



Database of Adverse Event Notifications - medicines

Medicine summary

You searched for the following **3 medicines** between **01/01/2019 – 07/08/2021**:

- COMIRNATY COVID-19 vaccine (BNT162b2 (mRNA))
- COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified))
- COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector))

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Medicine summary

Results

Number of reports (cases): 46438

(Multiple adverse events have been reported for some patients)

Number of cases with a single suspected medicine: 45778

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

Number of cases where death was a reported outcome: 448

(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 |
|--|--------------------------------------|--------------------------------|--|---|
| Injury, poisoning and procedural complications | Adverse event following immunisation | 113 | 108 | 101 |
| Respiratory, thoracic and mediastinal disorders | Dyspnoea | 2070 | 2033 | 40 |
| Respiratory, thoracic and mediastinal disorders | Pulmonary embolism | 644 | 628 | 33 |
| Nervous system disorders | Cerebrovascular accident | 179 | 174 | 31 |
| Cardiac disorders | Cardiac arrest | 40 | 37 | 28 |
| Gastrointestinal disorders | Vomiting | 2382 | 2360 | 27 |
| General disorders and administration site conditions | Concomitant disease progression | 44 | 39 | 27 |
| General disorders and administration site conditions | Malaise | 1747 | 1724 | 24 |
| Cardiac disorders | Myocardial infarction | 85 | 84 | 19 |
| Blood and lymphatic system disorders | Thrombocytopenia | 354 | 340 | 17 |
| Infections and infestations | Pneumonia | 132 | 125 | 16 |

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|--|---------------------------------------|--------------------------------|--|---|
| General disorders and administration site conditions | General physical health deterioration | 11 | 10 | 10 |
| Nervous system disorders | Lethargy | 6671 | 6638 | 9 |
| Respiratory, thoracic and mediastinal disorders | Pneumonia aspiration | 14 | 13 | 9 |
| General disorders and administration site conditions | Death | 9 | 9 | 9 |
| Gastrointestinal disorders | Nausea | 6878 | 6816 | 8 |
| Nervous system disorders | Loss of consciousness | 99 | 97 | 8 |
| Nervous system disorders | Cerebral haemorrhage | 20 | 19 | 8 |
| Gastrointestinal disorders | Abdominal pain | 2121 | 2110 | 7 |
| General disorders and administration site conditions | Concomitant disease aggravated | 299 | 291 | 7 |
| Respiratory, thoracic and mediastinal disorders | Respiratory failure | 13 | 12 | 7 |
| General disorders and administration site conditions | Multiple organ dysfunction syndrome | 12 | 12 | 7 |
| General disorders and administration site conditions | Influenza like illness | 1702 | 1680 | 6 |
| Musculoskeletal and connective tissue disorders | Pain in extremity | 1546 | 1513 | 6 |
| Psychiatric disorders | Confusional state | 272 | 266 | 6 |
| Nervous system disorders | Somnolence | 154 | 153 | 6 |
| Gastrointestinal disorders | Diarrhoea | 2278 | 2258 | 5 |
| Skin and subcutaneous tissue disorders | Rash | 2185 | 2165 | 5 |
| Respiratory, thoracic and mediastinal disorders | Cough | 1141 | 1126 | 5 |
| Nervous system disorders | Syncope | 904 | 891 | 5 |
| Vascular disorders | Thrombosis | 193 | 184 | 5 |
| Investigations | Oxygen saturation decreased | 43 | 41 | 5 |
| Cardiac disorders | Acute myocardial infarction | 36 | 34 | 5 |
| Cardiac disorders | Cyanosis | 22 | 21 | 5 |
| Vascular disorders | Cyanosis | 22 | 21 | 5 |
| Nervous system disorders | Depressed level of consciousness | 18 | 18 | 5 |
| Nervous system disorders | Haemorrhage intracranial | 12 | 11 | 5 |
| Musculoskeletal and connective tissue disorders | Myalgia | 11076 | 10993 | 4 |
| Musculoskeletal and connective tissue disorders | Arthralgia | 6423 | 6360 | 4 |

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. Please read all the important information at the beginning of this report.

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|--|--|--------------------------------|--|---|
| Cardiac disorders | Tachycardia | 759 | 747 | 2 |
| Vascular disorders | Hypertension | 675 | 670 | 2 |
| Eye disorders | Vision blurred | 600 | 585 | 2 |
| Musculoskeletal and connective tissue disorders | Back pain | 589 | 575 | 2 |
| Investigations | Heart rate increased | 317 | 311 | 2 |
| General disorders and administration site conditions | Peripheral swelling | 312 | 303 | 2 |
| Vascular disorders | Pallor | 193 | 192 | 2 |
| Infections and infestations | Nasopharyngitis | 190 | 188 | 2 |
| Injury, poisoning and procedural complications | Vaccination error | 189 | 171 | 2 |
| Blood and lymphatic system disorders | Immune thrombocytopenia | 62 | 58 | 2 |
| General disorders and administration site conditions | Oedema peripheral | 61 | 56 | 2 |
| Psychiatric disorders | Delirium | 54 | 54 | 2 |
| Renal and urinary disorders | Haematuria | 39 | 39 | 2 |
| Investigations | Heparin-induced thrombocytopenia test positive | 30 | 30 | 2 |
| Respiratory, thoracic and mediastinal disorders | Tachypnoea | 26 | 26 | 2 |
| Nervous system disorders | Cerebral infarction | 24 | 24 | 2 |
| Vascular disorders | Haemorrhage | 21 | 19 | 2 |
| Renal and urinary disorders | Acute kidney injury | 20 | 20 | 2 |
| Nervous system disorders | Ischaemic stroke | 15 | 15 | 2 |
| Blood and lymphatic system disorders | Splenic infarction | 14 | 14 | 2 |
| Gastrointestinal disorders | Haematemesis | 13 | 13 | 2 |
| Gastrointestinal disorders | Visceral venous thrombosis | 12 | 11 | 2 |
| Respiratory, thoracic and mediastinal disorders | Pulmonary thrombosis | 9 | 9 | 2 |
| Gastrointestinal disorders | Gastrointestinal haemorrhage | 8 | 8 | 2 |
| Vascular disorders | Infarction | 7 | 7 | 2 |
| Infections and infestations | Urosepsis | 6 | 6 | 2 |
| Hepatobiliary disorders | Hepatic failure | 5 | 5 | 2 |
| Respiratory, thoracic and mediastinal disorders | Aspiration | 4 | 4 | 2 |
| Vascular disorders | Circulatory collapse | 3 | 3 | 2 |

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Authorised by Craig Kelly, for the United Australia Party, Brisbane

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