

Proquad Vaccine Analysis Print.

All UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with the Proquad vaccine from the 1st January 2026 up to and including 4th September 2026.

Report run: 4th September 2026

Earliest reaction date: 7th January 2026

Reaction MedDRA SOC Name	Reaction MedDRA HLT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
Eye disorders	Eye disorders NEC	Ocular disorders NEC	Eye pain	1	0
			Eye swelling	1	0
	Ocular infections, irritations and inflammations	Iris and uveal tract infections, irritations and inflammations	Uveitis	1	0
	Vision disorders	Visual impairment and blindness (excl colour blindness)	Blindness	1	0
	Total			4	0
Gastrointestinal disorders	Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	4	0
	Gastrointestinal signs and symptoms	Nausea and vomiting symptoms	Vomiting	10	0
	Oral soft tissue conditions	Oral soft tissue swelling and oedema	Lip swelling	1	0
	Total			15	0
General disorders and administration site conditions	Administration site reactions	Injection site reactions	Injection site discharge	1	0
			Injection site erythema	3	0
			Injection site swelling	1	0
		Vaccination site reactions	Vaccination site erythema	1	0
			Vaccination site rash	1	0
			Vaccination site swelling	2	0
			Vaccination site vesicles	1	0
	Body temperature conditions	Febrile disorders	Pyrexia	8	0
	General system disorders NEC	Asthenic conditions	Fatigue	1	0
		General signs and symptoms NEC	Crying	1	0
			Induration	1	0
			Local reaction	1	0
			Peripheral swelling	2	0
			Swelling	2	0
		Inflammations	Inflammation	1	0
		Pain and discomfort NEC	Pain	1	0
			Tenderness	1	0
	Total			29	0
Immune system disorders	Allergic conditions	Anaphylactic and anaphylactoid responses	Anaphylactic reaction	1	0
	Total			1	0
Infections and infestations	Bacterial infectious disorders	Bacterial infections NEC	Arthritis bacterial	1	0
			Cellulitis	4	0

	Infections - pathogen unspecified	Bone and joint infections	Osteomyelitis	1	0
		Ear infections	Ear infection	1	0
		Infections NEC	Infection	1	0
			Injection site infection	1	0
		Skin structures and soft tissue infections	Rash pustular	1	0
	Viral infectious disorders	Herpes viral infections	Oral herpes	1	0
			Varicella	1	0
			Varicella zoster virus infection	1	0
	Total			13	0
	Injury, poisoning and procedural complications	Exposures, chemical injuries and poisoning	Occupational exposures	Occupational exposure to product	2
Pathways and sources of exposure			Exposure via eye contact	1	0
			Exposure via skin contact	1	0
Injuries NEC		Cranial nerve injuries	Optic nerve injury	1	0
		Eye injuries NEC	Injury corneal	1	0
		Non-site specific injuries NEC	Fall	1	0
		Skin injuries NEC	Contusion	1	0
Medication errors and other product use errors and issues		Accidental exposures to product	Accidental exposure to product	3	0
		Medication errors, product use errors and issues NEC	Poor quality device used	1	0
		Product administration errors and issues	Accidental underdose	1	0
Overdoses and underdoses NEC		Overdoses NEC	Overdose	1	0
Total			14	0	
Investigations	Physical examination and organ system status topics	Physical examination procedures and organ system status	Body temperature increased	1	0
			Skin temperature	1	0
	Total			2	0
Metabolism and nutrition disorders	Appetite and general nutritional disorders	Appetite disorders	Decreased appetite	2	0
		General nutritional disorders NEC	Feeding disorder	1	0
			Poor feeding infant	1	0
	Total			4	0
Musculoskeletal and connective tissue disorders	Muscle disorders	Muscle infections and inflammations	Myositis	1	0
	Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue conditions NEC	Musculoskeletal stiffness	1	0
	Total			2	0
Nervous system disorders	Headaches	Headaches NEC	Headache	1	0
	Movement disorders (incl parkinsonism)	Tremor (excl congenital)	Tremor	1	0
	Neurological disorders NEC	Disturbances in consciousness NEC	Loss of consciousness	1	0
			Syncope	2	0
		Neurological signs and symptoms NEC	Unresponsive to stimuli	1	0

		Sensory abnormalities NEC	Dysgeusia	1	0
	Seizures (incl subtypes)	Seizures and seizure disorders NEC	Febrile convulsion	3	0
			Seizure	1	0
	Total			11	0
Product issues	Device issues	Device issues NEC	Device connection issue	4	0
			Device leakage	4	0
	Product quality, supply, distribution, manufacturing and quality system issues	Product quality issues NEC	Product design issue	2	0
	Total			10	0
Psychiatric disorders	Anxiety disorders and symptoms	Anxiety symptoms	Stress	1	0
	Deliria (incl confusion)	Confusion and disorientation	Disorientation	1	0
	Mood disorders and disturbances NEC	Emotional and mood disturbances NEC	Emotional distress	2	0
			Irritability	1	0
	Sleep disorders and disturbances	Dyssomnias	Poor quality sleep	1	0
	Total			6	0
Respiratory, thoracic and mediastinal disorders	Respiratory disorders NEC	Coughing and associated symptoms	Cough	1	0
	Total			1	0
Skin and subcutaneous tissue disorders	Angioedema and urticaria	Urticarias	Urticaria	4	0
	Epidermal and dermal conditions	Bullous conditions	Blister	1	0
			Erythema multiforme	1	0
		Erythemas	Erythema	7	0
		Pruritus NEC	Pruritus	1	0
		Rashes, eruptions and exanthems NEC	Rash	10	0
			Rash erythematous	3	0
			Rash morbilliform	1	0
			Rash vesicular	3	0
	Total			31	0
Vascular disorders	Decreased and nonspecific blood pressure disorders and shock	Circulatory collapse and shock	Neurogenic shock	1	0
	Vascular disorders NEC	Peripheral vascular disorders NEC	Cyanosis	2	0
			Flushing	1	0
		Site specific vascular disorders NEC	Pallor	3	0
	Total			7	0
TOTAL REACTIONS FOR DRUG				150	
TOTAL REPORTS				63	
TOTAL FATAL OUTCOME REPORTS				0	