



Australian Government

Patient Name:



Information on COVID-19 Vaccine AstraZeneca

About the vaccine

COVID-19 Vaccine AstraZeneca can prevent people from becoming ill from COVID-19. This vaccine does not contain any live SARS-CoV-2 virus, and cannot give you COVID-19. It contains the genetic code for an important part of the SARS-CoV-2 virus called the spike protein. This code is inserted into a harmless common cold virus (an adenovirus), which brings it into your cells. Your body then makes copies of the spike protein, and your immune system learns to recognise and fight 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.

Vaccination is voluntary and free. 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.

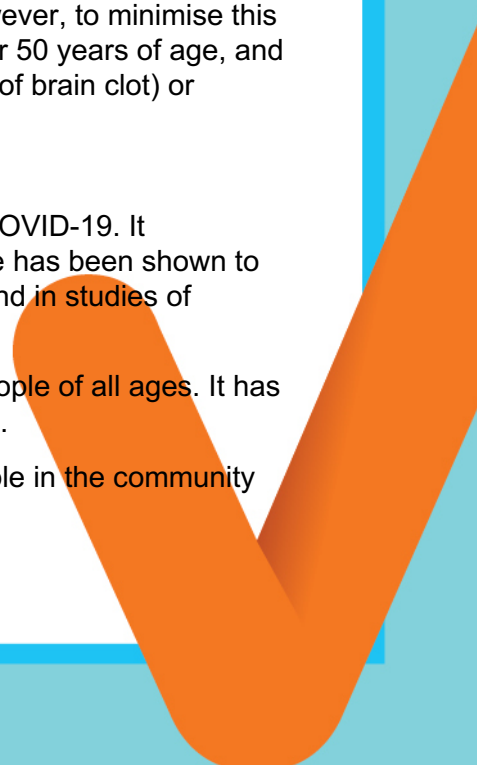
COVID-19 Vaccine AstraZeneca can be used in people aged 18 and above, and is safe and effective. A very rare side effect reported after the AstraZeneca vaccine is 'thrombosis with thrombocytopenia syndrome' (TTS), which involves blood clotting and low blood platelet levels. The benefits of vaccination greatly outweigh the risk of this condition. However, to minimise this risk, Comirnaty (Pfizer) is the preferred COVID-19 vaccine for adults under 50 years of age, and for people with a past history of cerebral venous sinus thrombosis (a type of brain clot) or heparin induced thrombocytopenia (a rare reaction to heparin treatment).

Benefits of vaccination

COVID-19 Vaccine AstraZeneca protects people from becoming ill from COVID-19. It particularly prevents severe illness, hospitalisation and death. The vaccine has been shown to be highly effective in both clinical trials (before it was registered for use) and in studies of people vaccinated in the 'real world' in England and Scotland.

COVID-19 is a very serious disease which can cause serious illness in people of all ages. It has caused millions of deaths and hundreds of millions of infections worldwide.

Vaccination helps protect both individual people and also benefits all people in the community by reducing the spread of COVID-19.



Risks of vaccination

As with any vaccine, you may have some temporary side effects after receiving a COVID-19 vaccine. Common side effects after COVID-19 Vaccine AstraZeneca include: injection site pain or tenderness, tiredness, headache, muscle pain, and fever and chills. Most side effects are mild and temporary, going away within 1-2 days. As with any medicine or vaccine, there may be rare and/or unknown side effects.

As with any medicine or vaccine, there may be rare and/or unknown side effects.

Thrombosis with thrombocytopenia syndrome (TTS)

COVID-19 Vaccine AstraZeneca appears to be associated with a rare side effect called thrombosis with thrombocytopenia syndrome (TTS), which has been reported in several countries overseas.

What is TTS?

TTS involves blood clots (thrombosis) and low levels of blood platelets (thrombocytopenia), and occurs about 4-20 days after vaccination. The blood clots can occur in different parts of the body, such as the brain (called cerebral venous sinus thrombosis or CVST) or in the abdomen.

The mechanism that causes TTS is not fully understood, but it appears similar to heparin-induced thrombocytopenia (or HIT), a rare reaction to heparin treatment.

How common is TTS?

