Vaxzevria® (previously COVID-19 Vaccine AstraZeneca)

This vaccine has **provisional approval** in Australia to protect people aged 18 years and older against COVID-19 disease. The 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.

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this vaccine, speak to your healthcare provider (e.g. doctor, nurse or pharmacist).

▼ This vaccine is new. Please report side effects. See the full CMI for further details.

1. Why am I being given VAXZEVRIA?

VAXZEVRIA contains the active ingredient ChAdOx1-S. This vaccine is used to protect people aged 18 years and older against COVID-19. For more information, see Section 1. Why am I being given VAXZEVRIA? in the full CMI.

2. What should I know before I am given VAXZEVRIA?

You should not receive VAXZEVRIA if you have ever had an allergic reaction to VAXZEVRIA or any of the ingredients listed at the end of the CMI, have had a major blood clot occurring at the same time as having low levels of platelets (thrombocytopenia) after receiving any COVID-19 vaccine or have had capillary leak syndrome (a condition causing fluid leakage from small blood vessels). **Talk to your healthcare provider if you have or have had any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**
VAXZEVRIA should not be given to children under 18 years.
For more information, see Section 2. What should I know before I am given VAXZEVRIA? in the full CMI.

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

Medicines (including other vaccines) that may impact whether you should be given this vaccine or not are listed in Section 3. What if I am taking, have recently taken or might take other medicines or vaccines? in the full CMI.

4. How am I given VAXZEVRIA?

VAXZEVRIA will be given to you by a healthcare provider. It is injected into a muscle (usually in the upper arm). You will receive 2 injections with the second injection given 4-12 weeks after the first injection. You may receive a booster dose (third dose) at least 3 months after the second injection of the primary course with VAXZEVRIA or another approved COVID-19 vaccine. More instructions can be found in Section 4. How am I given VAXZEVRIA? in the full CMI.

5. What should I know about being given VAXZEVRIA?

General	As with any vaccine, VAXZEVRIA 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	VAXZEVRIA has no known effect on the ability to drive/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/use machines.

For more information, see Section 5. What should I know about being given VAXZEVRIA? in the full CMI.

6. Are there any side effects?

Most side effects are mild to moderate in nature and resolve within a few days. Fewer side effects were reported after the second dose.

Some very rare serious side effects, such as major blood clots in combination with low levels of blood platelets, very low levels of blood platelets with or without bleeding, capillary leak syndrome, inflammation of the nerves and/or spinal cord (or allergic reactions, may require urgent medical attention or hospitalisation.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This vaccine 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 other healthcare provider, or directly at www.tga.gov.au/reporting-problems.

VAXZEVRIA® (previously COVID-19 Vaccine AstraZeneca)

Active ingredient: *ChAdOx1-S*

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.

Consumer Medicine Information (CMI)

This leaflet provides important information about VAXZEVRIA. **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 VAXZEVRIA.**

Where to find information in this leaflet:

1. Why am I being given VAXZEVRIA?

VAXZEVRIA 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 (SARS-CoV-2).

VAXZEVRIA 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 VAXZEVRIA?

Warnings

You should not receive VAXZEVRIA 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.
- Have had a major blood clot occurring at the same time as having low levels of platelets (thrombocytopenia) after receiving any COVID-19 vaccine.
- Have had capillary leak syndrome (CLS; a condition causing fluid leakage from small blood vessels).

Check with your healthcare provider before vaccination if:

- You have ever had a severe allergic reaction after any other vaccine injection or after you were given VAXZEVRIA in the past;
- 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 ever had a blood clot in the past or if you have an autoimmune disorder (illness where the body's immune system attacks its own cells) including immune thrombocytopenia (ITP; previously known as idiopathic thrombocytopenic purpura);
- You have ever had a serious medical condition (heparin induced thrombocytopenia; HIT) where your blood platelet levels became very low (thrombocytopenia) after taking heparin (a blood thinning medicine)
- You have a problem with bleeding or bruising, or if you are taking a blood thinning medicine (anticoagulant);
- You have ever had capillary leak syndrome (CLS; a condition causing fluid leakage from small blood vessels)
- You have ever fainted or felt stressed (eg dizziness, increased heart rate, difficulty in breathing, sweating, tingling feeling and/or feeling anxious) when you have been given an injection including other vaccines.
- You have any other medical conditions
- You take any medicines for any other condition including any recent or planned vaccines

Blood disorders

Very rare cases of blood clots with low levels of blood platelets have been observed following vaccination with VAXZEVRIA. The majority of these cases occurred within the first 21 days following vaccination but have also been reported after this period. Some had a fatal outcome.

Blood clots, including clots in the brain, not associated with low levels of blood platelets have been observed following vaccination with VAXZEVRIA. However, it has not been determined whether these events were due to the vaccine. Some had a fatal outcome.

Very low levels of blood platelets (immune thrombocytopenia), that can be associated with bleeding, have been reported very rarely, usually within the first four weeks following vaccination with Vaxzevria.

Seek urgent medical attention if from a few days following vaccination you:

- Experience a severe or persistent headache, blurred vision, confusion or seizures (fits)
- Develop shortness of breath, chest pain, leg swelling, leg pain or persistent abdominal pain
- Notice unexplained bleeding, unusual skin bruising or pinpoint round spots beyond the site of vaccination

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 VAXZEVRIA 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 VAXZEVRIA in children and adolescents younger than 18 years of age.

