COVID-19 Vaccine (ChAdOx1-S [recombinant])

Vaxzevria™
5×10^{10} viral particles
Solution for Injection (IM)

Viral Vaccine

Read all of this leaflet carefully.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your healthcare provider.

What is in this leaflet

1. What COVID-19 Vaccine (ChAdOx1-S [recombinant]) [Vaxzevria] is and what it is used for
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1 WHAT COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [VAXZEVRIA] IS AND WHAT IT IS USED FOR

COVID-19 Vaccine (ChAdOx1-S [recombinant]) [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).

COVID-19 Vaccine (ChAdOx1-S [recombinant]) [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 COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [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 healthcare provider.

Warnings and precautions

Tell your healthcare provider before vaccination:

- If you have ever had a severe allergic reaction after any other vaccine injection or after you were given COVID-19 Vaccine (ChAdOx1-S [recombinant]) [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 in the past 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 healthcare provider before you are given the vaccine.

Very rare cases of blood clots with low levels of blood platelets have been observed following vaccination with COVID-19 Vaccine (ChAdOx1-S [recombinant]) [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 COVID-19 Vaccine (ChAdOx1-S [recombinant]) [Vaxzevria]. However, it has not been determined whether these events were due to the vaccine. Some cases had a fatal outcome.

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

As with any vaccine, COVID-19 Vaccine (ChAdOx1-S [recombinant]) [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.

Children and adolescents

No data are currently available on the use of COVID-19 Vaccine (ChAdOx1-S [recombinant]) [Vaxzevria] in children and adolescents younger than 18 years of age.

Other medicines and COVID-19 Vaccine (ChAdOx1-S [recombinant]) [Vaxzevria]

Tell your healthcare provider 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, **tell your healthcare provider**. There are limited data on the use of COVID-19 Vaccine (ChAdOx1-S [recombinant]) [Vaxzevria] in pregnant or breastfeeding women. Your healthcare provider will discuss with you whether you can be given the vaccine.

Driving and using machines

COVID-19 Vaccine (ChAdOx1-S [recombinant]) [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.

3 HOW COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [VAXZEVRIA] IS GIVEN

COVID-19 Vaccine (ChAdOx1-S [recombinant]) [Vaxzevria] is injected 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 COVID-19 Vaccine (ChAdOx1-S [recombinant]) [Vaxzevria].

The second injection can be given between 4 and 12 weeks after the first injection.

When COVID-19 Vaccine (ChAdOx1-S [recombinant]) [Vaxzevria] is given for the first injection, COVID-19 Vaccine (ChAdOx1-S [recombinant]) [Vaxzevria] (and not another vaccine against COVID-19) should be given for the second injection to complete vaccination course.

If you miss an injection

If you forget to go back at the scheduled time, ask your healthcare provider for advice. It is important that you return for your second injection of COVID-19 Vaccine (ChAdOx1-S [recombinant]) [Vaxzevria].

You may receive a booster injection of COVID-19 Vaccine (ChAdOx1-S [recombinant]) [Vaxzevria]. The booster injection may be given at least 6 months after the second injection.

A single booster/third dose of the COVID-19 Vaccine (ChAdOx1-S [recombinant]) [Vaxzevria] may be administered as a heterologous booster dose at least 6 months following completion of primary vaccination with another authorized COVID-19 vaccine when the potential benefits outweigh any potential risks.

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 COVID-19 Vaccine (ChAdOx1-S [recombinant]) [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

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)

If you notice any side effects not mentioned in this leaflet, please inform your healthcare provider.

Reporting of suspected adverse reactions

For suspected adverse events following immunization, please report to the Food and Drug Administration (FDA) at www.fda.gov.ph.

Adverse events of concern in association with COVID-19 Vaccine (ChAdOx1 S [recombinant]) [Vaxzevria] can also be reported to AstraZeneca via www.azcovid-19.com, or at https://contactazmedical.astrazeneca.com/.

You should seek medical attention immediately at the first sign of any adverse events following immunization.

5 STORING COVID-19 VACCINE (CHADOX1-S [RECOMBINANT]) [VAXZEVRIA]

Keep out of the sight and reach of children.

Your healthcare provider is responsible for storing this vaccine and disposing of any unused product correctly.

6 FURTHER INFORMATION

What COVID-19 Vaccine (ChAdOx1-S [recombinant]) [Vaxzevria] contains

The **active substance** is COVID-19 Vaccine (ChAdOx1-S [recombinant]).

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.
**Corresponding to not less than 2.5×10^{8} infectious units (Inf.U)

This product contains genetically modified organisms (GMOs).

The **other ingredients** are L-histidine, L-histidine hydrochloride monohydrate, magnesium chloride hexahydrate, polysorbate 80, ethanol, sucrose, sodium chloride, disodium edetate dihydrate (EDTA), water for injection.

7 EMERGENCY USE AUTHORIZATION (EUA) HOLDER

AstraZeneca Pharmaceuticals (Phils.), Inc.

8 REGISTRATION NUMBER

Not applicable.

9 DATE OF FIRST AUTHORIZATION

Emergency Use Authorization granted on 28 January 2021 for COVID-19 Vaccine (ChAdOx1-S [recombinant]) [Vaxzevria] manufactured at Catalent Anagni S.R.L. – Italy.

Emergency Use Authorization granted on 05 May 2021 for COVID-19 Vaccine (ChAdOx1-S [recombinant]) [Vaxzevria] manufactured at Siam Bioscience Co., Ltd. – Thailand.

Emergency Use Authorization granted on 10 September 2021 for COVID-19 Vaccine (ChAdOx1-S [recombinant]) [Vaxzevria] manufactured at SK Bioscience Co., Ltd. – Republic of Korea.

10 DATE OF REVISION OF THE TEXT

November 2021
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Based on CPIL dated 02 November 2021 ANGEL Reference: Doc ID-004379267 v8.0 and FDA Philippines Supplemental Authorization dated 15 November 2021 ANGEL Reference: Doc ID-004725110 v1.0

CAUTION
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

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