



Australian Government



# Patient Information

## AstraZeneca Vaccine and the COVID-19 vaccination program

The Australian Government received advice and recommendations from the Australian Technical Advisory Group on Immunisation (ATAGI) about the AstraZeneca vaccine.

There has been a link between the AstraZeneca vaccine and a condition involving thrombosis (blood clotting) with thrombocytopenia (low blood platelet counts). This is an extremely rare condition.

Comirnaty (Pfizer) is the preferred COVID-19 vaccine for adults under 50 years of age at this time. However, adults under 50 years of age may still choose to receive the AstraZeneca vaccine if they have weighed up the benefits and the risks. Talk to your doctor or immunisation provider to help inform your decision.

All adults are recommended to be vaccinated against COVID-19. The risk of severe illness and death from COVID-19 progressively increases with age in older adults, which means that older adults will have a higher benefit from vaccination.

More information on what this means can be found at [www.health.gov.au/covid19-vaccines](http://www.health.gov.au/covid19-vaccines)

This recommendation is made out of an abundance of caution and the AstraZeneca vaccine is safe for the vast majority of people.

### What is thrombosis with thrombocytopenia syndrome?

This is a rare potential side effect of the AstraZeneca vaccine, currently estimated to affect about 4 to 6 people out of a million people who receive the AstraZeneca vaccine. It can be very serious and can cause long-term disability and death.

The condition causes thrombosis (blood clotting) and thrombocytopenia (low blood platelet counts). The blood clots can occur at different parts of the body, including the brain (this is called cerebral venous sinus thrombosis) and in the abdomen. The low level of blood platelets can potentially cause bleeding.

**Thrombosis:** This is when a blood clot forms. A blood clot prevents blood flowing normally through the body.

**Thrombocytopenia:** A condition in which a person has a low blood platelet count. Platelets (thrombocytes) are colourless blood cells that help blood clot. Platelets stop bleeding by clumping and forming plugs in blood vessel injuries.

### When does this typically occur?

The onset of reported cases was between 4 to 20 days after vaccination with the first dose of AstraZeneca COVID-19 vaccine. The syndrome has not been reported after the second dose of this vaccine.

### How common is thrombosis with thrombocytopenia syndrome?

Current estimates, based on information from Europe and the UK, suggest a rate of around 4-6 cases per million people who receive the AstraZeneca vaccine.

In Australia, the Vaccine Safety Investigation Group have assessed a person with thrombosis and thrombocytopenia admitted to a Melbourne hospital. This occurred after the individual received the AstraZeneca COVID-19 vaccine. The Vaccine Safety Investigation Group concluded this is a new syndrome likely linked to the AstraZeneca COVID-19 vaccine.

As at 8 April, there is a possible second case in Australia, which is being reviewed by the Therapeutic Goods Administration (TGA) as part of a formal causality assessment.

### Are any groups more at risk of this thrombosis with thrombocytopenia syndrome?

So far, the majority of the cases reported in Europe have occurred in younger adults and more commonly in women, however cases have also been reported in men, and in older people.

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 frontline healthcare workers that were prioritised for vaccination.

Based on the available information, we do not know if there are any pre-existing medical conditions that may contribute to this syndrome.

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

This condition can present as:

- 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
  - may be accompanied by nausea and vomiting
- neurological symptoms such as:
  - blurred vision
  - difficulty with speech
  - drowsiness
  - seizures
- shortness of breath
- chest pain

- swelling in your leg
- persistent abdominal (belly) pain
- tiny blood spots under the skin away from the site of injection.

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

### **Do the benefits of the AstraZeneca vaccine outweigh any risk?**

Yes. The benefits of vaccination still clearly outweigh the risks. This is particularly for older people who have a higher risk of severe illness from COVID-19, and who appear to have a lower risk of thrombosis with thrombocytopenia syndrome after vaccination.

For people under 50 years of age, another COVID-19 vaccine brand is preferred, if available. However, adults under 50 should still consider having the AstraZeneca vaccine. They should do this after considering the benefits and risks of vaccination. The risks of dying or having severe disease from COVID-19 are generally lower in healthy younger adults, whereas it is possible that there is a higher risk (although still very rare) of the thrombosis with thrombocytopenia syndrome after vaccination.

### **What if you are aged 50 and under and are booked in to receive your first dose of AstraZeneca?**

If you are booked in to receive your first dose of the AstraZeneca COVID-19 vaccine and you are younger than 50 years old, please talk to your health professional. They will help you to decide if the benefits of vaccination outweigh the risks from COVID-19 for you.

### **How do people aged 50 years and under book an appointment for the Pfizer vaccine? Where is it available?**

The COVID-19 vaccination program is currently being modified in light of the ATAGI advice. This will include review of how and where the Pfizer vaccine can be received. More information will be provided as soon as possible.

### **What if you have received your first dose of AstraZeneca and are due for your second dose?**

So far, all reported cases of thrombosis with thrombocytopenia syndrome have occurred after the first dose of the AstraZeneca COVID-19 vaccine. Based on this, ATAGI recommends that if you have received your first dose of the AstraZeneca vaccine without this side effect, you can receive your second dose as planned, even if you are younger than 50 years of age.

### **What about people with heparin induced thrombocytopenia (HIT) and central venous sinus thrombosis (CVST)?**

The new clotting syndrome appears to be different to heparin induced thrombocytopenia and central venous sinus thrombosis. However, in people with a history of heparin induced thrombocytopenia or central venous sinus thrombosis, the Pfizer (Comirnaty) vaccine is preferred over the AstraZeneca COVID-19 vaccination at this time. The Pfizer (Comirnaty) vaccine is not associated with thrombosis with thrombocytopenia syndrome.

### **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, 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 thrombosis with thrombocytopenia syndrome. The overall rate of blood clots has not risen in countries which have extensively used the AstraZeneca vaccine with millions of doses administered.

### **For more information**

Speak to your healthcare professional or vaccination provider if you have further questions about the AstraZeneca vaccine.