HEALTH CANADA HAS AUTHORIZED THE SALE OF THIS COVID-19 VACCINE UNDER AN INTERIM ORDER[1]

AstraZeneca COVID-19 Vaccine

COVID-19 Vaccine (ChAdOx1-S [recombinant])

INFORMATION FOR THE PUBLIC

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. Individuals can complete the vaccination course with either AstraZeneca COVID-19 Vaccine or COVISHIELD.

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REVIEWED BY PAAB

MEMBER OF INNOVATIVE MEDICINES CANADA

VAX2102E

About this guide

- This guide is for people who are interested in learning more about the vaccine.
- It only provides information about AstraZeneca COVID-19 Vaccine, known as ChAdOx1-S (recombinant) COVID-19 Vaccine. It does not cover other non-ChAdOx1-S (recombinant) COVID-19 vaccines, COVID-19 treatments or the COVID-19 disease.
- It does not include Health Canada, Public Health Agency of Canada, provincial or local public health advice.

There is a separate guide written for healthcare professionals available at www.azcovid-19.com.

You should also check the Health Canada Patient Medication Information section of the Product Monograph available at www.azcovid-19.com.

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How to use this guide

- Click on the **tabs** (above) or the links in **Contents** to navigate to each section of this guide
- Click on **underlined links** to go to content

What the vaccine is

About the vaccine

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.[1]

It is designed to stimulate your immune system to provide protection against the coronavirus (SARS-CoV-2). This is the virus that causes the disease COVID-19, which makes some people very ill and can even lead to death.[1]

The vaccine contains a modified common cold virus. The "modified virus" technology used for this vaccine has already been tested as a way to make vaccines for other diseases.[17]

What is in the vaccine

The vaccine is made up of an **active** ingredient and other **inactive** ingredients to allow the vaccine to be given by injection. The inactive ingredients also keep the vaccine stable (stop it from changing)[8], but there are no preservatives used.[1]

The **active ingredient** is a modified common cold virus, originally found in chimpanzees. This virus has been altered in the laboratory so it cannot multiply inside your body.[1]

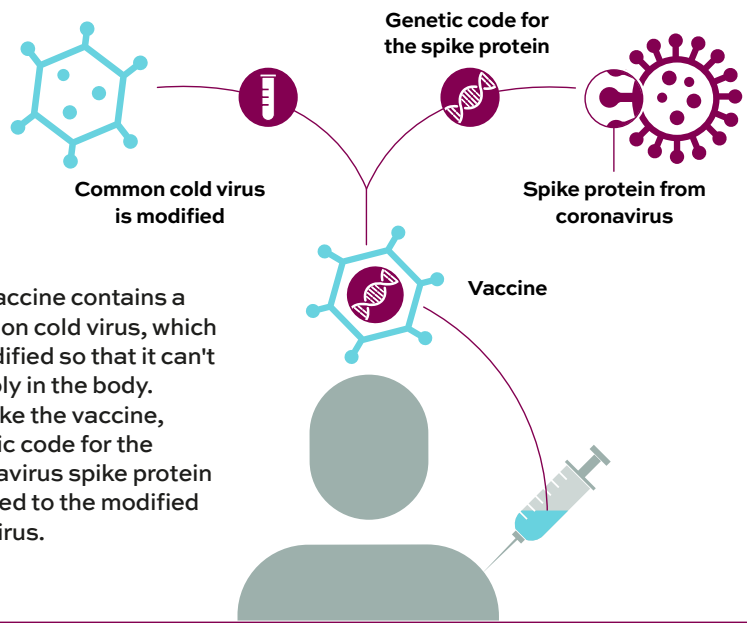
The **inactive ingredients** are L-Histidine; L-Histidine hydrochloride monohydrate (both amino acids); magnesium chloride hexahydrate (supports activities inside cells); polysorbate 80 (a stabilizer); ethanol (alcohol); sucrose (sugar); sodium chloride (salt); disodium edetate dihydrate (EDTA, a binding agent); water for injection.[8]

The ingredients of this vaccine cannot cause COVID-19 or colds.[1]

Click to see more details on:

- ▶ *How the vaccine works*
- ▶ *Does it contain eggs or other animal ingredients?*
- ▶ *Does it contain latex?*
- ▶ *Does it contain genetically modified organisms?*
- ▶ *Information on the ingredients*

How the vaccine is made



The vaccine contains a common cold virus, which is modified so that it can't multiply in the body. To make the vaccine, genetic code for the coronavirus spike protein is added to the modified cold virus.

