Janssen COVID-19 Vaccine
FACT SHEET

bsi. ISO 9001:2015 Quality Management
FS 739935

BMRA MEDICINES REGULATORY AUTHORITY
Promoting access to safe medicnes

Botswana Medicines Regulatory Authority (BoMRA) has listed Janssen COVID-19 vaccine for emergency use for active immunisation to prevent coronavirus disease (COVID-19). This Fact Sheet contains information about Janssen COVID-19 Vaccine to help you as a healthcare provider.

Name Of The Medicinal Product And Pharmaceutical Form

Janssen COVID-19 Vaccine suspension for injection

Qualitative And Quantitative Composition

One dose (0.5ml) contains Adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein (Ad26.COV2-S), not less than 8.92 log10 infectious units (Inf.U).

Excipients:

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

Clinical Information

Therapeutic indications:
Janssen COVID-19 vaccine is used for active immunisation of individuals aged 18 years and older to prevent COVID-19 disease. The use of Janssen COVID-19 vaccine should be in accordance with guidelines issued by Ministry of Health and Wellness (MoHW), Botswana.

Vaccination Schedule

Janssen COVID-19 vaccine is administered intramuscularly only. Janssen COVID-19 vaccine must not be injected subcutaneously, intravascularly and intradermally. This is a one dose vaccine. However, ongoing clinical trials will determine the need for and benefits of booster doses.

Contraindications

Hypersensitivity to the active ingredient or to any of the excipients listed (under excipients section). Clinicians must use their clinical judgment and guidelines issued by MoHW to determine some of the contraindications.

Traceability

For traceability purposes, the name and the batch number of the administered vaccine should be clearly recorded in the immunisation logbooks provided at the vaccination site.

Special Warnings And Precautions

Hypersensitivity and anaphylaxis

Anaphylaxis have been reported following immunization with Janssen COVID-19 vaccine. Therefore, standard operating procedures on management of anaphylaxis must be available, staff must be trained to identify and treat patients who develop anaphylactic shock following immunisation. MoHW recommends observation of vaccinees for at least 15 minutes following vaccination.

Concurrent illness
Vaccination should be postponed for individuals with acute severe febrile or exacerbated chronic conditions. However, vaccination should not be postponed for mild infections. Healthcare providers should use their clinical judgement to determine the suitability of vaccinating individuals.

Immunocompromised individuals
The efficacy, safety and immunogenicity of Janssen COVID-19 vaccine is not established in individuals who are immunocompromised and those on immunosuppressants. Therefore, the protection for such individuals maybe low.

Duration of protection
Clinical trails are ongoing to determine the duration of protection.

Limitations of vaccine effectiveness
Studies shows that protection starts 14 days after receiving the dose of Jassen COVID-19 vaccine.

Fertility, pregnancy, and lactation
Pregnancy
Data available on the use of Janssen COVID-19 vaccine in pregnant women is insufficient to make informed conclusions on risk associated with the vaccine in pregnancy. Pregnant women should only be vaccinated when benefits of vaccination outweigh the potential risks. Preclinical studies carried out did not show any adverse events (female fertility, embryo-foetal or postnatal development) after animal models were challenged with 1ml of the Janssen COVID-19 vaccine.

Breast-feeding
No data available to assess the effects of Janssen COVID-19 vaccine in breast fed infants whose mothers got the vaccine.

Fertility
There is no clinical data to assess the effects of Janssen COVID-19 vaccine on fertility, Hower, preclinical studies did not show any effect of Janssen COVID-19 Vaccine on fertility.
Effects on ability to drive and use machines.

There is no direct evidence that suggest that Janssen can affect one's ability to drive. However, some adverse events mentioned below may affect one's ability to drive or use machines.

Interaction with other medicinal products and other forms of interaction
No clinical studies that investigated interaction between Janssen COVID-19 vaccine and other medicines / vaccines has been done. Janssen COVID-19 vaccine should not be mixed with other vaccines / products in the same syringe.

Side effects

The following adverse events following vaccination were noticed during clinical trials. They are listed in the decreasing order of frequency of seriousness and occurrence. For this document, the frequency is defined as follows: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000), Unknown (cannot be estimated from available data).

