

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

AstraZeneca COVID-19 Vaccine

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

AstraZeneca COVID-19 VACCINE (manufactured by AstraZeneca) and COVISHIELD (manufactured by Serum Institute of India) are ChAdOx1-S recombinant vaccines developed by AstraZeneca and the University of Oxford. Health Canada has reviewed the manufacturing information for these vaccines and found them to be comparable.

Health Canada has authorized the sale of this COVID-19 vaccine under an Interim Order. 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 AstraZeneca COVID-19 Vaccine.

What is AstraZeneca COVID-19 Vaccine used for?

AstraZeneca COVID-19 Vaccine 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 AstraZeneca COVID-19 Vaccine work?

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

AstraZeneca COVID-19 Vaccine 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, AstraZeneca COVID-19 Vaccine 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 AstraZeneca COVID-19 Vaccine?

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

AstraZeneca COVID-19 Vaccine 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 or 8 doses, one dose is 0.5 mL.

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

- 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 AstraZeneca COVID-19 Vaccine***). If you are not sure, talk to your healthcare professional;
- Have had an allergic reaction to a previous dose of AstraZeneca COVID-19 Vaccine/COVISHIELD;
- Have had a major blood clot occurring at the same time as having low levels of platelets (thrombocytopenia) after receiving any AstraZeneca COVID-19 Vaccine/COVISHIELD;
- Have previously experienced episodes of capillary leak syndrome (see ***What are possible side effects from using AstraZeneca COVID-19 Vaccine***);
- 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 AstraZeneca COVID-19 Vaccine. Talk about any health conditions or problems you may have, including if you:

- Have any allergies or previous problems following administration of AstraZeneca COVID-19/COVISHIELD Vaccine 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 idiopathic thrombocytopenic purpura (ITP);
- Have had a history of venous sinus thrombosis in the brain (CVST) with low platelets (thrombocytopenia) or a history of heparin-induced thrombocytopenia (HIT);
- Have previously experienced episodes of capillary leak syndrome (see ***What are possible side effects from using AstraZeneca COVID-19 Vaccine***);
- 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.

Neurological events

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 AstraZeneca COVID-19 Vaccine/COVISHIELD. Seek immediate medical attention if you develop weakness and paralysis in the extremities that can progress to the chest and face.

Driving and using machines

AstraZeneca COVID-19 Vaccine has no known effect on the ability to drive and use machines. However, side effects listed in ***What are possible side effects from using AstraZeneca COVID-19 Vaccine*** 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 AstraZeneca COVID-19 Vaccine is given:

- A healthcare provider 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 AstraZeneca COVID-19 Vaccine.

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 either AstraZeneca COVID-19 Vaccine or COVISHIELD.

Overdose:

In the event of suspected overdose with AstraZeneca COVID-19 Vaccine, 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 AstraZeneca COVID-19 Vaccine.

What are possible side effects from using AstraZeneca COVID-19 Vaccine?

Like all medicines, AstraZeneca COVID-19 Vaccine 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.

Severe allergic reaction (anaphylaxis), severe swelling of the lips, mouth, throat (which may cause difficulty in swallowing or breathing) have been reported following AstraZeneca COVID-19 Vaccine. 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

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 AstraZeneca COVID-19 Vaccine in post-authorization use. The majority of the cases occurred within the first 3 weeks following vaccination and some cases had a fatal outcome. Very rare cases of low blood platelets (thrombocytopenia) have also been reported. 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

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.

Very rare cases of capillary leak syndrome (CLS) have been reported following vaccination with AstraZeneca COVID-19 Vaccine. 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.

Side effects that have been reported with AstraZeneca COVID-19 Vaccine 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

These are not all the possible side effects you may have when taking AstraZeneca COVID-19 Vaccine. 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 AstraZeneca COVID-19 Vaccine:

- 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, or www.azcovid-19.com, or by calling 1-800-668-6000.

This leaflet was prepared by AstraZeneca Canada Inc., Mississauga, Ontario L4Y 1M4

© AstraZeneca 2021

Last Revised: AUG-13-2021