



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# COVID-19 Vaccine AstraZeneca

Active ingredient: ChAdOx1-S

## Consumer Medicine Information

This vaccine has **provisional approval** in Australia to protect people aged 18 years and older against COVID-19 disease. This approval has been granted on the basis of short term efficacy and safety data. Evidence of longer term efficacy and safety from ongoing clinical trials and vaccination in the community continues to be gathered and assessed.

This leaflet provides important information about COVID-19 Vaccine AstraZeneca. **You should also speak to your healthcare provider (e.g. doctor, nurse or pharmacist) if you would like further information or if you have any concerns or questions about using this COVID-19 Vaccine.**

**Where to find information in this leaflet:**

1. Why am I being given COVID-19 Vaccine AstraZeneca?
2. What should I know before I am given this COVID-19 vaccine
3. What if I am taking, have recently taken or might take other medicines or vaccines?
4. How I am given this COVID-19 Vaccine?
5. What should I know about being given this COVID-19 Vaccine?
6. Are there any side effects?
7. Product details

### 1. Why am I being given COVID-19 Vaccine AstraZeneca?

**COVID-19 Vaccine AstraZeneca contains the active ingredient ChAdOx1-S. This vaccine is used to protect people aged 18 years and older against COVID-19.**

COVID-19 is caused by a virus called coronavirus (SARSCoV-2).

COVID-19 Vaccine AstraZeneca stimulates the body's natural defences (immune system). It causes the body to produce its own protection (antibodies) against the virus. This will help to protect you against COVID-19 in the future. None of the ingredients in this vaccine can cause COVID-19.

### 2. What should I know before I am given this COVID-19 vaccine

#### Warnings

**You should not receive COVID-19 Vaccine AstraZeneca if:**

- you are allergic to this vaccine or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this vaccine.

**Check with your healthcare provider before vaccination if:**

- You have ever had a severe allergic reaction (anaphylaxis) after any other vaccine injection;
- Your immune system does not work properly (immunodeficiency) or are taking medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants or cancer medicines);
- You currently have a severe infection with a high temperature (over 38°C);
- You have a problem with bleeding or bruising, or if you are taking a blood thinning medicine (anticoagulant);
- You have any other medical conditions
- You take any medicines for any other condition including any recent or planned vaccines

After vaccination you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

#### Pregnancy and breastfeeding

Check with your healthcare provider if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby. There are limited data on the use of COVID-19 Vaccine AstraZeneca in pregnant or breastfeeding women. Your

healthcare provider will discuss with you whether you can be given the vaccine.

### *Children and adolescents*

No data are currently available on the use of COVID-19 Vaccine AstraZeneca in children and adolescents younger than 18 years of age.

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## 3. What if I am taking, have recently taken or might take other medicines or vaccines?

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Tell your healthcare provider if you are taking, have recently taken, or might take, any other vaccines or medicines including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Medicines (including other vaccines) that may impact whether you should be given this vaccine or not include the following (see also Section 2 above):**

- medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants or cancer medicines);
- blood thinning medicines (anticoagulant)
- any other vaccine including any other COVID-19 vaccines

**Check with your healthcare provider if you are not sure about what vaccines, medicines, vitamins or supplements you are taking or have recently taken and if these may affect this COVID-19 Vaccine.**

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## 4. How I am given this COVID-19 Vaccine?

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### *How COVID-19 Vaccine AstraZeneca is given*

COVID-19 Vaccine AstraZeneca will be given to you by a healthcare provider. It is injected into a muscle (usually in the upper arm).

**You will receive 2 (0.5 mL per dose) injections. You will be told when you need to return for your second injection of COVID-19 Vaccine AstraZeneca.**

The second injection can be given between 4 and 12 weeks after the first injection.

When COVID-19 Vaccine AstraZeneca is given for the first injection, COVID-19 Vaccine AstraZeneca (and not another vaccine against COVID-19) should be given for the second injection to complete vaccination course.

### *If you forget to get your second injection*

If you forget to go back at the scheduled time, ask your healthcare provider for advice. It is important that you return for your second injection of COVID-19 Vaccine AstraZeneca. If you miss a scheduled second injection you may not achieve maximum protection.

