DISCLAIMER: THIS PRODUCT IS APPROVED UNDER MALAYSIA CONDITIONAL REGISTRATION FOR PHARMACEUTICAL PRODUCTS DURING DISASTER GUIDELINE. THE ADMINISTRATION OF THE PRODUCT IS PURELY BASED ON INDIVIDUAL'S PREFERENCE

VAXZEVRIA

Solution for Injection
COVID-19 Vaccine (ChAdOx1-S [recombinant]), 5×10^{10} viral particles

What is in this leaflet

What Vaxzevria is used for

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

Vaxzevria is given to adults aged 18 years and older.

How Vaxzevria works

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.

Before you use Vaxzevria

When you must not use it

The vaccine must not be given:

- If you are allergic to the active substance or any of the other ingredients of this vaccine (see *Ingredient* subsection).
- 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.

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.

Before you start to use it

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 have ever fainted following any needle injection;
- If you have a severe infection with a high body temperature (over 38°C). However, you can have your vaccination if you have mild fever or upper airway infection like a cold;
- If you have ever had a blood clot in the past or if you have an autoimmune disorder (illness where the body's immune system attacks its own cells) including immune thrombocytopenia (ITP).
- 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 21 days following vaccination. 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 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.

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

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 unexplained bleeding, skin bruising or pinpoint round spots beyond the site of vaccination which appears after a few days.

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.

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

How to use Vaxzevria
How much to use & when to use it
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, it is recommended that the second injection to complete the primary vaccination course should also be with Vaxzevria.

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 another authorized COVID-19 vaccine.

If you forget to use it
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 schedule injection, you may not be fully protected against COVID-19.

If you use too much (overdose)
Not applicable

While you are using Vaxzevria
Things you must do
Not applicable

Things you must not do
Not applicable

Things to be careful of
Pregnancy
If you are pregnant, think you may be pregnant, or are planning to have a baby, tell your healthcare provider. Your healthcare provider 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
Some of the side effects of Vaxzevria listed in this leaflet (see *Side effects* section) 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.

Side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them. If you notice any side effects not mentioned in this leaflet, please tell your doctor, pharmacist or nurse.

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
- 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 (>38ºC)
- being sick (vomiting) or diarrhea
- flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills.
- physical weakness or lack of energy

Uncommon (may affect up to 1 in 100 people)
- sleepiness, feeling dizzy, or deep unresponsiveness and inactivity
- decreased appetite
- enlarged lymph nodes
- excessive sweating, itchy skin or rash
- abdominal pain
- muscle spasms
- sensation like numbness, tingling, pins and needles (paraesthesia)
- reduced sensation of touch (hypoaesthesia)
- 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)
- 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)
- serious nerve inflammation, which may cause paralysis and difficulty breathing (Guillain-Barré syndrome [GBS])

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)
- capillary leak syndrome (a condition causing fluid leakage from small blood vessels)
- low blood platelets caused by an autoimmune disorders (immune thrombocytopenia)
- inflammation of the spinal cord (transverse myelitis)
- inflammation of blood vessels in the skin, often with a rash and small red or purple spots (cutaneous vasculitis)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage & Disposal of Vaxzevria

Storage
- 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 the vaccine after the expiry date which is stated on the carton.
- Store in a refrigerator (2°C to 8°C).
- Do not freeze.
- Keep vials in outer carton 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 solution is discoloured or particles are observed. Do not shake.

Disposal

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.

Product Description

What it looks like

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.
- 8 dose vial (4 ml) in packs of 10 vials.

Ingredients

Active Ingredient

One dose (0.5 ml) contains: COVID-19 Vaccine (ChAdOx1-S* recombinant), 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).

Inactive Ingredient
- L-histidine
- L-histidine hydrochloride monohydrate
- Magnesium chloride hexahydrate
- Polysorbate 80

- Ethanol
- Sucrose
- Sodium chloride
- Disodium edetate dihydrate
- Water for injections.

Sodium and alcohol content
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.

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