

Case Series Drug Analysis Print

Name: FOI 21/590 Typhoid Vaccine (VIVOTIF)

Report Run Date: 29-Jun-2021

Data Lock Date: 08-Apr-2021 19:00:04

Earliest Reaction Date: 22-Jun-1992

MedDRA Version: MedDRA 23.1

FOI 21/590 Typhoid Vaccine (VIVOTIF): All UK suspected, spontaneous adverse drug reactions reports associated with the Typhoid vaccine (VIVOTIF) until 08/04/2021

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

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

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

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Reaction Name	Total	Fatal
Eye disorders		
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Swelling of eyelid	2	0
<i>Visual disorders NEC</i>		
Diplopia	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Visual impairment	1	0
Eye disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	18	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	1	0
<i>Faecal abnormalities NEC</i>		
Mucous stools	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	24	0
Abdominal pain upper	8	0
Abdominal tenderness	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Enterocolitis	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	3	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Frequent bowel movements	1	0
Oesophageal spasm	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	24	0
Vomiting	17	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematochezia	2	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	2	0
<i>Peritoneal and retroperitoneal fibrosis and adhesions</i>		
Retroperitoneal fibrosis	1	0
<i>Stomatitis and ulceration</i>		
Mouth ulceration	2	0
Gastrointestinal disorders SOC TOTAL	110	0

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General disorders		
<i>Adverse effect absent</i>		
No adverse event	1	0
<i>Asthenic conditions</i>		
Asthenia	4	0
Fatigue	5	0
Malaise	9	0
<i>Febrile disorders</i>		
Pyrexia	10	0
<i>Feelings and sensations NEC</i>		
Chills	6	0
Feeling abnormal	1	0
Feeling cold	1	0
Feeling hot	4	0
Feeling of body temperature change	1	0
<i>Gait disturbances</i>		
Gait disturbance	1	0
<i>General signs and symptoms NEC</i>		
Influenza like illness	6	0
Peripheral swelling	3	0
Swelling	1	0
Swelling face	1	0
<i>Pain and discomfort NEC</i>		
Chest discomfort	5	0
Chest pain	4	0
Discomfort	1	0
Pain	3	0
General disorders SOC TOTAL	67	0

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Infections		
<i>Abdominal and gastrointestinal infections</i>		
Gastroenteritis	2	0
<i>Bacterial infections NEC</i>		
Cellulitis	1	0
<i>Caliciviral infections</i>		
Gastroenteritis norovirus	1	0
<i>Infections NEC</i>		
Infection	1	0
<i>Infectious transmissions</i>		
Infection via vaccinee	1	0
<i>Salmonella infections</i>		
Typhoid fever	3	0
<i>Upper respiratory tract infections</i>		
Tonsillitis	1	0
<i>Viral infections NEC</i>		
Post viral fatigue syndrome	1	0
Infections SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Injuries		
<i>Product administration errors and issues</i>		
Inappropriate schedule of product administration	1	0
Product administration error	2	0
<i>Product storage errors and issues in the product use system</i>		
Product storage error	1	0
<i>Skin injuries NEC</i>		
Contusion	1	0
<i>Vaccination related complications</i>		
Vaccination failure	2	0
Injuries SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Investigations		
<i>Protein analyses NEC</i>		
C-reactive protein increased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	1	0
Investigations SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	4	0
<i>Diabetes mellitus (incl subtypes)</i>		
Type 2 diabetes mellitus	1	0
Metabolic disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Joint related signs and symptoms</i>		
Arthralgia	3	0
Joint swelling	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Pain in extremity	2	0
Muscle & tissue disorders SOC TOTAL	6	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebrovascular accident	1	0
<i>Disturbances in consciousness NEC</i>		
Lethargy	4	0
Loss of consciousness	1	0
Syncope	4	0
<i>Encephalitis NEC</i>		
Encephalitis autoimmune	1	0
<i>Headaches NEC</i>		
Headache	9	0
<i>Nervous system disorders NEC</i>		
Cerebral disorder	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	6	0
<i>Paraesthesias and dysaesthesias</i>		
Paraesthesia	2	0
<i>Peripheral neuropathies NEC</i>		
Polyneuropathy	1	0
<i>Structural brain disorders NEC</i>		
Brain injury	1	0
<i>Tremor (excl congenital)</i>		
Tremor	2	0
Nervous system disorders SOC TOTAL	33	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Anxiety symptoms</i>		
Anxiety	2	0
Nervousness	1	0
Psychiatric disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Urinary tract signs and symptoms NEC</i>		
Polyuria	1	0
Renal pain	1	0
Renal & urinary disorders SOC TOTAL	2	0

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Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	3	0
<i>Bronchospasm and obstruction</i>		
Asthma	1	0
Wheezing	1	0
<i>Coughing and associated symptoms</i>		
Cough	3	0
<i>Parenchymal lung disorders NEC</i>		
Interstitial lung disease	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	1	0
Rhinorrhoea	1	0
Respiratory disorders SOC TOTAL	11	0

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Skin disorders		
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	1	0
Hyperhidrosis	8	0
<i>Erythemas</i>		
Erythema	1	0
<i>Panniculitides</i>		
Erythema nodosum	1	0
<i>Pruritus NEC</i>		
Pruritus	2	0
<i>Psoriatic conditions</i>		
Psoriasis	1	0
<i>Purpura and related conditions</i>		
Petechiae	1	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	6	0
Rash erythematous	3	0
Rash maculo-papular	1	0
Rash papular	1	0
Rash pruritic	2	0
<i>Urticarias</i>		
Urticaria	9	0
Skin disorders SOC TOTAL	37	0

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Vascular disorders		
<i>Peripheral vascular disorders NEC</i>		
Hot flush	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	1	0
Vascular disorders SOC TOTAL	3	0
TOTAL REACTIONS FOR DRUG	309	0
TOTAL REPORTS	117	