



Australian Government



# Information on Spikevax (Moderna) COVID-19 vaccine

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## About the vaccine

**Moderna** 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 4 – 6 weeks apart. In special circumstances the interval may be longer. Moderna 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 broken down quickly by the body.

To prevent COVID-19, everyone who is eligible for a COVID-19 vaccine should get vaccinated, with a few exceptions specified in this information sheet. Vaccination is voluntary. 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

Very large clinical trials have shown that Moderna is effective in preventing COVID-19 in people aged 12 years and older. Adults who had two doses of Moderna were about 94 percent less likely to become ill from COVID-19 than people who did not get the vaccine. The vaccine was also effective in people aged over 65 years (86%) and in adolescents aged 12-17 years.

Protection against COVID-19 starts from about two 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 percent effective, so it is possible that you can still get infected and sick from COVID-19 after vaccination. We do not know how long the protection from Moderna will last. We will learn more about this over time. We currently do not know exactly how effective COVID-19 vaccines are at preventing spread of the virus.

This means that even vaccinated people could be infected with the virus that causes COVID-19, and 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 Moderna, 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

Moderna is a very safe vaccine and has been given to millions of people around the world. Most side effects are mild. For more information, refer to: [www.health.gov.au/resources/publications/covid-19-vaccination-after-your-spikevax-moderna-vaccine](https://www.health.gov.au/resources/publications/covid-19-vaccination-after-your-spikevax-moderna-vaccine).

Moderna and Comirnaty (Pfizer) vaccines both have a very rare risk of heart inflammation (myocarditis or pericarditis). This is more commonly seen in males aged under 30 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 ATAGI Weekly COVID-19 meeting updates, available at: [www.health.gov.au/committees-and-groups/australian-technical-advisory-group-on-immunisation-atagi#statements](https://www.health.gov.au/committees-and-groups/australian-technical-advisory-group-on-immunisation-atagi#statements).

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 at: [www.tga.gov.au](https://www.tga.gov.au). 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 to the TGA yourself, please visit: [www.tga.gov.au/reporting-suspected-side-effects-associated-covid-19-vaccine](https://www.tga.gov.au/reporting-suspected-side-effects-associated-covid-19-vaccine).

## Who can receive this vaccine

The TGA has granted provisional approval for use of Moderna in people aged 12 years and over.

## 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. Moderna/Pfizer)
- **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. Moderna or Pfizer) 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. Moderna or Pfizer)
- **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 Moderna

People with a history of any of the following conditions can receive Moderna 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) or current inflammatory cardiac illness e.g., myocarditis and pericarditis
- acute rheumatic fever or acute rheumatic heart disease (i.e., with active myocardial inflammation)
- 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 severe immunocompromise are recommended to have a third dose of Moderna for their initial course.

The Australian Government strongly recommends people with immunocompromise receive COVID-19 vaccination. Moderna 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.

Since some people with immunocompromise may have a reduced response to the vaccine, it is important to consider other preventative measures such as physical distancing after vaccination.

### Women who are pregnant or breastfeeding

Pregnant women and adolescents 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 Moderna is safe for pregnant women and breastfeeding women. You can discuss the decision in relation to timing of vaccination with your health professional.

If you are breastfeeding, you can have Moderna. 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. You can have Moderna after you recover from COVID-19, or may defer for up to 6 months after recovery. If you have ongoing illness from COVID-19, discuss the best timing of vaccination with your treating doctor.

### **Moderna and children**

Moderna has been provisionally approved for use in people aged 12 years or older, and cannot be given to younger people.