



Information on COVID-19 Vaccine AstraZeneca

About the vaccine

COVID-19 Vaccine AstraZeneca is a vaccine that can prevent people from becoming ill from COVID-19. COVID-19 Vaccine AstraZeneca does not contain any live SARS-CoV-2 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. The spike protein has been inserted into a harmless common cold 'carrier' virus (an adenovirus). The adenovirus carrier brings the spike protein into your cells so that they can read it and make copies of the spike protein. Your immune system will then learn to recognise and fight against the SARS-CoV-2 virus. The adenovirus has been modified so that it cannot replicate once it is inside cells. This means it cannot spread to other cells and cause infection.

To prevent COVID-19, everyone aged 16 years and older should get vaccinated. The COVID-19 Vaccine AstraZeneca is suitable for people aged 18 years and older, with a few exceptions specified in this information sheet. People aged 16 and 17 years can receive a different vaccine (Comirnaty, the Pfizer COVID-19 vaccine). 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.

You should also be aware of the current investigation into a rare type of blood clotting reported after COVID-19 Vaccine AstraZeneca. It is not currently known if this unusual and rare condition is caused by that vaccine.

Benefits of the vaccine

A combination of several clinical trials showed that COVID-19 Vaccine AstraZeneca is effective in preventing COVID-19 in people aged 18 years and older. People who had two doses of COVID-19 Vaccine AstraZeneca were about 62-70 per cent less likely to get COVID-19 than people who did not get the vaccine. Because of the small number of people aged 65 years or older included in the trial, we are not as sure if the vaccine is equally effective in people over the age of 65 years compared with younger adults. However, none of these older people who received the vaccines got severe COVID-19 disease or required hospital treatment. Early experience in Scotland showed that COVID-19 vaccination was effective in preventing older people requiring hospital treatment for COVID-19, and most of them received COVID-19 Vaccine AstraZeneca. More data on the effectiveness of this vaccine in older adults is expected to be available soon.

Protection against COVID-19 starts from about 3 weeks after the first dose of COVID-19 Vaccine AstraZeneca. While one dose may give some protection, it may only last for the short-term up to about 12 weeks. The second dose boosts antibody levels and is likely to prolong the duration of protection. In the clinical trial described above, the vaccine appeared to be more effective when people had a longer interval between the 2 doses. This is why it is better to receive 2 doses about 12 weeks apart. 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 COVID-19 Vaccine AstraZeneca will last after completing the two doses. 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 COVID-19 Vaccine AstraZeneca, 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

People aged 18 years and older can receive this COVID-19 Vaccine AstraZeneca.

Certain groups of people are prioritised to receive vaccines first because they are at higher risk of exposure to the COVID-19 virus (e.g. workers in border or quarantine facilities, a healthcare facility or aged-care facility) or severe illness and death from COVID-19 (e.g. are older or have underlying medical conditions), or if they work in services critical to societal functioning.

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 same COVID-19 vaccine, or
- anaphylaxis after exposure to any component of a COVID-19 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
- a mast cell disorder
- cerebral venous sinus thrombosis (a type of brain clot) or heparin-induced thrombocytopenia syndrome (HITS; a rare reaction to heparin treatment) in the past

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 to decide the best timing for injection.

Special circumstances to discuss before vaccination

Safety investigation into rare blood clotting condition after vaccination

Rare cases of a serious unusual condition of blood clots (thrombosis) associated with low blood platelet levels (thrombocytopenia) occurring in the brain or abdomen have been reported following the COVID-19 Vaccine AstraZeneca. These cases have been rare and mostly reported overseas. One case has been reported in Australia on 1 April 2020 following administration of approximately 400,000 doses of COVID-19 Vaccine AstraZeneca.

It is not yet certain if this condition is caused by the vaccine. This is still being investigated.

People should discuss this information when considering the benefits and risks of COVID-19 vaccination with their immunisation provider.

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. COVID-19 Vaccine AstraZeneca does not behave like a 'live vaccine'. The adenovirus carrier has been modified so that it cannot replicate or spread to other cells, and it cannot cause infection. 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 COVID-19 Vaccine AstraZeneca did not include people with immunocompromise. A clinical trial is being conducted of COVID-19 Vaccine AstraZeneca given to people with stable HIV infection, with results expected in a few months. We do not know if COVID-19 Vaccine AstraZeneca is as effective in people with immunocompromise compared to the rest of the population. It is possible that COVID-19 Vaccine AstraZeneca 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

If you are breastfeeding, you can have COVID-19 Vaccine AstraZeneca. You do not need to stop breastfeeding after vaccination.

Pregnant women are not routinely recommended to have COVID-19 Vaccine AstraZeneca, but can consider vaccination:

- if they are at higher risk of getting COVID-19, for example due to their occupation, or
- if they have risk factors for severe illness, for example due to pre-existing medical conditions.

If you are pregnant, your healthcare provider can help you to assess the benefits and risks of vaccination.

People with a history of COVID-19

If you have ever 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.

COVID-19 Vaccine AstraZeneca and children

COVID-19 Vaccine AstraZeneca has only been provisionally approved for use in people aged 18 years or older, and cannot be given to younger people. The risk of COVID-19, especially severe disease, in children is lower than in older adolescents and adults.

Safety of COVID-19 Vaccine AstraZeneca

Increased funding for vaccine research, and access to very large numbers of volunteers for research studies have meant COVID-19 Vaccine AstraZeneca and other COVID-19 vaccines have been developed quickly. The combination of several large clinical trials involving around 57,000 people confirmed COVID-19 Vaccine AstraZeneca to be safe and effective.

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 <u>TGA website</u>.

The safety of COVID-19 vaccines will be monitored continuously throughout the COVID-19 vaccination program. Suspected side effects can be reported 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 <u>TGA website</u> for information on how to report suspected side effects associated with COVID-19 vaccines.