

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

Report run: 15/05/2025
Earliest reaction date: 30/09/2004

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
Blood and lymphatic system disorders	Anaemias nonhaemolytic and marrow depression	Anaemias NEC	Anaemia	1	0
	Platelet disorders	Thrombocytopenias	Thrombocytopenia	1	0
	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Lymphadenopathy	3	0
	Total			5	0
Cardiac disorders	Cardiac arrhythmias	Rate and rhythm disorders NEC	Bradycardia	3	0
			Tachycardia	1	0
	Total			4	0
Congenital, familial and genetic disorders	Eye disorders congenital	Lens disorders congenital	Cataract congenital	3	0
	Musculoskeletal and connective tissue disorders congenital	Connective tissue disorders congenital	Hypermobility syndrome	1	0
		Musculoskeletal and connective tissue disorders of limbs congenital	Polydactyly	1	0
			Syndactyly	1	0
	Total			6	0
Ear and labyrinth disorders	Aural disorders NEC	Ear disorders NEC	Ear pain	1	0
	Hearing disorders	Hearing losses	Deafness	1	0
		Hyperacusia	Hyperacusis	1	0
	Inner ear and VIIIth cranial nerve disorders	Inner ear signs and symptoms	Vertigo	2	0
	Total			5	0
Eye disorders	Eye disorders NEC	Lacrimation disorders	Lacrimation increased	1	0
		Ocular disorders NEC	Eye disorder	1	0
			Eye pain	1	0
			Eye swelling	1	0
	Ocular infections, irritations and inflammations	Ocular infections, inflammations and associated manifestations	Eye pruritus	1	0
	Ocular neuromuscular disorders	Ocular nerve and muscle disorders	Eye movement disorder	5	0
			Strabismus	1	0
		Pupil disorders	Mydriasis	1	0
			Pupil fixed	1	0
	Ocular sensory symptoms NEC	Ocular sensation disorders	Hypoaesthesia eye	1	0
	Vision disorders	Visual disorders NEC	Vision blurred	1	0
		Visual impairment and blindness (excl colour blindness)	Visual impairment	1	0
	Total			16	0
Gastrointestinal disorders	Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	10	0
		Gastrointestinal atonic and hypomotility disorders NEC	Constipation	1	0
		Gastrointestinal dyskinetic disorders	Change of bowel habit	1	0
	Gastrointestinal signs and symptoms	Gastrointestinal and abdominal pains (excl oral and throat)	Abdominal pain	2	0
			Abdominal pain upper	4	0
		Gastrointestinal signs and symptoms NEC	Odynophagia	1	0
		Nausea and vomiting symptoms	Nausea	14	0
			Vomiting	36	0
	Oral soft tissue conditions	Oral soft tissue disorders NEC	Oral disorder	1	0
		Oral soft tissue signs and symptoms	Oral discomfort	1	0
			Oral pain	1	0
			Paraesthesia oral	4	0
		Oral soft tissue swelling and oedema	Lip swelling	2	0
	Tongue conditions	Tongue disorders	Tongue ulceration	1	0
		Tongue signs and symptoms	Swollen tongue	1	0
	Total			79	0
General disorders and administration site conditions	Administration site reactions	Administration site reactions NEC	Administration site erythema	1	0
			Administration site rash	1	0
			Administration site swelling	1	0
		Application site reactions	Application site exfoliation	1	0
			Application site swelling	1	0
		Injection site reactions	Injection site bruising	4	0
			Injection site dermatitis	1	0
			Injection site discolouration	5	0
			Injection site discomfort	2	0
			Injection site erythema	82	0
			Injection site induration	15	0
			Injection site inflammation	46	0
			Injection site irritation	3	0
			Injection site joint warmth	1	0