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

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 VAXZEVRIA.

4. How am I given VAXZEVRIA?

How VAXZEVRIA is given

VAXZEVRIA will be given to you by a healthcare provider. It is injected into a muscle (usually in the upper arm).

Primary vaccination course

You will receive 2 (0.5 mL per dose) injections as part of the primary vaccination course. You will be told when you need to return for your second injection of VAXZEVRIA.

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

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

Booster dose

You may also receive a third booster injection of VAXZEVRIA. The booster injection may be given at least 3 months after the second injection of your primary vaccination course with VAXZEVRIA or another approved COVID-19 vaccine (eg mRNA vaccine).

If you forget to get your second injection or booster injection

If you forget to go back at the scheduled time for your second injection or your booster injection, ask your healthcare provider for advice. It is important that you return for your second injection and/or any recommended booster injections of VAXZEVRIA. If you miss a scheduled second or booster injections you may not achieve maximum protection.

If you use too much VAXZEVRIA

As VAXZEVRIA 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 VAXZEVRIA, tell your healthcare provider immediately.

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

5. What should I know about being given VAXZEVRIA?

As with any vaccine, VAXZEVRIA 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.

VAXZEVRIA 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.

6. Are there any side effects?

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. Fewer side effects were reported after the second dose However, some side effects may need medical attention.

After vaccination, you may have more than one side effect at the same time (for example, muscle pain/ache, joint pain, headaches, chills and generally feeling unwell).

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
• Tenderness, pain, warmth, redness, itching or swelling where the injection is given	**Speak to your healthcare provider if you have any of**

Less serious side effects	What to do
• Generally feeling unwell • Feeling tired (fatigue) • Flu like symptoms such as fever/feeling feverish (high temperatures), sore throat, runny nose, cough and/or chills • Feeling dizzy • Headache • Feeling sick (nausea), being sick (vomiting), diarrhoea or abdominal pain • Muscle pain/ache, joint pain, pain in legs or arms • ringing in the ears (tinnitus) • decreased appetite • inflammation of blood vessels in the skin, often with a rash and small red or purple spots (cutaneous vasculitis)	**these less serious side effects and they worry you.** **Medicines containing paracetamol can be taken if you need relief from side effects such as pain and/or fever.**

Serious side effects

Serious side effects	What to do
Low levels of blood platelets (with or without major blood clots or bleeding (thrombocytopenia or immune thrombocytopenia) have been observed very rarely. Get medical attention immediately if from a few days following vaccination you get any of the following symptoms: • experience a severe or persistent headache, blurred vision, confusion or seizures (fits) • develop shortness of breath, chest pain, leg swelling, leg pain or persistent abdominal pain • notice unexplained bleeding, unusual skin bruising or pinpoint round spots beyond the site of vaccination	**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.** You may need urgent medical attention or hospitalisation.
Very rare cases of capillary leak syndrome (CLS) have been reported. Get medical attention immediately if you get any of the following symptoms in the days following vaccination: • rapid swelling of the arms and legs, • sudden weight gain, and • feeling faint (low blood pressure)	**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.** You may need urgent medical attention or hospitalisation.
Very rare cases of Guillain-Barré syndrome (GBS) and Acute Disseminated Encephalomyelitis (ADEM) have been reported. GBS and ADEM are rare immune disorders that can cause inflammation in the brain and spinal cord that damages myelin – the protective covering of nerve fibres. Get medical attention immediately if you get any of the following symptoms: Pain, numbness, paralysis, confusion, difficulty breathing, muscle weakness in the arms and legs, which may progress to the chest and face. Very rare cases of transverse myelitis (inflammation of the spinal cord) have been reported. Get medical attention immediately if you get any of the following symptoms: weakness in the arms or legs, sensory symptoms (such as tingling, numbness, pain or loss of pain sensation), localized or radiating back pain, bladder and bowel symptoms.	**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.** You may need urgent medical attention or hospitalisation.
All injectable vaccines have the potential for an allergic reaction after you are injected. Some of the symptoms of an allergic reaction may include: • swelling of the face, lips, tongue, mouth, throat and/or other parts of the body • shortness of breath, wheezing or difficulty breathing • fainting, dizziness, feeling lightheaded (due to a drop in blood pressure) • changes in your heartbeat • rash, itching or hives on the skin	**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.** You may need urgent medical attention or hospitalisation.

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 and include the vaccine name (VAXZEVRIA) 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 VAXZEVRIA contains

Active ingredient (main ingredient)	One dose (0.5 mL) contains: ChAdOx1-S* $5x10^{10}$ viral particles (vp) [corresponding to not less than 2.5×10^8 infectious units (Inf.U)]
Other ingredients (inactive ingredients)	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).

VAXZEVRIA does not contain any preservatives and the vial stopper is not made with natural rubber latex.

What this vaccine looks like

VAXZEVRIA is approved for the following multidose vial packs (Aust R 349072):

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

Sponsor

AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
MACQUARIE PARK NSW 2113

Telephone: - 1800 805 342

This leaflet was prepared on 17 April 2023

Vaxzevria is a registered trade mark of the AstraZeneca group of companies.

Doc ID-004490139 v22