

INFORMATION

AstraZeneca/Vaxzevria® COVID-19 Vaccine

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Please read this information sheet carefully and ensure all your questions have been answered by a health care provider before receiving the vaccine.

- **COVID-19** is an infectious disease caused by a new coronavirus (SARS-CoV-2). COVID-19 was recognized for the first time in December 2019 and has since spread around the world to cause a pandemic. The virus that causes COVID-19 is mainly passed from an infected person to others when the infected person coughs, sneezes, sings, talks or breathes. It is important to note that infected people can spread the infection even if they have no symptoms.
- [About 7% of people diagnosed with COVID-19 in Canada](#) require hospitalization and about 2% of people die. Even people with mild symptoms may feel unwell for a long time after a COVID-19 infection.

How does this vaccine protect against COVID-19?

- The vaccine causes our body to produce protection (such as antibodies) to help keep us from becoming sick if we are exposed to the COVID-19 virus.
- The vaccine uses a method that involves taking another virus (called an adenovirus), weakening it so it cannot grow, and inserting the viral genetic material as part of the COVID-19 virus to help our body make protection against the COVID-19 virus.
- In large clinical studies, AstraZeneca (AZ) Vaxzevria® was effective in preventing COVID-19 in the majority of the people who received the vaccine. It also prevented almost all cases of hospitalization and death.

Who can receive this COVID-19 vaccine?

- Adults 18 years and older can receive first and second doses.

Who should not have this COVID-19 vaccine?

Check with your healthcare provider or a public health nurse before you get this vaccine if you:

- have an allergy to any of the vaccine ingredients
- had a severe or unusual side effect after this vaccine or one like it
- have had a tuberculosis (TB) skin test in the last 2-3 days or need TB blood work done
- have received a monoclonal antibody or convalescent plasma for treatment or prevention of COVID-19
- had a major venous or arterial thrombosis with thrombocytopenia after getting this or another viral vector COVID-19 vaccine
- have a history of cerebral venous sinus thrombosis (CVST) with thrombocytopenia
- have a history of heparin-induced thrombocytopenia (HIT)
- have had thrombotic anti-phospholipid antibody syndrome (APS)
- have a history of capillary leak syndrome
- are pregnant (should only receive an mRNA COVID-19 vaccine, unless there are contraindications)
- If you have any symptoms that could be due to COVID-19, you should not go out to get vaccinated because you could spread the

infection to others. Talk with your health care provider, or call 811, about your symptoms and getting a COVID-19 test. Your health care provider will advise you when you are able to receive the vaccine.

- If you belong to one of the following groups you **MUST** consult your health care provider prior to receiving:
 - » All stem cell transplant recipients.
- If you belong to one of the following groups, it is preferred you contact your health care provider prior to receiving the vaccine:
 - » are receiving treatment with immunosuppressive medications to determine the optimal time to receive the COVID-19 vaccine.
 - » have an autoimmune disease that affects the neurological system.

Always tell your healthcare provider if you have allergies or if you have had a side effect from a vaccine, medication or other product in the past.

How is the vaccine administered?

- The vaccine is given as a needle in the muscle of the upper arm.
- All Health Canada approved COVID-19 vaccines can be given at the same time as other non-COVID-19 vaccines; no intervals are needed before or after COVID-19 vaccine administration.

What are common reactions to this vaccine?

- In the AstraZeneca study, half of the people who received the vaccine were monitored for at least two months. Serious adverse events included one person with a high fever and one person with neurologic problem (transverse myelitis) that was considered possibly related to the vaccine. People who have received the vaccines in studies continue to be monitored for any longer term side effects.
- Side effects can develop up to 3 days after receiving the vaccine. Although these side effects are not serious to your health, they may make you feel unwell for a day or two; they will go away on their own. These side effects are expected and can indicate the vaccine is working to produce protection. In the study, side effects included the following:

- » pain, redness or swelling where the needle was given
- » enlarged lymph nodes in the underarm
- » fever, chills
- » joint pain
- » headache
- » nausea and vomiting
- » tiredness
- » muscle pain

- There have been very rare reports of serious blood clots and low levels of blood platelets, in some cases with bleeding, following immunization with this vaccine. This includes severe cases presenting in unusual sites such as the brain and abdomen. The reaction typically occurs 4 to 28 days, but may occur up to 42 days after vaccination. The number of people who are affected



following immunization with this vaccine is about one out of every 26,000 to one out of every 100,000 persons after the first dose and about one out of every 600,000 persons after the second dose.

