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.
- If you have a previous diagnosis of capillary leak syndrome (a condition causing fluid leakage from small blood vessels).

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 previously had Guillain-Barré syndrome (temporary loss of feeling and movement) after being given Vaxzevria.
- If you previously had transverse myelitis (inflammation of the spinal cord) after being given Vaxzevria.
- If you have risk factors for blood clots in your veins (venous thromboembolism (VTE)).

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.

Blood disorders
Very rare blood clots 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 (e.g., brain, bowel, liver, spleen) and excessive clotting or bleeding throughout the body. The majority of these cases occurred within the first three weeks following vaccination. Some cases had a fatal outcome. Fewer cases have been reported after the second dose compared to after the first dose.

Blood clots in the brain, not associated with low level of blood platelets have been observed very rarely following vaccination with Vaxzevria. The majority of these cases occurred within the first four weeks following vaccination. Some cases had a fatal outcome.

Blood clots in veins (venous thromboembolism (VTE)) have been observed following vaccination with Vaxzevria.

Very low levels of blood platelets (immune thrombocytopenia), that can be associated with bleeding, have been reported very rarely, usually within the first four weeks following vaccination with Vaxzevria.

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 following vaccination severe or persistent headaches, blurred vision, confusion or seizures (fits) after vaccination, or experience unexplained bleeding or skin bruising or pinpoint round spots beyond the site of vaccination which appears after a few days (see section 4).

Capillary leak syndrome
Very rare cases of capillary leak syndrome (CLS) have been reported following vaccination with Vaxzevria. 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 immediate medical attention if you develop these symptoms in the days following vaccination.

Neurological events
Guillain-Barré syndrome (GBS):
Seek immediate medical attention if you develop weakness and paralysis in the extremities that can progress to the chest and face (Guillain-Barré syndrome). This has been reported very rarely after vaccination with Vaxzevria.

Inflammation of the spinal cord (transverse myelitis, TM):
Seek immediate medical attention if you develop signs of weakness in the arms or legs, sensory symptoms (such as tingling, numbness, pain or loss of pain sensation) and urinary or bowel dysfunction. This has been reported very rarely after vaccination with Vaxzevria.

Risk of severe adverse events after a booster dose
The risk of severe adverse events (such as blood disorders including thrombosis with thrombocytopenia syndrome, VTE, CLS, GBS, TM) after a booster dose of Vaxzevria is unknown.

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.

Primary vaccination course
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.

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.

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.

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 doctor, pharmacist or nurse.

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, fever 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
- being sick (vomiting), diarrhoea or abdominal pain
- mild and transient decreased level of blood platelets (laboratory findings)
- pain in legs or arms
- flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills
- physical weakness or lack of energy
- feeling dizzy

Uncommon (may affect up to 1 in 100 people)
- sleepiness or deep unresponsiveness and inactivity
- decreased appetite
- enlarged lymph nodes
- excessive sweating, itchy skin, rash or hives
- muscle spasms
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)
- decreased feeling or sensitivity, especially in the skin (hypoaesthesia)

- persistent ringing in the ears (tinnitus)

Rare (may affect up to 1 in 1,000 people)
- one-sided facial drooping

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
- serious nerve inflammation, which may cause paralysis and difficulty breathing (Guillain-Barré syndrome [GBS])

Not known (cannot be estimated from the available data)
- severe allergic reaction (anaphylaxis)
- hypersensitivity
- rapid swelling under the skin in areas such as the face, lips, mouth and throat (which may cause difficulty in swallowing or breathing)
- capillary leak syndrome (a condition causing fluid leakage from small blood vessels)
- very low levels of blood platelets (immune thrombocytopenia) that can be associated with bleeding (see section 2, Blood disorders)
- blood clots in the brain, not associated with low level of blood platelets (see section 2, Blood disorders)
- blood clots in veins (venous thromboembolism (VTE))
- inflammation of the spinal cord (transverse myelitis)
- inflammation of blood vessels in the skin, often with a rash or small red or purple, flat, round spots under the skin's surface or bruising (cutaneous vasculitis)

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: https://coronavirus-yellowcard.mhra.gov.uk/ 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.

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) use within 6 hours when stored at temperatures up to 30°C. After this time, the vial must be discarded. Do not return it to the refrigerator. Alternatively, an opened vial may be stored in a refrigerator (2°C – 8°C) for a maximum of 48 hours if it is immediately returned to the refrigerator following each puncture.

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

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), ethanol, sucrose, sodium chloride, 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.

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.

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This leaflet was last revised in 11/2023

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.

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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 primary 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.

A booster dose (third dose) of 0.5 ml may be given to individuals who completed the primary vaccination course with Vaxzevria or an mRNA COVID-19 vaccine. The third dose should be administered at least 3 months after completing the primary 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 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.

Disposal

Any unused vaccine or waste material should be disposed of in compliance with the local guidance for pharmaceutical waste. Potential spills should be disinfected with agents with viricidal activity against adenovirus.