



**Australian Government**

**Department of Health**

**Therapeutic Goods Administration**

# Database of Adverse Event Notifications - medicines

## Medicine summary

You searched for the following **1 medicine** between **01/01/2020 – 17/08/2021**:

- COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified))

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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): 307

(Multiple adverse events have been reported for some patients)

Number of cases with a single suspected medicine: 298

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

Number of cases where death was a reported outcome: 19

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

MedDRA system organ class <sup>i</sup>	MedDRA reaction term <sup>ii</sup>	Number of cases <sup>iii</sup>	Number of cases with a single suspected medicine <sup>iv</sup>	Number of cases where death was a reported outcome <sup>v</sup>
Nervous system disorders	Headache	107	106	0
General disorders and administration site conditions	Pyrexia	61	60	1
Musculoskeletal and connective tissue disorders	Myalgia	56	54	1
General disorders and administration site conditions	Chills	46	45	0
General disorders and administration site conditions	Fatigue	45	43	0
Musculoskeletal and connective tissue disorders	Arthralgia	41	40	1
Gastrointestinal disorders	Nausea	39	37	0
General disorders and administration site conditions	Malaise	29	27	4
Nervous system disorders	Dizziness	27	26	0
General disorders and administration site conditions	Injection site pain	24	24	0
General disorders and administration site conditions	Injection site reaction	23	22	0
Musculoskeletal and connective tissue disorders	Pain in extremity	20	19	1
General disorders and administration site conditions	Chest pain	16	16	1
Gastrointestinal disorders	Vomiting	16	15	2
Respiratory, thoracic and mediastinal disorders	Dyspnoea	15	15	0
Respiratory, thoracic and mediastinal disorders	Cough	13	12	0
Gastrointestinal disorders	Diarrhoea	13	11	1
Gastrointestinal disorders	Abdominal pain	11	10	0
Nervous system disorders	Lethargy	11	11	0
Nervous system disorders	Paraesthesia	10	10	0
General disorders and administration site conditions	Influenza like illness	9	8	0

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Vascular disorders	Hypertension	8	8	0
Blood and lymphatic system disorders	Lymphadenopathy	8	8	0
Nervous system disorders	Tremor	8	8	0
Cardiac disorders	Tachycardia	7	7	0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	7	7	0
Injury, poisoning and procedural complications	Adverse event following immunisation	7	7	7
General disorders and administration site conditions	Asthenia	6	6	0
Skin and subcutaneous tissue disorders	Hyperhidrosis	6	5	0
General disorders and administration site conditions	Feeling cold	6	6	0
Psychiatric disorders	Insomnia	6	5	0
Cardiac disorders	Palpitations	6	6	0
Skin and subcutaneous tissue disorders	Rash	6	6	0
Metabolism and nutrition disorders	Decreased appetite	6	6	0
Musculoskeletal and connective tissue disorders	Back pain	6	6	0
Skin and subcutaneous tissue disorders	Pruritus	5	4	0
Skin and subcutaneous tissue disorders	Urticaria	4	4	0
General disorders and administration site conditions	Chest discomfort	4	4	0
Nervous system disorders	Hypoaesthesia	4	4	0
General disorders and administration site conditions	Pain	4	4	0
Injury, poisoning and procedural complications	Fall	4	4	0
Immune system disorders	Hypersensitivity	4	4	0
Eye disorders	Eye pain	4	4	0
Gastrointestinal disorders	Abdominal pain upper	4	4	0
Nervous system disorders	Presyncope	4	4	1
Nervous system disorders	Syncope	4	4	0
General disorders and administration site conditions	Gait disturbance	3	3	0
Nervous system disorders	Somnolence	3	3	0

