



Australian Government

Department of Health

Therapeutic Goods Administration

Database of Adverse Event Notifications - medicines

Medicine summary

You searched for the following **4 medicines** between **01/01/1971 – 01/12/2018**:

- Aristo (Carbimazole)
- Carbazole (Carbimazole)
- Neo-mercazole (Carbimazole)
- Tradename not specified (Carbimazole)

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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): 438

(Multiple adverse events have been reported for some patients)

Number of cases with a single suspected medicine: 327

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

Number of cases where death was a reported outcome: 13

(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
Skin and subcutaneous tissue disorders	Urticaria	59	44	0
Blood and lymphatic system disorders	Agranulocytosis	57	47	5
Blood and lymphatic system disorders	Neutropenia	52	40	1
Skin and subcutaneous tissue disorders	Pruritus	51	36	0
Skin and subcutaneous tissue disorders	Rash	49	41	0
General disorders and administration site conditions	Pyrexia	39	30	1
Musculoskeletal and connective tissue disorders	Arthralgia	32	26	0
Gastrointestinal disorders	Nausea	19	15	0
Infections and infestations	Pharyngitis	19	15	1
Skin and subcutaneous tissue disorders	Rash maculo-papular	19	11	0
Hepatobiliary disorders	Hepatic function abnormal	16	11	0
Musculoskeletal and connective tissue disorders	Arthritis	13	10	0
Musculoskeletal and connective tissue disorders	Myalgia	13	10	0
Hepatobiliary disorders	Jaundice	12	10	1
Blood and lymphatic system disorders	Leukopenia	12	11	0
Gastrointestinal disorders	Vomiting	12	10	1
Skin and subcutaneous tissue disorders	Rash erythematous	11	5	0
Nervous system disorders	Headache	11	10	0
General disorders and administration site conditions	Chills	10	9	0
Product issues	Product substitution issue	9	9	0
Gastrointestinal disorders	Abdominal pain	8	5	1

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
Gastrointestinal disorders	Mouth ulceration	8	8	0
General disorders and administration site conditions	Malaise	8	5	1
Respiratory, thoracic and mediastinal disorders	Dyspnoea	8	3	2
General disorders and administration site conditions	Asthenia	8	5	0
Hepatobiliary disorders	Hepatitis cholestatic	7	7	0
Hepatobiliary disorders	Hepatitis	7	5	0
Gastrointestinal disorders	Diarrhoea	6	4	1
Skin and subcutaneous tissue disorders	Rash pruritic	6	4	0
Skin and subcutaneous tissue disorders	Hyperhidrosis	6	4	0
Vascular disorders	Hypotension	6	0	2
Blood and lymphatic system disorders	Febrile neutropenia	6	6	0
Investigations	Liver function test increased	5	4	0
General disorders and administration site conditions	Oedema peripheral	5	3	0
Blood and lymphatic system disorders	Lymphadenopathy	5	4	0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	5	5	0
Blood and lymphatic system disorders	Pancytopenia	5	4	2
Musculoskeletal and connective tissue disorders	Myositis	5	5	0
General disorders and administration site conditions	Fatigue	4	2	0
Vascular disorders	Vasculitis	4	2	0
Infections and infestations	Sepsis	4	2	3
General disorders and administration site conditions	Face oedema	4	4	0
Investigations	Weight decreased	4	3	0
Skin and subcutaneous tissue disorders	Alopecia	4	3	0
General disorders and administration site conditions	Oedema	4	4	0
Skin and subcutaneous tissue disorders	Purpura	4	0	0
Metabolism and nutrition disorders	Decreased appetite	4	3	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
Gastrointestinal disorders	Abdominal pain upper	4	3	0
Endocrine disorders	Hyperthyroidism	3	1	1
Nervous system disorders	Lethargy	3	3	0
Infections and infestations	Conjunctivitis	3	3	0
Nervous system disorders	Tremor	3	3	0
Endocrine disorders	Hypothyroidism	3	1	0
Nervous system disorders	Dizziness	3	1	0
Hepatobiliary disorders	Hepatitis acute	3	3	0
General disorders and administration site conditions	Pain	3	3	0
Blood and lymphatic system disorders	Eosinophilia	3	2	0
Blood and lymphatic system disorders	Aplastic anaemia	3	2	1
Skin and subcutaneous tissue disorders	Rash macular	3	2	0
Respiratory, thoracic and mediastinal disorders	Bronchospasm	3	0	0
Gastrointestinal disorders	Dyspepsia	3	3	0
Gastrointestinal disorders	Dysphagia	3	2	0
General disorders and administration site conditions	Peripheral swelling	3	2	0
Blood and lymphatic system disorders	Anaemia	3	3	0
Blood and lymphatic system disorders	Bone marrow failure	3	2	1
Blood and lymphatic system disorders	Thrombocytopenia	3	0	0
Musculoskeletal and connective tissue disorders	Myopathy	3	3	0
Respiratory, thoracic and mediastinal disorders	Cough	3	1	1
Injury, poisoning and procedural complications	Foetal exposure during pregnancy	3	3	0
Investigations	Antineutrophil cytoplasmic antibody positive	2	1	0
Psychiatric disorders	Agitation	2	1	1
Nervous system disorders	Neuropathy peripheral	2	2	0
Immune system disorders	Hypersensitivity	2	2	0
Skin and subcutaneous tissue disorders	Erythema	2	1	0

