

FOI 2025/00385 - Rotarix Rotavirus Vaccine Analysis Print.

All UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with the Rotarix Rotavirus vaccine up to and including 14/05/2025.

Report run: 15/05/2025

Earliest reaction date: 20/06/2008

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	Anaemias NEC	Anaemia	1	0
		Marrow depression and hypoplastic anaemias	Myelosuppression	1	0
	Haematological disorders NEC	Haematological disorders	Mastocytosis	1	0
	Platelet disorders	Thrombocytopenias	Immune thrombocytopenia	2	0
			Thrombocytopenia	3	0
	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Lymphadenitis	1	0
			Lymphadenopathy	1	0
	White blood cell disorders	Leukocytoses NEC	Lymphocytic infiltration	1	0
		Neutropenias	Neutropenia	1	0
	Total			12	0
Cardiac disorders	Cardiac arrhythmias	Rate and rhythm disorders NEC	Bradycardia	5	0
			Bradycardia neonatal	1	0
			Tachycardia	8	0
		Supraventricular arrhythmias	Supraventricular tachycardia	1	0
		Ventricular arrhythmias and cardiac arrest	Cardiac arrest	5	2
			Cardiac arrest neonatal	2	2
			Cardio-respiratory arrest	4	1
			Ventricular fibrillation	1	0
	Cardiac disorders, signs and symptoms NEC	Cardiac disorders NEC	Cardiovascular disorder	1	0
	Pericardial disorders	Pericardial disorders NEC	Pericardial effusion	1	0
			Pericardial haemorrhage	1	0
	Total			30	5
Congenital, familial and genetic disorders	Immune system disorders congenital	Immune system abnormalities congenital	Omenn syndrome	2	0

	Skin and subcutaneous tissue disorders congenital	Skin and subcutaneous tissue disorders congenital NEC	Acrodermatitis enteropathica	1	0
	Total			3	0
Ear and labyrinth disorders	Aural disorders NEC	Ear disorders NEC	Ear pain	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	Anterior eye structural change, deposit and degeneration	Cataract conditions	Cataract	1	0
	Eye disorders NEC	Ocular disorders NEC	Eye oedema	1	0
			Eye swelling	2	0
			Periorbital oedema	1	0
	Ocular haemorrhages and vascular disorders NEC	Ocular bleeding and vascular disorders NEC	Eye haemorrhage	1	0
	Ocular infections, irritations and inflammations	Lid, lash and lacrimal infections, irritations and inflammations	Swelling of eyelid	1	0
		Ocular infections, inflammations and associated manifestations	Ocular hyperaemia	3	0
	Ocular neuromuscular disorders	Ocular nerve and muscle disorders	Eye movement disorder	5	0
			Strabismus	1	0
		Pupil disorders	Miosis	1	0
			Mydriasis	2	0
	Vision disorders	Visual impairment and blindness (excl colour blindness)	Cortical visual impairment	1	0
			Visual impairment	1	0
	Total			21	0
Gastrointestinal disorders	Abdominal hernias and other abdominal wall conditions	Abdominal hernias NEC	Abdominal hernia	1	0
	Anal and rectal conditions NEC	Anal and rectal disorders NEC	Anal fissure	2	0
			Rectal discharge	1	0
		Anal and rectal signs and symptoms	Rectal tenesmus	3	0

