

Combined Hepatitis A and Typhoid Vaccine Analysis Print.

All UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with the Combined Hepatitis A and Typhoid vaccine up to and including 5th May 2025.

Report run: 06/05/2025

Earliest reaction date: 17/07/1999

Reaction MedDRA SOC Name	Reaction MedDRA HLGT 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	Pancytopenia	1	0
	Coagulopathies and bleeding diatheses (excl thrombocytopenic)	Bleeding tendencies	Increased tendency to bruise	1	0
		Coagulopathies	Disseminated intravascular coagulation	1	0
	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	Lymphadenopathy	8	0
		Spleen disorders	Splenic haemorrhage	1	0
			Splenomegaly	1	0
	Total			13	0
Cardiac disorders	Cardiac arrhythmias	Rate and rhythm disorders NEC	Bradycardia	4	0
			Tachycardia	1	0
		Ventricular arrhythmias and cardiac arrest	Cardiac arrest	1	0
	Cardiac disorders, signs and symptoms NEC	Cardiac signs and symptoms NEC	Palpitations	1	0
	Coronary artery disorders	Coronary artery disorders NEC	Arteriosclerosis coronary artery	1	0
		Ischaemic coronary artery disorders	Angina pectoris	1	0
	Heart failures	Left ventricular failures	Left ventricular failure	1	1
	Myocardial disorders	Myocardial disorders NEC	Cardiomegaly	1	0
	Total			11	1