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Skin and subcutaneous tissue disorders	Photosensitivity reaction	2	1	0
Hepatobiliary disorders	Liver injury	2	2	0
Infections and infestations	Pneumonia	2	1	1
Skin and subcutaneous tissue disorders	Stevens-Johnson syndrome	2	1	0
Nervous system disorders	Ataxia	2	2	0
Skin and subcutaneous tissue disorders	Swelling face	2	1	0
Congenital, familial and genetic disorders	Hypospadias	2	2	0
Gastrointestinal disorders	Oral pain	2	1	0
General disorders and administration site conditions	Generalised oedema	2	1	0
Hepatobiliary disorders	Hepatocellular injury	2	2	0
Congenital, familial and genetic disorders	Congenital nose malformation	2	2	0
Nervous system disorders	Hypoaesthesia	2	1	0
Hepatobiliary disorders	Hepatic failure	2	1	1
Musculoskeletal and connective tissue disorders	Systemic lupus erythematosus	2	2	0
Nervous system disorders	Syncope	2	1	0
Congenital, familial and genetic disorders	Ear malformation	2	2	0
General disorders and administration site conditions	Drug ineffective	2	1	0
Congenital, familial and genetic disorders	Congenital eye disorder	2	2	0
General disorders and administration site conditions	Chest pain	2	1	0
Pregnancy, puerperium and perinatal conditions	Foetal death	2	2	1
Cardiac disorders	Atrial fibrillation	2	1	0
Vascular disorders	Circulatory collapse	2	1	2
Investigations	Aspartate aminotransferase increased	2	0	0
Investigations	Liver function test abnormal	2	1	0
Musculoskeletal and connective tissue disorders	Joint swelling	2	2	0
Nervous system disorders	Paresis	2	2	0
Psychiatric disorders	Insomnia	2	2	0