- There have been very rare reports in Europe and the United Kingdom of capillary leak syndrome following immunization with this vaccine. This syndrome is a very rare, serious condition that causes fluid leakage from small blood vessels (capillaries) resulting in swelling mainly in the arms and legs, low blood pressure, thickening of the blood, and low levels of albumin (an important protein in blood).
- There have been very rare reports of an autoimmune condition called immune thrombocytopenia following immunization with viral vector vaccines that causes bleeding, bruising, shortness of breath, chest pain, leg pain and swelling and small purple spots beyond the injection site.
- Very rare events of demyelinating disorders, such as Guillain-Barré syndrome (GBS) have been reported following vaccination with this COVID-19 vaccine. Most people fully recover from GBS but some have remaining symptoms and fatal cases can occur.
- Health Canada and the Public Health Agency of Canada (PHAC) are actively monitoring reports of myocarditis (inflammation of the heart) and/or pericarditis (inflammation of the outer lining of the heart) following immunization with a COVID-19 vaccine in Canada. There have been a small number of cases reported in Canada (mostly following mRNA vaccination), and it is not yet known if there is any relationship between these events and the vaccines.
- Rarely allergic reactions can occur after receiving a vaccine. Symptoms of an allergic reaction include hives (bumps on the skin that are often very itchy), swelling of your face, tongue or throat, or difficulty breathing. The clinic staff are prepared to manage an allergic reaction should it occur. Seek immediate medical care if you develop any of these symptoms.
- It is important to note that **you cannot get COVID-19 infection from the vaccine.**
- **If you have any concerns about the symptoms you develop after receiving the vaccine, call 811. If you received your vaccination from a pharmacist, please consult them first when possible.**

For more information please speak with the person providing the vaccine or contact your local public health office, your physician, nurse practitioner, or by calling 811.

What measures have been put in place to safely provide immunizations during COVID-19?

Health care providers are being very careful to prevent the spread of COVID-19 when offering immunizations. Examples of extra safety measures include the following:

- You will be asked about any COVID-19 symptoms when you arrive at the clinic. People with symptoms of COVID-19 should not attend the clinic.
- You will be asked to wear a mask while at the clinic, as well as to clean your hands, and to stay at least 2 metres (6 feet) from others (except those you live with).
- The staff will also be wearing personal protective equipment and will be cleaning their hands before and after each client.
- Other measures may also be put in place in clinics. Be sure to read and follow any signs or instructions provided.

What should you do after receiving the vaccine?

- You will be asked to **wait at least 15 minutes** after receiving the vaccine to be sure you are feeling well. Longer waiting times of 30 minutes may be recommended if there is concern about a possible vaccine allergy. You may be asked by the health care provider to wait in the clinic, or if an adult is with you and you have a warm, dry place to wait (such as in your vehicle), you may be asked to wait outside of the clinic. Inform a health care provider right away if you feel unwell while waiting. You should not leave the clinic (or clinic parking lot) for at least 15 to 30 minutes after receiving your vaccine, based on the recommendation of the health care provider.
- **Once you leave the clinic, call 911 right away if you develop any serious symptoms or symptoms of an allergic reaction** such as hives (bumps on the skin that are often very itchy), swelling of your face, tongue or throat, or difficulty breathing. Inform your health care provider of any concerning side effects after receiving the vaccine.
- Continue to follow the recommendations of local public health officials to prevent spread of COVID-19, which may include wearing a mask, staying at least 2 metres from others and limiting/avoiding contact with others outside your household.
- **Keep your immunization record with information about the COVID-19 vaccine in a safe place.**

When should I return for my next vaccine dose?

- Evidence shows an 8 week interval is optimal between first and second doses but the minimum interval of 28 days will still be provided if people choose the shorter interval. Bring your immunization record with you when you come for your next dose.
- If you received COVISHIELD or AstraZeneca Vaxzevria® as your first dose you will have the choice of AstraZeneca Vaxzevria® or an mRNA vaccine (Pfizer/Moderna) for your next/additional dose. mRNA vaccines are preferred for the next dose based on early evidence suggesting there may be an increased immune response when receiving an mRNA as a second dose, but the real world effect of that is unknown. You may still receive AstraZeneca Vaxzevria® for the next dose.
- Eligible high risk individuals should receive an additional/ 'booster' dose of mRNA vaccine 28 days after their second dose.
- It is recommend that individuals who received two doses of AstraZeneca/COVISHIELD as their primary series receive an mRNA booster vaccine at 6 months after completion of their primary series. A viral vector vaccine (AstraZeneca or Janssen) could be given to those for whom there is a contraindication to an mRNA.

What does this vaccine contain?

- Medicinal ingredient: COVID-19 Vaccine ChAdOx1-S [recombinant]. Non-medicinal ingredients: Disodium edetate dihydrate (EDTA), Ethanol, L-Histidine, L-Histidine hydrochloride monohydrate, Magnesium chloride hexahydrate, Polysorbate 80, Sodium chloride, Sucrose, Water for injection.