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Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	3	3	0
Eye disorders	Vision blurred	3	3	0
General disorders and administration site conditions	Injection site erythema	3	3	0
General disorders and administration site conditions	Concomitant disease aggravated	3	3	0
Musculoskeletal and connective tissue disorders	Neck pain	3	3	0
Gastrointestinal disorders	Abdominal discomfort	3	3	0
Gastrointestinal disorders	Paraesthesia oral	3	3	0
General disorders and administration site conditions	Peripheral swelling	3	2	0
Nervous system disorders	Migraine	3	3	0
Respiratory, thoracic and mediastinal disorders	Dysphonia	3	2	0
Eye disorders	Photophobia	3	3	0
Injury, poisoning and procedural complications	Contusion	3	3	0
Skin and subcutaneous tissue disorders	Cold sweat	3	3	0
General disorders and administration site conditions	Injection site discomfort	3	3	0
Psychiatric disorders	Confusional state	3	3	0
Vascular disorders	Deep vein thrombosis	3	2	1
Reproductive system and breast disorders	Menstrual disorder	2	2	0
Vascular disorders	Lymphoedema	2	1	0
Gastrointestinal disorders	Swollen tongue	2	2	0
General disorders and administration site conditions	General physical health deterioration	2	2	2
Infections and infestations	Urinary tract infection	2	1	0
Respiratory, thoracic and mediastinal disorders	Pulmonary thrombosis	2	2	2
Gastrointestinal disorders	Oral pain	2	2	0
General disorders and administration site conditions	Death	2	2	2
Respiratory, thoracic and mediastinal disorders	Aphonia	2	2	0
General disorders and administration site conditions	Injection site bruising	2	2	0
Vascular disorders	Hot flush	2	2	0

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Eye disorders	Lacrimation increased	2	1	0
Infections and infestations	Injection site cellulitis	2	2	0
Injury, poisoning and procedural complications	Vaccination error	2	2	0
Musculoskeletal and connective tissue disorders	Joint swelling	2	2	0
Nervous system disorders	Dysgeusia	2	2	0
Vascular disorders	Hypotension	2	1	0
Ear and labyrinth disorders	Ear pain	2	2	0
Vascular disorders	Pallor	2	2	0
Respiratory, thoracic and mediastinal disorders	Sneezing	2	2	0
Cardiac disorders	Cardio-respiratory distress	1	1	0
Eye disorders	Visual impairment	1	1	0
Gastrointestinal disorders	Constipation	1	0	0
Gastrointestinal disorders	Gingival disorder	1	1	0
Immune system disorders	Anaphylactic reaction	1	1	0
Metabolism and nutrition disorders	Dehydration	1	0	0
Nervous system disorders	Balance disorder	1	1	0
Nervous system disorders	Monoplegia	1	1	0
Psychiatric disorders	Disorientation	1	1	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal swelling	1	1	0
Cardiac disorders	Atrial fibrillation	1	1	0
Cardiac disorders	Myocardial ischaemia	1	1	1
Ear and labyrinth disorders	Deafness	1	1	0
Ear and labyrinth disorders	Ear congestion	1	0	0
Immune system disorders	Bacille Calmette-Guerin scar reactivation	1	1	0
Musculoskeletal and connective tissue disorders	Limb discomfort	1	1	0
Musculoskeletal and connective tissue disorders	Muscle spasms	1	1	0
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	1	1	0
Respiratory, thoracic and mediastinal disorders	Nasal congestion	1	1	0
Skin and subcutaneous tissue disorders	Acne	1	1	0

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Blood and lymphatic system disorders	Neutrophilia	1	0	0
Cardiac disorders	Angina pectoris	1	1	0
General disorders and administration site conditions	Mucosal hypertrophy	1	1	0
General disorders and administration site conditions	Swelling face	1	1	0
Infections and infestations	Infection	1	1	0
Investigations	Antipsychotic drug level increased	1	0	0
Investigations	Blood immunoglobulin E increased	1	1	0
Investigations	Heart rate increased	1	1	0
Nervous system disorders	Cerebrovascular accident	1	1	0
Nervous system disorders	Facial paralysis	1	1	0
Nervous system disorders	Mental impairment	1	1	0
Reproductive system and breast disorders	Postmenopausal haemorrhage	1	1	0
Respiratory, thoracic and mediastinal disorders	Hypopnoea	1	1	0
Gastrointestinal disorders	Cheilitis	1	1	0
General disorders and administration site conditions	Drug ineffective	1	1	0
General disorders and administration site conditions	Oedema peripheral	1	1	0
General disorders and administration site conditions	Thirst	1	1	0
Infections and infestations	Respiratory syncytial virus bronchitis	1	0	0
Musculoskeletal and connective tissue disorders	Plantar fasciitis	1	1	0
Psychiatric disorders	Abnormal dreams	1	1	0
Skin and subcutaneous tissue disorders	Swelling face	1	1	0
Eye disorders	Blindness	1	0	0
Gastrointestinal disorders	Abdominal pain lower	1	0	0
General disorders and administration site conditions	Injection site swelling	1	1	0
Musculoskeletal and connective tissue disorders	Muscular weakness	1	1	0
Renal and urinary disorders	Urine odour abnormal	1	0	0
Respiratory, thoracic and mediastinal disorders	Respiratory failure	1	1	1

