

Boostrix IPV 4-in-1 Vaccine Analysis Print.  
All UK spontaneous suspected Adverse Drug Reaction (ADR)  
reports associated with the Boostrix IPV 4-in-1 vaccine up to and including  
14/05/2025.

Report run: 15/05/2025

Earliest reaction date: 06/11/2013

Reaction MedDRA SOC Name	Reaction MedDRA HLT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal		
Blood and lymphatic system disorders	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Lymphadenopathy	3	0		
	<b>Total</b>			<b>3</b>	<b>0</b>		
Cardiac disorders	Cardiac arrhythmias	Rate and rhythm disorders NEC	Tachycardia	1	0		
	<b>Total</b>			<b>1</b>	<b>0</b>		
Congenital, familial and genetic disorders	Cardiac and vascular disorders congenital	Cardiac septal defects congenital	Ventricular septal defect	1	0		
	Gastrointestinal tract disorders congenital	Oral cavity disorders congenital NEC	Tethered oral tissue	1	0		
	<b>Total</b>			<b>2</b>	<b>0</b>		
Ear and labyrinth disorders	Aural disorders NEC	Ear disorders NEC	Ear swelling	1	0		
	Inner ear and VIIIth cranial nerve disorders	Inner ear signs and symptoms	Tinnitus	1	0		
			Vertigo	1	0		
	<b>Total</b>			<b>3</b>	<b>0</b>		
Eye disorders	Eye disorders NEC	Ocular disorders NEC	Eye swelling	3	0		
			Periorbital oedema	2	0		
	Ocular infections, irritations and inflammations	Lid, lash and lacrimal infections, irritations and inflammations Ocular infections, inflammations and associated manifestations	Eyelid rash	1	0		
			Eye discharge	1	0		
			Eye pruritus	1	0		
			Ocular hyperaemia	1	0		
	Ocular neuromuscular disorders	Ocular nerve and muscle disorders	Eye movement disorder	1	0		
	Ocular sensory symptoms NEC	Ocular sensation disorders	Asthenopia	1	0		
			Photophobia	1	0		
	Vision disorders	Visual disorders NEC	Vision blurred	1	0		
		Visual impairment and blindness (excl colour blindness)	Blindness	1	0		
<b>Total</b>			<b>14</b>	<b>0</b>			
Gastrointestinal disorders	Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	12	0		
		Gastrointestinal atonic and hypomotility disorders NEC	Constipation	2	0		
			Gastrooesophageal reflux disease	1	0		
	Gastrointestinal signs and symptoms	Gastrointestinal and abdominal pains (excl oral and throat)	Abdominal pain	1	0		
			Abdominal pain upper	7	0		
		Gastrointestinal signs and symptoms NEC	Abdominal discomfort	2	0		
			Dysphagia	1	0		
		Nausea and vomiting symptoms	Nausea	12	0		
	Vomiting	21	0				
	Oral soft tissue conditions	Oral soft tissue signs and symptoms	Oral pain	1	0		
		Oral soft tissue swelling and oedema	Lip swelling	1	0		
		Stomatitis and ulceration	Stomatitis	1	0		
	Salivary gland conditions	Oral dryness and saliva altered	Dry mouth	1	0		
<b>Total</b>			<b>63</b>	<b>0</b>			
General disorders and administration site conditions	Administration site reactions	Administration site reactions NEC	Administration site rash	1	0		
		Application site reactions	Application site pruritus	1	0		
	Injection site reactions		Application site swelling	1	0		
			Injection site bruising	1	0		
			Injection site erythema	4	0		
			Injection site hypoesthesia	1	0		
			Injection site mass	1	0		
			Injection site pain	8	0		
			Injection site pruritus	1	0		
			Injection site reaction	1	0		
			Injection site swelling	2	0		
			Injection site warmth	2	0		
			Vaccination site reactions		Vaccination site erythema	8	0
					Vaccination site induration	1	0
					Vaccination site inflammation	3	0
					Vaccination site irritation	1	0
	Vaccination site joint erythema	1			0		
	Vaccination site mass	2			0		
	Vaccination site pain	11			0		
	Vaccination site paraesthesia	1			0		
	Vaccination site pruritus	1			0		
	Vaccination site rash	2			0		
	Body temperature conditions	Febrile disorders	Pyrexia	35	0		
	General system disorders NEC	Asthenic conditions	Asthenia	4	0		
			Fatigue	23	0		
			Malaise	4	0		
		Feelings and sensations NEC		Chills	5	0	
				Feeling abnormal	1	0	
				Feeling cold	1	0	
				Feeling hot	6	0	
		Gait disturbances	Gait inability	1	0		
		General signs and symptoms NEC		Crying	2	0	
				Illness	2	0	

