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COVID-19 VACCINE ASTRAZENECA

Solution for Injection

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

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What COVID-19 Vaccine

AstraZeneca is used for

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

COVID-19 Vaccine AstraZeneca is given to adults aged 18 years and older.

How COVID-19 Vaccine AstraZeneca 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 COVID-19 Vaccine AstraZeneca

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).

Children and adolescents

COVID-19 Vaccine AstraZeneca is not recommended for children aged below 18 years. Currently there is not enough information available on the use of COVID-19 Vaccine AstraZeneca 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 COVID-19 Vaccine AstraZeneca 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 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 COVID-19 Vaccine AstraZeneca 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 COVID-19 Vaccine AstraZeneca 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 COVID-19 Vaccine AstraZeneca. 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 fourteen days 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, or persistent abdominal pain following vaccination.

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

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 COVID-19 Vaccine AstraZeneca

How much to use & when to use it

COVID-19 Vaccine AstraZeneca 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 COVID-19 Vaccine AstraZeneca. 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 COVID-19 Vaccine AstraZeneca is given for the first injection, the second injection to complete the vaccination course should also be with COVID-19 Vaccine AstraZeneca.

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 COVID-19 Vaccine AstraZeneca. If you miss a scheduled injection, you may not be fully protected against COVID-19.

If you use too much (overdose)

Not applicable

While you are using COVID-19 Vaccine AstraZeneca

Things you must do

Not applicable

Things you must not do

Not applicable

Things to be careful of

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before you received this vaccine.

Driving and using machines

Some of the side effects of COVID-19 Vaccine AstraZeneca 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.

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 COVID-19 Vaccine AstraZeneca:

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 diarrhea

Uncommon (may affect up to 1 in 100 people)

- sleepiness or feeling dizzy
- decreased appetite
- enlarged lymph nodes
- excessive sweating, itchy skin or rash

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

Storage & Disposal of COVID-19 Vaccine AstraZeneca

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. The expiry date refers to the last day of that month.
- 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

COVID-19 Vaccine AstraZeneca 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.

MAL number:

MALXXXXXXXXXACZ

Manufacturer

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Product Registration Holder

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