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Vascular disorders	Peripheral ischaemia	2	1	0
Blood and lymphatic system disorders	Lymphopenia	2	1	0
Gastrointestinal disorders	Stomatitis	2	2	0
Cardiac disorders	Tachycardia	2	1	0
Congenital, familial and genetic disorders	Multiple congenital abnormalities	2	1	0
Hepatobiliary disorders	Hyperbilirubinaemia	2	1	0
Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	2	0	0
Endocrine disorders	Goitre	2	2	0
Nervous system disorders	Somnolence	2	1	0
Respiratory, thoracic and mediastinal disorders	Nasal disorder	2	2	0
Infections and infestations	Neutropenic sepsis	2	2	0
Skin and subcutaneous tissue disorders	Dermatitis bullous	2	2	0
Nervous system disorders	Paraesthesia	2	1	0
Gastrointestinal disorders	Tooth disorder	2	2	0
Investigations	Transaminases increased	2	0	0
Infections and infestations	Gingivitis	2	2	0
Metabolism and nutrition disorders	Increased appetite	2	1	0
Nervous system disorders	Dysgeusia	2	2	0
Congenital, familial and genetic disorders	Ventricular septal defect	1	1	0
Endocrine disorders	Secondary hypogonadism	1	1	0
Endocrine disorders	Thyrotoxic crisis	1	1	0
Eye disorders	Periorbital oedema	1	1	0
Gastrointestinal disorders	Eructation	1	1	0
Psychiatric disorders	Panic attack	1	1	0
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	1	0	0
Gastrointestinal disorders	Haematochezia	1	0	0
Gastrointestinal disorders	Salivary hypersecretion	1	1	0
General disorders and administration site conditions	Influenza like illness	1	0	0
Infections and infestations	Tonsillitis	1	1	0
Investigations	Gamma-glutamyltransferase increased	1	0	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
Nervous system disorders	Cerebrovascular accident	1	1	0
Respiratory, thoracic and mediastinal disorders	Dysphonia	1	1	0
Respiratory, thoracic and mediastinal disorders	Epistaxis	1	1	0
Respiratory, thoracic and mediastinal disorders	Pulmonary vasculitis	1	0	0
Gastrointestinal disorders	Abdominal distension	1	1	0
Metabolism and nutrition disorders	Acidosis	1	0	1
General disorders and administration site conditions	Therapeutic response increased	1	0	0
Musculoskeletal and connective tissue disorders	Muscle spasms	1	1	0
Musculoskeletal and connective tissue disorders	Synovitis	1	0	0
Nervous system disorders	Seizure	1	0	0
Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	1	0	0
Skin and subcutaneous tissue disorders	Lichenoid keratosis	1	1	0
Investigations	Neutrophil count decreased	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm malignant	1	1	0
Nervous system disorders	Migraine	1	1	0
Renal and urinary disorders	Urinary incontinence	1	1	0
Investigations	Hepatic enzyme abnormal	1	1	0
Psychiatric disorders	Somnambulism	1	1	0
Skin and subcutaneous tissue disorders	Dermatitis	1	1	0
Cardiac disorders	Ventricular tachycardia	1	1	0
Gastrointestinal disorders	Glossitis	1	1	0
Infections and infestations	Rhinitis	1	1	0
Metabolism and nutrition disorders	Hypokalaemia	1	0	0
Renal and urinary disorders	Acute kidney injury	1	1	0
Renal and urinary disorders	Renal pain	1	1	0
Congenital, familial and genetic disorders	Aplasia cutis congenita	1	1	0
Eye disorders	Exophthalmos	1	0	1
Hepatobiliary disorders	Hepatorenal syndrome	1	0	1
Immune system disorders	Serum sickness-like reaction	1	0	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
Investigations	International normalised ratio increased	1	1	0
Musculoskeletal and connective tissue disorders	Back pain	1	1	0
Immune system disorders	Serum sickness	1	1	0
Injury, poisoning and procedural complications	Product dispensing error	1	0	0
Metabolism and nutrition disorders	Hypoglycaemia	1	0	0
Psychiatric disorders	Depression	1	1	0
Reproductive system and breast disorders	Gynaecomastia	1	1	0
Blood and lymphatic system disorders	Splenomegaly	1	1	0
Investigations	Anti-thyroid antibody	1	0	0
Investigations	White blood cell count decreased	1	1	0
Musculoskeletal and connective tissue disorders	Pain in extremity	1	1	0
Investigations	Antiphospholipid antibodies	1	0	0
Nervous system disorders	Depressed level of consciousness	1	0	1
Nervous system disorders	Hepatic encephalopathy	1	0	1
Respiratory, thoracic and mediastinal disorders	Pleural effusion	1	1	0
Cardiac disorders	Cardiomegaly	1	0	1
Congenital, familial and genetic disorders	Polydactyly	1	0	0
General disorders and administration site conditions	Hypothermia	1	0	1
