



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.

## 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 28 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 it may be 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. More women than men have been vaccinated in some countries as they are a large proportion of frontline healthcare workers and have been prioritised for vaccination.

Currently there are no confirmed pre-existing or past medical conditions that increase the risk of TTS. However, there is a theoretical concern that the following rare conditions might increase the risk of TTS: cerebral venous sinus thrombosis (a type of brain clot), heparin induced thrombocytopenia (a rare reaction to heparin treatment), idiopathic splanchnic vein thrombosis (blood clots in the abdominal veins) or antiphospholipid syndrome with thrombosis.

#### 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?

If you have had your first dose without any serious side effects (such as a severe allergic reaction), it is safe for you to have the second dose. UK data suggests that the risk of TTS is much lower after the second dose, with 23 cases reported to date out of 15.7 million second doses of the AstraZeneca COVID-19 vaccine given. This translates into an estimated rate of 1.5 cases per million second doses (compared to a reported risk of 14.2 cases per million first doses in the UK).

#### What symptoms does thrombosis with thrombocytopenia syndrome usually cause?

TTS is rare and occurs around 4 to 28 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. 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 breastfeeding or pregnant. You do not need to stop breastfeeding after vaccination.

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.