			Influenza like illness	7	0	
			Local reaction	1	0	
			Peripheral swelling	21	0	
			Prolapse	1	0	
			Swelling	5	0	
			Swelling face	2	0	
		Inflammations	Inflammation	4	0	
		Oedema NEC	Localised oedema	1	0	
		Pain and discomfort NEC	Chest pain	1	0	
			Discomfort	2	0	
			Pain	8	0	
			Tenderness	2	0	
	Therapeutic and nontherapeutic effects (excl toxicity)	Therapeutic and nontherapeutic responses	Adverse drug reaction	6	0	
			Product ineffective	1	0	
	<b>Total</b>			<b>216</b>	<b>0</b>	
Immune system disorders	Allergic conditions	Allergic conditions NEC	Hypersensitivity	3	0	
		Anaphylactic and anaphylactoid responses	Anaphylactic reaction	4	0	
			Anaphylactoid reaction	1	0	
		Atopic disorders	Seasonal allergy	1	0	
	Autoimmune disorders	Autoimmune disorders NEC	Autoimmune disorder	1	0	
	Immune disorders NEC	Immune and associated conditions NEC	Bacille Calmette-Guerin scar reactivation	1	0	
	<b>Total</b>			<b>11</b>	<b>0</b>	
Infections and infestations	Bacterial infectious disorders	Bacterial infections NEC	Bacterial infection	1	0	
			Cellulitis	2	0	
		Bordetella infections	Pertussis	1	0	
	Infections - pathogen unspecified	Ear infections	Otitis media	1	0	
		Infections NEC	Infection	4	0	
		Skin structures and soft tissue infections	Skin infection	1	0	
	Urinary tract infections	Urinary tract infection	1	0		
	<b>Total</b>			<b>11</b>	<b>0</b>	
Injury, poisoning and procedural complications	Exposures, chemical injuries and poisoning	Exposures associated with pregnancy, delivery and lactation	Exposure during pregnancy	11	0	
			Foetal exposure during pregnancy	4	0	
			Maternal exposure during pregnancy	45	0	
			Maternal exposure timing unspecified	1	0	
	Injuries NEC	Site specific injuries NEC	Limb injury	1	0	
		Skin injuries NEC	Contusion	1	0	
			Skin wound	1	0	
	Medication errors and other product use errors and issues	Medication errors, product use errors and issues NEC	Medication error	1	0	
			Wrong technique in product usage process	1	0	
		Product administration errors and issues	Accidental overdose	1	0	
			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	3	0	
		Wrong product administered	1	0		
	<b>Total</b>			<b>77</b>	<b>0</b>	
Investigations	Cardiac and vascular investigations (excl enzyme tests)	Cardiac auscultatory investigations	Cardiac murmur	1	0	
		Heart rate and pulse investigations	Heart rate increased	3	0	
	Haematology investigations (incl blood groups)	Platelet analyses	Platelet count decreased	1	0	
	Hepatobiliary investigations	Hepatobiliary function diagnostic procedures	Hepatic enzyme abnormal	1	0	
	Neurological, special senses and psychiatric investigations	Neurologic diagnostic procedures	Lumbar puncture	1	0	
	Physical examination and organ system status topics	Physical examination procedures and organ system status	Body temperature decreased	1	0	
			Body temperature increased	3	0	
		<b>Total</b>			<b>11</b>	<b>0</b>
Metabolism and nutrition disorders	Appetite and general nutritional disorders	Appetite disorders	Decreased appetite	9	0	
	<b>Total</b>			<b>9</b>	<b>0</b>	
Musculoskeletal and connective tissue disorders	Joint disorders	Arthropathies NEC	Arthritis	1	0	
		Joint related signs and symptoms	Arthralgia	7	0	
	Muscle disorders	Muscle pains	Myalgia	5	0	
		Muscle related signs and symptoms NEC	Muscle spasms	2	0	
			Muscle swelling	1	0	
		Muscle weakness conditions	Muscular weakness	2	0	
	Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue conditions NEC	Limb mass	1	0	
			Musculoskeletal and connective tissue pain and discomfort	Back pain	3	0
				Limb discomfort	2	0
				Neck pain	3	0
	Pain in extremity	13	0			
Synovial and bursal disorders	Bursal disorders	Bursitis	1	0		
	<b>Total</b>			<b>41</b>	<b>0</b>	
Nervous system disorders	Headaches	Headaches NEC	Headache	22	0	
			Tension headache	1	0	
		Migraine headaches	Migraine	1	0	
	Movement disorders (incl parkinsonism)	Dyskinesias and movement disorders NEC	Hypokinesia	1	0	

