

Moderna COVID-19 Vaccine FACT SHEET



FS 739935



Promoting access to safe medicines

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

What does the fact sheet contain?

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What Moderna COVID-19 vaccine is and what it is used for?

Moderna COVID-19 vaccine is a vaccine made by Moderna TX, Inc. It is used for active immunisation to prevent moderate-to-severe COVID-19 disease, 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.

What does Moderna COVID-19 vaccine contain?

Active ingredient of Moderna COVID-19 vaccine is Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2.

Other ingredients are:

- Sucrose
- Sodium acetate
- Acetic acid
- Tromethamine hydrochloride
- Tromethamine
- SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate
- Cholesterol
- 1,2-distearoyl-sn-glycero-3-phosphocholine
- PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol

Vaccination schedule

Moderna Covid-19 vaccine has been authorised for emergency use in people aged 18 years and above. You will receive two injections at least 28 days apart but may be extended to 42 days. You will be injected on your upper arm.

If you are immunocompromised, you may receive a third dose of the Moderna COVID-19 vaccine at least 1 month after the second dose.

What you need to know before you receive Moderna COVID-19 vaccine

Do not receive Moderna COVID-19 vaccine:

- if you have ever had a severe allergic reaction or 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. Discuss this with a healthcare professional.

Warnings and Precautions

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

- You had an allergic reaction after receiving Moderna COVID-19 vaccine or any other vaccine
- If you have flu-like symptoms or any other infection with high temperature (over 38°C). Vaccination is at the discretion of healthcare worker based on his/her clinical judgement.
- 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 provider will advise you
- If you have uncontrolled severe chronic diseases
- If you are pregnant / breastfeeding
- If you have received other COVID-19 vaccine
- If you have fainted when receiving a vaccine or injection.

If you have any other questions or concerns ask your health care provider, they will provide you with the correct information.

Side effects

Moderna COVID-19 vaccine like any other COVID-19 vaccine has side effects. They are usually mild and go away within 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. They are listed in the decreasing order of frequency of seriousness and occurrence. For this document, the frequency is defined as follows: very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$), rare ($\geq 1/10,000$ to $< 1/1,000$), very rare ($< 1/10,000$).

Very common: headache, nausea and vomiting, muscle and joint aches, pain and swelling at injected site, tiredness, chills and swollen or tender lymph nodes.

Common: redness at injection site, swelling where the injection is given, joint pain, cough, and fever.

Uncommon: rash, muscle weakness, arm, or leg pain, feeling weak, feeling generally unwell, sneezing, sore throat, back pain, tremor, and excessive sweating.

Rare: allergic reaction.

Very Rare: myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart).

Chest pain of varying severity has been reported after receiving Moderna COVID-19 vaccine. This is common amongst young adults (≤ 30 years old) often after receiving second dose. Therefore, it is advised that adolescence and young adults should refrain from strenuous exercise and sporting activities for about 2 weeks after receiving Moderna COVID-19 vaccine.

Please notify the nearest healthcare facility as soon as possible if you experience any side effects or discomfort, even the ones not listed above.

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

Market Authorisation Holder

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