

Boostrix IPV Pregnancy Vaccine Analysis Print.
 All UK spontaneous suspected Adverse Drug Reaction (ADR) reports
 associated with the Boostrix IPV vaccine where patient was a
 pregnant woman up to and including 12/01/2025.

Report run: 13/01/2025.

Earliest reaction date: 29/07/2014

Reaction MedDRA SOC Name	Reaction MedDRA HLGT 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	1	0
	Total			1	0
Cardiac disorders	Cardiac arrhythmias	Rate and rhythm disorders NEC	Tachycardia	1	0
	Total			1	0
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
Total			3	0	
Eye disorders	Eye disorders NEC	Ocular disorders NEC	Eye swelling	1	0
	Ocular infections, irritations and inflammations	Lid, lash and lacrimal infections, irritations and inflammations	Eyelid rash	1	0
	Vision disorders	Visual disorders NEC	Vision blurred	1	0
		Visual impairment and blindness (excl colour blindness)	Blindness	1	0
Total			4	0	
Gastrointestinal disorders	Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	7	0
		Gastrointestinal atonic and hypomotility disorders NEC	Constipation	1	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	4	0

	Gastrointestinal signs and symptoms NEC	Abdominal discomfort	2	0	
		Dysphagia	1	0	
	Nausea and vomiting symptoms	Nausea	7	0	
		Vomiting	8	0	
Oral soft tissue conditions	Oral soft tissue swelling and oedema	Lip swelling	1	0	
Salivary gland conditions	Oral dryness and saliva altered	Dry mouth	1	0	
	Total		34	0	
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
			Application site swelling	1	0
		Injection site reactions	Injection site erythema	1	0
			Injection site hypoesthesia	1	0
			Injection site pain	5	0
			Injection site warmth	1	0
		Vaccination site reactions	Vaccination site erythema	4	0
			Vaccination site inflammation	2	0
			Vaccination site mass	1	0
			Vaccination site pain	8	0
			Vaccination site rash	1	0
			Vaccination site swelling	2	0
			Vaccination site vesicles	1	0
			Vaccination site warmth	4	0
	Body temperature conditions	Febrile disorders	Pyrexia	10	0
	General system disorders NEC	Asthenic conditions	Asthenia	4	0
Fatigue			14	0	
Malaise			3	0	
Feelings and sensations NEC		Chills	2	0	
		Feeling abnormal	1	0	

			Feeling hot	2	0
	General signs and symptoms NEC		Crying	1	0
			Illness	2	0
			Influenza like illness	6	0
			Local reaction	1	0
			Peripheral swelling	8	0
			Prolapse	1	0
			Swelling	1	0
			Swelling face	1	0
		Pain and discomfort NEC		Discomfort	1
			Pain	6	0
			Tenderness	2	0
	Therapeutic and nontherapeutic effects (excl toxicity)	Therapeutic and nontherapeutic responses	Therapeutic product ineffective	1	0
	Total			101	0
Immune system disorders	Allergic conditions	Anaphylactic and anaphylactoid responses	Anaphylactic reaction	2	0
			Anaphylactoid reaction	1	0
	Total			3	0
Infections and infestations	Infections - pathogen unspecified	Ear infections	Otitis media	1	0
	Total			1	0
Injury, poisoning and procedural complications	Exposures, chemical injuries and poisoning	Exposures associated with pregnancy, delivery and lactation	Exposure during pregnancy	11	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
	Medication errors and other product use errors and issues	Medication errors, product use errors and issues NEC	Wrong technique in product usage process	1	0
		Product administration errors and issues	Product administered at inappropriate site	2	0
	Total			62	0
Investigations	Cardiac and vascular investigations (excl enzyme tests)	Heart rate and pulse investigations	Heart rate increased	2	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 increased	1	0
	Total			6	0

Metabolism and nutrition disorders	Appetite and general nutritional disorders	Appetite disorders	Decreased appetite	2	0	
	Total			2	0	
Musculoskeletal and connective tissue disorders	Joint disorders	Joint related signs and symptoms	Arthralgia	5	0	
	Muscle disorders	Muscle pains	Myalgia	4	0	
			Muscle related signs and symptoms NEC	Muscle spasms	2	0
				Muscle swelling	1	0
	Musculoskeletal and connective tissue disorders NEC	Muscle weakness conditions	Muscular weakness	2	0	
		Musculoskeletal and connective tissue conditions NEC	Musculoskeletal and connective tissue pain and discomfort	Limb mass	1	0
	Back pain			2	0	
	Limb discomfort			2	0	
	Neck pain			3	0	
	Synovial and bursal disorders	Bursal disorders	Bursitis	Pain in extremity	9	0
Total						32
Nervous system disorders	Headaches	Headaches NEC	Headache	15	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	Disturbances in consciousness NEC	Lethargy	3	0	
			Somnolence	3	0	
			Syncope	1	0	
		Neurological signs and symptoms NEC	Brain fog	1	0	
			Dizziness	6	0	
		Paraesthesias and dysaesthesias	Burning sensation	1	0	
			Paraesthesia	2	0	
	Sensory abnormalities NEC	Neuralgia	2	0		
	Speech and language abnormalities	Speech disorder	1	0		
Seizures (incl subtypes)	Seizures and seizure disorders NEC	Epilepsy	1	0		
Total			39	0		
Psychiatric disorders	Depressed mood disorders and disturbances	Mood alterations with depressive symptoms	Tearfulness	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	
	Total			3	0	
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	0	
			Genital swelling	1	0	
Total			3	0		
Respiratory, thoracic and mediastinal disorders	Respiratory disorders NEC	Breathing abnormalities	Dyspnoea	1	0	
			Coughing and associated symptoms	Cough	5	0
				Productive cough	1	0
	Respiratory tract signs and symptoms	Upper respiratory tract signs and symptoms	Dry throat	1	0	
			Oropharyngeal pain	5	0	
			Rhinorrhoea	3	0	
Upper respiratory tract congestion	1	0				

	Upper respiratory tract disorders (excl infections)	Nasal congestion and inflammations	Nasal congestion	1	0
	Total			18	0
Skin and subcutaneous tissue disorders	Angioedema and urticaria	Urticarias	Urticaria	1	0
	Epidermal and dermal conditions	Dermatitis and eczema	Dermatitis allergic	1	0
		Erythemas	Erythema	8	0
		Exfoliative conditions	Skin exfoliation	1	0
		Photosensitivity and photodermatosis conditions	Photosensitivity reaction	1	0
		Pruritus NEC	Pruritus	5	0
		Rashes, eruptions and exanthems NEC	Rash Rash pruritic	4 1	0 0
	Skin and subcutaneous tissue disorders NEC	Skin and subcutaneous conditions NEC	Skin mass	1	0
	Skin appendage conditions	Apocrine and eccrine gland disorders	Cold sweat	1	0
			Hyperhidrosis	2	0
	Total			26	0
Vascular disorders	Decreased and nonspecific blood pressure disorders and shock	Vascular hypotensive disorders	Hypotension	1	0
	Vascular disorders NEC	Peripheral vascular disorders NEC	Cyanosis	1	0
	Total			2	0
TOTAL REACTIONS FOR DRUG				341	
TOTAL REPORTS				91	
TOTAL FATAL OUTCOME REPORTS					0