

## 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
2. What you need to know before you are given Vaxzevria
3. How Vaxzevria is given
4. Possible side effects
5. How to store Vaxzevria
6. Contents of the pack and other information

#### **1. What Vaxzevria is and what it is used for**

Vaxzevria is a vaccine used for preventing COVID-19, caused by a virus called coronavirus (SARS-CoV-2).

Vaxzevria is given to adults aged 18 years and older.

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 are given Vaxzevria**

##### **Do not have the vaccine:**

- If you are allergic to any of the active substances or any of the other ingredients 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 the vaccine.
- If you have a previous diagnosis of capillary leak syndrome (a condition causing fluid leakage from small blood vessels).

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. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue. Contact your doctor or healthcare

professional immediately or go to the nearest hospital emergency room right away if you have an allergic reaction. It can be life-threatening;

- If you have ever fainted following any needle injection;
- If you currently have a severe infection with a high temperature (over 38°C). However, a mild fever or infection, like a cold, are not reasons to delay vaccination;
- If you have ever had a condition known as heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2), or a blood clot in the sinus veins in the brain;
- 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 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) or Transverse Myelitis (inflammation of the spinal cord) after being given Vaxzevria.

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.

#### *Blood disorders*

Extremely rare cases of blood clots with low levels of blood platelets (thrombosis with thrombocytopenia syndrome) have 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 3 weeks following vaccination but some have also been reported after this period. Some cases were life-threatening or had a fatal outcome. It is important to remember the benefits of vaccination to give protection against COVID-19 still outweigh any potential risks.

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.

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.

If you experience any of the following from around 4 days after vaccination you should seek medical advice urgently:

- a severe headache that is not relieved with simple painkillers or is getting worse or feels worse when you lie down or bend over
- an unusual headache that may be accompanied by blurred vision, confusion, difficulty with speech, weakness, drowsiness or seizures (fits)
- rash that looks like small bruises or bleeding under the skin beyond the injection site, or any unexplained bleeding
- shortness of breath, chest pain, leg swelling, leg pain or persistent abdominal (tummy) pain.

Tell your doctor, pharmacist or nurse if you experienced a blood clot occurring at the same time as low levels of platelets after receiving a previous dose of the vaccine.

#### *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.

As with any vaccine, the 2-dose vaccination course of Vaxzevria may not fully protect all those who receive it. It is not yet known how long you will be protected for. No data are currently available in

individuals with a weakened immune system or who are taking chronic treatment that suppresses or prevents immune responses.

#### *Neurological events*

Seek immediate medical attention if you develop weakness and paralysis in the extremities that are persistent and can affect both sides of the body at the same time and can progress to the chest and face (Guillain-Barré Syndrome). This has been reported very rarely after vaccination with Vaxzevria.

Extremely rare cases of acute disseminated encephalomyelitis (inflammation in the brain and spinal cord) have been reported 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, numbness or tingling in the extremities, changes to your state of awareness, alertness or wakefulness, changes to your eyesight, or seizures.

#### **Children and adolescents**

Vaxzevria is not recommended for children aged below 18 years. 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**

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 listed in section 4 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 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 given as an injection of 0.5 ml 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 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 the second injection to complete the primary 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.

You may receive a third (booster) injection of Vaxzevria. The booster injection may be given at least 3 months after you have completed the primary vaccination course with Vaxzevria.

#### 4. Possible side effects

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

**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
- hives or rash
- nausea or vomiting
- stomach pain

In clinical studies with the vaccine, fewer side effects were reported after the second dose and those that were reported were milder in nature when compared to after the first dose.

If side effects such as pain and/or fever are troublesome, medicines containing paracetamol can be taken.

**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
- generally feeling unwell
- feeling tired (fatigue)
- chills, fever or feeling feverish
- headache
- feeling sick (nausea)
- joint pain or muscle ache

**Common** (may affect up to 1 in 10 people)

- swelling, redness or a lump at the injection site
- 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
- ringing in the ears (tinnitus)
- sensation like numbness, tingling, pins and needles (paraesthesia)
- reduced sensation of touch (hypoesthesia)

**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)

- Following widespread use of the vaccine there have been extremely rare reports of blood clots in combination with low level of blood platelets. When these blood clots do occur, they may be in unusual or atypical locations (e.g. brain, liver, bowel, spleen)
- 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)
- rapid swelling under the skin in areas such as the face, lips, mouth and throat (which may cause difficulty in swallowing or breathing) (angioedema)
- low blood platelets (thrombocytopenia)
- hypersensitivity
- 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)
- inflammation of the spinal cord which may cause muscle weakness, localised or radiating back pain, bladder and bowel symptoms and changes in sensation (transverse myelitis)
- inflammation of blood vessels in the skin, often with a rash and small red or purple spots (cutaneous vasculitis)

In clinical trials there were very rare reports of events associated with inflammation of the nervous system, which may cause numbness, pins and needles, and/or loss of feeling. However, it is not confirmed whether these events were due to the vaccine.

\* Some people have reported a sudden feeling of cold with shivering/shaking accompanied by a rise in temperature, possibly with sweating, headache (including migraine-like headaches), nausea, muscle aches and feeling unwell, starting within a day of having the vaccine and usually lasting for a day or two.

If your fever is high and lasts longer than two or three days, or you have other persistent symptoms, this might not be due to side effects of the vaccine and you should follow appropriate advice according to your symptoms.

### **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.

If you are concerned about a side-effect it can be reported directly via the Coronavirus Yellow Card reporting site <https://coronavirus-yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store and 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 vaccine.

## **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.

### **Storage**

Do not use Vaxzevria 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 to protect from light.

The vaccine does not contain any preservative and should be administered by a healthcare professional. After the first dose is withdrawn, the vaccine should be used as soon as practically possible and within 6 hours. During use it can be stored from 2°C to 25°C.

### **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 using agents with activity against adenovirus.

## **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  $2.5 \times 10^8$  infectious units

\*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 (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. The suspension is colourless to slightly brown, clear to slightly opaque.

Pack sizes (not all pack sizes may be marketed):

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

### **Marketing Authorisation Holder**

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#### Other sources of information



[www.azcovid-19.com](http://www.azcovid-19.com)

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000

Please be ready to give the following information:

<b>Product name</b>	<b>Reference number</b>
Vaxzevria	17901/0355
suspension for injection	

This is a service provided by the Royal National Institute of the Blind.