

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### VAXZEVRIA™

#### COVID-19 Vaccine (ChAdOx1-S [recombinant]), Solution for Intramuscular Injection

This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about VAXZEVRIA.

#### Serious Warnings and Precautions

A combination of major blood clots and low level of platelets, in some cases together with bleeding, has been observed very rarely following vaccination with VAXZEVRIA in post-authorization use (see ***What are possible side effects from using VAXZEVRIA?***)

#### What is VAXZEVRIA used for?

VAXZEVRIA is a vaccine used to prevent the coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus. It can be given to adults 18 years of age and older.

#### How does VAXZEVRIA work?

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

VAXZEVRIA stimulates the body's natural defences (immune system), by causing the body to produce its own protection (antibodies) against the SARS-CoV-2 virus that causes the COVID-19 infection. You cannot get COVID-19 from this vaccine.

The vaccine is given by injection with a needle, usually in the upper arm, and will require two doses given between 4 and 12 weeks apart. Individuals may not be optimally protected until after receiving the second dose of the vaccine. As with any vaccine, VAXZEVRIA may not fully protect all those who receive it. It is not yet known how long people who receive the vaccine will be protected.

Even after you have had both doses of the vaccine, continue to follow the recommendations of local public health officials to prevent spread of COVID-19.

#### What are the ingredients in VAXZEVRIA?

Medicinal ingredients: ChAdOx1-S [recombinant]

Non-medicinal ingredients:

- Ethanol,
- Disodium edetate dihydrate (EDTA),
- L-Histidine,
- L-Histidine hydrochloride monohydrate,
- Magnesium chloride hexahydrate,
- Polysorbate 80,
- Sodium chloride,

- Sucrose,
- Water for injection

**VAXZEVRIA comes in the following dosage forms:**

Clear to opalescent, colourless to slightly brown, particle-free, preservative-free, solution for injection. It is provided in a multiple dose vial of 10 doses, one dose is 0.5 mL.

**You should not receive VAXZEVRIA if you:**

- Have had a severe allergic reaction to any of the medicinal ingredients or any of the other ingredients in this vaccine (see ***What are the ingredients in VAXZEVRIA***). If you are not sure, talk to your healthcare professional;
- Had an allergic reaction to a previous dose of VAXZEVRIA;
- Have had a major blood clot occurring at the same time as having low levels of platelets (thrombocytopenia) after receiving VAXZEVRIA;
- Have previously experienced episodes of capillary leak syndrome (see ***What are possible side effects from using VAXZEVRIA***);
- Have any symptoms that could be due to COVID-19. Talk with your healthcare professional about your symptoms and getting a COVID-19 test. Your healthcare professional will advise you when you are able to receive the vaccine.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VAXZEVRIA. Talk about any health conditions or problems you may have, including if you:**

- Had any allergies or previous problems following administration of VAXZEVRIA such as an allergic reaction or breathing problems, or major venous or arterial thrombosis with thrombocytopenia;
- Have ever had a blood clot or low blood platelets (thrombocytopenia) in the past or if you have an autoimmune disorder (illness where the body's immune system attacks its own cells) including very low levels of blood platelets;
- Have ever had venous sinus thrombosis in the brain (CVST) with low platelets (thrombocytopenia) or heparin-induced thrombocytopenia (HIT), or CVST without thrombocytopenia;
- Have previously experienced episodes of capillary leak syndrome;
- Have had a severe allergic reaction after any other vaccine injection;
- Have a weakened immune system due to a medical condition (immunodeficiency) or are on a medicine that affects your immune system (such as high-dose corticosteroids, immunosuppressants or cancer medicines);
- Currently have a severe infection with a high temperature (over 38°C);
- Have a problem with bleeding or bruising, or if you are taking a blood thinning medicine (anticoagulant);
- Are pregnant, think you may be pregnant or plan to become pregnant;
- Are breastfeeding or plan to breastfeed.

**If you are not sure if any of the above applies to you, talk to your healthcare professional before you are given the vaccine.**

## Driving and using machines

VAXZEVRIA has no known effect on the ability to drive and use machines. However, side effects listed in ***What are possible side effects from using VAXZEVRIA*** may impact your ability to drive and use machines. If you feel unwell, do not drive or use machines.

## Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Tell your healthcare professional if you are taking, have recently taken or might take, any other medicines or vaccines.

## How VAXZEVRIA is given:

- A healthcare professional will inject the vaccine into a muscle (intramuscular injection), usually in your upper arm.
- During and after each injection of the vaccine, your doctor, pharmacist or nurse will watch over you for around 15 minutes to monitor for signs of an allergic reaction.

## Usual dose:

You will receive 2 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.

It is very important that you return for the second injection, or the vaccine may not work as well.

Individuals should complete the vaccination course with VAXZEVRIA.

