



Australian Government



# Information on Spikevax (Moderna) COVID-19 vaccine

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## About the vaccine

**Spikevax (Moderna)** is a vaccine that can prevent people from becoming ill from COVID-19. Two doses are required, usually given 4-6 weeks apart (in special circumstances the interval may be longer). The Moderna 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 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  $\geq 12$  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).

### Who can receive this vaccine

The Therapeutic Goods Administration (TGA) has granted provisional approval for use of Spikevax (Moderna) in people aged  $\geq 12$  years.

### 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 or Comirnaty (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) myocarditis or pericarditis
- Acute rheumatic fever (i.e., with active myocardial inflammation) or acute rheumatic heart disease (i.e., with active cardiac 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 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. Moderna is not a live vaccine. It is safe in people with immunocompromise.

People with severe immunocompromise are recommended to have a third dose 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 Moderna did not include people with immunocompromise, except for a small group of people with stable HIV. We do not know if Moderna is as effective in people with immunocompromise compared to the rest of the population. It is possible that Moderna 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 and adolescents should be routinely offered one of the mRNA-based COVID-19 vaccines, 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. Your provider may advise you 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.

## Moderna and children

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

## Ensuring the safety of Moderna

Moderna 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 30,000 people confirmed Moderna 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 Vaxzevria (AstraZeneca) vaccine. The AstraZeneca vaccine is made in a

different way from Moderna. There is no evidence of this condition being linked to the Moderna 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 [TGA website](#) for information on how to report suspected side effects associated with COVID-19 vaccines.