More details on what is in the vaccine

Does it contain eggs or other animal ingredients?

- AstraZeneca COVID-19 Vaccine does not contain milk, lactose, soya, egg, maize/corn starch, peanuts or gluten.[8]
- None of the vaccine ingredients are of human or animal origin, however the active ingredient of the vaccine is grown using cells that are of human origin. None of these cells remain after the vaccine is purified and is ready to be given.[1,8]
- Information on the ingredients is included in the public guide. Individuals can use this information to decide whether the vaccine is compliant with their own religious belief systems.

Does it contain latex?

AstraZeneca COVID-19 Vaccine does not contain latex (including the vial and its stopper).[8,9]

Does it contain preservatives?

AstraZeneca COVID-19 Vaccine does not contain any preservatives.[1]

Is it a live vaccine?

This vaccine is not like 'traditional' live vaccines (which contain weakened live bacteria or virus) and it does not contain live coronavirus. The modified common cold virus is live, but it cannot multiply or spread throughout the body.[5,6,10] If your immune system does not work properly (immunodeficiency) or you are taking medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants or cancer medicines), **talk to your doctor or healthcare professional** before you are given the vaccine.[1]

See ***How the vaccine works*** and ***The vaccine cannot give you COVID-19 or flu***.

The carrier virus has been genetically modified in two ways to make this vaccine[1,13]:

- The genetic code needed for the virus to multiply has been removed and cannot cause the common cold.
- The genetic code for the coronavirus spike protein has been added.

These changes to the common cold virus allow the vaccine to deliver the spike protein genetic code to your cells without causing COVID-19.[13] For more information, see ***How the vaccine works***.

More details on what is in the vaccine

How the vaccine works

After the vaccine is injected, it carries the genetic code for the spike protein into your body's cells. Your body starts to produce the spike protein on its own.

Immune cells in your blood recognize the spike protein as being an 'invader', and this starts a reaction by the immune system.

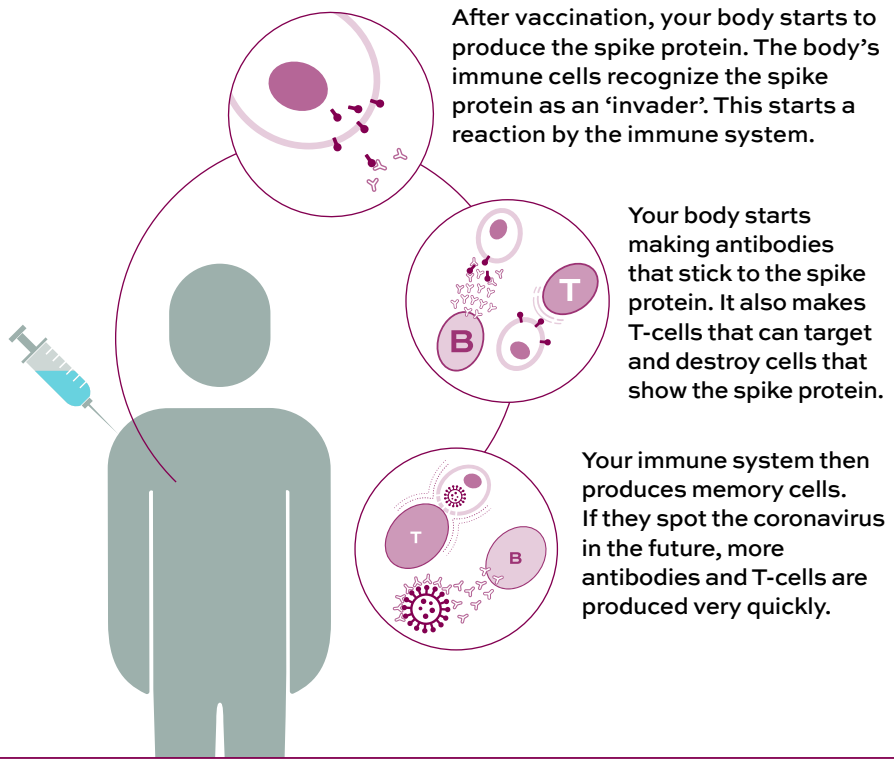
Your body starts making antibodies and immune cells, called T-cells, that can target and destroy cells that show the spike protein. The immune cells also call for more immune cells to be produced, to help fight the 'invaders'.