Hepatobiliary disorders	Cholestasis	1	1	0
Injury, poisoning and procedural complications	Medication error	1	0	0
Investigations	Activated partial thromboplastin time prolonged	1	0	0
Reproductive system and breast disorders	Amenorrhoea	1	0	0
Skin and subcutaneous tissue disorders	Rash vesicular	1	1	0
Gastrointestinal disorders	Pancreatitis	1	0	0
Investigations	Troponin increased	1	1	0
Investigations	Alanine aminotransferase increased	1	1	0
Musculoskeletal and connective tissue disorders	Joint effusion	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
Musculoskeletal and connective tissue disorders	Polyarthritis	1	1	0
Renal and urinary disorders	Chromaturia	1	1	0
Congenital, familial and genetic disorders	Hernia congenital	1	0	0
Investigations	Ammonia increased	1	0	0
Investigations	Prothrombin level decreased	1	0	0
Infections and infestations	Candida infection	1	1	0
Musculoskeletal and connective tissue disorders	Rhabdomyolysis	1	1	0
Nervous system disorders	Coma hepatic	1	0	1
Psychiatric disorders	Delirium	1	0	1
Respiratory, thoracic and mediastinal disorders	Throat tightness	1	1	0
Skin and subcutaneous tissue disorders	Rash papular	1	1	0
Cardiac disorders	Bradycardia	1	0	1
Congenital, familial and genetic disorders	Goitre congenital	1	0	0
Congenital, familial and genetic disorders	Skull malformation	1	1	0
Infections and infestations	Infection	1	1	0
Psychiatric disorders	Confusional state	1	0	0
Renal and urinary disorders	Proteinuria	1	0	0
Nervous system disorders	Aphasia	1	1	0
Respiratory, thoracic and mediastinal disorders	Pulmonary fibrosis	1	0	0
Cardiac disorders	Palpitations	1	1	0
Eye disorders	Blindness	1	0	1
Gastrointestinal disorders	Abdominal discomfort	1	1	0
Hepatobiliary disorders	Jaundice cholestatic	1	1	0
Injury, poisoning and procedural complications	Overdose	1	0	0
Metabolism and nutrition disorders	Hyponatraemia	1	0	0
Nervous system disorders	Neuralgia	1	1	0
Gastrointestinal disorders	Dry mouth	1	1	0
General disorders and administration site conditions	Condition aggravated	1	1	0
Musculoskeletal and connective tissue disorders	Osteoarthritis	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
Injury, poisoning and procedural complications	Exposure during pregnancy	1	1	0
Psychiatric disorders	Fear	1	1	0
Skin and subcutaneous tissue disorders	Urticarial vasculitis	1	1	0
Gastrointestinal disorders	Constipation	1	0	0
Gastrointestinal disorders	Lip swelling	1	1	0
General disorders and administration site conditions	Acute phase reaction	1	0	0
Investigations	Hepatic enzyme increased	1	0	0
Musculoskeletal and connective tissue disorders	Arthropathy	1	0	0
Gastrointestinal disorders	Tongue ulceration	1	1	0
Investigations	Blood alkaline phosphatase increased	1	0	0
Nervous system disorders	Muscle contractions involuntary	1	1	0
Psychiatric disorders	Nightmare	1	1	0
Respiratory, thoracic and mediastinal disorders	Pulmonary haemorrhage	1	0	0
Respiratory, thoracic and mediastinal disorders	Respiratory failure	1	0	1
Skin and subcutaneous tissue disorders	Angioedema	1	1	0
Vascular disorders	Flushing	1	0	0
Psychiatric disorders	Paranoia	1	0	0
Congenital, familial and genetic disorders	Choanal atresia	1	1	0
Congenital, familial and genetic disorders	Congenital musculoskeletal anomaly	1	0	0
Investigations	Blood creatine phosphokinase increased	1	1	0
Nervous system disorders	Encephalopathy	1	1	0
Gastrointestinal disorders	Retching	1	1	0
Nervous system disorders	Extrapyramidal disorder	1	1	0
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	1	0	0
Renal and urinary disorders	Glomerulonephritis rapidly progressive	1	0	0
Respiratory, thoracic and mediastinal disorders	Lung infiltration	1	1	0
Vascular disorders	Vasodilatation	1	0	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
Ear and labyrinth disorders	Ear pain	1	1	0
Gastrointestinal disorders	Oesophagitis	1	1	0
Gastrointestinal disorders	Oral mucosal erythema	1	1	0
Skin and subcutaneous tissue disorders	Dry skin	1	0	0
Investigations	Blood count abnormal	1	1	0
Metabolism and nutrition disorders	Hypochloraemia	1	0	0
Cardiac disorders	Cardiac arrest	1	0	1
Nervous system disorders	Ageusia	1	1	0
Nervous system disorders	Altered state of consciousness	1	0	1
Renal and urinary disorders	Urinary retention	1	1	0
Skin and subcutaneous tissue disorders	Erythema nodosum	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