



Australian Government



# Information on COVID-19 Pfizer (Comirnaty) vaccine

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## About the vaccine

Comirnaty (Pfizer Australia Pty Ltd) is a vaccine that can prevent people from becoming ill from COVID-19. Comirnaty does not contain any live virus, and it cannot give you COVID-19. It contains the genetic code for an important part of the SARS-CoV-2 virus called the spike protein. After getting the vaccine, your body makes copies of the spike protein. Your immune system will then learn to recognise and fight against the SARS-CoV-2 virus, which causes COVID-19. The genetic code is then broken down quickly by the body.

Vaccination is voluntary and free. You can discuss any concerns or questions you have about COVID-19 vaccination with your immunisation provider and/or your GP before you receive the vaccine.

## Benefits of the vaccine

A very large clinical trial showed that Comirnaty is effective in preventing COVID-19 in people aged 16 years and older. People who had two doses of Comirnaty were about 95 per cent less likely to get symptomatic COVID-19 than people who did not get the vaccine. It was equally effective in people over the age of 65 years, as well as people with some stable pre-existing medical conditions.

Protection against COVID-19 starts from about 2–3 weeks after the first dose. While one dose may give some protection, it may only last for the short-term. Two doses will give optimal protection. No vaccine is 100 per cent effective, so it is possible that you can still get sick from COVID-19 after vaccination. We do not know how long the protection from Comirnaty will last. We will learn more about this over time.

We currently do not know how effective COVID-19 vaccines are at preventing spread of the virus. This means that SARS-CoV-2 could potentially still infect a vaccinated person. Even if they have no symptoms or only mild symptoms they could still pass it on to others.

This is why it is important to continue other preventative measures like:

- physical distancing
- hand washing
- wearing a face mask
- COVID-19 testing and quarantine/isolation as required by your state/territory.

If you have been vaccinated with two doses of Comirnaty, you should still get a COVID-19 test if you have symptoms that meet testing criteria according to your local health authority (e.g. fever, cough, sore throat).

### Who can receive this vaccine

Comirnaty is licensed by the Therapeutic Goods Administration (TGA) in people aged  $\geq 12$  years. Australian Technical Advisory Group on Immunisation (ATAGI) recommends for all people aged 16 years and older, and certain adolescents aged 12-15 years can receive Comirnaty:

- Children with specified medical conditions that increase their risk of severe COVID-19
- Aboriginal and Torres Strait Islander children aged 12-15 years
- All children aged 12-15 years in remote communities, as part of broader community outreach vaccination programs that provide vaccines for all ages ( $\geq 12$  years)

ATAGI will make recommendations for the use of Comirnaty in all other children aged 12-15 years within the coming months.

### Who should not receive this vaccine

You should not receive this vaccine if you have had:

- anaphylaxis (a type of severe allergic reaction) to a previous dose of the vaccine
- anaphylaxis after exposure to any component of the vaccine, including polyethylene glycol (PEG)
- myocarditis and/or pericarditis attributed to a previous dose of the vaccine
- any other serious adverse event attributed to a previous dose of the vaccine

### Precautions for vaccination

People with certain conditions may need additional precautions such as staying for 30 minutes of observation after having their vaccine or consulting an allergy specialist. Tell your immunisation provider if you have had:

- an **allergic reaction to a previous dose** of a COVID-19 vaccine or to an ingredient of the vaccine
- **anaphylaxis to other vaccines or to other medicines**. Your provider can check to ensure there are no common ingredients with the COVID-19 vaccine you are receiving
- confirmed mastocytosis with recurrent anaphylaxis that requires treatment.

If **you have a bleeding disorder** or you are **taking a blood-thinning medication** (anticoagulant), tell your immunisation provider. Your immunisation provider can help determine whether it is safe for you to have an intramuscular injection, and help decide the best timing for injection.

## Special circumstances to discuss before vaccination

### People with precautionary conditions for Comirnaty

People with a history of any of the following conditions can receive Comirnaty but advice should be sought from a cardiologist about the best timing of vaccination and whether any additional precautions are recommended:

- Inflammatory cardiac illness e.g., myocarditis, pericarditis, endocarditis
- Acute rheumatic fever
- Dilated cardiomyopathy (for people under 30 years of age)
- Congenital heart disease
- Severe heart failure
- Heart transplant recipients

### People with weakened immune systems (immunocompromise)

People with immunocompromise includes those who have a medical condition that weakens their immune system. It also includes those who may be taking medications that suppress their immune system.

The Australian Government strongly recommends people with immunocompromise receive COVID-19 vaccination. Comirnaty is not a live vaccine. It is safe in people with immunocompromise.

People with immunocompromise, including those living with HIV, have a higher risk of severe illness from COVID-19, including a higher risk of death.

Clinical trials for Comirnaty did not include people with immunocompromise, except for a small group of people with stable HIV. We do not know if Comirnaty is as effective in people with immunocompromise compared to the rest of the population. It is possible that Comirnaty might not be as effective in people with immunocompromise as it is in the general population. It is important to continue other preventative measures such as physical distancing after vaccination.

### Women who are pregnant or breastfeeding

Pregnant women should be routinely offered Comirnaty at any stage of pregnancy. If you are trying to become pregnant you do not need to delay vaccination or avoid becoming pregnant after vaccination.

Pregnant women with COVID-19 have an increased risk of severe illness and adverse pregnancy outcomes. Real-world evidence has shown that Comirnaty is safe for pregnant women and breastfeeding women.

If you are breastfeeding, you can have Comirnaty. You do not need to stop breastfeeding after vaccination.

### People with a history of COVID-19

If you have had COVID-19 in the past, tell your immunisation provider. Your provider may advise to wait for up to six months after recovery before having a COVID-19 vaccine. If you have ongoing illness from COVID-19, discuss the best timing of vaccination with your treating doctor.

### Comirnaty and children

Comirnaty has been provisionally approved for use in people aged 12 years or older, and cannot be given to younger people. ATAGI recommends certain adolescents aged 12-15 years can receive Comirnaty at this time. ATAGI will make recommendations for the use of Comirnaty in all other children aged 12-15 years within the coming months.

## Ensuring the safety of Comirnaty

Comirnaty and other COVID-19 vaccines have been developed quickly due to increased funding for vaccine research, and access to very large numbers of volunteers for research studies. A large clinical trial involving around 44,000 people confirmed Comirnaty to be safe and effective.

The TGA assesses all vaccines in Australia. This ensures that, in order for a vaccine to be approved, it is safe, effective and manufactured to a very high quality standard. A description of the process for approval of COVID-19 vaccines is available on the [TGA website](#).

The safety of COVID-19 vaccines will be monitored continuously throughout the COVID-19 vaccination program.

There are reports of a very rare side effect involving blood clotting with low blood platelet count after receiving the COVID-19 Vaccine AstraZeneca. The COVID-19 Vaccine AstraZeneca vaccine is made in a different way. There is no evidence of this condition being linked to the Comirnaty COVID-19 vaccine.

You can report suspected side effects to your vaccination provider or other healthcare professional. They will then make a formal report on your behalf to your state or territory health department or directly to the Therapeutic Goods Administration (TGA).

If you would prefer to report it yourself, please visit the [TGA website](#) for information on how to report suspected side effects associated with COVID-19 vaccines.