

FOI 2025/00385- Infanrix Hexa 6-in-1 Vaccine Analysis Print.

All UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with the Infanrix Hexa 6-in-1 vaccine up to and including 14/05/2025.

Report run: 15/05/2025

Earliest reaction date: 27/01/2015

Reaction MedDRA SOC Name	Reaction MedDRA HLT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
Blood and lymphatic system disorders	Anaemias nonhaemolytic and marrow depression	Marrow depression and hypoplastic anaemias	Myelosuppression	1	0
	Platelet disorders	Thrombocytopenias	Immune thrombocytopenia	2	0
			Thrombocytopenia	1	0
	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Lymphadenopathy	3	0
	White blood cell disorders	Leukocytoses NEC	Lymphocytic infiltration	1	0
		Neutropenias	Neutropenia	1	0
	Total			9	0
Cardiac disorders	Cardiac arrhythmias	Rate and rhythm disorders NEC	Bradycardia	3	0
			Tachycardia	9	0
		Ventricular arrhythmias and cardiac arrest	Cardiac arrest	2	1
			Cardiac arrest neonatal	2	2
			Cardio-respiratory arrest	3	2
			Ventricular fibrillation	1	0
	Total			20	5
Congenital, familial and genetic disorders	Gastrointestinal tract disorders congenital	Oral cavity disorders congenital NEC	Tethered oral tissue	1	0
	Total			1	0
Ear and labyrinth disorders	Aural disorders NEC	Ear disorders NEC	Ear pain	1	0
			Ear swelling	4	0
	Total			5	0
Eye disorders	Anterior eye structural change, deposit and degeneration	Cataract conditions	Cataract	1	0
	Eye disorders NEC	Ocular disorders NEC	Dark circles under eyes	1	0
			Eye oedema	1	0
			Eye swelling	1	0
			Ocular discomfort	1	0
	Ocular haemorrhages and vascular disorders NEC	Conjunctival and corneal bleeding and vascular disorders	Conjunctival haemorrhage	1	0
		Ocular bleeding and vascular disorders NEC	Eye haemorrhage	1	0
	Ocular infections, irritations and inflammations	Ocular infections, inflammations and associated manifestations	Ocular hyperaemia	2	0
	Ocular neuromuscular disorders	Ocular nerve and muscle disorders	Eye movement disorder	3	0
			Gaze palsy	3	0
			Strabismus	1	0
			Anisocoria	1	0
			Miosis	1	0
			Mydriasis	1	0
	Ocular sensory symptoms NEC	Ocular sensation disorders	Photophobia	1	0
	Vision disorders	Visual disorders NEC	Vision blurred	1	0
		Visual impairment and blindness (excl colour blindness)	Visual impairment	1	0
	Total			22	0

Gastrointestinal disorders	Dental and gingival conditions	Gingival disorders, signs and symptoms NEC	Gingival discolouration	1	0
	Gastrointestinal conditions NEC	Gastrointestinal disorders NEC	Gastrointestinal disorder	3	0
	Gastrointestinal haemorrhages NEC	Non-site specific gastrointestinal haemorrhages	Haematochezia	6	0
	Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	51	0
			Diarrhoea haemorrhagic	1	0
		Gastrointestinal atonic and hypomotility disorders NEC	Constipation	12	0
			Gastrooesophageal reflux disease	8	0
		Gastrointestinal dyskinetic disorders	Infant dyschezia	1	0
		Gastrointestinal spastic and hypermotility disorders	Frequent bowel movements	2	0
	Gastrointestinal signs and symptoms	Dyspeptic signs and symptoms	Dyspepsia	2	0
			Abnormal faeces	4	0
		Faecal abnormalities NEC	Faecaloma	1	0
			Faeces discoloured	11	0
			Faeces hard	1	0
			Faeces pale	1	0
			Mucous stools	8	0
		Flatulence, bloating and distension	Abdominal distension	1	0
			Flatulence	7	0
		Gastrointestinal and abdominal pains (excl oral and throat)	Abdominal pain	12	0
			Abdominal pain upper	15	0
		Gastrointestinal signs and symptoms NEC	Abdominal discomfort	3	0
		Nausea and vomiting symptoms	Nausea	2	0
			Regurgitation	2	0
			Retching	2	0
			Vomiting	47	0
			Vomiting projectile	16	0
	Gastrointestinal stenosis and obstruction	Gastrointestinal stenosis and obstruction NEC	Intussusception	1	0
	Oral soft tissue conditions	Oral soft tissue swelling and oedema	Lip swelling	2	0
	Salivary gland conditions	Oral dryness and saliva altered	Salivary hypersecretion	1	0
		Salivary gland enlargements	Salivary gland enlargement	1	0
	Tongue conditions	Tongue signs and symptoms	Protrusion tongue	1	0
	Total			226	0
General disorders and administration site conditions	Administration site reactions	Injection site reactions	Injection site induration	1	0
			Injection site mass	3	0
			Injection site pain	1	0
			Injection site pruritus	1	0
			Injection site swelling	2	0
			Injection site vesicles	1	0
	Vaccination site reactions		Extensive swelling of vaccinated limb	2	0
			Vaccination site discomfort	1	0
			Vaccination site erythema	12	0
			Vaccination site haemorrhage	1	0
			Vaccination site induration	2	0