### *If you use too much COVID-19 Vaccine AstraZeneca*

As COVID-19 Vaccine AstraZeneca is given under the close supervision of a healthcare provider it is unlikely that you will be given too much.

If you are concerned that you have been given too much COVID-19 Vaccine AstraZeneca, tell your healthcare provider immediately.

**You should do this even if there are no signs of discomfort or poisoning.**

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## 5. What should I know about being given this COVID-19 Vaccine?

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As with any vaccine, COVID-19 Vaccine AstraZeneca may not protect everyone who is vaccinated from COVID-19. It is not yet known how long people who receive the vaccine will be protected for.

### *Driving or using machines*

**Be careful before you drive or use any machines or tools until you know how this vaccine affects you.**

COVID-19 Vaccine AstraZeneca has no known effect on the ability to drive and use machines. However, side effects listed in section 6 may impact your ability to drive and use machines. If you feel unwell, do not drive or use machines.

### *Looking after your vaccine*

Your healthcare provider is responsible for storing this vaccine and disposing of any unused product correctly.

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## 6. Are there any side effects?

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All vaccines can have side effects. If you do experience any side effects, most of them are mild to moderate in nature and resolve within a few days. However, some side effects may need medical attention.

See the information below and, if you need to, ask your healthcare provider if you have any further questions about side effects.

### **Less serious side effects**

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>Tenderness, pain, warmth, redness, itching or swelling where the injection is given</li> <li>Generally feeling unwell</li> <li>Feeling tired (fatigue)</li> <li>Chills, fever or feeling feverish</li> <li>Headache</li> <li>Feeling sick (nausea)</li> <li>Muscle pain/ache, joint pain</li> </ul>	<p><b>Speak to your healthcare provider if you have any of these less serious side effects and they worry you.</b></p> <p>Medicines containing paracetamol can be taken if you need relief from side effects such as pain and/or fever.</p>

## Serious side effects

Serious side effects	What to do
<p>All injectable vaccines have the potential for an allergic reaction after you are injected.</p> <p>Some of the symptoms of an allergic reaction may include:</p> <ul style="list-style-type: none"> <li>rash, itching or hives on the skin</li> <li>swelling of the face, lips, tongue or other parts of the body</li> <li>shortness of breath, wheezing or difficulty breathing</li> <li>fainting, dizziness, feeling lightheaded (due to a drop in blood pressure)</li> </ul>	<p><b>Tell your healthcare provider straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your healthcare provider if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems) and include the vaccine name (COVID-19 Vaccine AstraZeneca) and batch/lot number if available. By reporting side effects, you can help provide more information on the safety of this vaccine.

## 7. Product details

This vaccine is only available with a doctor's prescription.

**What COVID-19 Vaccine AstraZeneca contains**

<b>Active ingredient (main ingredient)</b>	One dose (0.5 mL) contains: ChAdOx1-S* 5x10 <sup>10</sup> viral particles (vp)
<b>Other ingredients (inactive ingredients)</b>	histidine, histidine hydrochloride monohydrate, sodium chloride, magnesium chloride hexahydrate, disodium edetate, sucrose, ethanol absolute, polysorbate 80 and water for injections.

\* Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike glycoprotein. The vaccine is manufactured using material originally sourced from a human embryo (Human Embryo Kidney cells: HEK293).

**Do not take this vaccine if you are allergic to any of these ingredients.**

This product contains genetically modified organisms (GMOs).

COVID-19 Vaccine AstraZeneca does not contain any preservatives and the vial stopper is not made with natural rubber latex.

## What this vaccine looks like

COVID-19 Vaccine AstraZeneca is approved<sup>^</sup> for the following multidose vial packs (Aust R 349072):

- 4mL (8 dose) vial in packs of 10 vials
- 5mL (10 dose) vial in packs of 10 vials.

<sup>^</sup>not all pack sizes may be available in Australia

## Sponsor

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For COVID-19 Vaccine

AstraZeneca enquiries contact 1800 343 949

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