Reaction MedDRA SOC Name	Reaction MedDRA HLGHT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
Congenital, familial and genetic disorders	Congenital and hereditary disorders NEC	Congenital disorders NEC	Congenital anomaly	1	0
	Musculoskeletal and connective tissue disorders congenital	Musculoskeletal and connective tissue disorders of limbs congenital	Developmental hip dysplasia	1	0
		Musculoskeletal and connective tissue disorders of skull congenital	Plagiocephaly	1	0
		Musculoskeletal and connective tissue disorders of trunk congenital (excl spine)	Synostosis	1	0
		Musculoskeletal disorders congenital NEC	Dysmorphism	1	0
	Neurological disorders congenital	Cerebral disorders congenital	Anencephaly	1	0
	Renal and urinary tract disorders congenital	Renal disorders congenital	Renal aplasia	1	0
	Respiratory disorders congenital	Pulmonary and bronchial disorders congenital	Pulmonary malformation	1	0
	Skin and subcutaneous tissue disorders congenital	Skin and subcutaneous tissue disorders congenital NEC	Birth mark	1	0
			Congenital skin dimples	1	0
			Dermoid cyst	1	0
	Total			11	0
Ear and labyrinth disorders	Aural disorders NEC	Ear disorders NEC	Ear pain	1	0
	Hearing disorders	Hearing losses	Deafness neurosensory	1	0
			Deafness unilateral	1	0
	Inner ear and VIIIth cranial nerve disorders	Inner ear disorders NEC	Vestibular disorder	1	0
		Inner ear signs and symptoms	Tinnitus	1	0
			Vertigo	4	0
	Total			9	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG 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	7	0
			Periorbital oedema	1	0
	Ocular infections, irritations and inflammations	Lid, lash and lacrimal infections, irritations and inflammations	Eyelid oedema	2	0
			Eye irritation	1	0
		Ocular infections, inflammations and associated manifestations	Eye pruritus	2	0
			Retinal, choroid and vitreous infections and inflammations	1	0
	Ocular neuromuscular disorders	Ocular nerve and muscle disorders	Eye movement disorder	5	0
	Ocular sensory symptoms NEC	Ocular sensation disorders	Photophobia	4	0
	Vision disorders	Visual disorders NEC	Vision blurred	6	0
			Blindness transient	1	0
		Visual impairment and blindness (excl colour blindness)	Visual impairment	1	0
	Total			32	0
Gastrointestinal disorders	Dental and gingival conditions	Gingival disorders, signs and symptoms NEC	Gingival pain	1	0
	Gastrointestinal conditions NEC	Gastrointestinal disorders NEC	Gastrointestinal disorder	2	0
	Gastrointestinal motility and defaecation conditions	Diarrhoea (excl infective)	Diarrhoea	18	0
		Gastrointestinal atonic and hypomotility disorders NEC	Constipation	1	0
		Gastrointestinal spastic and hypermotility disorders	Irritable bowel syndrome	1	0
	Gastrointestinal signs and symptoms	Faecal abnormalities NEC	Faeces pale	2	0
		Flatulence, bloating and distension	Abdominal distension	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Gastrointestinal and abdominal pains (excl oral and throat)	Abdominal pain	9	0
			Abdominal pain lower	1	0
			Abdominal pain upper	7	0
			Abdominal tenderness	1	0
		Gastrointestinal signs and symptoms NEC	Abdominal discomfort	3	0
			Abdominal symptom	3	0
			Dysphagia	3	0
		Nausea and vomiting symptoms	Nausea	38	0
			Vomiting	19	0
	Gastrointestinal stenosis and obstruction	Gastrointestinal stenosis and obstruction NEC	Ileus	1	0
	Gastrointestinal ulceration and perforation	Intestinal ulcers and perforation NEC	Intestinal perforation	1	0
	Oral soft tissue conditions	Oral soft tissue signs and symptoms	Oral pain	2	0
			Paraesthesia oral	4	0
		Oral soft tissue swelling and oedema	Lip swelling	4	0
			Mouth swelling	1	0
		Stomatitis and ulceration	Mouth ulceration	2	0
			Stomatitis	1	0
	Salivary gland conditions	Oral dryness and saliva altered	Salivary hypersecretion	1	0
		Salivary gland enlargements	Parotid gland enlargement	1	0
	Tongue conditions	Tongue disorders	Glossitis	1	0
			Tongue disorder	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Tongue signs and symptoms	Swollen tongue	4	0
			Tongue oedema	1	0
	Total			135	0
General disorders and administration site conditions	Administration site reactions	Injection site reactions	Injected limb mobility decreased	1	0
			Injection site erythema	1	0
			Injection site granuloma	1	0
			Injection site inflammation	1	0
			Injection site movement impairment	2	0
			Injection site oedema	1	0
			Injection site pain	7	0
			Injection site reaction	5	0
			Injection site swelling	2	0
			Injection site warmth	2	0
	Vaccination site reactions		Vaccination site erythema	2	0
			Vaccination site pain	8	0
			Vaccination site pruritus	1	0
			Vaccination site warmth	1	0
	Body temperature conditions	Febrile disorders	Pyrexia	40	0
	Fatal outcomes	Death and sudden death	Death	1	4
	General system disorders NEC	Adverse effect absent	No adverse event	1	0
		Asthenic conditions	Asthenia	13	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Fatigue	33	0
			Malaise	36	0
		Feelings and sensations NEC	Chills	14	0
			Feeling abnormal	6	0
			Feeling cold	1	0
			Feeling drunk	1	0
			Feeling hot	8	0
			Feeling of body temperature change	5	0
			Sensation of foreign body	1	0
			Thirst	3	0
		Gait disturbances	Gait disturbance	2	0
		General signs and symptoms NEC	Condition aggravated	1	0
			Induration	1	0
			Influenza like illness	13	0
			Local reaction	1	0
			Moaning	1	0
			Peripheral swelling	4	0
			Swelling	4	0
			Swelling face	2	0
		Inflammations	Inflammation	1	0
		Oedema NEC	Face oedema	4	0
			Oedema peripheral	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Pain and discomfort NEC	Chest discomfort	8	0
			Chest pain	4	0
			Discomfort	2	0
			Pain	13	0
			Tenderness	1	0
	Therapeutic and nontherapeutic effects (excl toxicity)	Therapeutic and nontherapeutic responses	Drug ineffective	4	0
			Therapy non-responder	1	0
			Vaccination failure	4	0
	Tissue disorders NEC	Mass conditions NEC	Nodule	1	0
	Total			271	4
Hepatobiliary disorders	Bile duct disorders	Obstructive bile duct disorders (excl neoplasms)	Bile duct stone	1	0
	Hepatic and hepatobiliary disorders	Cholestasis and jaundice	Cholestasis	2	0
			Jaundice	10	0
		Hepatocellular damage and hepatitis NEC	Hepatitis	2	0
			Hepatitis acute	3	0
	Total			18	0
Immune system disorders	Allergic conditions	Allergic conditions NEC	Hypersensitivity	8	0
		Allergies to foods, food additives, drugs and other chemicals	Food allergy	1	0
		Anaphylactic and anaphylactoid responses	Anaphylactic reaction	11	0
			Anaphylactic shock	2	0
			Anaphylactoid reaction	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Autoimmune disorders	Autoimmune disorders NEC	Autoimmune disorder	2	0
	Total			25	0
Infections and infestations	Bacterial infectious disorders	Salmonella infections	Typhoid fever	9	0
		Streptococcal infections	Pneumococcal sepsis	1	1
	Infections - pathogen unspecified	Central nervous system and spinal infections	Myelitis	2	0
		Ear infections	Ear infection	1	0
		Eye and eyelid infections	Conjunctivitis	1	0
		Infections NEC	Vestibulitis	1	0
		Lower respiratory tract and lung infections	Lower respiratory tract infection	1	0
			Pneumonia	1	0
		Muscle and soft tissue infections	Necrotising fasciitis	1	0
		Upper respiratory tract infections	Pharyngitis	1	0
			Sinusitis	1	0
			Tonsillitis	1	0
			Upper respiratory tract infection	1	0
		Urinary tract infections	Cystitis	1	0
		Vascular infections	Lymphangitis	1	0
	Protozoal infectious disorders	Giardia infections	Giardiasis	1	0
	Viral infectious disorders	Arenaviral infections	Choriomeningitis lymphocytic	1	0
		Flaviviral infections	Yellow fever vaccine-associated neurotropic disease	1	0
		Hepatitis virus infections	Hepatitis A	5	0