Dental and gingival conditions	Gingival disorders, signs and symptoms NEC	Gingival swelling	1	0
		Noninfective gingivitis	1	0
Gastrointestinal conditions NEC	Gastrointestinal disorders NEC	Gastrointestinal disorder	9	0
Gastrointestinal haemorrhages NEC	Intestinal haemorrhages	Rectal haemorrhage	15	0
		Haematemesis	4	0
	Non-site specific gastrointestinal haemorrhages	Haematochezia	115	0
		Melaena	3	0
Gastrointestinal inflammatory conditions	Colitis (excl infective)	Allergic colitis	1	0
		Colitis	1	0
		Necrotising colitis	4	2
	Gastritis (excl infective)	Gastritis	1	0
		Reflux gastritis	2	0
	Gastrointestinal inflammatory disorders NEC	Enterocolitis	2	0
		Gastrointestinal inflammation	1	0
		Gastrointestinal tract irritation	2	0
		Necrotising enterocolitis neonatal	3	1
	Oesophagitis (excl infective)	Eosinophilic oesophagitis	1	0
		Oesophagitis	1	0
Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	365	0
		Diarrhoea haemorrhagic	13	0
		Infantile diarrhoea	1	0
	Gastrointestinal atonic and hypomotility disorders NEC	Constipation	62	0
		Duodenogastric reflux	1	0
		Gastrooesophageal reflux disease	27	0
		Infrequent bowel movements	4	0
		Intestinal dilatation	3	0
	Gastrointestinal dyskinetic disorders	Bowel movement irregularity	8	0
		Change of bowel habit	5	0
		Dyschezia	4	0
		Gastrointestinal motility disorder	4	0
		Infant dyschezia	1	0

	Gastrointestinal spastic and hypermotility disorders	Frequent bowel movements	12	0
Gastrointestinal signs and symptoms	Abdominal findings abnormal	Gastrointestinal sounds abnormal	5	0
	Dyspeptic signs and symptoms	Dyspepsia	3	0
		Epigastric discomfort	2	0
		Eructation	1	0
	Faecal abnormalities NEC	Abnormal faeces	28	0
		Faecaloma	1	0
		Faeces discoloured	39	0
		Faeces hard	1	0
		Faeces soft	1	0
		Mucous stools	52	0
	Flatulence, bloating and distension	Abdominal distension	26	0
		Aerophagia	1	0
		Flatulence	73	0
	Gastrointestinal and abdominal pains (excl oral and throat)	Abdominal pain	95	0
		Abdominal pain lower	1	0
		Abdominal pain upper	76	0
		Abdominal rigidity	3	0
		Abdominal tenderness	3	0
		Gastrointestinal pain	3	0
		Infantile colic	1	0
	Gastrointestinal signs and symptoms NEC	Abdominal discomfort	30	0
		Dysphagia	3	0
	Nausea and vomiting symptoms	Discoloured vomit	1	0
		Infantile spitting up	5	0
		Infantile vomiting	5	0
		Nausea	5	0
		Regurgitation	8	0
		Retching	25	0
		Vomiting	224	0
		Vomiting projectile	32	0
Gastrointestinal stenosis and obstruction	Gastrointestinal stenosis and obstruction NEC	Intestinal obstruction	1	0
		Intussusception	57	0
		Volvulus	1	0
Gastrointestinal vascular conditions	Gastrointestinal necrosis and gangrene (excl gangrenous hernia)	Gastrointestinal necrosis	2	0

		Gastrointestinal vascular occlusion and infarction	Intestinal ischaemia	1	0	
	Oral soft tissue conditions	Oral soft tissue disorders NEC	Lip blister	1	0	
		Oral soft tissue signs and symptoms	Lip discolouration	1	0	
			Lip erythema	1	0	
			Oral discomfort	1	0	
			Oral mucosal blistering	1	0	
			Oral mucosal discolouration	1	0	
		Oral soft tissue swelling and oedema	Lip swelling	5	0	
		Stomatitis and ulceration	Stomatitis	2	0	
	Salivary gland conditions	Oral dryness and saliva altered	Salivary hypersecretion	2	0	
		Salivary gland enlargements	Salivary gland enlargement	1	0	
	Tongue conditions	Tongue signs and symptoms	Swollen tongue	5	0	
			Tongue discomfort	1	0	
			Tongue movement disturbance	1	0	
	Total				1,522	3
	General disorders and administration site conditions	Administration site reactions	Application site reactions	Application site irritation	1	0
			Injection site reactions	Injection site erythema	3	0
Injection site swelling				1	0	
Injection site vesicles				1	0	
Vaccination site reactions			Vaccination site bruising	1	0	
			Vaccination site erythema	2	0	
			Vaccination site granuloma	1	0	
			Vaccination site haematoma	1	0	
			Vaccination site mass	7	0	
			Vaccination site pain	1	0	
			Vaccination site rash	1	0	
			Vaccination site reaction	1	0	