		Vaccination site inflammation	5	0
		Vaccination site mass	12	0
		Vaccination site pain	7	0
		Vaccination site rash	4	0
		Vaccination site swelling	9	0
		Vaccination site vesicles	1	0
		Vaccination site warmth	2	0
Body temperature conditions	Body temperature altered	Hyperthermia	1	0
	Febrile disorders	Pyrexia	141	0
Fatal outcomes	Death and sudden death	Death	7	7
		Sudden death	4	4
		Sudden infant death syndrome	4	4
General system disorders NEC	Asthenic conditions	Asthenia	7	0
		Decreased activity	1	0
		Fatigue	7	0
		Malaise	13	0
	Feelings and sensations NEC	Chills	6	0
		Feeling abnormal	1	0
		Feeling cold	1	0
		Feeling hot	4	0
		Thirst decreased	2	0
	Gait disturbances	Gait disturbance	3	0
		Gait inability	1	0
	General signs and symptoms NEC	Condition aggravated	3	0
		Crying	73	0
		Developmental delay	2	0
		Developmental regression	1	0
		General physical health deterioration	1	0
		Glassy eyes	3	0
		High-pitched crying	10	0
		Illness	4	0
		Induration	1	0
		Influenza like illness	1	0
		Moaning	2	0
		Multiple organ dysfunction syndrome	1	0
		Peripheral swelling	19	0
		Screaming	23	0
		Secretion discharge	1	0
		Swelling	10	0
		Swelling face	5	0
	Inflammations	Inflammation	10	0
		Systemic inflammatory response syndrome	1	0
	Oedema NEC	Oedema	2	0
		Oedema peripheral	1	0
	Pain and discomfort NEC	Axillary pain	1	0
		Discomfort	7	0
		Pain	26	0
		Tenderness	2	0
Therapeutic and nontherapeutic effects	Therapeutic and nontherapeutic responses	Drug ineffective	1	0
		Vaccination failure	5	0
Total			486	15