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		Herpes viral infections	Herpes simplex encephalitis	1	0
			Herpes zoster	2	0
		Influenza viral infections	Influenza	2	0
		Mumps viral infections	Mumps	1	0
		Viral infections NEC	Meningitis viral	1	0
			Viral diarrhoea	1	0
			Viral infection	1	0
	Total			41	1
Injury, poisoning and procedural complications	Exposures, chemical injuries and poisoning	Exposures associated with pregnancy, delivery and lactation	Exposure during pregnancy	6	0
			Foetal exposure during pregnancy	2	0
			Maternal exposure during pregnancy	1	0
			Maternal exposure timing unspecified	1	0
	Injuries NEC	Eye injuries NEC	Eyelid injury	1	0
		Non-site specific injuries NEC	Fall	1	0
		Site specific injuries NEC	Head injury	1	0
		Skin injuries NEC	Contusion	2	0
			Skin laceration	1	0
	Medication errors and other product use errors and issues	Medication errors, product use errors and issues NEC	Medication error	3	0
			Vaccination error	1	0
		Product administration errors and issues	Expired product administered	1	0
			Extra dose administered	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Inappropriate schedule of product administration	1	0
			Product administered to patient of inappropriate age	3	0
			Wrong product administered	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
		Underdoses NEC	Underdose	1	0
	Procedural related injuries and complications NEC	Vaccination related complications	Immunisation reaction	2	0
	Total			32	0
Investigations	Cardiac and vascular investigations (excl enzyme tests)	ECG investigations	Electrocardiogram abnormal	1	0
		Heart rate and pulse investigations	Heart rate decreased	1	0
			Heart rate increased	1	0
			Pulse abnormal	2	0
		Vascular tests NEC (incl blood pressure)	Blood pressure decreased	4	0
			Blood pressure diastolic increased	1	0
			Blood pressure immeasurable	2	0
	Haematology investigations (incl blood groups)	Coagulation and bleeding analyses	Activated partial thromboplastin time prolonged	1	0
			Blood fibrinogen increased	1	0
			International normalised ratio decreased	1	0
			Prothrombin time prolonged	1	0