		Vaccination site scar	1	0
		Vaccination site swelling	3	0
Body temperature conditions	Body temperature altered	Hyperthermia	1	0
		Hypothermia	1	0
	Febrile disorders	Pyrexia	153	0
Fatal outcomes	Death and sudden death	Death	10	9
		Sudden death	3	3
		Sudden infant death syndrome	5	5
General system disorders NEC	Asthenic conditions	Asthenia	5	0
		Decreased activity	1	0
		Fatigue	8	0
		Malaise	46	0
	Feelings and sensations NEC	Chills	5	0
		Feeling abnormal	7	0
		Feeling cold	2	0
		Feeling hot	5	0
	Gait disturbances	Gait disturbance	2	0
		Gait inability	1	0
	General signs and symptoms NEC	Condition aggravated	7	0
		Crying	121	0
		Developmental delay	1	0
		Discharge	1	0
		Foaming at mouth	1	0
		General physical health deterioration	2	0
		Glassy eyes	2	0
		High-pitched crying	11	0
		Illness	24	0
		Induration	2	0
		Irritability postvaccinal	3	0
		Moaning	1	0
		Multiple organ dysfunction syndrome	1	0
		Peripheral swelling	9	0
		Screaming	53	0
		Secretion discharge	4	0
		Swelling	1	0
		Swelling face	5	0
	Inflammations	Inflammation	1	0
	Oedema NEC	Oedema	1	0
		Oedema peripheral	2	0
	Pain and	Chest pain	1	0

		discomfort NEC	Discomfort	23	0
			Pain	46	0
			Tenderness	1	0
	Therapeutic and nontherapeutic effects (excl toxicity)	Therapeutic and nontherapeutic responses	Vaccination failure	5	0
	Total			609	17
Hepatobiliary disorders	Hepatic and hepatobiliary disorders	Cholestasis and jaundice	Jaundice	1	0
		Hepatobiliary signs and symptoms	Hepatosplenomegaly	2	0
	Total			3	0
Immune system disorders	Allergic conditions	Allergic conditions NEC	Hypersensitivity	10	0
			Multiple allergies	1	0
		Allergies to foods, food additives, drugs and other chemicals	Allergy to vaccine	2	0
			Food allergy	4	0
			Milk allergy	9	0
			Reaction to excipient	2	0
		Anaphylactic and anaphylactoid responses	Anaphylactic reaction	20	0
			Anaphylactic shock	1	0
		Atopic disorders	Atopy	1	0
	Immune disorders NEC	Immune and associated conditions NEC	Graft versus host disease	1	0
			Haemophagocytic lymphohistiocytosis	1	1
			Immune system disorder	1	0
	Immunodeficiency syndromes	Immunodeficiency disorders NEC	Hypogammaglobulin aemia	1	0
			Immunodeficiency	2	0
	Total			56	1
Infections and infestations	Ancillary infectious topics	Infectious transmissions	Infection via vaccinee	20	0
			Secondary transmission	1	0
	Bacterial infectious disorders	Bacterial infections NEC	Meningitis bacterial	2	0
			Skin bacterial infection	1	0
		Bordetella infections	Pertussis	1	0
		Salmonella infections	Salmonellosis	1	0
		Streptococcal infections	Toxic shock syndrome streptococcal	1	0
	Fungal infectious disorders	Candida infections	Oral candidiasis	3	0
		Pneumocystis infections	Pneumocystis jirovecii infection	1	0