			Injection site mass	9	0
			Injection site oedema	1	0
			Injection site pain	30	0
			Injection site pruritus	11	0
			Injection site rash	6	0
			Injection site reaction	45	0
			Injection site swelling	75	0
			Injection site urticaria	1	0
			Injection site vesicles	10	0
			Injection site warmth	20	0
	Vaccination site reactions	Extensive swelling of vaccinated limb		4	0
		Vaccination site bruising		2	0
		Vaccination site discharge		1	0
		Vaccination site discolouration		1	0
		Vaccination site discomfort		2	0
		Vaccination site erythema		63	0
		Vaccination site induration		2	0
		Vaccination site inflammation		7	0
		Vaccination site irritation		1	0
		Vaccination site joint erythema		2	0
		Vaccination site joint inflammation		1	0

			Vaccination site joint swelling	1	0
			Vaccination site mass	6	0
			Vaccination site pain	17	0
			Vaccination site pruritus	1	0
			Vaccination site rash	7	0
			Vaccination site reaction	8	0
			Vaccination site swelling	53	0
			Vaccination site vesicles	3	0
			Vaccination site warmth	29	0
Body temperature conditions	Febrile disorders	Pyrexia		68	0
Fatal outcomes	Death and sudden death	Death		1	1
General system disorders NEC	Asthenic conditions	Asthenia		1	0
		Fatigue		9	0
		Malaise		18	0
	Feelings and sensations NEC	Chills		3	0
		Feeling cold		1	0
		Feeling drunk		1	0
		Feeling hot		38	0
		Thirst		1	0
	General signs and symptoms NEC	Condition aggravated		1	0
		Crepitations		1	0
		Crying		5	0
		Discharge		1	0
		Disease progression		1	1
		Illness		3	0
		Induration		10	0
		Influenza like illness		1	0
		Local reaction		98	0
		Peripheral swelling		170	0
		Screaming		2	0
		Swelling		84	0
		Swelling face		4	0
	Inflammatons	Inflammation		61	0
	Mucosal findings abnormal	Mucosal disorder		1	0
	Oedema NEC	Localised oedema		1	0
		Oedema		2	0
		Oedema peripheral		5	0
	Pain and discomfort NEC	Chest discomfort		1	0
		Chest pain		2	0
		Discomfort		3	0
		Pain		22	0
		Tenderness		9	0
Therapeutic and nontherapeutic effects (excl toxicity)	Therapeutic and nontherapeutic responses	Adverse drug reaction		1	0
Total				1,210	2
Hepatobiliary disorders	Hepatic and hepatobiliary disorders	Cholestasis and jaundice	Cholestasis	1	0
			Jaundice	1	0
Total				2	0
Immune system disorders	Allergic conditions	Allergic conditions NEC	Hypersensitivity	17	0
			Type IV hypersensitivity reaction	1	0
	Allergies to foods, food additives, drugs and other chemicals	Drug hypersensitivity		1	0
		Milk allergy		1	0
		Reaction to excipient		1	0
	Anaphylactic and anaphylactoid responses	Anaphylactic reaction		7	0
Total				28	0
Infections and infestations	Bacterial infectious disorders	Bacterial infections NEC	Administration site cellulitis	5	0
			Application site cellulitis	1	0
			Cellulitis	53	0
			Injection site cellulitis	8	0
			Vaccination site cellulitis	14	0
	Bordetella infections	Pertussis		1	0
	Corynebacteria infections	Diphtheria		1	0
	Infections - pathogen unspecified	Ear infections	Ear infection	2	0
		Eye and eyelid infections	Conjunctivitis	1	0
		Infections NEC	Infection	4	0
			Injection site infection	2	0
			Localised infection	1	0
			Vaccination site infection	3	0
	Muscle and soft tissue infections	Muscle abscess		1	0
	Sepsis, bacteraemia, viraemia and fungaemia NEC	Sepsis		2	1
	Skin structures and soft tissue infections	Rash pustular		1	0
