



Australian Government

Department of Health

Therapeutic Goods Administration

Database of Adverse Event Notifications - medicines

Medicine summary

You searched for the following **3 medicines** between **01/01/2006 – 27/02/2019**:

- Lemtrada (Alemtuzumab)
- Mabcampath (Alemtuzumab)
- Tradename not specified (Alemtuzumab)

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Important information

The TGA uses adverse event reports to identify when a safety issue may be present. An adverse event report does not mean that the medicine is the cause of the adverse event. If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. The TGA strongly advises people taking prescription medicines not to change their medication regime without prior consultation with a health professional.

About the Database of Adverse Event Notifications (DAEN) - medicines

- The DAEN - medicines contains information from reports of adverse events that the TGA has received in relation to medicines including vaccines used in Australia.
- The DAEN - medicines does not contain all known safety information about a particular medicine. Please do not make an assessment about the safety of a medicine based on the information in the DAEN - medicines.

The TGA medicine safety monitoring program

More information about the DAEN - medicines and the TGA medicines safety monitoring program is available at:

- About the DAEN - medicines <<http://www.tga.gov.au/safety/daen-about.htm>>
- Medicines safety <<http://www.tga.gov.au/safety/information-medicines.htm>>

You are encouraged to report an adverse event suspected of being related to a medicine used in Australia. Reports of adverse events in relation to medicines and vaccines can be reported using the 'blue card' reporting form, by phone and online <<http://www.tga.gov.au/safety/problem.htm>>.

Other useful sources of information on Australian medicines

More information about a medicine is available from the Product Information (PI) <<http://www.tga.gov.au/hp/information-medicines-pi.htm>> and Consumer Medicine Information (CMI) <<http://www.tga.gov.au/consumers/information-medicines-cmi.htm>> leaflet or the labelling of the medicine. Australian Public Assessment Report for Prescription Medicines (AusPARs) <<http://www.tga.gov.au/industry/pm-auspar.htm>> for some prescription medicines, are also available from the TGA website. <<http://www.tga.gov.au>>
Your health professional can also provide help and assistance on how to use medicines.
Information on medicines used in Australia is available from NPS MedicineWise <<http://www.nps.org.au/>>.

About the release of this information

While reasonable care is taken to ensure that the information is an accurate record of the adverse events reported to the TGA, the TGA does not guarantee or warrant the accuracy, reliability, completeness or currency of the information or its usefulness in achieving any purpose.

To the fullest extent permitted by law, including but not limited to section 61A of the Therapeutic Goods Act 1989, the TGA will not be liable for any loss, damage, cost or expense incurred in or arising by reason of any person relying on this information.

Copyright restrictions apply to the DAEN - medicines <<http://www.tga.gov.au/about/website-copyright.htm>>.

Results

Number of reports (cases): 252

(Multiple adverse events have been reported for some patients)

Number of cases with a single suspected medicine: 245

(The TGA thinks there is a possibility that the medicine caused the adverse event)

Number of cases where death was a reported outcome: 5

(These reports of death may or may not have been a result of taking a medicine)