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		Haematological analyses NEC	Red blood cell sedimentation rate increased	1	0
		Red blood cell analyses	Red blood cell count increased	1	0
		White blood cell analyses	Lymphocyte count decreased	1	0
			Monocyte count increased	1	0
			White blood cell count increased	1	0
	Hepatobiliary investigations	Hepatobiliary function diagnostic procedures	Blood bilirubin increased	1	0
			Hepatic enzyme increased	2	0
			Liver function test abnormal	5	0
	Metabolic, nutritional and blood gas investigations	Carbohydrate tolerance analyses (incl diabetes)	Blood glucose increased	2	0
		Vitamin analyses	Vitamin D increased	1	0
	Microbiology and serology investigations	Bacteria identification and serology (excl mycobacteria)	Salmonella test positive	1	0
			Streptococcus test positive	1	0
	Physical examination and organ system status topics	Physical examination procedures and organ system status	Body temperature increased	4	0
			Weight decreased	3	0
	Protein and chemistry analyses NEC	Protein analyses NEC	C-reactive protein increased	2	0
	Renal and urinary tract investigations and urinalyses	Renal function analyses	Blood creatinine increased	1	0
	Respiratory and pulmonary investigations (excl blood gases)	Respiratory and pulmonary function diagnostic procedures	Vital capacity decreased	1	0
	Water, electrolyte and mineral investigations	Mineral and electrolyte analyses	Blood calcium decreased	1	0
	Total			46	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
Metabolism and nutrition disorders	Acid-base disorders	Mixed acid-base disorders	Acidosis	1	0
	Appetite and general nutritional disorders	Appetite disorders	Decreased appetite	10	0
		General nutritional disorders NEC	Feeding disorder	1	0
	Electrolyte and fluid balance conditions	Total fluid volume decreased	Dehydration	1	0
	Total			13	0
Musculoskeletal and connective tissue disorders	Bone disorders (excl congenital and fractures)	Bone related signs and symptoms	Bone pain	1	0
			Spinal pain	1	0
	Joint disorders	Arthropathies NEC	Arthritis	2	0
			Polyarthritis	1	0
		Joint related disorders NEC	Periarthritis	1	0
		Joint related signs and symptoms	Arthralgia	12	0
			Joint effusion	2	0
			Joint stiffness	3	0
		Rheumatoid arthropathies	Rheumatoid arthritis	1	0
		Spondyloarthropathies	Ankylosing spondylitis	1	0
	Muscle disorders	Muscle pains	Myalgia	18	0
		Muscle related signs and symptoms NEC	Muscle spasms	2	0
			Muscle tightness	2	0
			Muscle twitching	3	0
		Muscle tone abnormalities	Muscle rigidity	6	0
		Muscle weakness conditions	Muscular weakness	6	0
	Musculoskeletal and connective tissue disorders NEC	Musculoskeletal and connective tissue conditions NEC	Mobility decreased	2	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Musculoskeletal stiffness	10	0
		Musculoskeletal and connective tissue pain and discomfort	Back pain	7	0
			Flank pain	1	0
			Limb discomfort	3	0
			Neck pain	6	0
			Pain in extremity	11	0
	Total			102	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Gastrointestinal neoplasms malignant and unspecified	Pancreatic neoplasms malignant (excl islet cell and carcinoid)	Adenocarcinoma pancreas	1	0
	Nervous system neoplasms malignant and unspecified NEC	Nervous system neoplasms unspecified malignancy NEC	Brain neoplasm	1	0
	Total			2	0
Nervous system disorders	Central nervous system infections and inflammations	Myelitis (incl infective)	Myelitis transverse	1	0
	Central nervous system vascular disorders	Central nervous system haemorrhages and cerebrovascular accidents	Cerebral haemorrhage	1	1
	Cranial nerve disorders (excl neoplasms)	Facial cranial nerve disorders	Bell's palsy	3	0
			Facial paralysis	3	0
			Facial paresis	1	0
		Trigeminal disorders	Trigeminal neuralgia	2	0
	Demyelinating disorders	Demyelinating disorders NEC	Demyelination	1	0
		Multiple sclerosis acute and progressive	Multiple sclerosis	1	0
			Multiple sclerosis relapse	1	0
	Headaches	Headaches NEC	Headache	38	0

