Package leaflet: Information for the user

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

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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 used for preventing COVID-19 caused by the SARS-CoV-2 virus.

Vaxzevria is given to adults aged 18 years and older.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and specialised white blood cells that work against the virus, so giving protection against COVID-19. None of the ingredients in this vaccine can cause COVID-19.

2. What you need to know before you are given Vaxzevria

The vaccine must not be given:
- If you are allergic to the active substance or any of the other ingredients of this vaccine (listed in section 6).
- If you have had a blood clot occurring at the same time as having low levels of blood platelets (thrombosis with thrombocytopenia syndrome, TTS) after receiving Vaxzevria.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given Vaxzevria:
- 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 have ever fainted following any needle injection;
- If you have a severe infection with a high temperature (over 38°C). However, you can have your vaccination if you have a mild fever or upper airway infection like a cold;
- If you have a problem with bleeding or bruising, or if you are taking an anticoagulant medicine (to prevent blood clots);

- 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).

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, the 2-dose vaccination course of Vaxzevria may not fully protect all those who receive it. It is not known how long you will be protected for. Currently there are limited data on the efficacy of Vaxzevria in individuals aged 55 and older.

Blood disorders
Very rare blood clots, often in unusual locations (e.g. brain, bowel, liver, spleen), in combination with low level of blood platelets, in some cases together with bleeding, has been observed following vaccination with Vaxzevria. This included some severe cases with blood clots in different or unusual locations and excessive clotting or bleeding throughout the body. The majority of these cases occurred within the first three weeks following vaccination and occurred mostly in women under 60 years of age. Some cases had a fatal outcome.

Seek immediate medical attention if you develop shortness of breath, chest pain, leg swelling, leg pain or persistent abdominal pain following vaccination (see section 4).

Also, seek immediate medical attention if you experience after a few days severe or persistent headaches, blurred vision, confusion or seizures (fits) after vaccination, or experience skin bruising or pinpoint round spots beyond the site of vaccination which appears after a few days (see section 4).

Children and adolescents
Vaxzevria is not recommended for children aged below 18 years. Currently there is not enough information 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
If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before you receive this vaccine.

Driving and using machines
Some of the side effects of Vaxzevria listed in section 4 (Possible side effects) may temporarily reduce your ability to drive and use machines. If you feel unwell after vaccination, do not drive or use machines. Wait until any effects of the vaccine have worn off before you drive or use machines.

Vaxzevria contains sodium and alcohol (ethanol)
This medicine contains less than 1 mmol sodium (23 mg) per 0.5 ml dose, that is to say essentially ‘sodium-free’.
This medicine contains 2 mg of alcohol (ethanol) per 0.5 ml dose. The small amount of alcohol in this medicine will not have any noticeable effects.

3. How Vaxzevria is given

Vaxzevria is given as an injection of 0.5 ml into a muscle (usually in the 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.

You will receive 2 injections of Vaxzevria. The second injection can be given between 4 and 12 weeks after the first injection**.** You will be told when you need to return for your second injection.

When Vaxzevria is given for the first injection, the second injection to complete the vaccination course should also be with Vaxzevria.

If you miss an appointment for your second injection of Vaxzevria
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. If you miss a scheduled injection, you may not be fully protected against COVID-19.

4. Possible side effects

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

Blood clots in combination with low levels of blood platelets (thrombosis with thrombocytopenia syndrome, TTS) have been reported very rarely, see section 2.
Get medical attention immediately if within three weeks of 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
- wheezing
- swelling of your lips, face, or throat
- hives or rash
- nausea or vomiting
- stomach pain.

The following side effects may occur with Vaxzevria:

Very Common (may affect more than 1 in 10 people)
- tenderness, pain, warmth, itching, or bruising where the injection is given
- feeling tired (fatigue) or generally feeling unwell
- 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 (>38°C)
- being sick (vomiting) or diarrhoea
- low level of blood platelets

Uncommon (may affect up to 1 in 100 people)
- sleepiness or feeling dizzy
- decreased appetite
- enlarged lymph nodes
- excessive sweating, itchy skin or rash

Very Rare (may affect up to 1 in 10,000 people)
- blood clots often in unusual locations (e.g. brain, bowel, liver, spleen) in combination with low level of blood platelets

Not known (cannot be estimated from the available data)
- severe allergic reaction (anaphylaxis)
- hypersensitivity

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

Malta
ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

United Kingdom (Northern Ireland)
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Vaxzevria

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

Your doctor, pharmacist or nurse is responsible for storing this vaccine and disposing of any unused product correctly. The following information about storage, expiry, use and handling as well as disposal is intended for healthcare professionals.

Do not use this vaccine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).
Do not freeze.
Keep vials in outer carton in order to protect from light.

From the time of vial opening (first needle puncture) to administration store the vial for no more than 48 hours in a refrigerator (2°C–8°C). Within this time period the product may be kept and used at temperatures up to 30°C for a single period of up to 6 hours. After this time period, the product must be discarded. Do not return it to the refrigerator.

Discard the vial if the suspension is discoloured or particles are observed. Do not shake.

Vaxzevria contains genetically modified organisms (GMOs). Any unused vaccine or waste material should be disposed of in compliance with the local guidance for genetically modified organisms or biohazardous waste. Spills should be disinfected using agents with activity against adenovirus.

6. Contents of the pack and other information

What Vaxzevria contains
One dose (0.5 ml) contains:
Chimpanzee Adenovirus encoding the SARS-CoV-2 Spike glycoprotein ChAdOx1-S*, not less than 2.5×10^8 infectious units
*Produced in genetically modified human embryonic kidney (HEK) 293 cells and by recombinant DNA technology.

This product contains genetically modified organisms (GMOs).

The other excipients are L-histidine, L-histidine hydrochloride monohydrate, magnesium chloride hexahydrate, polysorbate 80 (E 433), sucrose, disodium edetate (dihydrate), water for injections (see section 2 "Vaxzevria contains sodium and alcohol").

What Vaxzevria looks like and contents of the pack
Suspension for injection (injection). The suspension is colourless to slightly brown, clear to slightly opaque.

Pack sizes:
- 8-dose multidose vial (4 ml) with stopper (elastomeric with aluminium overseal) in a pack of 10 vials. Each vial contains 8 doses of 0.5 ml.
- 10-dose multidose vial (5 ml) with stopper (elastomeric with aluminium overseal) in a pack of 10 vials. Each vial contains 10 doses of 0.5 ml.

Not all pack sizes may be marketed.

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This medicine has been given ‘conditional approval’. This means that there is more evidence to come about this medicine.
The European Medicines Agency will review new information on this medicine at least every year and this leaflet will be updated as necessary.

Other sources of information

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

www.azcovid-19.com

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

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

For storage and disposal, see section 5 “How to store Vaxzevria”.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Handling instructions and administration

This vaccine should be handled by a healthcare professional using aseptic technique to ensure the sterility of each dose.

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

The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products.

The Vaxzevria vaccination course consists of two separate doses of 0.5 ml each. The second dose should be administered between 4 and 12 weeks after the first dose. Individuals who have received the first dose of Vaxzevria should receive the second dose of the same vaccine to complete the vaccination course.

Each vaccine dose of 0.5 ml is withdrawn into a syringe for injection to be administered intramuscularly, preferably in the deltoid muscle of the upper arm. Use a new needle for administration, when possible.

It is normal for liquid to remain in the vial after withdrawing the final dose. An additional overfill is included in each vial to ensure that 8 doses (vial of 4 ml) or 10 doses (vial of 5 ml) of 0.5 ml can be delivered. Do not pool excess vaccine from multiple vials. Discard any unused vaccine.