## Overdose:

In the event of suspected overdose with VAXZEVRIA, contact your regional poison control centre.

## Missed Dose:

If you forget to go back to your healthcare professional at the scheduled time for your next dose, ask your healthcare professional for advice. It is important that you return for your second injection of VAXZEVRIA.

## What are possible side effects from using VAXZEVRIA?

Like all medicines, VAXZEVRIA can cause side effects, although not everybody gets them. Most side effects are mild to moderate in nature and resolve within a few days. Fewer side effects were reported after the second dose.

Side effects that have been reported with VAXZEVRIA were as follows:

### **Very Common** (may affect more than 1 in 10 people)

- tenderness, pain, warmth, or itching where the injection is given
- generally feeling unwell
- feeling tired (fatigue)
- chills or feeling feverish
- headache

- feeling sick (nausea)
- joint pain or muscle ache

**Common** (may affect up to 1 in 10 people)

- swelling or redness where the injection is given
- fever
- being sick (vomiting) or diarrhea
- pain in legs or arms
- flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills

**Uncommon** (may affect up to 1 in 100 people)

- sleepiness or feeling dizzy
- decreased appetite
- abdominal pain
- enlarged lymph nodes
- excessive sweating, itchy skin, rash or hives
- sensation like numbness, tingling, pins and needles (paraesthesia)
- reduced sensation of touch (hypoesthesia)
- ringing in the ears (tinnitus)

Severe allergic reaction (anaphylaxis), severe swelling of the lips, mouth, throat (which may cause difficulty in swallowing or breathing) have been reported following VAXZEVRIA. Should you develop any serious symptoms or symptoms that could be an allergic reaction, seek medical attention right away. Symptoms of an allergic reaction include:

- hives (bumps on the skin that are often very itchy)
- feeling faint or light-headed
- changes in your heartbeat
- swelling of your face, lips, tongue or throat
- difficulty breathing, shortness of breath or wheezing

Inflammation of blood vessels in the skin, often with a rash and small red or purple spots (cutaneous vasculitis) has been reported with unknown frequency.

A combination of major blood clots and low level of platelets, in some cases together with bleeding, has been observed very rarely following vaccination with VAXZEVRIA in post-authorization use. The majority of the cases occurred within the first 3 weeks following vaccination and 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. The majority of these cases occurred within the first four weeks following vaccination. Some cases had a fatal outcome.

Very low levels of blood platelets (immune thrombocytopenia), that can be associated with bleeding, have also been reported very rarely, usually within the first four weeks following vaccination with VAXZEVRIA. Seek medical attention right away if any of the following symptoms occur within the first month following vaccination:

- new severe headaches, worsening or persistent headaches, blurred vision, confusion or seizures
- shortness of breath, chest pain, leg swelling, leg pain or persistent abdominal pain

- unusual skin bruising or pinpoint round spots beyond the site of vaccination
- unexplained bleeding

Very rare cases of capillary leak syndrome (CLS) have been reported following vaccination with VAXZEVRIA. Some affected patients had a previous diagnosis of CLS. CLS is a serious, potentially fatal condition causing fluid leakage from small blood vessels (capillaries) resulting in rapid swelling of the arms and legs, sudden weight gain and feeling faint (low blood pressure). Seek medical attention right away if you develop these symptoms in the days following vaccination.

Guillain-Barré syndrome (GBS) is a neurological disorder where inflammation of peripheral nerves causes rapid muscle weakness and can sometimes lead to paralysis. This has been reported very rarely after vaccination with VAXZEVRIA. Seek immediate medical attention if you develop weakness and paralysis in the extremities that can progress to the chest and face.

Transverse Myelitis (TM) is a neurological disorder where the inflammation of the spinal cord causes weakness in the arms or legs, sensory symptoms (such as tingling, numbness, pain or loss of pain sensation) or problems with bladder or bowel function. This has been reported very rarely after vaccination with VAXZEVRIA. Seek immediate medical attention if you develop weakness, sensory symptoms or problems with bladder or bowel function.

After vaccination, you may have more than one side effect at the same time (for example, muscle/joint aches, headaches, chills and generally feeling unwell). If any of your symptoms are persistent, please seek advice from your healthcare professional.

These are not all the possible side effects you may have when taking VAXZEVRIA. If you experience any side effects not listed here, tell your healthcare professional.

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

### **Reporting Suspected Side Effects for Vaccines**

**For the general public:** Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and AstraZeneca Canada Inc. cannot provide medical advice.

**For healthcare professionals:** If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/form.html>) and send it to your local Health Unit.

### **Storage:**

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

Keep out of reach and sight of children.

**If you want more information about VAXZEVRIA:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website [www.astrazeneca.ca](http://www.astrazeneca.ca), or [www.azcovid-19.com](http://www.azcovid-19.com), or by calling 1-800-668-6000.

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