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Headache	38	36	0
Endocrine disorders	Basedow's disease	28	27	0
Skin and subcutaneous tissue disorders	Rash	26	24	0
Endocrine disorders	Hyperthyroidism	24	24	0
General disorders and administration site conditions	Fatigue	24	22	0
Blood and lymphatic system disorders	Immune thrombocytopenic purpura	22	21	0
General disorders and administration site conditions	Pyrexia	21	21	1
Nervous system disorders	Multiple sclerosis relapse	16	16	0
Respiratory, thoracic and mediastinal disorders	Dyspnoea	15	15	0
General disorders and administration site conditions	Chest discomfort	13	13	0
Blood and lymphatic system disorders	Neutropenia	12	12	0
Cardiac disorders	Tachycardia	12	12	0
Gastrointestinal disorders	Nausea	13	11	0
Investigations	Platelet count decreased	11	10	0
Infections and infestations	Upper respiratory tract infection	10	10	0
Gastrointestinal disorders	Diarrhoea	10	10	0
Musculoskeletal and connective tissue disorders	Back pain	10	10	0
Nervous system disorders	Dizziness	10	10	0
General disorders and administration site conditions	Malaise	12	10	0
Musculoskeletal and connective tissue disorders	Myalgia	11	10	0
Psychiatric disorders	Insomnia	11	10	0
General disorders and administration site conditions	Chest pain	9	9	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Condition aggravated	9	9	0
Infections and infestations	Urinary tract infection	12	9	1
Blood and lymphatic system disorders	Thrombocytopenia	9	9	0
Cardiac disorders	Bradycardia	8	8	0
General disorders and administration site conditions	Chills	9	8	0
General disorders and administration site conditions	Disease progression	8	8	1
Investigations	Blood thyroid stimulating hormone decreased	8	8	0
Cardiac disorders	Atrial fibrillation	8	8	0
Gastrointestinal disorders	Vomiting	9	8	0
Skin and subcutaneous tissue disorders	Pruritus	8	8	0
Vascular disorders	Hypotension	7	7	0
Infections and infestations	Herpes zoster	8	7	0
Cardiac disorders	Palpitations	7	7	0
Skin and subcutaneous tissue disorders	Rash generalised	7	7	0
Nervous system disorders	Hypoaesthesia	7	7	0
General disorders and administration site conditions	Pain	9	7	0
Blood and lymphatic system disorders	Lymphopenia	6	6	0
Cardiac disorders	Pericarditis	6	6	0
Endocrine disorders	Hypothyroidism	6	6	0
Gastrointestinal disorders	Constipation	7	6	0
Musculoskeletal and connective tissue disorders	Arthralgia	6	6	0
Vascular disorders	Hypertension	7	6	0
Nervous system disorders	Tremor	6	6	0
Investigations	Thyroxine free increased	6	6	0
Musculoskeletal and connective tissue disorders	Pain in extremity	7	6	0
Gastrointestinal disorders	Abdominal pain	5	5	0
Metabolism and nutrition disorders	Decreased appetite	5	5	0
Musculoskeletal and connective tissue disorders	Muscular weakness	6	5	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	5	5	0
Metabolism and nutrition disorders	Increased appetite	5	5	0
Infections and infestations	Lower respiratory tract infection	6	5	0
Renal and urinary disorders	Goodpasture's syndrome	5	5	0
Endocrine disorders	Autoimmune hypothyroidism	4	4	0
Musculoskeletal and connective tissue disorders	Muscle spasms	5	4	0
Investigations	Weight decreased	4	4	0
Nervous system disorders	Lethargy	4	4	0
Skin and subcutaneous tissue disorders	Hyperhidrosis	5	4	0
Investigations	Body temperature increased	4	4	0
Musculoskeletal and connective tissue disorders	Limb discomfort	4	4	0
Nervous system disorders	Paraesthesia	4	4	0
Endocrine disorders	Thyroiditis	4	4	0
Injury, poisoning and procedural complications	Foot fracture	4	4	0
Nervous system disorders	Migraine	4	4	0
Gastrointestinal disorders	Anal incontinence	4	4	0
Psychiatric disorders	Depression	4	4	0
Blood and lymphatic system disorders	Anaemia	4	4	0
Hepatobiliary disorders	Cholecystitis	3	3	0
Infections and infestations	Oral candidiasis	3	3	0
Investigations	Laboratory test abnormal	3	3	0
Vascular disorders	Flushing	4	3	0
Infections and infestations	Influenza	3	3	0
Injury, poisoning and procedural complications	Exposure during pregnancy	3	3	0
Vascular disorders	Haemorrhage	3	3	0
Infections and infestations	Gastroenteritis	3	3	0
Infections and infestations	Sepsis	3	3	1
Injury, poisoning and procedural complications	Contusion	4	3	0
Investigations	Blood alkaline phosphatase increased	3	3	0
Investigations	Heart rate increased	3	3	0

