



Information on COVID-19 Comirnaty (Pfizer) vaccine

Last updated: 3 December 2021

About the vaccine

Comirnaty (Pfizer) is a vaccine that can prevent people from becoming ill from COVID-19. Two doses are required initially (called the primary course). These 2 doses are usually given 3-6 weeks apart, In special circumstances the interval may be longer. The Pfizer vaccine can also be used for a booster dose in people aged 18 years and older. The booster dose is given 6 months or more after the primary course. The Pfizer COVID-19 vaccine 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 body breaks down the genetic code quickly.

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

Benefits of the vaccine

A very large clinical trial showed that Pfizer is effective in preventing COVID-19 in people aged 12 years and older. People who had two doses of Pfizer 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 improved protection. No vaccine is 100 per cent effective, so it is possible that you can still get sick from COVID-19 after vaccination.

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. However, the COVID-19 vaccines currently used in Australia is effective in reducing the likelihood of a vaccinated person transmitting the virus to close contacts if the person is infected.

This is why after vaccination 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 Pfizer, 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).

Booster doses

A booster dose refers to an additional vaccine dose after the primary vaccine course. It is intended to strengthen and prolong protection against COVID-19.

If you are 18 or older, you can receive an additional dose of Pfizer as a booster if it has been 6 months or more after your primary course. Booster doses are not recommended for younger people at this stage.

For more information on booster doses see <u>ATAGI recommendations on the use of a booster</u> dose of COVID-19 vaccine.

Who can receive this vaccine

People aged 12 years and older can receive Pfizer vaccine for their primary course.

People aged 18 years and older can receive Pfizer vaccine for their booster dose.

The Therapeutic Goods <u>Administration</u> (TGA) provisionally approved the Comirnaty Paediatric (Pfizer) COVID-19 vaccine for 5 to 11-year-olds on 5 December 2021.

Subject to ATAGI advice, it is expected a vaccination program for 5 to 11 year olds will commence from 10 January 2022. **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 an mRNA COVID-19 vaccine (i.e., Pfizer or Spikevax (Moderna))
- anaphylaxis after exposure to any component of the vaccine, including polyethylene glycol (PEG)
- any other serious adverse event, that following review by an experienced immunisation provider or medical specialist was attributed to a previous dose of an mRNA COVID-19 vaccine (i.e., Pfizer or Moderna) and without another cause identified

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 or to an ingredient of an mRNA COVID-19 vaccine (i.e Pfizer or Moderna)
- 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 Pfizer

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

- Recent (i.e., within the past 3 months) myocarditis or pericarditis
- Acute rheumatic fever (i.e., with active myocardial inflammation) or acute rheumatic heart disease
- Acute decompensated heart failure.

Tell your doctor if you had myocarditis or pericarditis diagnosed after a previous dose of Pfizer or Moderna.

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. Pfizer is not a live vaccine. It is safe in people with immunocompromise.

People with severe immunocompromise are recommended to have a third dose of Pfizer for their primary course. Severely immunocompromised people who received a third primary dose are not yet recommended to receive a booster dose (i.e. 4th dose). Further information on booster doses in this group will be provided soon.

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 Pfizer did not include people with immunocompromise, except for a small group of people with stable HIV. We do not know if Pfizer is as effective in people with immunocompromise compared to the rest of the population. It is possible that Pfizer 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

Women and adolescents who are pregnant should be routinely offered Pfizer or Moderna 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 Pfizer is safe for pregnant women and breastfeeding women.

If you are breastfeeding, you can have Pfizer. 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 doctor or immunisation provider. COVID-19 vaccination can be given after recovery from the infection, or can be deferred for up to six months after the acute illness in those who have had confirmed SARSCoV-2 infection, as evidence suggests that past infection reduces the risk of reinfection for at least 6 months.

Pfizer and children

Pfizer has been provisionally approved for use in people aged 5 years or older, and cannot be given to younger people.

Ensuring the safety of Pfizer

Pfizer has been safely given to hundreds of millions of people around the world. The Therapeutic Goods Administration 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 Pfizer 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 TGA.

If you would prefer to report it yourself, please visit the <u>TGA website</u> for information on how to report suspected side effects associated with COVID-19 vaccines.