Reaction MedDRA SOC Name	Reaction MedDRA HLG Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Migraine headaches	Basilar migraine	1	0
			Migraine	2	0
	Mental impairment disorders	Memory loss (excl dementia)	Amnesia	3	0
			Memory impairment	1	0
		Mental impairment (excl dementia and memory loss)	Disturbance in attention	1	0
			Mental impairment	1	0
	Movement disorders (incl parkinsonism)	Dyskinesias and movement disorders NEC	Dyskinesia	3	0
			Motor dysfunction	1	0
			Movement disorder	1	0
		Paralysis and paresis (excl cranial nerve)	Hemiplegia	1	0
			Paralysis	2	0
			Quadriparesis	1	0
		Tremor (excl congenital)	Tremor	6	0
	Neurological disorders NEC	Coordination and balance disturbances	Balance disorder	2	0
		Disturbances in consciousness NEC	Altered state of consciousness	2	0
			Consciousness fluctuating	1	0
			Depressed level of consciousness	1	0
			Lethargy	12	0
			Loss of consciousness	10	0
			Postictal state	1	0
			Somnolence	5	0
			Syncope	37	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Neurological signs and symptoms NEC	Brain fog	1	0
			Dizziness	40	0
			Dizziness postural	1	0
			Drooling	1	0
			Presyncope	4	0
			Tongue biting	1	0
			Unresponsive to stimuli	4	0
		Paraesthesias and dysaesthesias	Burning sensation	1	0
			Hypoaesthesia	11	0
			Paraesthesia	21	0
		Sensory abnormalities NEC	Ageusia	1	0
			Dysgeusia	3	0
			Neuralgia	4	0
			Taste disorder	1	0
		Speech and language abnormalities	Speech disorder	3	0
	Neuromuscular disorders	Muscle tone abnormal	Hypotonia	2	0
		Neuromuscular disorders NEC	Muscle contractions involuntary	2	0
			Neuromyopathy	1	0
	Peripheral neuropathies	Acute polyneuropathies	Guillain-Barre syndrome	2	0
		Chronic polyneuropathies	Demyelinating polyneuropathy	1	0
		Peripheral neuropathies NEC	Neuropathy peripheral	1	0
	Seizures (incl subtypes)	Generalised tonic-clonic seizures	Generalised tonic-clonic seizure	3	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Seizures and seizure disorders NEC	Epilepsy	1	0
			Seizure	14	0
			Seizure like phenomena	1	0
	Spinal cord and nerve root disorders	Lumbar spinal cord and nerve root disorders	Sciatica	1	0
	Total			273	1
Pregnancy, puerperium and perinatal conditions	Abortions and stillbirth	Abortion related conditions and complications	Anembryonic gestation	1	0
		Abortions spontaneous	Abortion spontaneous	11	0
		Stillbirth and foetal death	Stillbirth	1	0
	Foetal complications	Foetal complications NEC	Foetal distress syndrome	1	0
	Maternal complications of labour and delivery	Labour onset and length abnormalities	Premature delivery	1	0
	Maternal complications of pregnancy	Maternal complications of pregnancy NEC	Ectopic pregnancy	1	0
	Pregnancy, labour, delivery and postpartum conditions	Normal pregnancy, labour and delivery	Live birth	1	0
			Pregnancy	1	0
	Total			18	0
Product issues	Product quality, supply, distribution, manufacturing and quality system issues	Product quality issues NEC	Product complaint	2	0
	Total			2	0
Psychiatric disorders	Anxiety disorders and symptoms	Anxiety symptoms	Agitation	1	0
			Anxiety	1	0
		Panic attacks and disorders	Panic attack	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGt Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
	Changes in physical activity	Increased physical activity levels	Restlessness	1	0
	Deliria (incl confusion)	Confusion and disorientation	Confusional state	7	0
			Disorientation	5	0
	Disturbances in thinking and perception	Thinking disturbances	Thinking abnormal	2	0
	Mood disorders and disturbances NEC	Emotional and mood disturbances NEC	Irritability	1	0
		Fluctuating mood symptoms	Mood swings	1	0
	Schizophrenia and other psychotic disorders	Psychotic disorder NEC	Psychotic disorder	1	0
	Sleep disorders and disturbances	Disturbances in initiating and maintaining sleep	Insomnia	3	0
		Parasomnias	Abnormal dreams	1	0
		Sleep disorders NEC	Sleep disorder	1	0
	Total			26	0
Renal and urinary disorders	Nephropathies	Glomerulonephritis and nephrotic syndrome	Goodpasture's syndrome	1	0
	Urinary tract signs and symptoms	Bladder and urethral symptoms	Bladder pain	1	0
			Dysuria	1	0
			Fowler's syndrome	1	0
			Incontinence	1	0
			Micturition urgency	2	0
			Urinary incontinence	2	0
			Urinary retention	1	0
		Urinary abnormalities	Chromaturia	5	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
			Haematuria	1	0
			Proteinuria	1	0
		Urinary tract signs and symptoms NEC	Renal pain	1	0
	Total			18	0
Reproductive system and breast disorders	Menstrual cycle and uterine bleeding disorders	Menstruation and uterine bleeding NEC	Menstrual disorder	1	0
	Vulvovaginal disorders (excl infections and inflammations)	Vulvovaginal disorders NEC	Vaginal haemorrhage	1	0
	Total			2	0
Respiratory, thoracic and mediastinal disorders	Bronchial disorders (excl neoplasms)	Bronchospasm and obstruction	Bronchospasm	1	0
			Obstructive airways disorder	1	0
			Wheezing	4	0
	Respiratory disorders NEC	Breathing abnormalities	Dyspnoea	8	0
		Coughing and associated symptoms	Cough	2	0
	Respiratory tract signs and symptoms	Upper respiratory tract signs and symptoms	Choking	1	0
			Dysphonia	3	0
			Oropharyngeal pain	10	0
			Rhinorrhoea	2	0
			Sinus pain	1	0
			Throat irritation	2	0
			Throat tightness	1	0
	Upper respiratory tract disorders (excl infections)	Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	Laryngeal dyskinesia	1	0
		Nasal congestion and inflammations	Nasal congestion	2	0