Neurological disorders NEC	Coordination and balance disturbances	Balance disorder	1	0			
		Coordination abnormal	1	0			
	Disturbances in consciousness NEC		Depressed level of consciousness	1	0		
			Lethargy	3	0		
			Somnolence	5	0		
			Syncope	3	0		
			Neurological signs and symptoms NEC	Brain fog	1	0	
	Paraesthesias and dysaesthesias		Dizziness	9	0		
			Burning sensation	1	0		
			Hypoaesthesia	1	0		
	Sensory abnormalities NEC		Paraesthesia	3	0		
			Neuralgia	2	0		
	Speech and language abnormalities		Speech disorder	1	0		
	Neuromuscular disorders	Muscle tone abnormal		Hypotonia	1	0	
	Seizures (incl subtypes)	Seizures and seizure disorders NEC		Epilepsy	1	0	
				Febrile convulsion	2	0	
				Seizure	1	0	
<b>Total</b>				<b>62</b>	<b>0</b>		
Pregnancy, puerperium and perinatal conditions	Abortions and stillbirth	Stillbirth and foetal death	Foetal death	1	1		
			Stillbirth	3	3		
	Foetal complications	Foetal complications NEC		Foetal hypokinesia	4	0	
				Foetal growth restriction	2	0	
	Maternal complications of labour and delivery	Labour onset and length abnormalities		Premature delivery	1	0	
			Maternal complications of delivery NEC		Retained placenta or membranes	1	0
	Maternal complications of pregnancy	Hypertension associated disorders of pregnancy		Pre-eclampsia	1	0	
			Pregnancy complicated by maternal disorders		Gestational diabetes	1	0
	Neonatal and perinatal conditions	Gestational age and weight conditions		Premature baby	1	0	
			Neonatal hepatobiliary disorders		Jaundice neonatal	1	0
Pregnancy, labour, delivery and postpartum conditions	Normal pregnancy, labour and delivery		Live birth	2	0		
		<b>Total</b>		<b>18</b>	<b>4</b>		
Psychiatric disorders	Deliria (incl confusion)	Confusion and disorientation		Confusional state	1	0	
			Depressed mood disorders and disturbances		Mood alterations with depressive symptoms	1	0
	Disturbances in thinking and perception	Hallucinations (excl sleep-related)		Hallucination	1	0	
			Mood disorders and disturbances NEC		Emotional and mood disturbances NEC		Irritability
	Schizophrenia and other psychotic disorders	Psychotic disorder NEC		Psychotic disorder	1	0	
	Sleep disorders and disturbances	Disturbances in initiating and maintaining sleep		Insomnia	1	0	
	Suicidal and self-injurious behaviours NEC	Suicidal and self-injurious behaviour		Suicidal ideation	1	0	
	<b>Total</b>			<b>7</b>	<b>0</b>		
Renal and urinary disorders	Renal disorders (excl nephropathies)	Renal disorders NEC		Renal disorder	1	0	
				Single functional kidney	1	0	