Infections - pathogen unspecified	Abdominal and gastrointestinal infections	Diarrhoea infectious	1	0		
		Gastroenteritis	5	0		
		Peritonitis	1	0		
	Central nervous system and spinal infections	Meningitis	4	0		
		Meningitis aseptic	6	0		
	Ear infections	Ear infection	1	0		
		Otitis media	1	0		
	Infections NEC	Abscess	1	0		
		Infection	2	0		
	Lower respiratory tract and lung infections	Bronchitis	1	0		
		Lower respiratory tract infection	3	0		
		Pneumonia	1	0		
		Pneumonia aspiration	1	0		
	Sepsis, bacteraemia, viraemia and fungaemia NEC	Sepsis	8	0		
	Skin structures and soft tissue infections	Eczema infected	1	0		
		Skin infection	1	0		
	Upper respiratory tract infections	Croup infectious	1	0		
		Nasopharyngitis	1	0		
		Rhinitis	1	0		
	Urinary tract infections	Kidney infection	2	0		
		Urinary tract infection	4	0		
	Viral infectious disorders	Enteroviral infections NEC	Meningitis enteroviral	2	0	
		Influenza viral infections	Influenza	1	0	
		Rotaviral infections	Gastroenteritis rotavirus	10	0	
			Rotavirus infection	21	0	
		Viral infections NEC	Bronchiolitis	4	0	
			Gastritis viral	1	0	
			Gastroenteritis viral	3	0	
	Viral infection		3	0		
	Total			123	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	1	0
				Maternal exposure during breast feeding	1	0

		Exposures to agents or circumstances NEC	Exposure to vaccinated person	1	0
Injuries NEC	Non-site specific injuries NEC		Fall	1	0
			Wound secretion	1	0
	Skin injuries NEC		Contusion	10	0
			Scratch	1	0
			Skin abrasion	1	0
			Skin injury	1	0
Medication errors and other product use errors and issues	Accidental exposures to product		Accidental exposure to product	1	0
	Medication errors, product use errors and issues NEC		Medication error	3	0
	Product administration errors and issues		Accidental underdose	10	0
			Extra dose administered	4	0
			Inappropriate schedule of product administration	4	0
			Incomplete course of vaccination	1	0
			Incorrect route of product administration	1	0
			Product administered to patient of inappropriate age	4	0
			Wrong product administered	2	0
	Product preparation errors and issues		Product preparation issue	1	0
	Product prescribing errors and issues		Product prescribing error	1	0
	Product storage errors and issues in the product use system		Product storage error	3	0
Overdoses and underdoses NEC	Underdoses NEC		Underdose	2	0
	Total			56	0
Investigations	Cardiac and vascular investigations (excl enzyme tests)	Cardiac auscultatory investigations	Cardiac murmur	1	0

	Heart rate and pulse investigations	Heart rate decreased	1	0
		Heart rate increased	7	0
		Heart rate irregular	2	0
		Pulse abnormal	1	0
	Vascular tests NEC (incl blood pressure)	Capillary nail refill test abnormal	1	0
Enzyme investigations NEC	Tissue enzyme analyses NEC	Blood alkaline phosphatase increased	1	0
Haematology investigations (incl blood groups)	Red blood cell analyses	Haemoglobin decreased	1	0
		Lymphocyte count increased	1	0
		Neutrophil count decreased	1	0
		White blood cell count increased	3	0
Hepatobiliary investigations	Hepatobiliary function diagnostic procedures	Alanine aminotransferase increased	1	0
		Bilirubin conjugated increased	1	0
		Blood bilirubin increased	1	0
Metabolic, nutritional and blood gas investigations	Blood gas and acid base analyses	Oxygen saturation decreased	11	0
Microbiology and serology investigations	Bacteria identification and serology (excl mycobacteria)	Bacterial test positive	1	0
	Virus identification and serology	Rotavirus test positive	4	0
Neurological, special senses and psychiatric investigations	Cerebrospinal fluid tests (excl microbiology)	CSF white blood cell count increased	1	0
Physical examination and organ system status topics	Physical examination procedures and organ system status	Body temperature abnormal	4	0
		Body temperature decreased	1	0
		Body temperature fluctuation	3	0
		Body temperature increased	23	0