		Skin infection		1	0
	Upper respiratory tract infections	Nasopharyngitis		3	0
		Rhinitis		1	0
		Tonsillitis		2	0
		Upper respiratory tract infection		1	0
Mycobacterial infectious disorders	Tuberculous infections	Erythema induratum		4	0
Viral infectious disorders	Herpes viral infections	Herpes zoster		1	0
	Influenza viral infections	Influenza		2	0
	Molluscum contagiosum viral infections	Molluscum contagiosum		1	0
	Viral infections NEC	Gastroenteritis viral		1	0
Total				117	1
Injury, poisoning and procedural complications	Exposures, chemical injuries and poisoning	Exposures associated with pregnancy, delivery and lactation	Exposure during pregnancy	16	0
			Foetal exposure during pregnancy	12	0
			Maternal exposure during pregnancy	10	0
	Injuries NEC	Non-site specific injuries NEC	Fall	1	0
			Injury	1	0
	Reproductive system and breast injuries	Perineal injury		2	0
	Skin injuries NEC	Contusion		9	0
		Scar		1	0
		Skin abrasion		1	0

	Medication errors and other product use errors and issues	Medication errors, product use errors and issues NEC	Inadequate aseptic technique in use of product	1	0	
			Medication error	3	0	
			Product use in unapproved indication	3	0	
			Wrong technique in product usage process	3	0	
			Product administration errors and issues	Expired product administered	4	0
				Inappropriate schedule of product administration	8	0
				Product administered to patient of inappropriate age	1	0
				Wrong product administered	6	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		
	Underdoses NEC	Underdose	1	0		
Procedural related injuries and complications NEC	Non-site specific procedural complications	Administration related reaction	1	0		
		Wound dehiscence	1	0		
	Total		87	0		
Investigations	Cardiac and vascular investigations (excl enzyme tests)	Heart rate and pulse investigations	Heart rate decreased	3	0	
			Heart rate irregular	2	0	
			Radial pulse abnormal	1	0	
			Blood pressure decreased	1	0	
	Foetal and neonatal investigations	Foetal and neonatal diagnostic procedures	Foetal monitoring abnormal	1	0	
	Haematology investigations (incl blood groups)	White blood cell analyses	White blood cell count increased	1	0	
	Hepatobiliary investigations	Hepatobiliary function diagnostic procedures	Alanine aminotransferase increased	1	0	
			Liver function test abnormal	1	0	
	Metabolic, nutritional and blood gas investigations	Blood gas and acid base analyses	Oxygen saturation decreased	1	0	
	Physical examination and organ system status topics	Metabolism tests NEC	Urine ketone body present	1	0	
			Body temperature increased	7	0	
			Respiratory rate decreased	1	0	
	Protein and chemistry analyses NEC	Protein analyses NEC	C-reactive protein increased	1	0	
	Renal and urinary tract investigations and urinalyses	Renal function analyses	Blood creatinine increased	1	0	
			Urinalysis NEC	Protein urine present	1	0
	Total		24	0		
Metabolism and nutrition disorders	Acid-base disorders	Metabolic acidoses (excl diabetic acidoses)	Metabolic acidosis	1	0	
	Appetite and general nutritional disorders	Appetite disorders	Decreased appetite	11	0	
		General nutritional disorders NEC	Feeding disorder	1	0	
	Electrolyte and fluid balance conditions	Total fluid volume decreased	Dehydration	1	0	
	Food intolerance syndromes	Food malabsorption and intolerance syndromes (excl sugar intolerance)	Dairy intolerance	1	0	