	Urinary tract signs and symptoms	Urinary tract signs and symptoms NEC		Renal pain	1	0	
<b>Total</b>			<b>3</b>	<b>0</b>			
Reproductive system and breast disorders	Breast disorders	Breast signs and symptoms		Breast pain	1	0	
			Reproductive tract disorders NEC	Reproductive tract signs and symptoms NEC		Genital rash	1
	<b>Total</b>			<b>3</b>	<b>0</b>		
Respiratory, thoracic and mediastinal disorders	Respiratory disorders NEC	Breathing abnormalities		Dyspnoea	2	0	
			Coughing and associated symptoms		Cough	6	0
					Productive cough	1	0
					Sputum discoloured	1	0
	Respiratory tract signs and symptoms	Respiratory signs and symptoms NEC		Nasal flaring	1	0	
			Upper respiratory tract signs and symptoms		Choking	1	0
					Dry throat	1	0
					Oropharyngeal pain	7	0
					Rhinorrhoea	5	0
					Snoring	1	0
		Upper respiratory tract congestion	1	0			
Upper respiratory tract disorders (excl infections)	Nasal congestion and inflammations		Nasal congestion	1	0		
	Pharyngeal disorders (excl infections and neoplasms)		Pharyngeal swelling	1	0		
<b>Total</b>			<b>29</b>	<b>0</b>			
Skin and subcutaneous tissue disorders	Angioedema and urticaria	Urticarias		Urticaria	5	0	
	Epidermal and dermal conditions	Dermal and epidermal conditions NEC		Pain of skin	1	0	
				Skin induration	1	0	
				Skin reaction	1	0	
				Skin texture abnormal	1	0	
				Skin warm	1	0	
				Dermatitis and eczema	Dermatitis allergic	1	0
				Erythemas	Erythema	21	0
				Exfoliative conditions	Skin exfoliation	1	0
				Photosensitivity and photodermatitis conditions	Photosensitivity reaction	1	0
				Pruritus NEC	Pruritus	6	0
				Rashes, eruptions and exanthems NEC	Rash	12	0
					Rash macular	2	0
			Rash pruritic	1	0		
	Skin and subcutaneous tissue disorders NEC	Skin and subcutaneous conditions NEC		Skin mass	1	0	
	Skin appendage conditions	Acnes		Acne	1	0	
			Apocrine and eccrine gland disorders		Cold sweat	1	0
					Hyperhidrosis	2	0
					Hypohidrosis	1	0
	<b>Total</b>			<b>61</b>	<b>0</b>		

Vascular disorders	Arteriosclerosis, stenosis, vascular insufficiency and necrosis	Peripheral vasoconstriction, necrosis and vascular insufficiency	Peripheral coldness	1	0
	Decreased and nonspecific blood pressure disorders and shock	Vascular hypotensive disorders	Hypotension	1	0
	Vascular disorders NEC	Peripheral vascular disorders NEC	Cyanosis	1	0
		Site specific vascular disorders NEC	Pallor	1	0
<b>Total</b>			<b>4</b>	<b>0</b>	
<b>TOTAL REACTIONS FOR DRUG</b>			<b>649</b>		
<b>TOTAL REPORTS</b>			<b>206</b>		
<b>TOTAL FATAL OUTCOME REPORTS</b>				<b>4</b>	