Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medicines

Medicine summary

You searched for the following **3 medicines** between **01/01/2017 – 01/01/2018**:

- Ferinject 100mg/2mL (Ferric carboxymaltose)
- Ferinject 500mg/10mL (Ferric carboxymaltose)
- Ferinject Nos (Ferric carboxymaltose)

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.

Results

Number of reports (cases): 116

(Multiple adverse events have been reported for some patients)

Number of cases with a single suspected medicine: 115

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

Number of cases where death was a reported outcome: 0

(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	38	37	0
Skin and subcutaneous tissue disorders	Pruritus	17	16	0
Skin and subcutaneous tissue disorders	Rash	13	13	0
Immune system disorders	Anaphylactic reaction	10	10	0
Respiratory, thoracic and mediastinal disorders	Dyspnoea	10	10	0
Nervous system disorders	Headache	8	8	0
Skin and subcutaneous tissue disorders	Rash pruritic	7	7	0
General disorders and administration site conditions	Pyrexia	7	7	0
Skin and subcutaneous tissue disorders	Erythema	7	7	0
Cardiac disorders	Tachycardia	6	6	0
Musculoskeletal and connective tissue disorders	Myalgia	6	6	0
Gastrointestinal disorders	Nausea	6	6	0
Nervous system disorders	Paraesthesia	5	5	0
Respiratory, thoracic and mediastinal disorders	Throat tightness	5	5	0
General disorders and administration site conditions	Malaise	5	5	0
Vascular disorders	Hypotension	4	4	0
Nervous system disorders	Dizziness	4	4	0
General disorders and administration site conditions	Feeling hot	4	4	0
Vascular disorders	Flushing	4	4	0
Skin and subcutaneous tissue disorders	Angioedema	4	4	0
General disorders and administration site conditions	Chest pain	4	4	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	Chills	4	4	0
Musculoskeletal and connective tissue disorders	Arthralgia	3	3	0
General disorders and administration site conditions	Chest discomfort	3	3	0
Gastrointestinal disorders	Abdominal pain	3	3	0
Immune system disorders	Hypersensitivity	3	3	0
General disorders and administration site conditions	Feeling cold	3	3	0
Nervous system disorders	Lethargy	2	2	0
Skin and subcutaneous tissue disorders	Rash erythematous	2	2	0
Skin and subcutaneous tissue disorders	Swelling face	2	2	0
Nervous system disorders	Syncope	2	2	0
Nervous system disorders	Dysgeusia	2	2	0
Psychiatric disorders	Confusional state	2	2	0
Respiratory, thoracic and mediastinal disorders	Cough	2	2	0
Psychiatric disorders	Agitation	2	2	0
Immune system disorders	Anaphylactoid reaction	2	2	0
Nervous system disorders	Burning sensation	2	2	0
Musculoskeletal and connective tissue disorders	Back pain	2	2	0
Skin and subcutaneous tissue disorders	Cold sweat	2	2	0
Gastrointestinal disorders	Vomiting	2	2	0
Respiratory, thoracic and mediastinal disorders	Wheezing	2	2	0
Skin and subcutaneous tissue disorders	Pruritus generalised	2	2	0
Gastrointestinal disorders	Paraesthesia oral	2	2	0
General disorders and administration site conditions	Infusion site discolouration	2	2	0
General disorders and administration site conditions	Infusion site urticaria	1	1	0
Injury, poisoning and procedural complications	Exposure during pregnancy	1	1	0
Gastrointestinal disorders	Palatal swelling	1	1	0
Vascular disorders	Hot flush	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]
Investigations	Electrocardiogram change	1	1	0
Metabolism and nutrition disorders	Decreased appetite	1	1	0
General disorders and administration site conditions	Infusion site extravasation	1	1	0
General disorders and administration site conditions	Infusion site swelling	1	1	0
Injury, poisoning and procedural complications	Off label use	1	1	0
Gastrointestinal disorders	Hypoaesthesia oral	1	1	0
General disorders and administration site conditions	Infusion site erythema	1	1	0
Injury, poisoning and procedural complications	Prescribed overdose	1	1	0
Skin and subcutaneous tissue disorders	Generalised erythema	1	1	0
General disorders and administration site conditions	Concomitant disease aggravated	1	1	0
Investigations	Blood pressure increased	1	1	0
Psychiatric disorders	Anxiety	1	1	0
Gastrointestinal disorders	Abdominal discomfort	1	1	0
Cardiac disorders	Acute myocardial infarction	1	1	0
Psychiatric disorders	Delirium	1	1	0
Nervous system disorders	Depressed level of consciousness	1	1	0
Skin and subcutaneous tissue disorders	Dermatitis allergic	1	1	0
Gastrointestinal disorders	Diarrhoea	1	1	0
Eye disorders	Eye swelling	1	1	0
General disorders and administration site conditions	Fatigue	1	1	0
General disorders and administration site conditions	Feeling abnormal	1	1	0
Vascular disorders	Hypertension	1	1	0
Nervous system disorders	Hypoaesthesia	1	1	0
Metabolism and nutrition disorders	Hypocalcaemia	1	1	0
Metabolism and nutrition disorders	Hypophosphataemia	1	1	0
Nervous system disorders	Tongue paralysis	1	1	0
Nervous system disorders	Unresponsive to stimuli	1	1	0
Respiratory, thoracic and mediastinal disorders	Tachypnoea	1	1	0
Psychiatric disorders	Tangentiality	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]
Respiratory, thoracic and mediastinal disorders	Throat irritation	1	1	0
Skin and subcutaneous tissue disorders	Rash generalised	1	1	0
Nervous system disorders	Seizure	1	1	0
Skin and subcutaneous tissue disorders	Skin discolouration	1	1	0
Musculoskeletal and connective tissue disorders	Muscle spasms	1	1	0
Metabolism and nutrition disorders	Hyperglycaemia	1	1	0
Skin and subcutaneous tissue disorders	Hyperhidrosis	1	1	0
Respiratory, thoracic and mediastinal disorders	Hypoxia	1	1	0
General disorders and administration site conditions	Influenza like illness	1	1	0
Musculoskeletal and connective tissue disorders	Joint swelling	1	1	0
Respiratory, thoracic and mediastinal disorders	Laryngeal oedema	1	1	0
Psychiatric disorders	Paranoia	1	1	0
Psychiatric disorders	Persecutory delusion	1	1	0
Skin and subcutaneous tissue disorders	Photosensitivity reaction	1	1	0
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	1	1	0
Metabolism and nutrition disorders	Polydipsia	1	1	0
Vascular disorders	Pallor	1	1	0
Cardiac disorders	Palpitations	1	1	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