			Food intolerance	1	0	
	Glucose metabolism disorders (incl diabetes mellitus)	Diabetes mellitus (incl subtypes)	Diabetes mellitus inadequate control	1	0	
		Hypoglycaemic conditions NEC	Hypoglycaemia neonatal	1	0	
	Total		18	0		
Musculoskeletal and connective tissue disorders	Bone disorders (excl congenital and fractures)	Bone related signs and symptoms	Bone pain	1	0	
	Joint disorders	Joint related signs and symptoms	Arthralgia	6	0	
			Joint effusion	1	0	
			Joint stiffness	2	0	
			Joint swelling	1	0	
			Rheumatoid arthropathies	Juvenile idiopathic arthritis	1	0
			Rheumatoid arthritis	1	0	
	Muscle disorders	Muscle infections and inflammations	Myositis	3	0	
		Muscle pains	Myalgia	6	0	
		Muscle related signs and symptoms NEC	Muscle fatigue	1	0	
			Muscle spasms	3	0	
			Muscle swelling	1	0	
			Muscle twitching	3	0	
			Muscle tone abnormalities	Floppy infant	1	0
			Muscle rigidity	3	0	
		Muscle weakness conditions	Muscular weakness	4	0	
	Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue conditions NEC	Mobility decreased	1	0	
			Musculoskeletal stiffness	5	0	
			Weight bearing difficulty	1	0	
		Musculoskeletal and connective tissue pain and discomfort	Back pain	4	0	
			Limb discomfort	2	0	
			Pain in extremity	34	0	
	Total		85	0		
Nervous system disorders	Central nervous system infections and inflammations	Encephalitis NEC	Encephalitis post immunisation	1	0	
		Myelitis (incl infective)	Myelitis transverse	1	0	
	Cranial nerve disorders (excl neoplasms)	Facial cranial nerve disorders	Bell's palsy	1	0	
			Facial paralysis	2	0	
	Headaches	Headaches NEC	Headache	15	0	
			Tension headache	1	0	
			Migraine headaches	2	0	
	Mental impairment disorders	Memory loss (excl dementia)	Memory impairment	1	0	
	Movement disorders (incl parkinsonism)	Dyskinesias and movement disorders NEC	Dyskinesia	3	0	
			Hypokinesia	1	0	
			Movement disorder	1	0	
			Psychomotor hyperactivity	1	0	
		Dystonias	Opisthotonus	1	0	
	Neurological disorders NEC	Tremor (excl congenital)	Tremor	4	0	
		Coordination and balance disturbances	Balance disorder	1	0	
			Coordination abnormal	1	0	
			Hand-eye coordination impaired	1	0	
		Cortical dysfunction NEC	Dyspraxia	1	0	
			Disturbances in consciousness NEC	Depressed level of consciousness	1	0
				Lethargy	2	0

			Loss of consciousness	5	0
			Somnolence	9	0
			Syncope	20	0
		Neurological signs and symptoms NEC	Dizziness	11	0
			Head discomfort	1	0
			Presyncope	3	0
			Unresponsive to stimuli	7	0
			Hypoaesthesia	2	0
		Paraesthesias and dysaesthesias	Paraesthesia	4	0
		Sensory abnormalities NEC	Allodynia	1	0
			Sensory disturbance	1	0
		Speech and language abnormalities	Speech disorder	2	0
	Neuromuscular disorders	Muscle tone abnormal	Hypotonia	12	0
		Neuromuscular disorders NEC	Hypotonic-hyporesponsive episode	2	0
	Peripheral neuropathies	Acute polyneuropathies	Guillain-Barre syndrome	2	0
	Seizures (incl subtypes)	Absence seizures	Petit mal epilepsy	1	0
		Generalised tonic-clonic seizures	Generalised tonic-clonic seizure	2	0
		Seizures and seizure disorders NEC	Epilepsy	1	0
			Febrile convulsion	1	0
			Myoclonic epilepsy	1	0
			Neonatal seizure	1	0
			Partial seizures	1	0
			Seizure	5	0
			Seizure like phenomena	1	0
	Sleep disturbances (incl subtypes)	Narcolepsy and hypersomnia	Hypersomnia	1	0