Hepatobiliary disorders	Hepatic and hepatobiliary disorders	Cholestasis and jaundice	Jaundice	1	0
			Jaundice cholestatic	1	0
		Hepatocellular damage and hepatitis NEC	Hepatitis	1	0
	Total			3	0
Immune system disorders	Allergic conditions	Allergic conditions NEC	Allergy to metals	1	0
			Hypersensitivity	10	0
			Multiple allergies	1	0
		Allergies to foods, food additives, drugs and other chemicals	Allergy to vaccine	2	0
			Food allergy	5	0
			Milk allergy	4	0
		Anaphylactic and anaphylactoid responses	Anaphylactic reaction	10	0
			Anaphylactic shock	1	0
		Atopic disorders	Atopy	1	0
			Seasonal allergy	1	0
	Immune disorders NEC	Immune and associated conditions NEC	Bacille Calmette-Guerin scar reactivation	1	0
			Haemophagocytic lymphohistiocytosis	1	1
			Immune system disorder	1	0
	Immunodeficiency syndromes	Immunodeficiency disorders NEC	Immunodeficiency	1	0
	Total			40	1
Infections and infestations	Bacterial infectious disorders	Bacterial infections NEC	Cellulitis	11	0
			Meningitis bacterial	1	0
			Skin bacterial infection	1	0
			Vaccination site cellulitis	1	0
		Bordetella infections	Pertussis	3	0
		Haemophilus infections	Haemophilus infection	4	0
			Meningitis haemophilus	1	0
		Staphylococcal infections	Staphylococcal infection	1	0
	Infections - pathogen unspecified	Central nervous system and spinal infections	Meningitis	2	0
			Meningitis aseptic	2	0
		Ear infections	Ear infection	1	0
		Infections NEC	Abscess	4	0
			Abscess limb	3	0
			Infection	1	0
			Vaccination site abscess	1	0
			Vaccination site infection	2	0
		Lower respiratory tract and lung infections	Bronchitis	1	0
			Lower respiratory tract infection	1	0
			Pneumonia	2	0
			Pneumonia aspiration	1	0
		Sepsis, bacteraemia, viraemia and fungaemia NEC	Sepsis	1	0
		Skin structures and soft tissue infections	Eczema infected	1	0
			Skin infection	3	0
		Upper respiratory tract infections	Croup infectious	1	0
			Nasopharyngitis	1	0
		Urinary tract infections	Urinary tract infection	2	0
	Viral infectious disorders	Enteroviral infections NEC	Meningitis enteroviral	1	0
		Viral infections NEC	Bronchiolitis	3	0
			Viral infection	1	0

			Viral rash	1	0
	Total			59	0
Injury, poisoning and procedural complications	Exposures, chemical injuries and poisoning	Exposures associated with pregnancy, delivery and lactation	Exposure via breast milk	1	0
			Foetal exposure during pregnancy	2	0
			Maternal exposure during breast feeding	1	0
	Injuries NEC	Muscle, tendon and ligament injuries	Muscle injury	2	0
		Non-site specific injuries NEC	Wound secretion	1	0
		Skin injuries NEC	Contusion	8	0
			Scratch	1	0
			Skin injury	1	0
	Medication errors and other product use errors and issues	Medication errors, product use errors and issues NEC	Medication error	8	0
			Vaccination error	1	0
			Wrong technique in product usage process	3	0
		Product administration errors and issues	Accidental overdose	2	0
			Accidental underdose	2	0
			Inappropriate schedule of product administration	2	0
			Incorrect dose administered	6	0
			Product administered at inappropriate site	1	0
			Product administered to patient of inappropriate age	4	0
			Wrong product administered	1	0
		Product preparation errors and issues	Product preparation error	1	0
			Product preparation issue	6	0
		Product prescribing errors and issues	Product prescribing error	1	0
		Product storage errors and issues in the product use system	Product storage error	1	0
	Overdoses and underdoses NEC	Overdoses NEC	Overdose	1	0
	Total			57	0
Investigations	Cardiac and vascular investigations (excl enzyme tests)	Cardiac function diagnostic procedures	Cardiac output decreased	1	0
		Heart rate and pulse investigations	Heart rate decreased	1	0
			Heart rate increased	1	0
			Pulse abnormal	1	0
	Haematology investigations (incl blood groups)	Red blood cell analyses	Haemoglobin decreased	1	0
		White blood cell analyses	Lymphocyte count increased	1	0
	Hepatobiliary investigations	Hepatobiliary function diagnostic procedures	Alanine aminotransferase increased	1	0
	Immunology and allergy investigations	Immunoglobulin analyses	Blood immunoglobulin G increased	2	0
	Metabolic, nutritional and blood gas investigations	Blood gas and acid base analyses	Oxygen saturation decreased	2	0
	Physical examination and organ system status topics	Physical examination procedures and organ system status	Body temperature abnormal	1	0
			Body temperature decreased	1	0