The immune system then goes on to produce memory cells. These memory cells can spot the coronavirus in the future, by recognizing the spike protein on the surface of the coronavirus. If the immune cells do come across the coronavirus in your body, they can call for more antibodies and T-cells to be produced very quickly. This helps stop the coronavirus from spreading and helps reduce the damage caused by the COVID-19 disease.[1,13]

Click to see more details on:

- ▶ *Does it contain eggs or other animal ingredients?*
- ▶ *Does it contain latex?*

How the vaccine works in the body



Who the vaccine is for

The vaccine is used to protect people aged 18 years and older against COVID-19.[1]

People who have had COVID-19 may be eligible to receive the vaccine. Speak to your doctor or healthcare professional if you should or are eligible to receive the vaccine.[1]

You should not receive the vaccine[1]:

- If you have ever had a **severe allergic reaction** to any of the active or inactive ingredients or a past dose of the AstraZeneca vaccine, listed in ***What is in the vaccine***.
- If you have any symptoms that could be due to COVID-19.
- If you are not sure, talk to your doctor or healthcare professional.

There are also important precautions that you should consider and discuss with your doctor or healthcare professional before you get your vaccine. See ***Precautions***.

Click to see more details on:

- ▶ *Which ages is it suitable for?*
- ▶ *Is it suitable for all ethnic groups?*
- ▶ *What if I'm pregnant or breast-feeding?*
- ▶ *Will the vaccine affect my ongoing condition?*
- ▶ *Can I have it with other vaccines?*
- ▶ *Can I have it with other medicines?*

Precautions

Important! Talk to your doctor or healthcare professional[1]:

- If you have any allergies or previous problems following administration of AstraZeneca COVID-19 Vaccine such as an allergic reaction or breathing problems.
- If you have ever had a **severe allergic reaction** after any other vaccine injection.
- If you 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).
- 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 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.
- If you currently have a severe infection with a high temperature (over 38°C).
- If you have a **problem with bleeding or bruising**, or if you are taking a blood thinning medicine (anticoagulant).
- If you have fainted during or after previous vaccinations so that you can be vaccinated lying down.

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

A combination of 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. Seek immediate medical attention if you develop shortness of breath, chest pain, leg swelling, or persistent abdominal pain following vaccination. Also, seek immediate medical attention if you experience after a few days severe or persistent headaches or blurred vision, or experience skin bruising or pinpoint round spots beyond the site of vaccination which appears after a few days.

Which ages is it suitable for?

This vaccine is suitable for adults aged 18 and over.[1]
No information is available yet on the use of the vaccine in children or adolescents younger than 18 years of age.[1]

Is it suitable for all ethnic groups?

This vaccine is suitable for all ethnic groups. Clinical trials have been conducted in UK, US, Brazil, South Africa, Kenya, India and Japan. There were no restrictions regarding ethnicity.[1]

What if I'm pregnant or breast-feeding?

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, **talk to your doctor or healthcare professional** before receiving the vaccine. There is limited information on the use of AstraZeneca COVID-19 Vaccine in pregnant or breast-feeding women. Your doctor or healthcare professional will discuss with you whether you can be given the vaccine.[1]

Precautions

Will the vaccine affect my ongoing condition?

If you have an underlying health condition, **talk to your doctor or healthcare professional** about whether the AstraZeneca COVID-19 Vaccine is suitable for you.[1]

Can I have it with other vaccines?

