

Australian Government

Department of Health

Therapeutic Goods Administration

Database of Adverse Event Notifications - medicines

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Important information! The TGA uses adverse event reports to identify when a <u>safety issue (//www.tga.gov.au/safety/daen-safety-monitoring.htm)</u> may be present.

- An adverse event report does **not** mean that the medicine is the <u>cause (//www.tga.gov.au/safety/daen-about.htm#causality)</u> 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 (http://www.healthdirect.org.au/) 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 (http://www.healthdirect.org.au/) .

4 medicines selected between 01/10/2021 - 21/10/2021.

23 MedDRA Reaction Terms selected.

Search results

The results are shown in two tabs.

Number of reports (cases): 703

Number of cases with a single suspected medicine: 678

Number of cases where death was a reported outcome: 10

More information on the search results

Medicine summary

List of reports

Medicine summary

The medicine summary groups reported adverse events together. Patients may have reported multiple adverse events.

Further information about the medicine summary (http://www.tga.gov.au/safety/daen-about-results.htm#medicine-summary)

Information on printing search results (http://www.tga.gov.au/safety/daen-consumer-qa.htm)

Sort by: Number of cases - highest first

Print version of this report

		<u>report</u>			
MedDRA system organ class	MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary (http://www.nlm.nih.gov/medlineplus/mplusdictionary.html).	Number of cases	Number of cases with a single suspected medicine	Number of cases where death was a reported outcome	
Cardiac disorders	Pericarditis (http://www.merriam-webster.com/medlineplus/Pericarditis)	387	374	0	
Cardiac disorders	Myocarditis (http://www.merriam-webster.com/medlineplus/Myocarditis)	178	168	1	
Cardiac disorders	Tachycardia (http://www.merriam-webster.com/medlineplus/Tachycardia)	83	81	0	
Cardiac disorders	Pericardial (http://www.merriam-webster.com/medlineplus/Pericardial) effusion (http://www.merriam-webster.com/medlineplus/effusion)	26	24	0	
Cardiac disorders	<u>Cardiac (http://www.merriam-webster.com/medlineplus/Cardiac) flutter</u> (http://www.merriam-webster.com/medlineplus/flutter)	18	18	0	
Cardiac disorders	Myocardial (http://www.merriam-webster.com/medlineplus/Myocardial) infarction (http://www.merriam-webster.com/medlineplus/infarction)	13	13	1	
Cardiac disorders	Bradycardia (http://www.merriam-webster.com/medlineplus/Bradycardia)	10	10	2	

MedDRA system organ class	MedDRA reaction term Click on a term below to search the MedlinePlus medical dictionary (http://www.nlm.nih.qov/medlineplus/mplusdictionary.html).	Number of cases	Number of cases with a single suspected medicine	Number of cases where death was a reported outcome
Cardiac disorders	Acute (http://www.merriam-webster.com/medlineplus/Acute) myocardial (http://www.merriam-webster.com/medlineplus/myocardial) infarction (http://www.merriam-webster.com/medlineplus/infarction)	8	7	0
Cardiac disorders	Cardiac (http://www.merriam-webster.com/medlineplus/Cardiac) arrest (http://www.merriam-webster.com/medlineplus/arrest)	6	6	3
Cardiac disorders	<u>Cardiac (http://www.merriam-webster.com/medlineplus/Cardiac)</u> <u>failure</u> (http://www.merriam-webster.com/medlineplus/failure)	4	4	1
Cardiac disorders	Postural (http://www.merriam-webster.com/medlineplus/Postural) orthostatic (http://www.merriam-webster.com/medlineplus/orthostatic) tachycardia (http://www.merriam-webster.com/medlineplus/tachycardia) syndrome (http://www.merriam-webster.com/medlineplus/syndrome)	4	4	0
Cardiac disorders	Supraventricular (http://www.merriam- webster.com/medlineplus/Supraventricular) tachycardia (http://www.merriam- webster.com/medlineplus/tachycardia)	4	4	0
Cardiac disorders	Ventricular (http://www.merriam-webster.com/medlineplus/Ventricular) tachycardia (http://www.merriam-webster.com/medlineplus/tachycardia)	4	4	0
Cardiac disorders	<u>Cardiac (http://www.merriam-webster.com/medlineplus/Cardiac)</u> <u>disorder</u> (http://www.merriam-webster.com/medlineplus/disorder)	3	3	0
Cardiac disorders	<u>Cardiomyopathy (http://www.merriam-webster.com/medlineplus/Cardiomyopathy)</u>	3	3	0
Cardiac disorders	<u>Cardio-respiratory (http://www.merriam-webster.com/medlineplus/Cardio-respiratory)</u> <u>arrest (http://www.merriam-webster.com/medlineplus/arrest)</u>	3	3	3
Cardiac disorders	Sinus (http://www.merriam-webster.com/medlineplus/Sinus) tachycardia (http://www.merriam-webster.com/medlineplus/tachycardia)	3	3	0
Cardiac disorders	Atrial (http://www.merriam-webster.com/medlineplus/Atrial) tachycardia (http://www.merriam-webster.com/medlineplus/tachycardia)	2	2	0
Cardiac disorders	Cardiac (http://www.merriam-webster.com/medlineplus/Cardiac) dysfunction (http://www.merriam-webster.com/medlineplus/dysfunction)	2	2	0
Cardiac disorders	Cardiomegaly (http://www.merriam-webster.com/medlineplus/Cardiomegaly)	2	2	0
Cardiac disorders	Cardiac (http://www.merriam-webster.com/medlineplus/Cardiac) discomfort (http://www.merriam-webster.com/medlineplus/discomfort)	1	1	0
Cardiac disorders	Cardiac (http://www.merriam-webster.com/medlineplus/Cardiac) failure (http://www.merriam-webster.com/medlineplus/failure) congestive (http://www.merriam-webster.com/medlineplus/congestive)	1	1	0
Cardiac disorders	Carditis (http://www.merriam-webster.com/medlineplus/Carditis)	1	1	0

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Important information on the Database of Adverse Event Notifications - medicines 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 (//www.tga.gov.au/safety/daen-about.htm)
- Medicines safety (//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 <u>'blue card' reporting form (//www.tga.gov.au/safety/problem.htm)</u>, <u>by phone (//www.tga.gov.au/safety/problem.htm)</u> and <u>online (//www.tga.gov.au/safety/problem.htm)</u>.

Other useful sources of information on Australian medicines

More information about a medicine is available from the <u>Product Information (PI) (//www.tga.gov.au/hp/information-medicines-pi.htm</u>) and <u>Consumer Medicine Information (CMI) (//www.tga.gov.au/consumers/information-medicines-cmi.htm</u>) leaflet or the labelling of the medicine. <u>Australian Public Assessment Report for Prescription Medicines (AusPARs) (//www.tga.gov.au/industry/pm-auspar.htm</u>) for some prescription medicines, are also available from the <u>TGA website</u> (//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.

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| A-Z guide (//www.tga.gov.au/z-guide) | Contact the TGA (//www.tga.gov.au/contact-tga)