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Endocrine disorders	Autoimmune thyroiditis	3	3	0
General disorders and administration site conditions	Oedema peripheral	3	3	0
Infections and infestations	Pneumocystis jirovecii pneumonia	3	3	1
Injury, poisoning and procedural complications	Off label use	3	3	0
Renal and urinary disorders	Haematuria	3	3	0
Skin and subcutaneous tissue disorders	Erythema	3	3	0
Eye disorders	Endocrine ophthalmopathy	3	3	0
Eye disorders	Vitreous floaters	3	3	0
Infections and infestations	Pneumonia	3	3	0
Psychiatric disorders	Anxiety	4	3	0
Skin and subcutaneous tissue disorders	Alopecia	3	3	0
Respiratory, thoracic and mediastinal disorders	Cough	3	3	0
General disorders and administration site conditions	Disease recurrence	4	3	0
Infections and infestations	Oral herpes	3	3	0
Investigations	Gamma-glutamyltransferase increased	3	3	0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	3	3	0
Infections and infestations	Tonsillitis	2	2	0
Skin and subcutaneous tissue disorders	Urticaria	2	2	0
Ear and labyrinth disorders	Ear pain	2	2	0
Gastrointestinal disorders	Abdominal discomfort	2	2	0
Gastrointestinal disorders	Gastrooesophageal reflux disease	2	2	0
General disorders and administration site conditions	Therapeutic response decreased	2	2	0
Infections and infestations	Candida infection	2	2	0
Infections and infestations	Cytomegalovirus infection	2	2	0
Infections and infestations	Gastroenteritis viral	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	2	2	0
Nervous system disorders	Ischaemic stroke	2	2	0
Skin and subcutaneous tissue disorders	Blister	2	2	0

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Gastrointestinal disorders	Colitis	2	2	0
General disorders and administration site conditions	Asthenia	3	2	0
General disorders and administration site conditions	Concomitant disease aggravated	2	2	0
Infections and infestations	Tooth infection	2	2	0
Investigations	Nuclear magnetic resonance imaging abnormal	2	2	0
Musculoskeletal and connective tissue disorders	Neck pain	2	2	0
Nervous system disorders	Multiple sclerosis	2	2	0
Reproductive system and breast disorders	Polymenorrhoea	2	2	0
Respiratory, thoracic and mediastinal disorders	Lung infiltration	2	2	0
Skin and subcutaneous tissue disorders	Night sweats	2	2	0
Blood and lymphatic system disorders	Acquired haemophilia	2	2	0
Blood and lymphatic system disorders	Haemolytic anaemia	2	2	0
Infections and infestations	Urosepsis	2	2	0
Investigations	Albumin urine present	2	2	0
Renal and urinary disorders	Renal impairment	2	2	0
Investigations	Platelet count abnormal	2	2	0
Nervous system disorders	Neuralgia	3	2	0
Nervous system disorders	Seizure	2	2	0
Respiratory, thoracic and mediastinal disorders	Haemoptysis	2	2	0
Vascular disorders	Peripheral coldness	2	2	0
Eye disorders	Vision blurred	2	2	0
Infections and infestations	Viral infection	2	2	0
Investigations	Blood thyroid stimulating hormone increased	2	2	0
Blood and lymphatic system disorders	Lymphadenopathy	2	2	0
Investigations	Blood pressure decreased	2	2	0
Renal and urinary disorders	Microalbuminuria	2	2	0
Renal and urinary disorders	Nephritis	2	2	0
Respiratory, thoracic and mediastinal disorders	Epistaxis	2	2	0

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Skin and subcutaneous tissue disorders	Rash pruritic	2	2	0
General disorders and administration site conditions	Temperature intolerance	2	2	0
Immune system disorders	Cytokine release syndrome	2	2	0
Investigations	JC polyomavirus test positive	2	2	0
Nervous system disorders	Post herpetic neuralgia	2	2	0
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	2	2	0
Skin and subcutaneous tissue disorders	Petechiae	2	2	0
Blood and lymphatic system disorders	Iron deficiency anaemia	2	2	0
Injury, poisoning and procedural complications	Fall	2	2	0
Investigations	Heart rate irregular	2	2	0
Nervous system disorders	Burning sensation	2	2	0
Nervous system disorders	Muscle spasticity	2	2	0
Nervous system disorders	Optic neuritis	2	2	0
Nervous system disorders	Presyncope	2	2	0
Infections and infestations	Folliculitis	2	2	0
Infections and infestations	Pneumonia legionella	2	2	0
Investigations	C-reactive protein increased	2	2	0
Investigations	Haemoglobin decreased	2	2	0
Nervous system disorders	Visual field defect	2	2	0
Renal and urinary disorders	Chromaturia	2	2	0
Renal and urinary disorders	Micturition urgency	2	2	0
Endocrine disorders	Toxic nodular goitre	1	1	0
Immune system disorders	Anaphylactic reaction	2	1	0
Infections and infestations	Escherichia infection	1	1	0
Infections and infestations	Genital herpes	1	1	0
Infections and infestations	Listeriosis	1	1	0
Infections and infestations	Localised infection	1	1	0
Infections and infestations	Mycobacterial infection	1	1	0
Infections and infestations	Oral fungal infection	1	1	0
Infections and infestations	Pneumonia viral	1	1	0
Infections and infestations	Post procedural infection	1	1	0
Investigations	Blood creatinine increased	1	1	0