This vaccine hasn't been tested for use with other vaccines. Talk to your doctor or healthcare professional if you have recently had or might have any other vaccines.[1] Ask your healthcare provider how long to wait after receiving the ChAdOx1-S (recombinant) COVID-19 Vaccine (AstraZeneca COVID-19 Vaccine or COVISHIELD) before you receive another routine vaccine.

Individuals should complete the COVID-19 vaccination course with either AstraZeneca COVID-19 Vaccine or COVISHIELD.[1]

Can I have it with other medicines?

This vaccine hasn't been tested for use with other medicines. Talk to your doctor or healthcare professional if you are taking, have recently taken or might take any other medicines.[1]

Benefits and side effects

Benefits of the vaccine[1,7,11,14,15,18]

Overall benefits

AstraZeneca COVID-19 Vaccine is designed to stimulate your immune system to provide protection against the coronavirus (SARS-CoV-2). This is the virus that causes the disease COVID-19, which makes some people very ill and can even lead to death.

How soon protection starts

There may be some protection starting after the first dose of the vaccine, but you will not be optimally protected until after receiving the second dose of the vaccine. As with any vaccination, AstraZeneca COVID-19 Vaccine may not protect everyone who is vaccinated.

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

How long protection lasts

Because the vaccine is new, there has not been time to confirm how long protection lasts. As with any vaccine, AstraZeneca COVID-19 Vaccine may not protect everyone who is vaccinated. It is not yet known how long people who receive the vaccine will be protected as research is still ongoing.

Will the vaccine change as the virus mutates?

Scientists will continue to evaluate all new mutations, and any impact these mutations have on how well the vaccines work.

Click to see more details on:

► *Will I need further doses in the future?*

Benefits and side effects

Possible side effects[1]

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

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

In clinical studies, most side effects were mild to moderate in nature and resolved within a few days. Fewer side effects were reported after the second dose.

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 common (may affect more than 1 in every 10 people):

- **Side effects where the injection is given** (injection site reactions):
  - tenderness
  - pain
  - warmth
  - itching
- **Other general side effects** (systemic reactions):
  - generally feeling unwell
  - feeling tired
  - chills or feeling feverish (temperature not measured)
  - headache
  - feeling sick (nausea)
  - joint pain or muscle ache

Common (may affect up to 1 in every 10 people):

- swelling or redness where the injection is given
- fever (measured temperature is 38° C or higher)
- 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

Benefits and side effects

Not known (the frequency cannot be determined from the available data):

- severe allergic reaction (anaphylaxis)
- severe swelling of the lips, mouth, throat (which may cause difficulty in swallowing or breathing)

If you have any concerns about side effects or your side effects do not go away, **talk to your doctor or healthcare professional**.

The vaccine cannot give you COVID-19 or flu

After vaccination, you may experience flu-like symptoms such as feeling tired, muscle/joint aches, headache, chills or fever. These side effects are common, and do not necessarily mean you have the flu or COVID-19.

None of the ingredients in this vaccine can cause COVID-19, flu or a common cold. See ***How the vaccine works*** for more details.

More details on side effects

Is there anything I can do to reduce side effects?

- You can take medicines containing acetaminophen or ibuprofen if you need relief from side effects such as pain and/or fever.[1]
- Talk to your doctor or healthcare professional if you have any further concerns.

Where can I report side effects?

You can report side effects directly as follows:

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.

Are there any long-term effects?

As this vaccine is new, long-term data is not yet available. However, AstraZeneca COVID-19 Vaccine has been given to thousands of people in clinical trials. They are being carefully monitored and will be followed up for 12 months. See also ***How long protection lasts***.

Will it affect my fertility?

There is currently no information available on fertility in humans. Further clinical trials are planned and relevant information will be provided to your doctor or healthcare professional when available.[1]

Getting the vaccine

How to get vaccinated

Vaccination will be offered in different ways, to different people, in different regions of the country. Check your local arrangement with a doctor or healthcare professional.

What you need to know before you are vaccinated

Important! Before you get vaccinated, please read the section called ***Precautions***.

