

Case Series Drug Analysis Print

Name: Boostrix & Boostrix-IPV FOI 21/1063

Report Run Date: 07-Oct-2021
Data Lock Date: 30-Sep-2021 18:30:04
Earliest Reaction Date: 06-Nov-2013
MedDRA Version: MedDRA 24.0

Boostrix & Boostrix-IPV FOI 21/1063: All UK spontaneous reports received up until 30-Sep-2021 for the Boostrix & Boostrix-IPV 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	1	0
Blood disorders SOC TOTAL	1	0

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

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

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

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Reaction Name	Total	Fatal
Eye disorders		
<i>Ocular disorders NEC</i>		
Eye swelling	1	0
<i>Ocular nerve and muscle disorders</i>		
Eye movement disorder	1	0
<i>Ocular sensation disorders</i>		
Photophobia	1	0
<i>Visual disorders NEC</i>		
Vision blurred	1	0
Eye disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	9	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	1	0
Abdominal pain upper	4	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	7	0
Vomiting	9	0
<i>Oral dryness and saliva altered</i>		
Dry mouth	1	0
Gastrointestinal disorders SOC TOTAL	36	0

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site rash	1	0
<i>Application and instillation site reactions</i>		
Application site pruritus	1	0
Application site swelling	1	0
<i>Asthenic conditions</i>		
Asthenia	3	0
Fatigue	13	0
Malaise	4	0
<i>Febrile disorders</i>		
Pyrexia	15	0
<i>Feelings and sensations NEC</i>		
Chills	2	0
Feeling abnormal	2	0
Feeling hot	2	0
<i>General signs and symptoms NEC</i>		
Crying	2	0
Illness	2	0
Influenza like illness	6	0
Local reaction	1	0
Peripheral swelling	7	0
Prolapse	1	0
Swelling	1	0
Swelling face	1	0
<i>Injection site reactions</i>		
Injection site erythema	1	0
Injection site hypoaesthesia	1	0
Injection site inflammation	1	0
Injection site pain	5	0
Injection site warmth	1	0
<i>Pain and discomfort NEC</i>		
Discomfort	1	0
Facial pain	1	0
Pain	7	0
Tenderness	1	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	3	0
<i>Vaccination site reactions</i>		
Vaccination site erythema	4	0
Vaccination site induration	1	0
Vaccination site mass	1	0
Vaccination site pain	7	0
Vaccination site swelling	2	0
Vaccination site warmth	1	0
General disorders SOC TOTAL	103	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Food allergy	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	2	0
Anaphylactic shock	1	0
Anaphylactoid reaction	1	0
Immune system disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Infections		
<i>Bacterial infections NEC</i>		
Bacterial infection	1	0
Cellulitis	1	0
<i>Bordetella infections</i>		
Pertussis	1	0
<i>Ear infections</i>		
Otitis media	1	0
<i>Infections NEC</i>		
Infection	1	0
Purulent discharge	1	0
<i>Urinary tract infections</i>		
Urinary tract infection	1	0
Infections SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	9	0
Foetal exposure during pregnancy	4	0
Maternal exposure during pregnancy	22	0
Maternal exposure timing unspecified	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	2	0
<i>Product administration errors and issues</i>		
Expired product administered	1	0
Extra dose administered	2	0
Product administered at inappropriate site	1	0
Product administered to patient of inappropriate age	1	0
Wrong product administered	1	0
<i>Skin injuries NEC</i>		
Contusion	1	0
Injuries SOC TOTAL	45	0

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Reaction Name	Total	Fatal
Investigations		
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate increased	2	0
<i>Liver function analyses</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	2	0
<i>Platelet analyses</i>		
Platelet count decreased	1	0
Investigations SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	2	0
Metabolic disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<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
Musculoskeletal stiffness	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	1	0
Limb discomfort	3	0
Neck pain	2	0
Pain in extremity	8	0
Muscle & tissue disorders SOC TOTAL	31	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Disturbances in consciousness NEC</i>		
Lethargy	3	0
Somnolence	3	0
Syncope	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Hypokinesia	1	0
<i>Headaches NEC</i>		
Headache	15	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
Seizure	1	0
<i>Sensory abnormalities NEC</i>		
Neuralgia	1	0
<i>Speech and language abnormalities</i>		
Speech disorder	1	0
Nervous system disorders SOC TOTAL	38	0

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

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Behaviour and socialisation disturbances</i>		
Aggression	1	0
<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
Psychiatric disorders SOC TOTAL	4	0

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

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Breast signs and symptoms</i>		
Breast pain	1	0
Reproductive & breast disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	1	0
<i>Coughing and associated symptoms</i>		
Cough	5	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Dry throat	1	0
Oropharyngeal pain	4	0
Rhinorrhoea	1	0
Upper respiratory tract congestion	1	0
Respiratory disorders SOC TOTAL	14	0

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Reaction Name	Total	Fatal
Skin disorders		
<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	9	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	1	0
<i>Pruritus NEC</i>		
Pruritus	4	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	4	0
Rash macular	1	0
Rash pruritic	1	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	1	0
<i>Urticarias</i>		
Urticaria	1	0
Skin disorders SOC TOTAL	26	0

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Haemorrhages NEC</i>		
Haemorrhage	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	1	0
Flushing	1	0
Vascular disorders SOC TOTAL	3	0
TOTAL REACTIONS FOR DRUG	351	4
TOTAL REPORTS	105	
TOTAL FATAL OUTCOME REPORTS		4