

Case Series Drug Analysis Print

Name: Viatim & Vivaxim FOI 21/1063

Report Run Date: 07-Oct-2021
Data Lock Date: 30-Sep-2021 18:30:04
Earliest Reaction Date: 30-Nov-2001
MedDRA Version: MedDRA 24.0

Viatim & Vivaxim FOI 21/1063: All UK spontaneous reports received up until 30-Sep-2021 for the Viatim & Vivaxim 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>Myocardial disorders NEC</i>		
Cardiomegaly	1	0
Cardiac disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear pain	1	0
<i>Hearing losses</i>		
Deafness unilateral	1	0
<i>Inner ear signs and symptoms</i>		
Vertigo	1	0
Ear disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Ocular disorders NEC</i>		
Eye swelling	2	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye irritation	1	0
Eye pruritus	1	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	2	0
<i>Ocular sensation disorders</i>		
Photophobia	1	0
<i>Retinal, choroid and vitreous infections and inflammations</i>		
Retinal vasculitis	1	0
<i>Visual disorders NEC</i>		
Vision blurred	3	0
Eye disorders SOC TOTAL	11	0

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Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	4	0
<i>Faecal abnormalities NEC</i>		
Faeces pale	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	2	0
Abdominal pain lower	1	0
Abdominal pain upper	4	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	1	0
Abdominal symptom	1	0
Dysphagia	1	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Irritable bowel syndrome	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	10	0
Vomiting	5	0
<i>Oral soft tissue signs and symptoms</i>		
Oral pain	1	0
Paraesthesia oral	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	1	0
<i>Tongue signs and symptoms</i>		
Swollen tongue	1	0
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Reaction Name	Total	Fatal
General disorders		
<i>Adverse effect absent</i>		
No adverse event	1	0
<i>Asthenic conditions</i>		
Asthenia	5	0
Fatigue	8	0
Malaise	14	0
<i>Febrile disorders</i>		
Pyrexia	12	0
<i>Feelings and sensations NEC</i>		
Chills	6	0
Feeling abnormal	3	0
Feeling cold	1	0
Feeling hot	2	0
Feeling of body temperature change	1	0
Sensation of foreign body	1	0
<i>Gait disturbances</i>		
Gait disturbance	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	1	0
Induration	1	0
Influenza like illness	6	0
Local reaction	1	0
Peripheral swelling	2	0
Swelling	2	0
<i>Inflammations</i>		
Inflammation	1	0
<i>Injection site reactions</i>		
Injection site pain	2	0
Injection site reaction	4	0
<i>Oedema NEC</i>		
Face oedema	1	0
<i>Pain and discomfort NEC</i>		
Chest discomfort	1	0
Chest pain	2	0
Discomfort	1	0
Pain	6	0
Tenderness	1	0
<i>Therapeutic and nontherapeutic responses</i>		
Drug ineffective	2	0
Therapy non-responder	1	0
<i>Vaccination site reactions</i>		
Vaccination site erythema	2	0
Vaccination site pain	4	0
General disorders SOC TOTAL	96	0