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Metabolism and nutrition disorders	Dehydration	2	1	0
Metabolism and nutrition disorders	Hypervitaminosis D	1	1	0
Musculoskeletal and connective tissue disorders	Inguinal mass	1	1	0
Nervous system disorders	Partial seizures	1	1	0
Nervous system disorders	Somnolence	1	1	0
Nervous system disorders	Tonic convulsion	1	1	0
Psychiatric disorders	Mood swings	1	1	0
Renal and urinary disorders	Proteinuria	1	1	0
Renal and urinary disorders	Renal infarct	1	1	0
Reproductive system and breast disorders	Menorrhagia	1	1	0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	1	1	0
Skin and subcutaneous tissue disorders	Dry skin	1	1	0
Vascular disorders	Hot flush	1	1	0
Blood and lymphatic system disorders	Histiocytosis haematophagic	1	1	0
Congenital, familial and genetic disorders	Factor VIII deficiency	1	1	0
Eye disorders	Glaucoma	1	1	0
Gastrointestinal disorders	Gastrointestinal motility disorder	1	1	0
Gastrointestinal disorders	Mouth ulceration	1	1	0
General disorders and administration site conditions	Drug ineffective	2	1	2
General disorders and administration site conditions	Inflammation	1	1	0
General disorders and administration site conditions	Therapeutic response unexpected	1	1	0
Infections and infestations	Appendicitis perforated	1	1	0
Infections and infestations	Kidney infection	1	1	0
Musculoskeletal and connective tissue disorders	Muscle rigidity	1	1	0
Musculoskeletal and connective tissue disorders	Polyarthritis	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid adenoma	1	1	0
Nervous system disorders	Paraparesis	1	1	0

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Renal and urinary disorders	Tubulointerstitial nephritis	1	1	0
Reproductive system and breast disorders	Metrorrhagia	1	1	0
Respiratory, thoracic and mediastinal disorders	Sinus congestion	1	1	0
Eye disorders	Lid lag	1	1	0
Gastrointestinal disorders	Frequent bowel movements	1	1	0
General disorders and administration site conditions	Treatment failure	2	1	0
Immune system disorders	Anaphylactic shock	2	1	0
Immune system disorders	Seasonal allergy	1	1	0
Infections and infestations	Listeria sepsis	1	1	0
Infections and infestations	Pyelonephritis	1	1	0
Infections and infestations	Streptococcal infection	1	1	0
Infections and infestations	Urinary tract infection bacterial	1	1	0
Investigations	Anti-thyroid antibody positive	1	1	0
Investigations	Blood creatine abnormal	1	1	0
Investigations	Coxsackie virus test positive	1	1	0
Investigations	Neutrophil count decreased	1	1	0
Investigations	Thyroxine free abnormal	1	1	0
Metabolism and nutrition disorders	Electrolyte imbalance	1	1	0
Musculoskeletal and connective tissue disorders	Ankylosing spondylitis	1	1	0
Musculoskeletal and connective tissue disorders	Back disorder	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	1	1	0
Nervous system disorders	Loss of consciousness	1	1	0
Renal and urinary disorders	Albuminuria	1	1	0
Renal and urinary disorders	Urinary retention	1	1	0
Reproductive system and breast disorders	Perineal pain	1	1	0
Respiratory, thoracic and mediastinal disorders	Dry throat	1	1	0
Respiratory, thoracic and mediastinal disorders	Pulmonary hypertension	1	1	0
Skin and subcutaneous tissue disorders	Rash follicular	1	1	0
Skin and subcutaneous tissue disorders	Rash maculo-papular	1	1	0