Scheduling other vaccinations (e.g. the flu vaccine)

The use of AstraZeneca COVID-19 Vaccine or COVISHIELD with other vaccines, including the flu vaccine, has not yet been assessed. Talk to your doctor or healthcare professional first if you have recently had or might have any other vaccinations.[1]

No known effect on driving

AstraZeneca COVID-19 Vaccine has no known effect on the ability to drive and use machines. However, side effects may impact your ability to drive and use machines. If you feel unwell, do not drive or use machines[1] – see ***Benefits and side effects***.

Food, drink and the vaccine

There are no known dietary effects or cautions when you have this vaccination. If you have a restricted diet, see also ***What is in the vaccine***.

Getting vaccinated if you are unwell

Talk to your doctor or healthcare professional before your vaccination if you are unwell, especially if you currently have a severe infection with a high temperature (over 38° C) including any symptoms associated with COVID-19. It is not recommended to vaccinate people with COVID-19 who are still symptomatic. Your vaccination may need to be postponed.[1] If you are unwell, you should not go into the clinic so that you don't spread it to others.

If you have a long-term illness, speak to your doctor or healthcare professional about whether AstraZeneca COVID-19 Vaccine is suitable for you. See also ***Who the vaccine is for***.

Getting vaccinated if you had previous COVID-19 infection

Individuals with previous COVID-19 infection can be vaccinated with AstraZeneca COVID-19 Vaccine once they are no longer infectious.[1]

What to expect when getting vaccinated[1]

How is the vaccine given?

This vaccine is injected by a healthcare professional into a muscle in your upper arm.

After receiving the vaccine, your healthcare professional will observe you for at least 15 minutes for any possible severe allergic reaction (anaphylaxis).

How many doses will I need?

You will receive 2 injections. The second injection can be given between 4 and 12 weeks after the first. Individuals should complete the vaccination course with either AstraZeneca COVID-19 Vaccine or COVISHIELD.[1]

Getting the vaccine

You will be told when you need to **return for your second injection** of AstraZeneca COVID-19 Vaccine or COVISHIELD.

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.[1]

Speak to your doctor or healthcare professional if you need flexibility around the dosing schedule.

What do I do if I miss an injection?

If you forget to go back at the scheduled time, ask your doctor or healthcare professional for advice on how to reschedule. It is important that you return for your second injection of AstraZeneca COVID-19 Vaccine.[1]

Will I need further doses in the future?

Two injections, between 4 and 12 weeks apart, is the currently recommended schedule.[1] Your doctor or healthcare professional will tell you what local guidance recommends and when to return for your second dose.

It is not yet known how long people who receive the vaccine will be protected for. Studies are planned to examine the long-term effects of the vaccine. See ***How long protection lasts***.

What to do after you are vaccinated

Continue to follow local guidance

Follow local rules on masks, handwashing and physical distancing, before and after vaccination, and ask your doctor or healthcare professional for advice.

As with any vaccine, AstraZeneca COVID-19 Vaccine may not protect everyone who is vaccinated.

Click to see more details on:

- ▶ *How long should I wait to travel?*
- ▶ *Will the vaccination affect a COVID-19 test?*

Your second dose[1]

Your doctor or healthcare professional **will tell you when you need to return** for your second injection of AstraZeneca COVID-19 Vaccine or COVISHIELD, which may be between 4 and 12 weeks after the first injection.

If you forget to go back at the scheduled time, ask your doctor or healthcare professional for advice. It is important that you return for your second injection of AstraZeneca COVID-19 Vaccine or COVISHIELD.

Click to see more details on:

- ▶ *I was given AstraZeneca COVID-19 Vaccine or COVISHIELD for my first dose – can I get a different vaccine for my second dose?*

Make sure you get your lot number and keep it safe

The person giving you the injection will give you an immunization record with the name of the vaccine, batch/lot number, and date of vaccination for the AstraZeneca COVID-19 Vaccine or COVISHIELD you receive. You need to keep it safe. This can help to trace the manufacturing details if they are never needed.

Learn more about COVID-19

Please refer to your national or local health authorities or get more information from the World Health Organization.

Getting the vaccine

What to do after you are vaccinated

How long should I wait to travel?

Follow local and international guidance.

Will the vaccination affect a COVID-19 test?

