



Australian Government



# Information on COVID-19 Vaccine AstraZeneca

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## 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. TTS is more common in younger adults. So to minimise this risk, Comirnaty (Pfizer) is the preferred COVID-19 vaccine for adults under 60 years of age, and for people with a past history of cerebral venous sinus thrombosis (a type of brain clot), heparin induced thrombocytopenia (a rare reaction to heparin treatment), idiopathic splanchnic thrombosis (blood clots in the abdominal veins) or antiphospholipid syndrome with thrombosis.

## 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 benefits all people in the community by reducing the spread of COVID-19.

## Who can receive this vaccine

People aged 18 years and older can receive COVID-19 Vaccine AstraZeneca. Comirnaty (Pfizer) is preferred over COVID-19 Vaccine AstraZeneca in people aged < 60 years. However, COVID-19 Vaccine AstraZeneca can be used in adults aged < 60 years if Comirnaty (Pfizer) is not available and if the person has made an informed decision based on an understanding of the risks and benefits. In outbreak settings, adults <60 years of age should strongly consider COVID-19 Vaccine AstraZeneca if they are unable to access Comirnaty (Pfizer).

## 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.

## Thrombosis with thrombocytopenia syndrome (TTS)

COVID-19 Vaccine AstraZeneca appears to be linked with a very rare side effect called thrombosis with thrombocytopenia syndrome (TTS).

### What is TTS?

TTS involves blood clots (thrombosis) and low levels of blood platelets (thrombocytopenia), and occurs around 4 to 42 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 (idiopathic splanchnic thrombosis).

TTS is rare, but it can make people very unwell and can lead to long term disability or death.

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.

### Are any groups more at risk of TTS?

The rate of TTS reported in Australia and overseas is higher in younger adults and appears more common in women. However cases have also been reported in men and in older people. It is not yet clear if women are at higher risk.

Based on current information, we have not identified any pre-existing medical conditions that may contribute to developing TTS or make it worse if it occurs.

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

Comirnaty (Pfizer) vaccine is recommended in people who have had one of the following rare causes of blood clots: cerebral venous sinus thrombosis, heparin-induced thrombocytopenia, idiopathic splanchnic thrombosis or antiphospholipid syndrome with thrombosis.

If you have had other types of blood clots in the past, such as deep vein thrombosis (DVT) or pulmonary embolism (PE), 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 developing TTS or becoming more ill from it if it occurs.

People with the following conditions *can receive* the AstraZeneca COVID-19 Vaccine:

- History of blood clots in typical sites
- Increased clotting tendency that is not immune-mediated
- Family history of blood clots
- History of ischaemic heart disease or stroke

- Current or past thrombocytopenia (low platelet count)
- Those receiving anticoagulation therapy

The overall rate of blood clots has not risen in countries which have extensively used the AstraZeneca vaccine. Blood clots occur commonly in the population, and not all blood clots that occur after AstraZeneca COVID-19 will be caused by the vaccine. If you develop a blood clot after vaccination, your doctor can do blood tests to determine the cause.

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

People of any age without contraindications who have had their first dose of COVID-19 Vaccine AstraZeneca without any serious adverse events should receive a second dose of the same vaccine. UK data suggests that the risk of TTS is much lower after the second dose, with 44 cases reported to date out of 22.8 million second doses of the AstraZeneca COVID-19 vaccine given. This translates into an estimated rate of 1.9 cases per million second doses (compared to a reported risk of 14.8 cases per million first doses in the UK).

### 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 vaccine
- anaphylaxis after exposure to any component of the vaccine, including polysorbate 80
- history of capillary leak syndrome
- TTS occurring after a previous dose of the vaccine
- any other serious adverse event attributed to a previous dose of the vaccine

### 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
- 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 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. The results of a clinical

trial of COVID-19 Vaccine AstraZeneca given to people with stable HIV infection are expected soon. 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**

Comirnaty (Pfizer) is the preferred vaccine in adults under 60 years of age, and women who are pregnant or breastfeeding. You do not need to stop breastfeeding after vaccination. Pregnant women who received a first dose of COVID-19 Vaccine AstraZeneca can receive either Comirnaty or COVID-19 Vaccine AstraZeneca for their second dose, although Comirnaty is preferred.

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.