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Eye disorders	Eyelid retraction	1	1	0
Eye disorders	Uveitis	1	1	0
Gastrointestinal disorders	Eosinophilic oesophagitis	1	1	0
Gastrointestinal disorders	Oral lichen planus	1	1	0
General disorders and administration site conditions	Injection site pain	1	1	0
Hepatobiliary disorders	Cholelithiasis	1	1	0
Infections and infestations	Gingivitis	1	1	0
Infections and infestations	Meningitis viral	1	1	0
Injury, poisoning and procedural complications	Ankle fracture	1	1	0
Injury, poisoning and procedural complications	Ligament rupture	1	1	0
Investigations	Fibrin D dimer increased	1	1	0
Metabolism and nutrition disorders	Diabetes mellitus	1	1	0
Musculoskeletal and connective tissue disorders	Joint hyperextension	1	1	0
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	1	1	0
Nervous system disorders	Memory impairment	1	1	0
Psychiatric disorders	Hypomania	1	1	0
Renal and urinary disorders	Dysuria	1	1	0
Reproductive system and breast disorders	Menstruation irregular	1	1	0
Reproductive system and breast disorders	Ovarian cyst	1	1	0
Skin and subcutaneous tissue disorders	Angioedema	1	1	0
Skin and subcutaneous tissue disorders	Decubitus ulcer	1	1	0
Skin and subcutaneous tissue disorders	Ecchymosis	1	1	0
Vascular disorders	Deep vein thrombosis	1	1	0
Vascular disorders	Thrombophlebitis	1	1	0
Eye disorders	Photophobia	1	1	0
Gastrointestinal disorders	Gingival bleeding	1	1	0
General disorders and administration site conditions	Feeling cold	1	1	0
General disorders and administration site conditions	Influenza like illness	2	1	0

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Infections and infestations	Pharyngitis	1	1	0
Injury, poisoning and procedural complications	Femur fracture	1	1	0
Investigations	Autoantibody positive	1	1	0
Investigations	Blood calcium abnormal	1	1	0
Investigations	Platelet aggregation increased	1	1	0
Investigations	Thyroid function test abnormal	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid cancer	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	1	1	0
Nervous system disorders	Cerebrovascular accident	2	1	0
Nervous system disorders	Sciatica	1	1	0
Renal and urinary disorders	Calculus urinary	1	1	0
Reproductive system and breast disorders	Breast haematoma	1	1	0
Respiratory, thoracic and mediastinal disorders	Nasal discomfort	1	1	0
Vascular disorders	Haematoma	1	1	0
Endocrine disorders	Goitre	1	1	0
Gastrointestinal disorders	Dysphagia	1	1	0
Gastrointestinal disorders	Gastric disorder	1	1	0
Gastrointestinal disorders	Gastritis	1	1	0
Gastrointestinal disorders	Gastrointestinal pain	1	1	0
Gastrointestinal disorders	Odynophagia	1	1	0
Gastrointestinal disorders	Tongue discolouration	1	1	0
General disorders and administration site conditions	Catheter site pain	1	1	0
General disorders and administration site conditions	Granuloma	1	1	0
Hepatobiliary disorders	Hepatic function abnormal	1	1	0
Immune system disorders	Autoimmune disorder	1	1	0
Infections and infestations	Cytomegalovirus enteritis	1	1	0
Infections and infestations	Fungal infection	1	1	0
Infections and infestations	Pneumonia cryptococcal	1	1	0
Infections and infestations	Respiratory tract infection	1	1	0
Infections and infestations	Streptococcal bacteraemia	1	1	0
Investigations	Blood thyroid stimulating hormone abnormal	1	1	0

