

# VAXZEVRIA

(previously COVID-19 Vaccine AstraZeneca)

COVID-19 Vaccine (ChAdOx1-S [recombinant]); solution for injection

## CONSUMER MEDICINE INFORMATION

### What is in this leaflet

This leaflet answers some of the common questions people ask about the **Vaxzevria**. It does not contain all the information that is known 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 this **Vaxzevria**.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **Vaxzevria** against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor.

Keep this leaflet with the medicine. You may need to read it again.

### What Vaxzevria is used for

**Vaxzevria** is a vaccine 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.

### Before you are given Vaxzevria

#### **You should not receive Vaxzevria if you;**

- 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).

#### **Before you receive Vaxzevria**

##### **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 or low blood platelets (thrombocytopenia) in the past;
- 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 any other medical conditions.
- You take any medicines for any other condition including any recent or planned vaccines.

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 cases had a fatal outcome.

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

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 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 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.

### ***Taking other medicines***

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:**

- 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 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).

**You will receive 2 (0.5 mL per dose) injections. 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 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 **Vaxzevria**. If you miss a scheduled second injection you may not achieve maximum protection.

### ***Things to be careful of***

**Vaxzevria** has no known effect on the ability to drive and use machines. However, side effects listed below may impact your ability to drive and use machines. If you feel unwell, do not drive or use machines

### 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
<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>• Flu like symptoms such as fever/feeling feverish, (high temperatures), sore throat, runny nose, cough and/or chills</li> <li>• Headache</li> <li>• Feeling sick (nausea), being sick (vomiting) or diarrhoea</li> <li>• Muscle pain/ache, joint pain, pain in legs or arms</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><b>Medicines containing paracetamol can be taken if you need relief from side effects such as pain and/or fever.</b></p>

#### Serious side effects

Serious side effects	What to do
<p>Low levels of blood platelets (thrombocytopenia) with or without major blood clots have been observed very rarely. <b>Get medical attention immediately</b> if from a few days following vaccination you get any of the following symptoms:</p> <ul style="list-style-type: none"> <li>• experience a severe or persistent headache, blurred vision, confusion or seizures (fits)</li> <li>• develop shortness of breath, chest pain, leg swelling, leg pain or persistent abdominal pain</li> <li>• notice unusual skin bruising or pinpoint round spots beyond the site of vaccination</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> <p>You may need urgent medical attention or hospitalisation.</p>

<p>Very rare cases of capillary leak syndrome (CLS) and have been reported.</p> <p>Get medical attention immediately if you get any of the following symptoms in the days following vaccination:</p> <ul style="list-style-type: none"> <li>• rapid swelling of the arms and legs,</li> <li>• sudden weight gain, and</li> <li>• feeling faint (low blood pressure)</li> </ul> <p>Very rare cases of Guillain-Barré syndrome (GBS) have been reported. GBS is a rare immune disorder that causes nerve inflammation. Symptoms may include pain, numbness, muscle weakness in the arms and legs, which may progress to the chest and face.</p>	<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> <p>You may need urgent medical attention or hospitalisation</p>
<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>• swelling of the face, lips, tongue, mouth, throat and/ 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> <li>• changes in your heartbeat</li> <li>• rash, itching or hives on the skin</li> <li>•</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> <p>You may need urgent medical attention or hospitalisation.</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 Centre for Adverse Reactions Monitoring (CARM) online at <https://nzphvc.otago.ac.nz/reporting/>. By reporting side effects, you can help provide more information on the safety of this vaccine.

**Important:** This leaflet alerts you to some of the situations when you should call your doctor. Other situations, which cannot be predicted, may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about having **Vaxzevria**.

### **After using Vaxzevria**

### **Storage and disposal**

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

### **Product description**

#### **What Vaxzevria looks like**

**Vaxzevria** is available in a 10 dose multidose vial (5 mL) in packs of 10 vials. Each vial contains 10 doses of 0.5 mL.

## **Ingredients**

### Active ingredient:

One dose (0.5 ml) contains: ChAdOx1-S\*  $5 \times 10^{10}$  viral particles (vp)\*\*

\*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) .

\*\* Corresponding to not less than  $2.5 \times 10^8$  infectious units (Inf.U)

This product contains genetically modified organisms (GMOs) under GMO regulations in other jurisdictions. Please note that under the Hazardous Substances and New Organisms (HSNO) Act 1996, this product is not considered to be an organism, and is therefore not considered a GMO in New Zealand.

### Inactive ingredients:

- L-histidine
- L-histidine hydrochloride monohydrate
- magnesium chloride hexahydrate
- polysorbate 80
- ethanol
- sucrose
- sodium chloride
- disodium edetate dihydrate (EDTA)
- water for injection.

<b>Marketed by:</b>
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AstraZeneca Limited  
PO Box 87453, Meadowbank  
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For **Vaxzevria** enquiries contact 0800 684 432.

**Vaxzevria** is a registered trademark of the AstraZeneca group of companies.

<b>Date of preparation</b>
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