There are two types of tests.[4]

- Having the vaccine will not lead to a positive PCR (Polymerase Chain Reaction) test for COVID-19. The vaccine does not contain live coronavirus or the part of the virus this test looks for.
- If you are receiving an antibody test, the antibodies produced after vaccination may affect the result. This only applies if the test looks for antibodies against the spike protein of the coronavirus.

I was given AstraZeneca COVID-19 Vaccine or COVISHIELD for my first dose – can I get a different vaccine for my second?

You should complete the vaccination course with either AstraZeneca COVID-19 Vaccine or COVISHIELD, and not another vaccine against COVID-19.[1]

Your healthcare professional will discuss this with you, and when you should get your second dose.

How the vaccine was tested

Development of AstraZeneca COVID-19 Vaccine has been fast, not rushed. The testing of coronavirus vaccines has been faster than usual because the pandemic is a health emergency. No risks have been taken with vaccine safety.

Regulatory agencies that authorize medicines have clear and strict rules for the authorization of any new medicine.

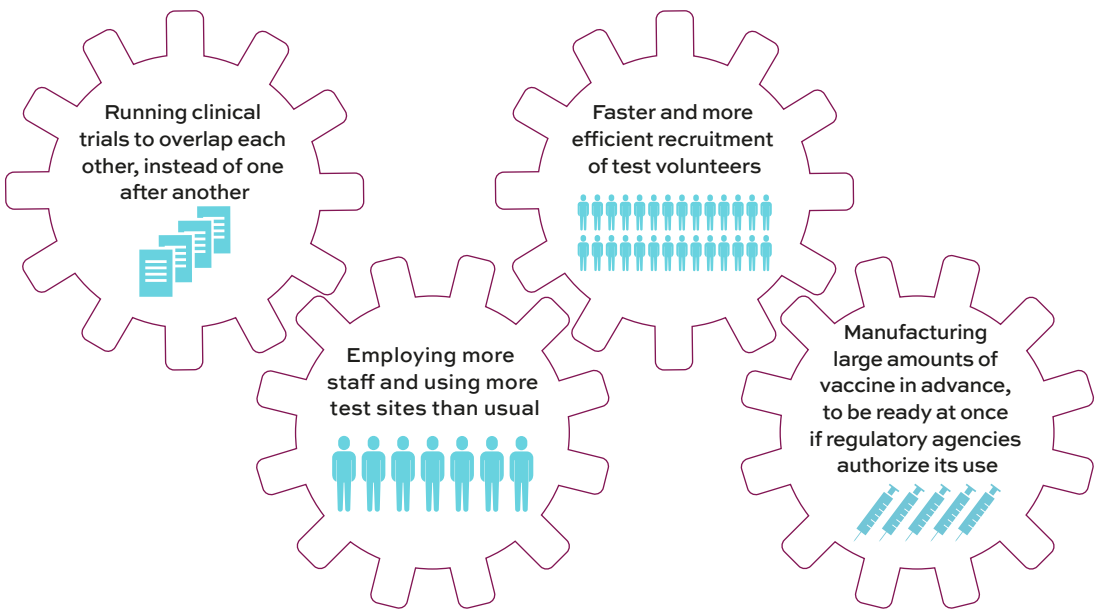
How much testing has been done

Worldwide, over 55,000 people have taken part in testing this vaccine as clinical trial participants, receiving either vaccine or a placebo.[2]

The "modified virus" technology used for this vaccine has already been tested and successfully used as a way to make vaccines for other diseases.[16,17]

More than **55,000 people** have taken part in clinical trials

How the development of AstraZeneca COVID-19 Vaccine has been accelerated



How the vaccine was authorized

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

One way that Health Canada has saved time is by conducting an ongoing review of AstraZeneca COVID-19 Vaccine during its development. Data from clinical trials have been provided to Health Canada as soon as it was available, instead of waiting until everything is finished.

AstraZeneca COVID-19 Vaccine was authorized for use in relation to the COVID-19 pandemic, in accordance with the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19. Terms and conditions were imposed upon the authorization with respect to quality, clinical, labelling, and Risk Management Plan requirements. For more information, refer to the Authorization Terms and Conditions for AstraZeneca COVID-19 Vaccine.

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