Read all of this leaflet carefully before the vaccine is given because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet
1. What COVID-19 Vaccine AstraZeneca is and what it is used for
2. What you need to know before you receive COVID-19 Vaccine AstraZeneca
3. How COVID-19 Vaccine AstraZeneca is given
4. Possible side effects
5. How to store COVID-19 Vaccine AstraZeneca
6. Contents of the pack and other information

1. What COVID-19 Vaccine AstraZeneca is and what it is used for

COVID-19 Vaccine AstraZeneca 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).

COVID-19 Vaccine AstraZeneca 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.

2. What you need to know before you receive COVID-19 Vaccine AstraZeneca

Do not have the vaccine:

- If you have ever had a severe allergic reaction to any of the active substances or any of the other ingredients listed in section 6.

If you are not sure, talk to your doctor, pharmacist or nurse.

Warnings and precautions

Tell your doctor, pharmacist or nurse before vaccination:

- If you have ever had a severe allergic reaction (anaphylaxis) after any other vaccine injection or after you were given COVID-19 Vaccine AstraZeneca in the past;
- If 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);
- 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 are not sure if any of the above applies to you, talk to your doctor, pharmacist or nurse before you are given the vaccine.
As with any vaccine, COVID-19 Vaccine AstraZeneca may not protect everyone who is vaccinated from COVID-19. It is not yet known how long people who receive the vaccine will be protected for.

**Children and adolescents**
No data are currently available on the use of COVID-19 Vaccine AstraZeneca in children and adolescents younger than 18 years of age.

**Other medicines and COVID-19 Vaccine AstraZeneca**
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take, any other medicines or vaccines.

**Pregnancy and breastfeeding**
If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, **tell your doctor, pharmacist or nurse**. There are limited data on the use of COVID-19 Vaccine AstraZeneca in pregnant or breastfeeding women. Your doctor, pharmacist or nurse will discuss with you whether you can be given the vaccine.

**Driving and using machines**
COVID-19 Vaccine AstraZeneca has no known effect on the ability to drive and use machines. However, side effects listed in section 4 may impact your ability to drive and use machines. If you feel unwell, do not drive or use machines.

**COVID-19 Vaccine AstraZeneca contains sodium and alcohol (ethanol)**
This medicine contains less than 1 mmol sodium (23 mg) per dose of 0.5 ml. This means that it is essentially ‘sodium-free’.
This medicine contains a very small amount of alcohol (0.002 mg of alcohol (ethanol) per dose of 0.5 ml). This is not enough to cause any noticeable effects.

3. **How COVID-19 Vaccine AstraZeneca is given**

COVID-19 Vaccine AstraZeneca is injected into a muscle (usually in the upper arm).

**You will receive 2 injections. You will be told when you need to return for your second injection of COVID-19 Vaccine AstraZeneca.**

The second injection can be given between 4 and 12 weeks after the first injection.

When COVID-19 Vaccine AstraZeneca is given for the first injection, COVID-19 Vaccine AstraZeneca (and not another vaccine against COVID-19) should be given for the second injection to complete vaccination course.

**If you miss an injection**
If you forget to go back at the scheduled time, ask your doctor, pharmacist or nurse for advice. It is important that you return for your second injection of COVID-19 Vaccine AstraZeneca.

4. **Possible side effects**

Like all medicines, this vaccine can cause side effects, although not everybody gets them. In clinical studies with the vaccine, most side effects were mild to moderate in nature and resolved within a few days. If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or nurse.

Medicines containing paracetamol can be taken if you need relief from side effects such as pain and/or fever.

Side effects that occurred during clinical trials with COVID-19 Vaccine AstraZeneca 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

If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or nurse.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system or [www.covax.azcovid-19.com](http://www.covax.azcovid-19.com). Include the vaccine brand and batch/lot number if available. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store COVID-19 Vaccine AstraZeneca

Keep this medicine out of the sight and reach of children.

Information about storage, expiry, and use and handling are described in the section intended for healthcare professionals at the end of the leaflet.

Your doctor, pharmacist or nurse is responsible for storing this vaccine and disposing of any unused product correctly.

6. Contents of the pack and other information

What COVID-19 Vaccine AstraZeneca contains
One dose (0.5 ml) contains:
COVID-19 Vaccine (ChAdOx1-S\(^*\) recombinant), not less than \(2.5 \times 10^8\) infectious units (Inf.U), which corresponds to \(5 \times 10^{10}\) viral particles
\(^*\)Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike glycoprotein. Produced in genetically modified human embryonic kidney (HEK) 293 cells.

This product contains genetically modified organisms (GMOs).

The other excipients are L-histidine, L-histidine hydrochloride monohydrate, magnesium chloride hexahydrate, polysorbate 80, ethanol, sucrose, sodium chloride, disodium edetate dihydrate, water for injections.

What COVID-19 Vaccine AstraZeneca looks like and contents of the pack
Solution for injection. The solution is colourless to slightly brown, clear to slightly opaque and particle free.

Pack sizes (not all pack sizes may be marketed):
10 dose vial (5 ml) in packs of 10 vials.
**Marketing Authorisation Holder**
AstraZeneca AB  
SE-151 85 Södertälje  
Sweden

**This leaflet was last revised in 02/2021**

**Other sources of information**

Scan the QR code with a mobile device to get this information in different languages.

![QR Code](https://www.covax.azcovid-19.com)

www.covax.azcovid-19.com

The following information is intended for healthcare professionals only:

**Storage**

Do not use COVID-19 Vaccine AstraZeneca after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store at 2-8°C.  
Do not freeze.  
Keep vials in outer carton to protect from light.

The vaccine does not contain any preservative. After first dose withdrawal, use the vial as soon as practically possible and within 6 hours (stored at 2°C to 8°C). Discard any unused vaccine.

**Administration**

COVID-19 Vaccine AstraZeneca is a colourless to slightly brown, clear to slightly opaque solution. The vaccine should be inspected visually for particulate matter and discolouration prior to administration. Discard the vial if the solution is discoloured or visible particles are observed. Do not shake the vial.

Each vaccine dose of 0.5 ml is withdrawn into a syringe for injection to be administered intramuscularly. Use a separate sterile needle and syringe for each individual.

Each vial contains at least the number of doses stated. It is normal for liquid to remain in the vial after withdrawing the final dose. When low dead volume syringes and/or needles are used, the amount remaining in the vial may be sufficient for an additional dose. Care should be taken to ensure a full 0.5 ml dose is administered. Where a full 0.5 ml dose cannot be extracted, the remaining volume should be discarded. Do not pool excess vaccine from multiple vials.

To facilitate the traceability of the vaccine, the name and the batch number of the administered product should be clearly recorded for each recipient. Instruct individuals to visit www.covax.azcovid-19.com to obtain this printed information in other languages.
Disposal
COVID-19 Vaccine AstraZeneca contains genetically modified organisms (GMOs). Any unused vaccine or waste material should be disposed of in accordance with local requirements. Spills should be disinfected with an appropriate antiviral disinfectant.