

- ▼ This vaccine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# COMIRNATY™ COVID-19 VACCINE

**Active ingredient:** BNT162b2 [mRNA]

This vaccine has **provisional approval** in Australia to prevent COVID-19 disease caused by SARS-CoV-2 virus in adults and adolescents from 12 years of age and older. This approval has been granted on the basis of short term safety and efficacy data. Evidence of longer term efficacy and safety from ongoing clinical trials and vaccination in the community continues to be gathered and assessed.

## Consumer Medicine Information (CMI)

This leaflet provides important information about using COMIRNATY. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about receiving COMIRNATY.**

**Where to find information in this leaflet:**

- [1. Why am I being given COMIRNATY?](#)
- [2. What should I know before I am given COMIRNATY?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given COMIRNATY?](#)
- [5. What should I know while being given COMIRNATY?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I being given COMIRNATY?

**COMIRNATY contains the active ingredient BNT162b2 [mRNA].** COMIRNATY is an mRNA (messenger ribonucleic acid) vaccine.

COMIRNATY is a vaccine given to prevent COVID-19 disease caused by SARS-CoV-2 virus in adults and adolescents from 12 years of age and older.

COMIRNATY works by triggering your immune system to produce antibodies and blood cells that work against the virus, to protect against COVID-19 disease.

### 2. What should I know before I am given COMIRNATY?

#### Warnings

**COMIRNATY should not be given:**

- if you are allergic to BNT162b2 [mRNA] or any of the ingredients listed at the end of this leaflet.

**Check with your doctor if you have:**

- had a severe allergic reaction or breathing problems after any other vaccine or after being given COMIRNATY in the past.
- fainted following any needle injection.
- a severe illness or infection with high fever. However, you can have your vaccination if you have a mild fever or upper airway infection like a cold.
- a weakened immune system, such as due to HIV infection or are on a medicine that affects your immune system.

- a bleeding disorder, bruise easily or are on a blood thinning medicine.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. [Are there any side effects?](#)

Very rare cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have been reported after vaccination with COMIRNATY. The cases have mostly occurred within two weeks following vaccination, more often after the second vaccination, and more often occurred in younger men. Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

You may develop a temporary, stress-related response associated with the process of receiving your injection. This may include dizziness, fainting, sweating, increased heart rate and/or anxiety.

As with any vaccine, COMIRNATY may not fully protect all those who receive it and it is not known how long you will be protected.

#### Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you receive this vaccine.

#### Children and adolescents

COMIRNATY should not be given to children under 12 years.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor or pharmacist if you have recently received any other vaccine.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect, or are affected by, COMIRNATY.**

### 4. How will I be given COMIRNATY?

- COMIRNATY will be given as an injection into the muscle of your upper arm by a doctor, nurse or pharmacist.

- You will be given one dose followed by a second dose at least 21 days later. If you miss the second dose, ask your doctor for advice.
- A doctor, nurse or pharmacist will observe you for at least 15 minutes after being given COMIRNATY.

## 5. What should I know while being given COMIRNATY?

### Things you should know

- If you receive one dose of COMIRNATY, you should receive a second dose of the same vaccine at least 21 days later to complete the vaccination schedule.
- You may not be protected against COVID-19 disease until at least seven days after your second dose.
- You may not be protected if you only receive one dose, so a second dose is important.

### Driving or using machines

#### Be careful before you drive or use any machines or tools until you know how COMIRNATY affects you.

Some of the side effects of COMIRNATY may temporarily affect your ability to drive or use machines.

### Storage of the vaccine

COMIRNATY is stored at -90°C to -60°C. It must be kept in the original package in order to protect from light.

A doctor, nurse or pharmacist will prepare the injection for you before you are given it.

### Getting rid of any unwanted vaccine

A doctor, nurse or pharmacist will dispose of any unused vaccine.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Very common side effects

Very common side effects	What to do
<ul style="list-style-type: none"> <li>pain/swelling at injection site</li> <li>tiredness</li> <li>headache</li> <li>muscle pain</li> <li>chills</li> <li>joint pain</li> <li>fever</li> </ul>	<p><b>Speak to your doctor if you have any of these very common side effects and they worry you.</b></p>

### Common side effects

Common side effects	What to do
<ul style="list-style-type: none"> <li>redness at injection site</li> <li>nausea</li> <li></li> </ul>	<p><b>Speak to your doctor if you have any of these common side effects</b></p>

Common side effects	What to do
	<p><b>and they worry you.</b></p>

### Uncommon side effects

Uncommon side effects	What to do
<ul style="list-style-type: none"> <li>enlarged lymph nodes</li> <li>feeling unwell</li> <li>arm pain</li> <li>insomnia</li> <li>decreased appetite</li> <li>excessive sweating</li> <li>night sweats</li> <li>physical weakness and/or lack of energy</li> <li></li> </ul>	<p><b>Speak to your doctor if you have any of these side effects and they worry you.</b></p>

### Rare side effects

Rare side effects	What to do
<ul style="list-style-type: none"> <li>temporary one-sided facial drooping</li> <li></li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice this side effect.</b></p>

### Other side effects (frequency unknown)

Other side effects (frequency unknown)	What to do
<ul style="list-style-type: none"> <li>severe allergic reaction</li> <li>allergic reactions such as rash, itching, hives or swelling of the face</li> <li>inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in chest pain, breathlessness and/or palpitations</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>
<ul style="list-style-type: none"> <li>diarrhoea</li> <li>vomiting</li> <li>pain in arm</li> </ul>	<p><b>Speak to your doctor if you have any of these side effects and they worry you.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/](http://www.tga.gov.au/)