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General disorders and administration site conditions	Injection site haemorrhage	1	1	0
Infections and infestations	Pneumonia	1	1	1
Nervous system disorders	Taste disorder	1	1	0
Respiratory, thoracic and mediastinal disorders	Epistaxis	1	1	0
Surgical and medical procedures	Lymphadenectomy	1	1	0
Vascular disorders	Circulatory collapse	1	1	1
Blood and lymphatic system disorders	Thrombocytopenia	1	1	0
Cardiac disorders	Pericarditis	1	1	0
Cardiac disorders	Ventricular extrasystoles	1	1	0
Ear and labyrinth disorders	Vertigo	1	1	0
Gastrointestinal disorders	Dysphagia	1	1	0
Gastrointestinal disorders	Lip blister	1	1	0
General disorders and administration site conditions	Feeling hot	1	1	0
Infections and infestations	COVID-19	1	1	0
Investigations	Heart rate decreased	1	1	0
Reproductive system and breast disorders	Menstruation delayed	1	1	0
Respiratory, thoracic and mediastinal disorders	Asthma	1	1	0
Respiratory, thoracic and mediastinal disorders	Tachypnoea	1	1	1
Skin and subcutaneous tissue disorders	Blister	1	1	0
Eye disorders	Eye inflammation	1	1	0
Gastrointestinal disorders	Anal incontinence	1	1	0
Gastrointestinal disorders	Gastric disorder	1	0	0
General disorders and administration site conditions	Injection site mass	1	1	0
Infections and infestations	Respiratory tract infection	1	0	0
Nervous system disorders	Cerebral infarction	1	1	1
Psychiatric disorders	Listless	1	1	0
Vascular disorders	Ischaemia	1	1	1
Investigations	Oxygen saturation decreased	1	1	0
Investigations	Troponin increased	1	1	0
Nervous system disorders	Ageusia	1	1	0



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Nervous system disorders	Bell's palsy	1	1	0
Renal and urinary disorders	Acute kidney injury	1	0	0
Skin and subcutaneous tissue disorders	Skin sensitisation	1	1	0
Cardiac disorders	Hypertensive heart disease	1	1	1
General disorders and administration site conditions	Gait inability	1	0	0
Infections and infestations	Gastroenteritis	1	0	0
Infections and infestations	Labyrinthitis	1	1	0
Infections and infestations	Oral herpes	1	1	0
Musculoskeletal and connective tissue disorders	Pain in jaw	1	1	0
Psychiatric disorders	Hallucination	1	1	0
Skin and subcutaneous tissue disorders	Angioedema	1	1	0
Skin and subcutaneous tissue disorders	Erythema	1	0	0
Blood and lymphatic system disorders	Leukocytosis	1	0	0
General disorders and administration site conditions	Discomfort	1	1	0
General disorders and administration site conditions	Injection site rash	1	1	0
Injury, poisoning and procedural complications	Product administered to patient of inappropriate age	1	1	0
Metabolism and nutrition disorders	Increased appetite	1	1	0
Nervous system disorders	Coordination abnormal	1	1	0
Renal and urinary disorders	Urinary retention	1	0	0
Reproductive system and breast disorders	Vaginal haemorrhage	1	1	0
Cardiac disorders	Arteriosclerosis coronary artery	1	1	1
Gastrointestinal disorders	Mouth ulceration	1	1	0
Gastrointestinal disorders	Salivary hypersecretion	1	1	0
General disorders and administration site conditions	Therapeutic response unexpected	1	1	0
Infections and infestations	Appendicitis	1	1	0
Nervous system disorders	Transient ischaemic attack	1	1	0
Surgical and medical procedures	Hospitalisation	1	0	0

## Footnotes

- <sup>i</sup> 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')
- <sup>ii</sup> 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.
- <sup>iii</sup> The number of cases for which each type of adverse event was reported
- <sup>iv</sup> Results show where a medicine is the only medicine suspected to be related to the adverse event
- <sup>v</sup> These reports of death may or may not have been the result of taking a medicine