	Structural brain disorders	Structural brain disorders NEC	Brain injury	1	0
	Total			140	0
Pregnancy, puerperium and perinatal conditions	Abortions and stillbirth	Stillbirth and foetal death	Foetal death	2	2
			Stillbirth	7	7
	Foetal complications	Foetal complications NEC	Foetal distress syndrome	1	0
			Foetal hypokinesia	7	0
	Foetal position and presentation abnormalities	Breech presentation	2	0	
	Maternal complications of labour and delivery	Labour onset and length abnormalities	Premature delivery	2	0
			Premature labour	2	0
			Premature rupture of membranes	1	0
			Prolonged labour	5	0
	Neonatal and perinatal conditions	Neonatal hepatobiliary disorders	Jaundice neonatal	1	0
		Umbilical cord complications	Umbilical cord thrombosis	1	0
	Placental, amniotic and cavity disorders (excl haemorrhages)	Amniotic fluid and cavity disorders of pregnancy NEC	Amniorrhoea	1	0
		Placental abnormalities (excl neoplasms)	Foetal vascular malperfusion	1	0
	Postpartum and puerperal disorders	Postpartum complications NEC	Postpartum haemorrhage	3	0
	Pregnancy, labour, delivery and postpartum conditions	Normal pregnancy, labour and delivery	Pregnancy	1	0
	Total			37	9
Psychiatric disorders	Anxiety disorders and symptoms	Anxiety symptoms	Anxiety	3	0
		Obsessive-compulsive disorders and symptoms	Obsessive-compulsive symptom	1	0
	Cognitive and attention disorders and disturbances	Attention deficit and disruptive behaviour disorders	Attention deficit hyperactivity disorder	1	0
	Communication disorders and disturbances	Speech and language usage disturbances	Disorganised speech	1	0
	Deliria (incl confusion)	Confusion and disorientation	Confusional state	1	0
	Developmental disorders NEC	Pervasive developmental disorders NEC	Autism spectrum disorder	7	0
	Disturbances in thinking and perception	Hallucinations (excl sleep-related)	Hallucination	1	0
			Hallucination, visual	1	0
	Eating disorders and disturbances	Eating disorders NEC	Eating disorder	1	0
	Mood disorders and disturbances NEC	Emotional and mood disturbances NEC	Anger	1	0
			Emotional distress	1	0
			Irritability	4	0
			Mood altered	1	0
		Fluctuating mood symptoms	Mood swings	1	0
		Mood disorders NEC	Apathy	1	0
			Listless	2	0
	Personality disorders and disturbances in behaviour	Behaviour and socialisation disturbances	Aggression	1	0
			Attention-seeking behaviour	1	0
	Psychiatric and behavioural symptoms NEC	Abnormal behaviour NEC	Abnormal behaviour	4	0
			Regressive behaviour	1	0
			Staring	3	0
	Sleep disorders and disturbances	Disturbances in initiating and maintaining sleep	Insomnia	1	0
		Sleep disorders NEC	Sleep disorder	1	0
	Total			40	0
Renal and urinary disorders	Renal disorders (excl nephropathies)	Renal disorders NEC	Renal disorder	1	0
		Renal failure and impairment	Renal impairment	1	0
		Renal obstructive disorders	Hydronephrosis	1	0
		Renal structural abnormalities and trauma	Pyelocaliectasis	1	0
	Urinary tract signs and symptoms	Bladder and urethral symptoms	Urinary incontinence	3	0
			Urinary retention	1	0
	Total			8	0
Reproductive system and breast disorders	Penile and scrotal disorders (excl infections and inflammations)	Penile disorders NEC (excl erection and ejaculation)	Penile swelling	1	0
	Vulvovaginal disorders (excl infections and inflammations)	Vulvovaginal disorders NEC	Vaginal haemorrhage	4	0