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Cholestasis	1	0
Jaundice	2	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis acute	3	0
Hepatic disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	2	0
Immune system disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Infections		
<i>Arenaviral infections</i>		
Choriomeningitis lymphocytic	1	0
<i>Flaviviral infections</i>		
Yellow fever vaccine-associated neurotropic disease	1	0
<i>Hepatitis virus infections</i>		
Hepatitis A	1	0
<i>Herpes viral infections</i>		
Herpes simplex encephalitis	1	0
Herpes zoster	1	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	1	0
<i>Mumps viral infections</i>		
Mumps	1	0
<i>Muscle and soft tissue infections</i>		
Necrotising fasciitis	1	0
<i>Salmonella infections</i>		
Typhoid fever	3	0
<i>Upper respiratory tract infections</i>		
Tonsillitis	1	0
<i>Urinary tract infections</i>		
Cystitis	1	0
<i>Vascular infections</i>		
Lymphangitis	1	0
<i>Viral infections NEC</i>		
Meningitis viral	1	0
Infections SOC TOTAL	15	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	2	0
Vaccination error	1	0
<i>Product administration errors and issues</i>		
Product administered to patient of inappropriate age	2	0
<i>Skin injuries NEC</i>		
Contusion	1	0
<i>Underdoses NEC</i>		
Underdose	1	0
<i>Vaccination related complications</i>		
Vaccination complication	1	0
Injuries SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Investigations		
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Streptococcus test positive	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate increased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature increased	1	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Vital capacity decreased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	1	0
Blood pressure diastolic increased	1	0
<i>White blood cell analyses</i>		
White blood cell count increased	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>General nutritional disorders NEC</i>		
Feeding disorder	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>		
Spinal pain	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	6	0
Joint effusion	1	0
Joint stiffness	2	0
<i>Muscle pains</i>		
Myalgia	8	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	1	0
Muscle tightness	1	0
<i>Muscle weakness conditions</i>		
Muscular weakness	3	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	6	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	2	0
Limb discomfort	1	0
Neck pain	3	0
Pain in extremity	5	0
Muscle & tissue disorders SOC TOTAL	40	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i>		
Adenocarcinoma pancreas	1	0
Neoplasms SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral haemorrhage	1	1
<i>Chronic polyneuropathies</i>		
Demyelinating polyneuropathy	1	0
<i>Demyelinating disorders NEC</i>		
Demyelination	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	7	0
Loss of consciousness	4	0
Somnolence	1	0
Syncope	9	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	3	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	2	0
Facial paralysis	1	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	1	0
<i>Headaches NEC</i>		
Headache	16	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Mental impairment	1	0
<i>Migraine headaches</i>		
Migraine	1	0
<i>Multiple sclerosis acute and progressive</i>		
Multiple sclerosis	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	16	0
<i>Paraesthesias and dysaesthesias</i>		
Hypoaesthesia	3	0
Paraesthesia	6	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Paralysis	1	0
Quadriparesis	1	0
<i>Seizures and seizure disorders NEC</i>		
Seizure	4	0
Seizure like phenomena	1	0
<i>Sensory abnormalities NEC</i>		
Ageusia	1	0
Neuralgia	3	0
Taste disorder	1	0
<i>Speech and language abnormalities</i>		
Speech disorder	2	0
<i>Tremor (excl congenital)</i>		
Tremor	1	0
Nervous system disorders SOC TOTAL	91	1

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	1	0
<i>Labour onset and length abnormalities</i>		
Premature delivery	1	0
Pregnancy conditions SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Confusion and disorientation</i>		
Confusional state	3	0
Disorientation	4	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	3	0
<i>Increased physical activity levels</i>		
Restlessness	1	0
<i>Panic attacks and disorders</i>		
Panic attack	1	0
<i>Parasomnias</i>		
Abnormal dreams	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	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>		
Bladder pain	1	0
Dysuria	1	0
Fowler's syndrome	1	0
Micturition urgency	1	0
Urinary incontinence	1	0
Urinary retention	1	0
<i>Urinary abnormalities</i>		
Chromaturia	3	0
Renal & urinary disorders SOC TOTAL	9	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	1	0
<i>Bronchospasm and obstruction</i>		
Wheezing	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	1	0
<i>Nasal disorders NEC</i>		
Epistaxis	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Dysphonia	1	0
Oropharyngeal pain	3	0
Rhinorrhoea	1	0
Throat irritation	1	0
Respiratory disorders SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Skin disorders		
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	1	0
Hyperhidrosis	6	0
Night sweats	1	0
<i>Bullous conditions</i>		
Erythema multiforme	1	0
<i>Dermal and epidermal conditions NEC</i>		
Skin discolouration	1	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	1	0
<i>Erythemas</i>		
Erythema	2	0
<i>Pruritus NEC</i>		
Pruritus	2	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	7	0
Rash erythematous	2	0
Rash macular	1	0
<i>Urticarias</i>		
Urticaria	2	0
Skin disorders SOC TOTAL	27	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Obstetric therapeutic procedures</i>		
Forceps delivery	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>Peripheral vascular disorders NEC</i>		
Flushing	4	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	1	0
Raynaud's phenomenon	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	3	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	1	0
Vascular disorders SOC TOTAL	12	0
TOTAL REACTIONS FOR DRUG	400	1
TOTAL REPORTS	108	
TOTAL FATAL OUTCOME REPORTS		1