Australian Government

COVID-19 VACCINATION

Information on Vaxzevria (AstraZeneca)

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About the vaccine

Vaxzevria (AstraZeneca) can prevent people from becoming ill from COVID-19. Two doses are required as part of the primary course. These 2 doses are usually given 4-12 weeks apart. The AstraZeneca vaccine can also be used as an additional booster dose, 6 months or more after the primary course, although Pfizer is preferred for this booster.

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.

Benefits of vaccination

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.

Booster doses

A booster dose refers to an additional vaccine dose after the primary vaccine course. It is intended to strengthen and prolong protection against COVID-19.

If you are 18 or older you can receive a booster dose if it has been 6 months or more after your primary course. Booster doses are not recommended for younger people at this stage.

Pfizer is preferred for the booster dose, including for people who have had two doses of AstraZeneca, however, AstraZeneca can be given to people who had AstraZeneca for their first two doses, or for people who cannot have the Pfizer vaccine for medical reasons (e.g., severe allergic reaction).For more information on boosters see ATAGI recommendations on the use of a booster dose of COVID-19 vaccine.

Who can receive this vaccine

People aged 18 years and older can receive AstraZeneca.

Pfizer or Moderna are preferred over AstraZeneca in people aged under 60 years. However, AstraZeneca can be used in adults aged under 60 years if Pfizer or Moderna is not available and if the person has made an informed decision based on an understanding of the risks and benefits.

Risks of vaccination

As with any vaccine, you may have some temporary side effects after receiving a COVID-19 vaccine. Common side effects after 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)

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?

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.

For more information on TTS please see: www.health.gov.au/initiatives-and-programs/covid-19-vaccines/advice-for-providers/tts

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

People of any age without contraindications who have had their first dose of 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, that following review by an experienced immunisation provider/medical specialist was attributed to a previous dose of the vaccine (and without another cause identified).

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.

Special circumstances to discuss before vaccination

People with precautionary conditions who are preferred not to have AstraZeneca

Pfizer or Moderna vaccine are 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
- 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 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. People with immunocompromise, including those living with HIV, have a higher risk of severe illness from COVID-19, including a higher risk of death.

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 severe immunocompromise are recommended to have a third dose of Pfizer 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.

Clinical trials for AstraZeneca did not include people with immunocompromise but many people with such conditions have now been vaccinated worldwide. The results of a clinical trial of AstraZeneca given to people with stable HIV infection are expected soon. We do not know if 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 immunocompromise.

Women who are pregnant or breastfeeding

Pfizer and Moderna are 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 AstraZeneca can receive either Pfizer, Moderna or AstraZeneca for their second dose, although Pfizer or Moderna are 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.

AstraZeneca and children

AstraZeneca has only been provisionally approved for use in people aged 18 years or older. It cannot be given to people younger than 18.

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.