

Comirnaty Pfizer

FACT SHEET



FS 739935



Promoting access to safe medicines

Botswana Medicines Regulatory Authority (BoMRA) has authorised Comirnaty (Pfizer CoVID-19 vaccine) for emergency use.

This fact sheet contains information about;

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

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

Comirnaty is used for active immunisation to prevent CoVID-19 disease caused by SARS-CoV-2 virus. The vaccine stimulates immune cells to produce antibodies that protect against CoVID-19 disease.

2. COMIRNATY VACCINE CONTAINS:

The active ingredient is Tozinameran (BNT162B2) CoVID-19 mRNA Vaccine. It also contains other ingredients listed below.

- cholesterol,
- potassium chloride,
- potassium dihydrogen phosphate,
- sodium chloride,
- disodium hydrogen phosphate dihydrate,
- sucrose,
- water for injections.

3. VACCINATION SCHEDULE

Comirnaty is given after dilution as an injection of 0.3 mL into deltoid muscle of your upper arm (see image 1).

You will receive 2 injections, given at least 21 days apart.

If you receive one dose of Comirnaty, you should receive a second dose of the same vaccine at least 21 days later to complete the vaccination series.

It takes at least 7 days for maximum protection against CoVID-19 disease after the second dose.



image 1

If you have any further questions about Comirnaty, ask your doctor, pharmacist, nurse, or any other healthcare professional.

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

Comirnaty vaccine should not be given:

If you are allergic to the active substance or any of the other ingredients of this vaccine (listed under 2). Signs of an allergic reaction may include swelling of the face or tongue, itchy skin rash, shortness of breath. Contact your doctor, nurse, or healthcare professional immediately or go to the nearest health facility immediately if you have an allergic reaction.

5. WARNINGS AND PRECAUTIONS

Talk to your doctor, pharmacist, nurse, and vaccinator before you are given the vaccine if you have:

- ever had a severe allergic reaction after any other vaccine injection or after you were given Comirnaty in the past
- a severe illness with high fever
- a weakened immune system, such as due to diabetic, HIV infection, or are on a medicine that affects your immune system prednisolone, tacrolimus, sirolimus, mycophenolate, leflunomide etc.
- a bleeding problem, bruise easily or use a medicine that thins blood clotting.

Talk to your Pharmacist, doctor, nurse, or any other healthcare professional if you are taking other medications, pregnant or breast-feeding.

As with any vaccine, Comirnaty may not fully protect all those who receive it. No data are currently available in individuals with a weakened immune system or who are taking chronic treatment that suppresses or prevents immune responses.

6. POSSIBLE SIDE EFFECTS

Comirnaty has side effects like any other vaccine. Most side effects are mild or moderate and go away within a few days of appearing. Notify health care professional if you experience any side effect. Healthcare professionals will then report to BoMRA.

The reported side effects include (List not exhaustive)

Pain at injection site, injection site swelling, redness at injection site, tiredness, headache, muscle pain, chills, joint pain, fever, nausea, enlarged lymph nodes, feeling unwell, and temporary one-sided facial drooping.

Breastfeeding/lactating mothers

Children of mothers who received Comirnaty vaccine may develop; irritability, poor sleep, increased drowsiness, fever, and up respiratory tract infection. Please notify healthcare providers as soon as possible if your child experiences the above-mentioned signs and symptoms or any other discomfort.



Chest pain of varying severity has been reported after receiving Comirnaty 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 Comirnaty 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.

7. MANUFACTURER

Pfizer Manufacturing Belgium NV Rijksweg 12, Puurs, 2870, Belgium