Metabolism and nutrition disorders			Breath sounds abnormal	1	0
			Respiratory rate decreased	3	0
			Respiratory rate increased	7	0
			Weight decreased	9	0
	Protein and chemistry analyses NEC	Chemistry analyses NEC	Inflammatory marker increased	1	0
		Protein analyses NEC	C-reactive protein increased	10	0
	Renal and urinary tract investigations and urinalyses	Urinalysis NEC	Blood urine present	1	0
			White blood cells urine	1	0
		Urinary tract function analyses NEC	Urine output decreased	2	0
	Respiratory and pulmonary investigations (excl blood gases)	Respiratory tract and thoracic imaging procedures	Chest X-ray abnormal	1	0
	Total			107	0
	Acid-base disorders	Metabolic acidoses (excl diabetic acidoses)	Metabolic acidosis	2	0
	Appetite and general nutritional disorders	Appetite disorders	Appetite disorder	3	0
			Decreased appetite	34	0
			Food refusal	3	0
			Hypophagia	6	0
		General nutritional disorders NEC	Abnormal loss of weight	5	0
			Failure to thrive	3	0
			Feeding disorder	9	0
			Food aversion	3	0
			Poor feeding infant	44	0
			Weight gain poor	6	0
	Electrolyte and fluid balance conditions	Fluid intake decreased	Fluid intake reduced	4	0
		Potassium imbalance	Hyperkalaemia	1	0
		Total fluid volume decreased	Dehydration	9	0
	Food intolerance syndromes	Food malabsorption and intolerance syndromes (excl sugar intolerance)	Dairy intolerance	7	0
			Food intolerance	2	0
			Milk soy protein intolerance	1	0

Musculoskeletal and connective tissue disorders		Sugar intolerance (excl glucose intolerance)	Lactose intolerance	14	0
	Iron and trace metal metabolism disorders	Zinc disorders	Zinc deficiency	1	0
	Total			157	0
	Joint disorders	Joint related signs and symptoms	Arthralgia	1	0
	Muscle disorders	Muscle pains	Myalgia	1	0
		Muscle related signs and symptoms NEC	Muscle spasms	4	0
			Muscle twitching	4	0
		Muscle tone abnormalities	Floppy infant	39	0
			Muscle rigidity	1	0
			Trismus	1	0
	Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue conditions NEC	Chest wall mass	1	0
			Infantile back arching	5	0
			Musculoskeletal stiffness	5	0
			Posture abnormal	1	0
		Musculoskeletal and connective tissue pain and discomfort	Limb discomfort	1	0
			Musculoskeletal pain	1	0
			Pain in extremity	4	0
	Total			69	0
Nervous system disorders	Cranial nerve disorders (excl neoplasms)	Eye movement disorders	Vlth nerve paralysis	1	0
	Encephalopathies	Encephalopathies toxic and metabolic	Metabolic encephalopathy	1	0
	Headaches	Headaches NEC	Headache	1	0
	Mental impairment disorders	Mental impairment (excl dementia and memory loss)	Disturbance in attention	2	0
	Movement disorders (incl parkinsonism)	Dyskinesias and movement disorders NEC	Dyskinesia	8	0
			Movement disorder	2	0
		Dystonias	Opisthotonus	2	0
		Tremor (excl congenital)	Tremor	5	0
	Neurological disorders NEC	Coordination and balance disturbances	Developmental coordination disorder	1	0
		Cortical dysfunction NEC	Sensory processing disorder	1	0

	Disturbances in consciousness NEC	Depressed level of consciousness	5	0
		Lethargy	21	0
		Loss of consciousness	10	0
		Somnolence	45	0
		Syncope	7	0
	Nervous system disorders NEC	Nervous system disorder	2	0
	Neurological signs and symptoms NEC	Drizzling	1	0
		Exaggerated startle response	1	0
		Fontanelle bulging	2	0
		Fontanelle depressed	2	0
		Hyporesponsive to stimuli	2	0
		Infant irritability	2	0
		Myoclonus	1	0
		Neurological decompensation	1	0
		Neurological symptom	1	0
		Pleocytosis	2	0
		Slow response to stimuli	1	0
		Unresponsive to stimuli	56	0
	Speech and language abnormalities	Speech disorder	3	0
Neuromuscular disorders	Autonomic nervous system disorders	Autonomic nervous system imbalance	1	0
	Muscle tone abnormal	Hypotonia	37	0
	Neuromuscular disorders NEC	Hypotonic-hyporesponsive episode	7	0
Seizures (incl subtypes)	Absence seizures	Petit mal epilepsy	2	0
	Generalised tonic-clonic seizures	Generalised tonic-clonic seizure	5	0
	Partial simple seizures NEC	Autonomic seizure	1	0
	Seizures and seizure disorders NEC	Epilepsy	4	0
		Febrile convulsion	9	0
		Infantile spasms	3	0
		Partial seizures	3	0
		Seizure	23	0

