

Janssen COVID-19 vaccine FACT SHEET



FS 739935



Promoting access to safe medicines

Botswana Medicines Regulatory Authority (BoMRA) has authorised Janssen COVID-19 vaccine for emergency use. This Fact Sheet contains information about Janssen COVID-19 Vaccine to help you understand the potential risks and benefits of receiving it during the current mass vaccination campaign under the Ministry of Health and Wellness.

WHAT DOES THE FACT SHEET CONTAIN?

1. What is Janssen COVID-19 vaccine and what is it used for?
2. What does Janssen COVID-19 vaccine contain?
3. Vaccination schedule
4. What you need to know before you receive Janssen COVID-19 vaccine
5. Warnings and Precautions
6. Side effects
7. Market Authorisation Holder

1. WHAT IS JANSSEN COVID-19 VACCINE AND WHAT IS IT USED FOR?

Janssen COVID-19 vaccine is a vaccine made by Johnson and Johnson that protects against COVID-19 infection. It is used for active immunisation to prevent moderate-to-severe COVID-19 disease caused by SARS-CoV-2 virus, reduce hospitalisation and mortality rate due to COVID-19 disease. The vaccine will stimulate your body to produce antibodies that protect against COVID-19 disease.

2. WHAT DOES JANSSEN COVID-19 VACCINE CONTAIN?

The active ingredient of Janssen COVID-19 vaccine is (Ad26.COVS-2-S [recombinant]).

Other ingredients are;

- 2-hydroxypropyl- β -cyclodextrin (HBCD)
- Citric acid monohydrate
- Ethanol
- Hydrochloric acid
- Polysorbate-80
- Sodium chloride
- Sodium hydroxide
- Trisodium citrate dihydrate
- Water for injections

3. VACCINATION SCHEDULE

Janssen COVID-19 vaccine has been authorised for emergency use in people aged 18 years and above. You will receive one injection on your upper arm (see image 1).



Image 1

4. WHAT YOU NEED TO KNOW BEFORE YOU RECEIVE JANSSEN COVID-19 VACCINE

Do not receive Janssen COVID-19 vaccine;

if you have ever had a severe allergic reaction or are allergic 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.

5. WARNINGS AND PRECAUTIONS

Talk to your doctor, pharmacist or nurse before receiving Janssen COVID-19 vaccine if;

- You have had an allergic reaction after receiving any other vaccine
- If you have flu-like symptoms or any other infection with high temperature (over 38°C). Please note that you may still get vaccinated if the healthcare professional finds out you have low fever or common cold
- If you are taking blood thinning medicine such as (Warfarin, rivaroxaban, dabigatran, apixaban, aspirin) or if you have blood clotting disorder or bruise easily
- 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 suspect that you have COVID-19 infection or had COVID-19 infection. Health care providers will advise you
- If you have history of blood clotting disorders (Deep vein thrombosis, pulmonary embolism, transverse sinus thrombosis with thrombocytopenia)
- If you have uncontrolled severe chronic diseases
- If you are pregnant / lactating
- If you have any other questions or concerns ask your health care provider, they will provide you with the correct information.

6. SIDE EFFECTS

Janssen COVID-19 vaccine like any other COVID-19 vaccine has side effects. They are usually mild and go away within a few days. However, if they persist or get worse, go to your nearest health care facility for consultation. Please note that not everyone will experience side effects. The following are side effects that have been reported;

Very common: may affect more than 1 in 10 people

- headache
- nausea
- muscle aches
- pain where the injection is given

- feeling very tired

Common: may affect up to 1 in 10 people

- redness at injection site
- swelling where the injection is given
- chills
- joint pain
- cough
- fever

Uncommon: may affect up to 1 in 100 people

- rash
- muscle weakness
- arm or leg pain
- feeling weak
- feeling generally unwell
- sneezing
- sore throat
- back pain
- tremor
- excessive sweating

Rare: may affect up to 1 in 1 000 people

- allergic reaction
- hives

Very Rare: may affect up to 1 in 10 000 people

Extremely rare side effects have been reported after widespread use of the Janssen COVID-19 vaccine, these include rare reports of blood clots in combination with low level of blood platelets. They usually occur in your brain, liver, bowel, spleen.

Report any discomfort that you may experience after vaccination to the nearest healthcare facility.

7. MARKET AUTHORISATION HOLDER

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