

AstraZeneca

FACT SHEET



FS 739935



Promoting access to safe medicines

Botswana Medicines Regulatory Authority (BoMRA) has authorised AstraZeneca COVID-19 vaccine for emergency use.

WHAT DOES THIS FACT SHEET CONTAIN?

1. What AstraZeneca (AZ) Vaccine is and what it is used for?
2. What does AZ Vaccine contain?
3. Vaccination schedule
4. What you need to know before you receive AZ Vaccine
5. Warnings and precautions
6. Side effects
7. Manufacturer

1. WHAT AZ VACCINE IS AND WHAT IT IS USED FOR?

AZ Vaccine is used for active immunisation to prevent COVID-19 disease caused by SARS-CoV-2 virus. The vaccine stimulates your body to produce antibodies that protect against COVID-19 disease.

2. AZ VACCINE CONTAINS:

The active ingredient is (ChAdOx1-S [recombinant]). It contains genetically modified organisms (GMOs).

It also contains other ingredients listed below;

- L-histidine
- Ethanol
- L-histidine hydrochloride monohydrate
- Sucrose
- Magnesium chloride
- Sodium chloride
- Hexahydrate
- Disodium edetate dihydrate
- Polysorbate 80
- Water for injections

3. VACCINATION SCHEDULE

AZ Vaccine is injected into deltoid muscle of your upper arm (see image 1)

You will receive 2 injections. You may receive the second injection between 8 and 12 weeks after the first injection. You will be informed about the date for the second dose at the vaccination site.

When AZ Vaccine is given for the first injection, the same (and not another vaccine against COVID-19) should be given for the second injection to complete vaccination course. It is important that you receive your second injection of AZ Vaccine for full protection.



Image 1

4. WHAT YOU NEED TO KNOW BEFORE YOU RECEIVE AZ VACCINE.

Do not receive the AZ Vaccine:

- If you have ever had a severe allergic reaction to the active ingredient or any of the other ingredients listed in section 2. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue
- If you have ever had a major blood clot occurring at the same time as having low levels of platelets after receiving any AZ Vaccine
- If you had ever had a condition known as heparin-induced thrombocytopenia and thrombosis

Tell your doctor, nurse, or pharmacist if you have any of the above conditions and if you have any concerns.

5. WARNINGS AND PRECAUTIONS

Tell your doctor, pharmacist, or nurse before vaccination:

- If you currently have any infection or flu like symptoms
- If you have a problem with bleeding or bruising, or if you are taking any blood thinning medicine (anticoagulant) such as Warfarin, rivaroxaban, dabigatran, apixaban, aspirin etc
- If you have ever had a severe allergic reaction (anaphylaxis) after any other vaccine injection
- If your immune system does not work properly or you are taking medicines that weaken the immune system such as prednisolone (any steroid), tacrolimus, sirolimus, leflunomide, mycophenolate
- If you have ever had a blood clot in the brain, or the autoimmune condition called antiphospholipid syndrome

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.

Rare cases of blood clots with low levels of platelets are reported in patients who received AZ Vaccine. Most of the cases occurred within 14 days after immunisation but, some cases occurred beyond 14 days. It is important to note that even though such cases happened, the potential benefit of vaccination outweighs the risks involved.

If you experience any side effects after vaccination you should seek medical advice urgently:

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

Even after receiving any other COVID-19 vaccine you may get infected by corona virus. However, the vaccine will protect you from severe disease, prevent hospitalisation and reduce mortality.

6. POSSIBLE SIDE EFFECT

AZ Vaccine has side effects like any other vaccine. Most side effects are mild or moderate and go away within a few days of appearing. All side effects must be reported to any health care professional who will forward them to BoMRA.

Side effects that are observed with AZ Vaccine are as follows:

- tenderness, pain, warmth, itching or bruising where the injection is given
- generally feeling unwell
- feeling tired (fatigue)
- chills or feeling feverish
- headache
- feeling sick (nausea)
- joint pain or muscle ache
- swelling, redness or a lump at the injection site
- fever
- being sick (vomiting) or diarrhoea
- flu-like symptoms, such as high temperature, sore throat, runny nose, cough, and chills. The list is not exhaustive

Please notify Healthcare professionals if you notice any of the side effects listed or any other discomfort you may experience.

OTHER INFORMATION;

No data are currently available on the use of AZ Vaccine in children and adolescents younger than 18 years of age.

Tell your doctor, pharmacist, or nurse if;

- you are taking any other medicines or vaccines
- you are pregnant or breastfeeding AZ Vaccine has no known effect on the ability to drive and use machines.

7. MANUFACTURES

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