Metabolism and nutrition disorders			Body temperature fluctuation	1	0
			Body temperature increased	10	0
			Breath sounds abnormal	1	0
			Respiratory rate decreased	1	0
			Respiratory rate increased	5	0
	Protein and chemistry analyses NEC	Protein analyses NEC	C-reactive protein increased	2	0
	Renal and urinary tract investigations and urinalyses	Urinary tract function analyses NEC	Urine output decreased	3	0
	Water, electrolyte and mineral investigations	Mineral and electrolyte analyses	Blood magnesium decreased	1	0
	Total			37	0
	Acid-base disorders	Metabolic acidoses (excl diabetic acidoses)	Lactic acidosis	1	0
			Metabolic acidosis	1	0
	Appetite and general nutritional disorders	Appetite disorders	Appetite disorder	1	0
			Decreased appetite	26	0
			Food refusal	2	0
			Hypophagia	2	0
			Increased appetite	1	0
		General nutritional disorders NEC	Feeding disorder	4	0
			Food aversion	1	0
			Poor feeding infant	20	0
			Weight gain poor	1	0
Musculoskeletal and connective tissue disorders	Electrolyte and fluid balance conditions	Fluid intake decreased	Fluid intake reduced	4	0
		Total fluid volume decreased	Dehydration	1	0
	Food intolerance syndromes	Food malabsorption and intolerance syndromes (excl enzyme deficiencies)	Dairy intolerance	1	0
			Food intolerance	3	0
	Total			69	0
	Joint disorders	Joint related disorders NEC	Periarthritis	1	0
			Arthralgia	1	0
			Joint swelling	2	0
	Muscle disorders	Muscle related signs and symptoms NEC	Muscle spasms	5	0
			Muscle tightness	1	0
			Muscle twitching	3	0
		Muscle tone abnormalities	Floppy infant	20	0
			Muscle rigidity	2	0
		Muscle weakness conditions	Muscular weakness	2	0
	Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue conditions NEC	Infantile back arching	4	0
			Limb mass	1	0
			Musculoskeletal stiffness	4	0
			Posture abnormal	1	0
			Weight bearing difficulty	2	0
		Musculoskeletal and connective tissue pain and discomfort	Flank pain	1	0
			Musculoskeletal pain	1	0
			Pain in extremity	10	0
		Soft tissue disorders NEC	Groin pain	1	0
	Total			62	0
Nervous system disorders	Cranial nerve disorders (excl neoplasms)	Eye movement disorders	VIth nerve paralysis	1	0
	Encephalopathies	Encephalopathies NEC	Encephalopathy	1	0
	Headaches	Headaches NEC	Headache	2	0
	Mental impairment disorders	Intellectual disabilities	Intellectual disability	1	0
		Mental impairment (excl dementia and memory loss)	Cognitive disorder	1	0
			Mental impairment	1	0

	Movement disorders (incl parkinsonism)	Dyskinesias and movement disorders NEC	Dyskinesia	8	0	
			Movement disorder	1	0	
			Psychomotor hyperactivity	1	0	
			Paralysis and paresis (excl cranial nerve)	Paralysis	1	0
			Tremor (excl congenital)	Tremor	3	0
	Neurological disorders NEC	Coordination and balance disturbances	Balance disorder	2	0	
			Nystagmus	1	0	
		Cortical dysfunction NEC	Aphasia	1	0	
		Disturbances in consciousness NEC	Depressed level of consciousness	1	0	
			Lethargy	8	0	
			Loss of consciousness	3	0	
			Postictal state	1	0	
			Somnolence	29	0	
			Syncope	4	0	
			Nervous system disorders NEC	Nervous system disorder	1	0
		Neurological signs and symptoms NEC	Dizziness	1	0	
			Fontanelle bulging	1	0	
			Hyporesponsive to stimuli	3	0	
			Infant irritability	1	0	
			Myoclonus	1	0	
			Unresponsive to stimuli	27	0	
		Speech and language abnormalities	Dysarthria	1	0	
			Speech disorder	2	0	
		Neuromuscular disorders	Muscle tone abnormal	Hypotonia	10	0
			Neuromuscular disorders NEC	Hypotonic- hyporesponsive episode	19	0
				Muscle spasticity	1	0
		Seizures (incl subtypes)	Absence seizures	Petit mal epilepsy	4	0
			Generalised tonic-clonic seizures	Generalised tonic- clonic seizure	6	0
	Seizures and seizure disorders NEC		Epilepsy	2	0	
			Epileptic encephalopathy	1	0	
			Febrile convulsion	12	0	
			Infantile spasms	3	0	
			Seizure	21	0	
			Status epilepticus	1	0	
	Sleep disturbances (incl subtypes)	Narcolepsy and hypersomnia	Hypersomnia	1	0	
		Sleep disturbances NEC	Sudden onset of sleep	1	0	
		Total		191	0	
	Pregnancy, puerperium and perinatal conditions	Neonatal and perinatal conditions	Gestational age and weight conditions	Poor weight gain neonatal	1	0
		Total		1	0	
	Product issues	Product quality, supply, distribution, manufacturing and quality system issues	Product quality issues NEC	Product quality issue	5	0
		Total		5	0	
	Psychiatric disorders	Anxiety disorders and symptoms	Anxiety disorders NEC	Separation anxiety disorder	1	0
			Anxiety symptoms	Agitation	5	0
				Anxiety	2	0
Nervousness				1	0	
	Fear symptoms and phobic disorders (incl social phobia)	Phonophobia	1	0		