	Total			5	0
Respiratory, thoracic and mediastinal disorders	Bronchial disorders (excl neoplasms)	Bronchospasm and obstruction	Wheezing	2	0
	Respiratory disorders NEC	Breathing abnormalities	Dyspnoea	6	0
			Respiration abnormal	1	0
			Respiratory depression	1	0
			Respiratory distress	1	0
			Conditions associated with abnormal gas exchange	Hypoxia	1
		Coughing and associated symptoms	Cough	15	0
	Respiratory tract signs and symptoms	Upper respiratory tract signs and symptoms	Oropharyngeal pain	4	0
			Rhinorrhoea	1	0
			Snoring	1	0
	Upper respiratory tract disorders (excl infections)	Nasal congestion and inflammations	Nasal congestion	2	0
		Nasal disorders NEC	Epistaxis	1	0

			Nasal pruritus	1	0
	Total			37	0
Skin and subcutaneous tissue disorders	Angioedema and urticaria	Angioedemas	Angioedema	1	0
		Urticarias	Urticaria	22	0
	Epidermal and dermal conditions	Bullous conditions	Blister	26	0
			Dermatitis bullous	1	0
			Erythema multiforme	2	0
		Dermal and epidermal conditions NEC	Dry skin	1	0
			Papule	1	0
			Skin discolouration	3	0
			Skin induration	2	0
			Skin lesion	3	0
			Skin reaction	10	0
			Skin texture abnormal	1	0
			Skin warm	15	0
		Dermatitis and eczema	Dermatitis	2	0
			Dermatitis allergic	3	0
			Eczema	4	0
			Skin irritation	3	0
		Erythemas	Erythema	218	0
		Exfoliative conditions	Skin exfoliation	1	0
		Photosensitivity and photodermatosis conditions	Photosensitivity reaction	1	0
		Pruritus NEC	Pruritus	39	0
		Rashes, eruptions and exanthems NEC	Rash	22	0
			Rash erythematous	9	0
			Rash macular	2	0
			Rash maculo-papular	1	0
			Rash morbilliform	1	0
			Rash pruritic	6	0
	Skin appendage conditions	Apocrine and eccrine gland disorders	Cold sweat	7	0
			Hyperhidrosis	2	0
		Nail and nail bed conditions (excl infections and infestations)	Nail discolouration	1	0
	Skin vascular abnormalities	Skin vascular conditions NEC	Skin oedema	1	0
	Total			407	0
Social circumstances	Lifestyle issues	Disability issues	Disability	1	0
			Immobile	1	0
		Social issues NEC	Impaired quality of life	1	0
	Total			3	0
Surgical and medical procedures	Nervous system, skull and spine therapeutic procedures	Nervous system therapeutic procedures NEC	Speech-language therapy	1	0
	Obstetric and gynaecological therapeutic procedures	Obstetric therapeutic procedures	Caesarean section	6	0
			Vacuum extractor delivery	1	0
	Therapeutic procedures and supportive care NEC	Therapeutic procedures NEC	Hospitalisation	1	0
	Total			9	0
Vascular disorders	Arteriosclerosis, stenosis, vascular insufficiency and necrosis	Peripheral vasoconstriction, necrosis and vascular insufficiency	Peripheral coldness	2	0
			Poor peripheral circulation	1	0
	Decreased and nonspecific blood pressure disorders and shock	Circulatory collapse and shock	Shock	1	0
			Hypotension	1	0
	Vascular disorders NEC	Non-site specific vascular disorders NEC	Hyperaemia	1	0
			Cyanosis	9	0
		Peripheral vascular disorders NEC	Flushing	3	0
			Pallor	24	0
	Vascular haemorrhagic disorders	Haemorrhages NEC	Haematoma	1	0
	Vascular hypertensive disorders	Vascular hypertensive disorders NEC	Hypertension	2	0
	Vascular infections and inflammations	Arterial infections and inflammations	Kawasaki's disease	1	0
	Total			46	0
TOTAL REACTIONS FOR DRUG				2,426	
TOTAL REPORTS				1,036	
TOTAL FATAL OUTCOME REPORTS					12