FREQUENCY	SIDE EFFECTS
Very common	Headache; nausea; muscle aches; pain at injection site; myalgia; fatigue
Common	Pyrexia; Redness at injection site; injection site erythema; chills; arthralgia (joint pain); cough; chills
Uncommon	Rash; muscle weakness; sneezing; sore throat; back pain; pain in extremity; tremor; excessive sweating; asthenia; malaise
Rare	Allergic reaction; hives
Very rare	Guillain-Barré syndrome; immune thrombocytopenia
Unknown	Severe allergic reaction

Post-authorisation safety data

Globally there are 51734 adverse vaccine reactions (Adverse Events Following Immunisation, AEFIs) reported as of 19th August 2021.
The most common reported (AEFI) is headache (27.8 %) followed by pyrexia (23.1%), chills (20.3%) and least reported is paraesthesia (3.6%). The occurrence rate of specific AEFIs for Janssen COVID-19 Vaccine is similar to other vaccines.

Of all the reported AEFIs, 10.5 % were considered serious. Cases are classified as serious if they resulted in life threatening, caused/prolonged hospitalization, disabling/incapacitating, congenital anomaly/birth defect, death, and other medically important condition. 1.7% resulted in death, 2.3% were life threatening, 7.5% caused prolonged hospitalisation, 1.9% were disabling/ incapacitating and 0.1 % were other medically important conditions.

Most AEFIs are reported within 7 days post vaccination and were mostly mild. AEFIs were common in people in the age group 18-59 years compared to those aged 60 years and above.

Adverse Events Of Special Interest (Aesi)

Guillain-Barré syndrome (GBS)

GBS is a rare condition where the immune cells attack the nerve cells which results in muscle weakness and tingling of lower extremities. As of 30th June 2021, there were 108 reported cases of GBS through spontaneous reporting from vaccination campaigns.

When the data was analysed 21 million doses of Jassen COVID-19 vaccines administered worldwide. GBS is occurrence is very rare. However, it is important that healthcare professionals are made aware of it and should also educate the public about what to look up for. HCPs should advice vaccinated people to seek medical attention immediately when they feel the following signs and symptoms.

- Difficulty in walking, breathing, speaking, or chewing
- Weakness in the hands, feet, face, chest with tingling sensations
- Problems in controlling the bladder and bowels

Immune thrombocytopenia (ITP)
ITP is a condition where the immune system attacks and destroy platelets which results in bleeding disorder. As of 18th June 2021, there were 120 cases of ITP worldwide. 27 cases were from clinical trials and 93 were spontaneous reports from vaccination campaigns worldwide for around 21 million doses of Janssen COVID-19 vaccine administered. HCPs are encouraged to advise people who are vaccinated to seek medical attention immediately when they experience the following signs and symptoms;

- Blood in urine or stools
- Easy or excessive bruising
- Unusually heavy menstrual flow
- Unexplained bleeding under into the skin, gums, or nose

Thrombosis with Thrombocytopenia syndrome (TTS)
There are reports of TTS post-authorisation use of Janssen COVID-19 vaccine. Most reports are from females aged 18-49 years. The occurrence rate in females aged 18-49 years is 7 reports per 1 million doses administered. However, the reports are very rare in females and males aged 50 years and above.

The symptoms usually occur within one to two weeks after vaccination. The clinical presentation of the events shares similar features with autoimmune heparin-induced thrombocytopenia (HITS). HCPs are advised to consider alternatives for individuals taking heparin suspected to have TTS following immunisation. Further, HCPs are encouraged to advise people who are vaccinated to seek medical attention immediately when they experience the following signs and symptoms;

- Chest pain
- Leg swelling
- shortness of breath
- Persistent abdominal pain
- Severe or persistent headaches
- Blurred vision

For more information about the COVID-19 vaccines contact BoMRA National Medicines Information Centre at 3731788/71 or email:nmic@bomra.co.bw.

Reporting of Adverse events Following Immunisation (AEFIs)

HCPs should educate patients about possible AEFIs and encourage them to visit their nearest healthcare facility if they experience any AEFIs or any discomfort after they are vaccinated. All AEFIs that healthcare workers get notified of must be reported to BoMRA.

Reporting of AEFI

AEFIs must be reported to BoMRA through EPI focal persons within your respective DHMTs.
Report all AEFI to BoMRA: aefi@bomra.co.bw,
WhatsApp numbers – 75846041; 75846037
AEFI Reporting Forms– You may download the forms from BoMRA website www.bomra.co.bw

For any other information contact us at
Phone - Call 3731754 /66/88/ 53 / 71

Market Authorisation Holder

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