			Seizure cluster	1	0
			Seizure like phenomena	2	0
			Status epilepticus	1	0
	Sleep disturbances (incl subtypes)	Narcolepsy and hypersomnia	Hypersomnia	5	0
		Sleep disturbances NEC	Sudden onset of sleep	1	0
	Total			294	0
Pregnancy, puerperium and perinatal conditions	Foetal complications	Foetal growth complications	Foetal growth restriction	1	0
	Neonatal and perinatal conditions	Neonatal metabolic and endocrine disorders	Hypothermia neonatal	1	0
		Newborn complications NEC	Neonatal disorder	1	0
	Total			3	0
Product issues	Product quality, supply, distribution, manufacturing and quality system issues	Product physical issues	Liquid product physical issue	1	0
		Product quality issues NEC	Product quality issue	22	0
	Total			23	0
Psychiatric disorders	Anxiety disorders and symptoms	Anxiety symptoms	Agitation	7	0
			Anxiety	1	0
			Stress	1	0
		Panic attacks and disorders	Panic attack	1	0
			Panic reaction	1	0
	Changes in physical activity	Increased physical activity levels	Restlessness	29	0
	Communication disorders and disturbances	Communications disorders	Communication disorder	1	0
	Depressed mood disorders and disturbances	Mood alterations with depressive symptoms	Depressed mood	3	0
	Developmental disorders NEC	Pervasive developmental disorders NEC	Autism spectrum disorder	4	0
	Disturbances in thinking and perception	Hallucinations (excl sleep-related)	Hallucination	1	0
			Hallucinations, mixed	1	0
	Eating disorders and disturbances	Eating disorders NEC	Selective eating disorder	8	0
	Mood disorders and disturbances NEC	Emotional and mood	Emotional disorder	2	0

		disturbances NEC	Emotional distress	12	0
			Irritability	74	0
			Mood altered	1	0
		Mood disorders NEC	Apathy	1	0
			Listless	5	0
	Personality disorders and disturbances in behaviour	Behaviour and socialisation disturbances	Personality change	1	0
			Social avoidant behaviour	2	0
	Psychiatric and behavioural symptoms NEC	Abnormal behaviour NEC	Abnormal behaviour	15	0
			Breath holding	7	0
			Regressive behaviour	2	0
			Staring	4	0
		Psychiatric symptoms NEC	Decreased eye contact	1	0
	Sleep disorders and disturbances	Disturbances in initiating and maintaining sleep	Insomnia	10	0
		Dyssomnias	Poor quality sleep	7	0
		Parasomnias	Sleep terror	1	0
		Sleep disorders NEC	Sleep disorder	15	0
	Total			218	0
Renal and urinary disorders	Renal disorders (excl nephropathies)	Renal failure and impairment	Acute kidney injury	1	0
	Urinary tract signs and symptoms	Urinary tract signs and symptoms NEC	Renal pain	1	0
	Total			2	0
Reproductive system and breast disorders	Reproductive tract disorders NEC	Reproductive tract disorders NEC (excl neoplasms)	Genital blister	1	0
	Total			1	0
Respiratory, thoracic and mediastinal disorders	Bronchial disorders (excl neoplasms)	Bronchospasm and obstruction	Wheezing	3	0
	Neonatal respiratory disorders	Neonatal hypoxic conditions	Cyanosis neonatal	1	0
			Infantile apnoea	3	0
			Neonatal hypoxia	4	0
	Respiratory disorders NEC	Breathing abnormalities	Apnoea	26	0
			Apnoeic attack	3	0
			Dyspnoea	47	0
			Grunting	2	0
			Hyperventilation	2	0
			Hypopnoea	9	0
			Respiration abnormal	5	0

