

## Case Series Drug Analysis Print

**Name: Boostrix Polio VAP**

Report Run Date: 12-Dec-2022

Data Lock Date: 09-Dec-2022 18:30:05

Earliest Reaction Date: 06-Nov-2013

MedDRA Version: MedDRA 25.1

Boostrix Polio VAP: All UK spontaneous ADR reports with Boostrix Polio since the start of the Yellow Card Scheme until 11/11/2022

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Lymphatic system disorders NEC</i>		
Lymphadenopathy	1	0
<b>Blood disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Cardiac septal defects congenital</i>		
Ventricular septal defect	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Eye disorders</b>		
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Eyelid rash	1	0
<i>Ocular disorders NEC</i>		
Eye swelling	2	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye discharge	1	0
Ocular hyperaemia	1	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	1	0
<i>Ocular sensation disorders</i>		
Photophobia	1	0
<b>Eye disorders SOC TOTAL</b>	<b>7</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	10	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	1	0
Abdominal pain upper	5	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	1	0
Gastrooesophageal reflux disease	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	2	0
Dysphagia	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	10	0
Vomiting	14	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	1	0
<i>Oral soft tissue signs and symptoms</i>		
Oral pain	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	1	0
<i>Stomatitis and ulceration</i>		
Stomatitis	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>49</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<b>Administration site reactions NEC</b>		
Administration site rash	1	0
<b>Application and instillation site reactions</b>		
Application site pruritus	1	0
Application site swelling	1	0
<b>Asthenic conditions</b>		
Asthenia	3	0
Fatigue	15	0
Malaise	3	0
<b>Febrile disorders</b>		
Pyrexia	21	0
<b>Feelings and sensations NEC</b>		
Chills	4	0
Feeling abnormal	1	0
Feeling cold	1	0
Feeling hot	2	0
<b>Gait disturbances</b>		
Gait inability	1	0
<b>General signs and symptoms NEC</b>		
Crying	2	0
Illness	1	0
Influenza like illness	6	0
Local reaction	1	0
Peripheral swelling	12	0
Prolapse	1	0
Swelling	2	0
Swelling face	2	0
<b>Injection site reactions</b>		
Injection site erythema	1	0
Injection site hypoaesthesia	1	0
Injection site pain	6	0
Injection site reaction	1	0
Injection site warmth	1	0
<b>Pain and discomfort NEC</b>		
Discomfort	1	0
Facial pain	1	0
Pain	7	0
Tenderness	1	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse drug reaction	4	0
<b>Vaccination site reactions</b>		
Vaccination site erythema	4	0
Vaccination site induration	1	0
Vaccination site inflammation	1	0
Vaccination site mass	1	0
Vaccination site pain	8	0
Vaccination site rash	1	0
Vaccination site swelling	2	0
Vaccination site warmth	2	0
<b>General disorders SOC TOTAL</b>	<b>125</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Food allergy	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	4	0
Anaphylactic shock	1	0
Anaphylactoid reaction	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>8</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i>Bacterial infections NEC</i>		
Bacterial infection	1	0
Cellulitis	2	0
<i>Bordetella infections</i>		
Pertussis	1	0
<i>Ear infections</i>		
Otitis media	1	0
<i>Infections NEC</i>		
Infection	3	0
Purulent discharge	1	0
<i>Urinary tract infections</i>		
Urinary tract infection	1	0
<b>Infections SOC TOTAL</b>	<b>10</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i><b>Exposures associated with pregnancy, delivery and lactation</b></i>		
Exposure during pregnancy	9	0
Foetal exposure during pregnancy	4	0
Maternal exposure during pregnancy	30	0
Maternal exposure timing unspecified	1	0
<i><b>Medication errors, product use errors and issues NEC</b></i>		
Medication error	1	0
<i><b>Product administration errors and issues</b></i>		
Expired product administered	1	0
Extra dose administered	2	0
Inappropriate schedule of product administration	1	0
Product administered at inappropriate site	2	0
Product administered to patient of inappropriate age	1	0
<i><b>Site specific injuries NEC</b></i>		
Limb injury	1	0
<i><b>Skin injuries NEC</b></i>		
Contusion	1	0
<b>Injuries SOC TOTAL</b>	<b>54</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate increased	2	0