TTS is very rare (4-6 cases per million doses), but it can make people very unwell and in about 1 in 4 cases has led to death. As at 8 April one case and one probable (likely) case has been reported in Australia on 1 April 2020, following administration of approximately 400,000 doses of COVID-19 Vaccine AstraZeneca.

Are any groups more at risk of TTS?

No specific risk factors have been confirmed for TTS.

In the countries that have reported TTS, more cases have occurred in adults under 60 years of age compared to older adults, and in women compared to men. However it is not yet clear if age and sex are risk factors, since the AstraZeneca vaccine was preferentially given to younger people in some countries, and since women make up a large proportion of the healthcare workers that were prioritised for vaccination.

As a precaution, in Australia Comirnaty (Pfizer) vaccine is preferred for adults under 50 years of age, since their risk of TTS may be slightly higher than older people, and since they have a lower risk of severe outcomes from COVID-19 compared to older adults.

Is the AstraZeneca vaccine safe in people who have had blood clots in the past?

Comirnaty (Pfizer) vaccine is preferred in people who have a past history of cerebral venous sinus thrombosis or heparin-induced thrombocytopenia, given the similarities between these conditions at TTS.

If you have had other types of blood clots in the past, or if you have risk factors for blood clots, you can still have the AstraZeneca vaccine. There is no evidence that people who have had a past history of other types of blood clots have an increased risk of TTS. The overall rate of blood clots has not risen in countries which have extensively used the AstraZeneca vaccine.

What if I have had my first dose of AstraZeneca vaccine?

All of the cases of TTS reported to date have occurred after the first dose of the vaccine. People who have had their first dose without any serious side effects can be confident in getting their second dose.

What symptoms does thrombosis with thrombocytopenia syndrome usually cause?

TTS is very rare and occurs around 4-20 days after vaccination. Symptoms can include abdominal pain and/or severe headache that does not settle with pain relief.

People should seek medical attention immediately if they experience these symptoms:

- a severe persistent headache with additional features:
 - appears at least 4 days *after* vaccination
 - does not improve with simple painkillers
 - may be worse when lying down or accompanied by nausea and vomiting
- neurological symptoms such as:
 - blurred vision
 - difficulty with speech
 - drowsiness
 - seizures
- shortness of breath or chest pain
- a swollen leg
- persistent abdominal (belly) pain
- tiny blood spots under the skin away from the site of injection together with symptoms above.

Things to consider before vaccination

Precautions

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**

If **you have a bleeding disorder** or you are **taking a blood-thinning medication** (anticoagulant), tell your immunisation provider. Your provider can help determine whether it is safe for you to have an intramuscular injection, and help to decide the best timing for injection.

People with weakened immune systems (immunocompromise)

People with immunocompromise includes those who have a medical condition or are taking medications that weaken their immune system. People with immunocompromise, including those living with HIV, have a higher risk of severe illness from COVID-19, including a higher risk of severe illness and death.

The Australian Government strongly recommends people with immunocompromise receive a COVID-19 vaccine. 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.

Clinical trials for COVID-19 Vaccine AstraZeneca did not include people with immunocompromised but many people with such conditions have now been vaccinated worldwide. 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 it might be less effective, and so it is important to continue other preventative measures such as physical distancing after vaccination.

For more information on use of the vaccine in immunocompromised see: [COVID-19 vaccination decision guide for people with immunocompromised](#).

Women who are pregnant or breastfeeding

If you are breastfeeding, it is preferable for you to have the Pfizer (Comirnaty) COVID-19 vaccine. This is the preferred vaccine in young adults. However, you can still have the COVID-19 Vaccine AstraZeneca if the benefits of vaccination outweigh the risks for you. You do not need to stop breastfeeding after vaccination.

Pregnant women are not routinely recommended to have COVID-19 vaccination. They 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. The Pfizer (Comirnaty) COVID-19 vaccine is preferred over the COVID-19 Vaccine AstraZeneca for pregnant women due to their age.

For more information on use of the vaccine in pregnancy and breastfeeding see: [COVID-19 vaccination decision guide for women who are pregnant, breastfeeding or planning pregnancy](#).

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.

Either COVID-19 vaccine brand can be used in people with a past history of COVID-19

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.

Vaccine safety and reporting adverse events

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