WHO PACKAGE LEAFLET

Package leaflet: Information for the user

Vaxzevria solution for injection
COVID-19 Vaccine (ChAdOx1-S [recombinant])

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 Vaxzevria is and what it is used for

Vaxzevria 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).

Vaxzevria 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 Vaxzevria

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 have had a major blood clot occurring at the same time as having low levels of platelets (thrombocytopenia) after receiving any COVID-19 vaccine.

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 after any other vaccine injection or after you were given Vaxzevria in the past;
- If you currently have a severe infection with a high temperature (over 38°C);
- If you have ever had a blood clot or if you have an autoimmune disorder (illness where the body's immune system attacks its own cells) including ITP (idiopathic thrombocytopenic purpura);
- If you have a problem with bleeding or bruising, or if you are taking a blood thinning medicine (anticoagulant);

- 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 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, Vaxzevria 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.

Blood disorders
Very rare cases of blood clots with low levels of blood platelets have been observed following vaccination with Vaxzevria. The majority of these cases occurred within the first 21 days 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. However, it has not been determined whether these events were due to the vaccine. Some cases had a fatal outcome.

Neurological disorders
Very rare cases of demyelinating disorders (disorders that affect the covering layer around the nerves), such as Guillain-Barré syndrome (GBS), have been observed following vaccination with Vaxzevria. However, it has not been determined whether these events were due to the vaccine. Seek urgent medical attention if you develop weakness and paralysis in the extremities that sometimes spreads to the chest and face.

Risk of very rare events after a booster dose
The risk of very rare events (such as blood disorders including thrombosis with thrombocytopenia syndrome) after a booster dose of Vaxzevria is unknown.

Seek urgent medical attention if from a few days following vaccination you:
- experience a severe or persistent headache, blurred vision, confusion or seizures (fits).
- develop shortness of breath, chest pain, leg swelling, leg pain or persistent abdominal pain.
- notice unusual skin bruising or pinpoint round spots beyond the site of vaccination.

Children and adolescents
No data are currently available on the use of Vaxzevria in children and adolescents younger than 18 years of age.

Other medicines and Vaxzevria
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take, any other medicines or vaccines.

Pregnancy and breastfeeding

Pregnancy
If you are pregnant, think you may be pregnant, or are planning to have a baby, **tell your doctor, pharmacist or nurse**. Your doctor, pharmacist or nurse will discuss with you the benefits and potential risks of receiving the vaccine during pregnancy.

Breastfeeding
Available data from animal studies and use of this vaccine in breastfeeding women do not suggest a risk to breastfed newborns/infants.

Driving and using machines
Vaxzevria 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.

Vaxzevria 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 (2 mg of alcohol (ethanol) per dose of 0.5 ml). This is not enough to cause any noticeable effects.

3. How Vaxzevria is given

Vaxzevria is injected into a muscle (usually in the upper arm).

Primary vaccination course
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.

When Vaxzevria is given for the first injection, it is recommended that Vaxzevria (and not another vaccine against COVID-19) should be given for the second injection to complete the primary 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 Vaxzevria.

Booster dose
You may receive a booster injection of Vaxzevria. The booster injection may be given at least 3 months after you have completed the primary vaccination course with Vaxzevria or an mRNA COVID-19 vaccine.

4. Possible side effects

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

Major blood clots in combination with low levels of blood platelets (thrombocytopenia) have been observed very rarely (with a frequency less than 1 in 100,000 vaccinated individuals).

Get medical attention immediately if from a few days following vaccination you get any of the following symptoms:

- experience a severe or persistent headache, blurred vision, confusion or seizures (fits)
- develop shortness of breath, chest pain, leg swelling, leg pain or persistent abdominal pain
- notice unusual skin bruising or pinpoint round spots beyond the site of vaccination

Get urgent medical attention if you get symptoms of a severe allergic reaction. Such reactions may include a combination of any of the following symptoms:

- feeling faint or light-headed
- changes in your heartbeat
- shortness of breath or wheezing
- swelling of your lips, face, or throat

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.

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

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 provider.

The following side effects may occur with Vaxzevria:

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

Very rare (may affect up to 1 in 10,000 people)
- major blood clots in combination with low levels of blood platelets (thrombocytopenia) have been observed with a frequency of less than 1 in 100,000 vaccinated individuals
- low blood platelets (thrombocytopenia)

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)

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. 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 Vaxzevria

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 Vaxzevria contains
One dose (0.5 ml) contains:
COVID-19 Vaccine (ChAdOx1-S* recombinant), not less than 2.5×10^8 infectious units (Inf.U), which corresponds to 5×10^{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 Vaxzevria 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

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Other sources of information

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

www.covax.azcovid-19.com

The following information is intended **for healthcare professionals only**:

Storage

Do not use Vaxzevria after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store at 2-8ºC.
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 2ºC to 8ºC). Discard any unused vaccine.

Administration

Vaxzevria 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

Vaxzevria 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.