
Bullous conditions		
Blister	2	0
Dermal and epidermal conditions NEC		
Dry skin	1	0
Papule	3	0
Scab	1	0
Skin lesion	2	0
Skin reaction	1	0
Dermatitis and eczema		
Dermatitis allergic	1	0
Dermatitis diaper	1	0
Eczema	1	0
Erythemas		
Erythema	4	0
Exfoliative conditions		
Skin exfoliation	1	0
Pruritus NEC		
Pruritus	12	0
Psoriatic conditions		
Psoriasis	1	0
Purpura and related conditions		
Petechiae	1	0
Rashes, eruptions and exanthems NEC		
Rash	15	0
Rash erythematous	2	0
Rash macular	1	0
Rash maculo-papular	2	0
Rash morbilliform	1	0
Rash papular	1	0
Rash pruritic	1	0
Rash vesicular	15	0
Skin vasomotor conditions		
Livedo reticularis	1	0
Urticarias		
Urticaria	3	0
Skin disorders SOC TOTAL	83	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Obstetric therapeutic procedures</i>		
Caesarean section	1	0
Surgical & medical procedures SOC TOTAL	1	0

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Vascular disorders		
<i>Circulatory collapse and shock</i>		
Circulatory collapse	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	5	0
Vascular disorders SOC TOTAL	6	0
TOTAL REACTIONS FOR DRUG	466	0
TOTAL REPORTS	153	