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		Nasal disorders NEC	Epistaxis	1	0
		Pharyngeal disorders (excl infections and neoplasms)	Pharyngeal swelling	1	0
	Total			41	0
Skin and subcutaneous tissue disorders	Angioedema and urticaria disorders	Angioedemas	Angioedema	4	0
		Urticarias	Urticaria	13	0
			Urticaria chronic	2	0
	Cornification and dystrophic skin disorders	Hyperkeratoses	Lichenoid keratosis	1	0
	Epidermal and dermal conditions	Bullous conditions	Dermatitis bullous	1	0
			Erythema multiforme	2	0
		Dermal and epidermal conditions NEC	Dry skin	2	0
			Papule	1	0
			Sensitive skin	1	0
			Skin discolouration	2	0
		Dermatitis and eczema	Dermatitis allergic	1	0
			Eczema	2	0
		Erythemas	Erythema	5	0
		Papulosquamous conditions	Pityriasis rosea	2	0
		Pruritus NEC	Pruritus	8	0
		Rashes, eruptions and exanthems NEC	Rash	18	0
			Rash erythematous	5	0
			Rash macular	5	0

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			Rash maculo-papular	1	0
			Rash pruritic	2	0
	Skin appendage conditions	Alopecias	Alopecia	1	0
		Apocrine and eccrine gland disorders	Cold sweat	3	0
			Hyperhidrosis	19	0
			Night sweats	2	0
	Skin vascular abnormalities	Purpura and related conditions	Petechiae	1	0
			Purpura	1	0
	Total			105	0
Surgical and medical procedures	Obstetric and gynaecological therapeutic procedures	Induced abortions	Abortion induced	1	0
		Obstetric therapeutic procedures	Forceps delivery	1	0
	Skin and subcutaneous tissue therapeutic procedures	Skin and subcutaneous tissue therapeutic procedures NEC	Dermal filler injection	1	0
	Total			3	0
Vascular disorders	Arteriosclerosis, stenosis, vascular insufficiency and necrosis	Peripheral vasoconstriction, necrosis and vascular insufficiency	Peripheral coldness	2	0
			Raynaud's phenomenon	1	0
	Decreased and nonspecific blood pressure disorders and shock	Circulatory collapse and shock	Circulatory collapse	6	0
			Shock	2	0
		Vascular hypotensive disorders	Hypotension	10	0
			Orthostatic hypotension	1	0
	Vascular disorders NEC	Peripheral vascular disorders NEC	Cyanosis	3	0
			Flushing	6	0
			Hot flush	1	0

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
		Site specific vascular disorders NEC	Pallor	15	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	Giant cell arteritis	1	0
	Total			50	0
Total				1,299	5

Number of ADR Reports

383