		Panic attacks and disorders	Panic reaction	1	0
Changes in physical activity		Increased physical activity levels	Restlessness	15	0
		Tic disorders	Tic	2	0
Cognitive and attention disorders and disturbances		Cognitive and attention disorders and disturbances NEC	Daydreaming	1	0
Communication disorders and disturbances		Communications disorders	Communication disorder	1	0
			Mutism	1	0
		Speech articulation and rhythm disturbances	Dysphemia	1	0
Depressed mood disorders and disturbances		Mood alterations with depressive symptoms	Decreased interest	1	0
			Depressed mood	1	0
Developmental disorders NEC		Pervasive developmental disorders NEC	Autism spectrum disorder	2	0
Mood disorders and disturbances NEC		Affect alterations NEC	Flat affect	1	0
			Anger	2	0
			Emotional distress	4	0
			Irritability	43	0
			Mood altered	2	0
		Mood disorders NEC	Listless	2	0
Personality disorders and disturbances in behaviour		Behaviour and socialisation disturbances	Personality change	1	0
			Self-destructive behaviour	1	0
			Social avoidant behaviour	2	0
Psychiatric and behavioural symptoms NEC		Abnormal behaviour NEC	Abnormal behaviour	8	0
			Behaviour disorder	1	0
			Breath holding	3	0
			Staring	4	0
		Psychiatric symptoms NEC	Decreased eye contact	1	0
Sleep disorders and disturbances		Disturbances in initiating and maintaining sleep	Insomnia	9	0
			Middle insomnia	1	0
		Dyssomnias	Poor quality sleep	6	0
		Parasomnias	Sleep terror	1	0
		Sleep disorders NEC	Sleep disorder	7	0
	Total			135	0
Renal and urinary disorders	Renal disorders (excl nephropathies)	Renal failure and impairment	Acute kidney injury	1	0
			Anuria	1	0
				2	0
Reproductive system and breast disorders	Reproductive tract disorders NEC	Reproductive tract disorders NEC (excl neoplasms)	Genital blister	1	0
	Testicular and epididymal disorders	Testicular and epididymal disorders NEC	Testicular pain	1	0
			Testicular swelling	1	0
	Total			3	0
Respiratory, thoracic and mediastinal disorders	Bronchial disorders (excl neoplasms)	Bronchospasm and obstruction	Wheezing	6	0
	Neonatal respiratory disorders	Neonatal hypoxic conditions	Brief resolved unexplained event	1	0
			Infantile apnoea	3	0
			Neonatal hypoxia	1	0
	Respiratory disorders NEC	Breathing abnormalities	Apnoea	13	0
			Dyspnoea	16	0
			Hypopnoea	4	0
			Irregular breathing	1	0
			Respiration abnormal	3	0
			Respiratory arrest	4	0
			Respiratory distress	2	0
			Tachypnoea	1	0