<i>Hepatobiliary function diagnostic procedures</i>		
Hepatic enzyme abnormal	1	0
<i>Neurologic diagnostic procedures</i>		
Lumbar puncture	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature increased	3	0
<i>Platelet analyses</i>		
Platelet count decreased	1	0
<b>Investigations SOC TOTAL</b>	<b>9</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i>Appetite disorders</i>		
Decreased appetite	4	0
<b>Metabolic disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Arthropathies NEC</i>		
Arthritis	1	0
<i>Bursal disorders</i>		
Bursitis	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	4	0
<i>Muscle pains</i>		
Myalgia	5	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle spasms	2	0
<i>Muscle weakness conditions</i>		
Muscular weakness	2	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Limb mass	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	1	0
Limb discomfort	2	0
Neck pain	1	0
Pain in extremity	8	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>28</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Disturbances in consciousness NEC</i>		
Lethargy	3	0
Somnolence	5	0
Syncope	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Hypokinesia	1	0
<i>Headaches NEC</i>		
Headache	14	0
Tension headache	1	0
<i>Migraine headaches</i>		
Migraine	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	5	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	1	0
Paraesthesia	3	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	1	0
Febrile convulsion	1	0
Seizure	1	0
<i>Sensory abnormalities NEC</i>		
Neuralgia	1	0
<i>Speech and language abnormalities</i>		
Speech disorder	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>40</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i><b>Foetal complications NEC</b></i>		
Foetal hypokinesia	4	0
<i><b>Foetal growth complications</b></i>		
Foetal growth restriction	2	0
<i><b>Gestational age and weight conditions</b></i>		
Premature baby	1	0
<i><b>Hypertension associated disorders of pregnancy</b></i>		
Pre-eclampsia	1	0
<i><b>Labour onset and length abnormalities</b></i>		
Premature delivery	1	0
<i><b>Maternal complications of delivery NEC</b></i>		
Retained placenta or membranes	1	0
<i><b>Neonatal hepatobiliary disorders</b></i>		
Jaundice neonatal	1	0
<i><b>Normal pregnancy, labour and delivery</b></i>		
Live birth	2	0
<i><b>Pregnancy complicated by maternal disorders</b></i>		
Gestational diabetes	1	0
<i><b>Stillbirth and foetal death</b></i>		
Foetal death	1	1
Stillbirth	3	3
<b>Pregnancy conditions SOC TOTAL</b>	<b>18</b>	<b>4</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Psychiatric disorders</b>		
<i>Emotional and mood disturbances NEC</i>		
Irritability	1	0
<i>Mood alterations with depressive symptoms</i>		
Tearfulness	1	0
<i>Suicidal and self-injurious behaviour</i>		
Suicidal ideation	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i>Renal disorders NEC</i>		
Single functional kidney	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Breast signs and symptoms</i>		
Breast pain	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital rash	1	0
Genital swelling	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i>Breathing abnormalities</i>		
Dyspnoea	1	0
<i>Coughing and associated symptoms</i>		
Cough	6	0
Productive cough	1	0
Sputum discoloured	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	1	0
<i>Respiratory signs and symptoms NEC</i>		
Nasal flaring	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Dry throat	1	0
Oropharyngeal pain	5	0
Rhinorrhoea	3	0
Snoring	1	0
Upper respiratory tract congestion	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>22</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	1	0
Hyperhidrosis	1	0
<i>Dermal and epidermal conditions NEC</i>		
Skin reaction	1	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	1	0
<i>Erythemas</i>		
Erythema	11	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	1	0
<i>Pruritus NEC</i>		
Pruritus	5	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	11	0
Rash macular	1	0
Rash pruritic	1	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	1	0
<i>Urticarias</i>		
Urticaria	3	0
<b>Skin disorders SOC TOTAL</b>	<b>38</b>	<b>0</b>

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<b>Vascular disorders</b>		
<i>Haemorrhages NEC</i>		
Haemorrhage	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>429</b>	<b>4</b>
<b>TOTAL REPORTS</b>	<b>139</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>4</b>