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Metabolism and nutrition disorders	Hyponatraemia	1	1	0
Metabolism and nutrition disorders	Iron deficiency	1	1	0
Musculoskeletal and connective tissue disorders	Flank pain	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin cancer	1	1	0
Reproductive system and breast disorders	Pelvic pain	1	1	0
Cardiac disorders	Sinus tachycardia	1	1	0
Cardiac disorders	Ventricular tachycardia	1	1	0
Endocrine disorders	Thyroid mass	1	1	0
Eye disorders	Eye pain	1	1	0
Gastrointestinal disorders	Abdominal pain upper	1	1	0
Gastrointestinal disorders	Retching	1	1	0
General disorders and administration site conditions	Feeling abnormal	1	1	0
General disorders and administration site conditions	Injection site reaction	1	1	0
General disorders and administration site conditions	Peripheral swelling	1	1	0
Infections and infestations	Mastitis	1	1	0
Injury, poisoning and procedural complications	Back injury	1	1	0
Injury, poisoning and procedural complications	Rib fracture	1	1	0
Investigations	Red blood cell count increased	1	1	0
Investigations	Thyroxine decreased	1	1	0
Investigations	White blood cell count decreased	1	1	0
Musculoskeletal and connective tissue disorders	Mobility decreased	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Metastatic malignant melanoma	1	1	0
Psychiatric disorders	Panic attack	1	1	0
Respiratory, thoracic and mediastinal disorders	Wheezing	1	1	0
Blood and lymphatic system disorders	Autoimmune haemolytic anaemia	1	1	0
Blood and lymphatic system disorders	Leukopenia	1	1	0
Eye disorders	Diplopia	1	1	0
Eye disorders	Exophthalmos	1	1	0

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Eye disorders	Extraocular muscle disorder	1	1	0
Gastrointestinal disorders	Mouth haemorrhage	1	1	0
General disorders and administration site conditions	Feeling jittery	1	1	0
Infections and infestations	Breast cellulitis	1	1	0
Infections and infestations	Cytomegalovirus colitis	1	1	0
Infections and infestations	Nasopharyngitis	1	1	0
Investigations	Blood pressure increased	1	1	0
Investigations	Eosinophil count increased	1	1	0
Investigations	White blood cells urine positive	1	1	0
Metabolism and nutrition disorders	Fluid overload	1	1	0
Metabolism and nutrition disorders	Weight fluctuation	1	1	0
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	B-cell lymphoma	1	1	0
Nervous system disorders	Movement disorder	1	1	0
Pregnancy, puerperium and perinatal conditions	Pregnancy	1	1	0
Reproductive system and breast disorders	Dysmenorrhoea	1	1	0
Reproductive system and breast disorders	Menstrual disorder	1	1	0
Blood and lymphatic system disorders	Coagulopathy	1	1	0
Cardiac disorders	Cardiac disorder	1	1	0
Endocrine disorders	Thyroid disorder	1	1	0
Gastrointestinal disorders	Hypoaesthesia oral	1	1	0
Infections and infestations	Cellulitis	1	1	0
Infections and infestations	Viral pharyngitis	1	1	0
Injury, poisoning and procedural complications	Infusion related reaction	1	1	0
Investigations	Blood creatine increased	1	1	0
Investigations	Electrocardiogram ST segment elevation	1	1	0
Investigations	Red blood cell sedimentation rate increased	1	1	0
Investigations	Sinus rhythm	1	1	0
Musculoskeletal and connective tissue disorders	Muscle tightness	1	1	0