Skin and subcutaneous tissue disorders		Conditions associated with abnormal gas exchange	Cyanosis central	1	0
			Respiratory acidosis	1	0
		Coughing and associated symptoms	Cough	12	0
			Haemoptysis	1	0
			Productive cough	3	0
			Sputum discoloured	1	0
	Respiratory tract signs and symptoms	Lower respiratory tract signs and symptoms	Hiccups	1	0
		Respiratory signs and symptoms NEC	Use of accessory respiratory muscles	1	0
		Upper respiratory tract signs and symptoms	Choking	1	0
			Dysphonia	1	0
			Oropharyngeal pain	2	0
			Rhinorrhoea	4	0
	Upper respiratory tract disorders (excl infections)	Laryngeal spasm, oedema and obstruction	Stridor	1	0
		Nasal disorders NEC	Epistaxis	2	0
	Total			87	0
	Angioedema and urticaria	Urticarias	Urticaria	23	0
			Urticaria chronic	1	0
			Urticaria pressure	1	0
	Epidermal and dermal conditions	Bullous conditions	Blister	4	0
			Dermatitis bullous	1	0
			Pemphigoid	1	0
		Dermal and epidermal conditions NEC	Dry skin	4	0
			Papule	3	0
			Skin burning sensation	1	0
			Skin discolouration	14	0
			Skin disorder	1	0
			Skin induration	2	0
			Skin lesion	1	0
			Skin plaque	1	0
			Skin reaction	2	0
			Skin swelling	2	0
			Skin warm	6	0
			Skin weeping	2	0
		Dermatitis and eczema	Dermatitis	2	0
			Dermatitis allergic	4	0
			Dermatitis atopic	2	0
			Dermatitis diaper	1	0
			Eczema	14	0
			Eczema asteatotic	1	0
			Eczema infantile	1	0
		Dermatitis ascribed to specific agent	Palmar-plantar erythrodysesthesia syndrome	1	0
		Erythemas	Erythema	41	0
		Exfoliative conditions	Skin exfoliation	2	0
		Pruritus NEC	Pruritus	7	0
		Rashes, eruptions and exanthems NEC	Rash	68	0
			Rash erythematous	14	0
			Rash macular	15	0
			Rash papular	7	0
			Rash pruritic	4	0
			Rash vesicular	5	0
	Skin and subcutaneous tissue disorders NEC	Skin and subcutaneous conditions NEC	Skin mass	1	0
		Skin and subcutaneous tissue ulcerations	Skin erosion	1	0
	Skin appendage conditions	Apocrine and eccrine gland disorders	Cold sweat	3	0
			Hyperhidrosis	3	0

	Skin vascular abnormalities	Purpura and related conditions	Petechiae	14	0
		Skin vasomotor conditions	Purpura	2	0
			Livedo reticularis	13	0
			Lividity	1	0
	Total			297	0
Social circumstances	Family issues	Bereavement issues	Death of relative	1	1
	Total			1	1
Surgical and medical procedures	Therapeutic procedures and supportive care NEC	Therapeutic procedures NEC	Injection	1	0
	Total			1	0
Vascular disorders	Arteriosclerosis, stenosis, vascular insufficiency and necrosis	Non-site specific necrosis and vascular insufficiency NEC	Fibromuscular dysplasia	1	0
			Peripheral coldness	5	0
			Poor peripheral circulation	2	0
	Decreased and nonspecific blood pressure disorders and shock	Circulatory collapse and shock	Circulatory collapse	3	0
		Vascular hypotensive disorders	Hypotension	1	0
	Vascular disorders NEC	Peripheral vascular disorders NEC	Cyanosis	12	0
			Flushing	1	0
		Site specific vascular disorders NEC	Pallor	45	0
	Vascular haemorrhagic disorders	Haemorrhages NEC	Haemorrhage	1	0
	Vascular hypertensive disorders	Vascular hypertensive disorders NEC	Hypertension	1	0
	Vascular infections and inflammations	Arterial infections and inflammations	Kawasaki's disease	1	1
	Total			73	1
TOTAL REACTIONS FOR DRUG				1,892	
TOTAL REPORTS				688	
TOTAL FATAL OUTCOME REPORTS					23