



Australian Government



# Information on COVID-19 Comirnaty (Pfizer) vaccine

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## 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 4 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 are 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).

## Safety of the vaccine

Pfizer has been safely given to hundreds of millions of people around the world. Spikevax (Moderna) and Pfizer COVID-19 vaccines both have a very rare risk of heart inflammation (myocarditis or pericarditis). This is more commonly seen in males aged under 30 years after the second dose. In some countries, myocarditis and pericarditis have been reported more commonly after Moderna than after Pfizer. Most people who have had these conditions after their vaccine have recovered fully. The benefits of vaccination outweigh this very rare risk and vaccination is still recommended for all eligible age groups.

For current information on the frequency and severity of myocarditis and pericarditis following Moderna and Pfizer, please refer to the Australian Technical Advisory Group on Immunisation Weekly COVID-19 meeting updates, available at the Department of Health website: [www.health.gov.au/news](http://www.health.gov.au/news).

## Who can receive this vaccine

People aged 5 years and older can receive the Pfizer COVID-19 vaccine for their primary course.

For more information about vaccination in children aged 5 to 11 years see the [consent form for parents and guardians of children aged 5 to 11 years](#).

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

## 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 years or older, you can receive an additional dose of Pfizer as a booster if it has been 4 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 [ATAGI recommendations on the use of a booster dose of COVID-19 vaccine](#).

## 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 aged 18 years and over who received a third primary dose are recommended to receive a booster dose (i.e. 4th dose) at 4 months, in line with the timing for the general population. 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.

Pregnant women aged 18 years or older who received their primary COVID-19 vaccination course 4 or more months ago are recommended to have a booster dose.

### **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 6 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**

The Therapeutic Goods Administration (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.

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 [TGA website](#) for information on how to report suspected side effects associated with COVID-19 vaccines.