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Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acrochordon	1	1	0
Nervous system disorders	Central nervous system lesion	1	1	0
Nervous system disorders	Restless legs syndrome	1	1	0
Respiratory, thoracic and mediastinal disorders	Throat irritation	1	1	0
Respiratory, thoracic and mediastinal disorders	Vocal cord dysfunction	1	1	0
Skin and subcutaneous tissue disorders	Haemorrhage subcutaneous	1	1	0
Eye disorders	Cataract subcapsular	1	1	0
Eye disorders	Dry eye	1	1	0
Eye disorders	Visual impairment	1	1	0
Gastrointestinal disorders	Tongue coated	1	1	0
General disorders and administration site conditions	Multiple organ dysfunction syndrome	1	1	0
Hepatobiliary disorders	Cholecystitis acute	1	1	0
Infections and infestations	Gastroenteritis salmonella	1	1	0
Investigations	Blood albumin abnormal	1	1	0
Investigations	Liver function test abnormal	2	1	0
Investigations	Urine protein/creatinine ratio increased	1	1	0
Musculoskeletal and connective tissue disorders	Muscle haemorrhage	1	1	0
Musculoskeletal and connective tissue disorders	Myositis	1	1	0
Nervous system disorders	Aphasia	1	1	0
Nervous system disorders	Balance disorder	1	1	0
Nervous system disorders	Sensory disturbance	1	1	0
Renal and urinary disorders	Urinary incontinence	1	1	0
Respiratory, thoracic and mediastinal disorders	Throat tightness	1	1	0
Skin and subcutaneous tissue disorders	Skin exfoliation	1	1	0
Blood and lymphatic system disorders	Febrile neutropenia	1	1	0
Blood and lymphatic system disorders	Splenomegaly	1	1	0
Endocrine disorders	Thyroid dermatopathy	1	1	0
Eye disorders	Eyelid oedema	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Eye disorders	Periorbital oedema	1	1	0
General disorders and administration site conditions	Gait inability	1	1	0
General disorders and administration site conditions	Thirst	1	1	0
Infections and infestations	Herpes simplex meningitis	1	1	0
Investigations	Human metapneumovirus test positive	1	1	0
Investigations	Liver function test increased	2	1	0
Nervous system disorders	Paraplegia	1	1	0
Nervous system disorders	Poor quality sleep	1	1	0
Psychiatric disorders	Mood altered	1	1	0
Skin and subcutaneous tissue disorders	Hair texture abnormal	1	1	0
Skin and subcutaneous tissue disorders	Swelling face	1	1	0
Blood and lymphatic system disorders	Hypercoagulation	1	1	0
Cardiac disorders	Atrial flutter	1	1	0
Endocrine disorders	Autoimmune thyroid disorder	1	1	0
Gastrointestinal disorders	Glossodynia	1	1	0
General disorders and administration site conditions	Ill-defined disorder	1	1	0
General disorders and administration site conditions	Oedema	1	1	0
Hepatobiliary disorders	Drug-induced liver injury	1	1	0
Immune system disorders	Anti-neutrophil cytoplasmic antibody positive vasculitis	1	1	0
Infections and infestations	Infection	1	1	0
Infections and infestations	Viral upper respiratory tract infection	1	1	0
Injury, poisoning and procedural complications	Inappropriate schedule of product administration	1	1	0
Investigations	Tri-iodothyronine free increased	1	1	0
Nervous system disorders	Status epilepticus	1	1	0
Psychiatric disorders	Depressed mood	1	1	0
Renal and urinary disorders	Polyuria	1	1	0
Reproductive system and breast disorders	Breast enlargement	1	1	0
Skin and subcutaneous tissue disorders	Hypersensitivity vasculitis	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Vascular disorders	Poor venous access	1	1	0
Gastrointestinal disorders	Dyspepsia	1	0	0
Gastrointestinal disorders	Inguinal hernia	1	0	0
General disorders and administration site conditions	Infusion site rash	1	0	0
General disorders and administration site conditions	Swelling	1	0	0
Infections and infestations	Meningitis aspergillus	1	0	0
Psychiatric disorders	Personality disorder	1	0	0
General disorders and administration site conditions	Gait disturbance	1	0	0
Blood and lymphatic system disorders	Bone marrow failure	1	0	1
General disorders and administration site conditions	Discomfort	1	0	0
Infections and infestations	Progressive multifocal leukoencephalopathy	1	0	1
Nervous system disorders	Dyskinesia	1	0	0
Nervous system disorders	Carpal tunnel syndrome	1	0	0
Infections and infestations	Toxoplasmosis	1	0	1
Reproductive system and breast disorders	Genital rash	1	0	0
Injury, poisoning and procedural complications	Tooth fracture	1	0	0
Psychiatric disorders	Suicidal ideation	1	0	0
Nervous system disorders	Lateral medullary syndrome	1	0	0
Psychiatric disorders	Adjustment disorder with depressed mood	1	0	0
Nervous system disorders	Serotonin syndrome	1	0	0

Footnotes

ⁱ A description of what, in general terms, was affected by the adverse event, as described by the Medical Dictionary for Regulatory Activities MedDRA (for example 'cardiac disorders')

ⁱⁱ A description of the adverse event as defined by MedDRA; these adverse events are grouped by system organ class. You can use the MedlinePlus medical dictionary <<http://www.nlm.nih.gov/medlineplus/mplusdictionary.html>> to look up terms.

ⁱⁱⁱ The number of cases for which each type of adverse event was reported

^{iv} Results show where a medicine is the only medicine suspected to be related to the adverse event

^v These reports of death may or may not have been the result of taking a medicine