			Respiratory arrest	12	0
			Respiratory distress	4	0
			Tachypnoea	3	0
		Conditions associated with abnormal gas exchange	Cyanosis central	1	0
		Coughing and associated symptoms	Cough	14	0
			Haemoptysis	1	0
			Productive cough	1	0
			Sputum discoloured	1	0
		Respiratory tract disorders NEC	Aspiration	1	0
			Respiratory disorder	1	0
	Respiratory tract signs and symptoms	Lower respiratory tract signs and symptoms	Rales	1	0
		Respiratory signs and symptoms NEC	Respiratory symptom	1	0
			Use of accessory respiratory muscles	2	0
		Upper respiratory tract signs and symptoms	Choking	14	0
			Choking sensation	1	0
			Increased viscosity of upper respiratory secretion	1	0
			Nasal obstruction	1	0
			Oropharyngeal pain	1	0
			Rhinorrhoea	6	0
			Sneezing	2	0
	Upper respiratory tract disorders (excl infections)	Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	Reflux laryngitis	1	0
		Nasal congestion and inflammations	Nasal congestion	3	0
		Nasal disorders NEC	Epistaxis	3	0
	Total			181	0
Skin and subcutaneous tissue disorders	Angioedema and urticaria	Angioedemas	Angioedema	1	0
		Urticarias	Urticaria	16	0
			Urticaria pressure	1	0
	Epidermal and dermal conditions	Bullous conditions	Blister	4	0
			Dermatitis bullous	1	0

		Erythema multiforme	1	0
		Pemphigoid	1	0
	Dermal and epidermal conditions NEC	Dry skin	5	0
		Papule	4	0
		Scab	1	0
		Skin discolouration	16	0
		Skin disorder	1	0
		Skin fissures	1	0
		Skin lesion	1	0
		Skin plaque	1	0
		Skin reaction	2	0
		Skin warm	6	0
	Dermatitis and eczema	Dermatitis	1	0
		Dermatitis allergic	4	0
		Dermatitis atopic	2	0
		Dermatitis diaper	2	0
		Eczema	17	0
		Eczema infantile	1	0
	Dermatitis ascribed to specific agent	Palmar-plantar erythrodysaesthesia syndrome	1	0
	Erythemas	Erythema	51	0
	Exfoliative conditions	Skin exfoliation	1	0
	Pruritus NEC	Pruritus	6	0
	Rashes, eruptions and exanthems NEC	Rash	59	0
		Rash erythematous	9	0
		Rash macular	11	0
		Rash maculo-papular	2	0
		Rash papular	4	0
		Rash pruritic	4	0
		Rash vesicular	1	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	3	0
		Hyperhidrosis	4	0
	Pilar disorders NEC	Hair growth abnormal	1	0
Skin vascular abnormalities	Purpura and related conditions	Henoch-Schonlein purpura	1	0
		Petechiae	14	0
		Purpura	6	0

		Skin haemorrhages	Skin haemorrhage	1	0
		Skin vasomotor conditions	Livedo reticularis	16	0
	Total			286	0
Surgical and medical procedures	Therapeutic procedures and supportive care NEC	Dietary and nutritional therapies	Cows milk free diet	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 vasoconstriction, necrosis and vascular insufficiency	Peripheral coldness	7	0
	Decreased and nonspecific blood pressure disorders and shock	Circulatory collapse and shock	Circulatory collapse	5	0
			Hypoperfusion	1	0
			Shock	3	0
	Vascular disorders NEC	Non-site specific vascular disorders NEC	Microangiopathy	1	0
			Venoocclusive disease	1	0
		Peripheral vascular disorders NEC	Cyanosis	23	0
			Flushing	1	0
		Site specific vascular disorders NEC	Pallor	78	0
	Vascular haemorrhagic disorders	Haemorrhages NEC	Haematoma	1	0
			Haemorrhage	3	0
	Vascular hypertensive disorders	Vascular hypertensive disorders NEC	Hypertension	2	0
	Total			127	0
TOTAL REACTIONS FOR DRUG				3,907	
TOTAL REPORTS				1,395	
TOTAL FATAL OUTCOME REPORTS					26