Comirnaty Pfizer

FACT SHEET FOR HEALTHCARE PROFESSIONALS

Botswana Medicines Regulatory Authority (BoMRA) has authorised Comirnaty for emergency use. Comirnaty (Tozinameran -BNT162B2) may prevent CoVID-19 infection and prevent severe CoVID-19 disease.

NAME OF THE MEDICINAL PRODUCT AND PHARMACEUTICAL FORM

COVID-19 mRNA Vaccine Comirnaty (Tozinameran - BNT162B2) concentrate for solution for injection

QUALITATIVE AND QUANTITATIVE COMPOSITION

Vaccine Comirnaty is a multidose vial and must be reconstituted before use. A vail of (0.45 mL) contains 6 doses of 30 mcg of BNT162b2 RNA (encapsulated in lipid nanoparticles). Comirnaty Vaccine is a highly purified single-stranded, 5'-capped messenger RNA (mRNA). mRNA is produced through cell-free in-vitro transcription from the corresponding DNA template that encodes viral spike (S) protein of corona virus.

EXCIPIENTS:

This vaccine contains polyethylene glycol/macrogol (PEG) as part of ALC-0159.

- ALC-0315 = (4-hydroxybutyl) azanediyl) bis (hexane-6,1-diyl) bis (2-hexyldecanoate),
- ALC-0159 = 2- [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide,
- 1,2-Distearoyl-sn-glycero-3-phosphocholine,
- cholesterol,
- potassium chloride,
- potassium dihydrogen phosphate,
- sodium chloride,
- disodium hydrogen phosphate dihydrate,
- sucrose,
- water for injections

CLINICAL INFORMATION

Therapeutic indications;
Active immunisation of individuals aged 16 years and older to prevent COVID-19 disease.
The use of Comirnaty should be in accordance with guidelines issued by Ministry of Health and Wellness (MoHW), Botswana.

VACCINATION SCHEDULE

Immunisation of individuals aged 16 years and older. Comirnaty is not approved for use on individuals below 16 years in Botswana, even though in other countries it has been approved for use in individuals aged 12 years and above.

ADMINISTRATION AND PREPARATION

Comirnaty is administered intramuscularly only. Comirnaty must not be injected vaccine, subcutaneously, intravascularly and intradermally.
One will receive two doses (0.3 mL each) at least 21 days apart.
Manufactures do not recommend interchangeability of Comirnaty vaccine with any other COVI-19 vaccines. There is no evidence available that demonstrates the effectiveness of vaccines when used interchangeably. Therefore, people must receive 1st and 2nd dose of Comirnaty only to complete the vaccination series.
Maximum protection is achieved until at least 7 days after the second dose has been administered.
The multidose vial is stored frozen and must be thawed prior to reconstitution. Reconstitute the vial as per the instructions provided by the manufacturer and using the diluent provided.

CONTRAINDICATIONS

Hypersensitivity to the active ingredient or to any of the excipients listed (under 2). Clinicians must use their clinical judgment and guidelines issued by MoHW to determine some of the contraindications.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Hypersensitivity and anaphylaxis

Anaphylaxis have been reported following immunization with Comirnaty. 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. If one experience anaphylaxis after the first dose of the Comirnaty the second one should not be given.

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.

GENERAL RECOMMENDATIONS

- People with acute severe febrile illness should not get vaccinated, their vaccination must be postponed to a later date.
- People on anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection, should not be vaccinated unless the benefit clearly outweighs the risk of immunisation.
- Immunocompromised individuals and those on immunosuppressant therapy, may have a diminished immune response. There is no evidence that supports concomitant use of immunosuppressants and Comirnaty.
- As with any vaccine, vaccination with Comirnaty may not protect all vaccine recipients.
- There is no data available on the use of Comirnaty in persons that have previously received a full or partial vaccine with another COVID-19 vaccine.
- Interaction with other medicinal products and other forms of interaction
- Interaction studies have not been done. Therefore, there is no data available on the use of Comirnaty

with other medical products.
- Administration of Comirnaty with other vaccines has not been studied.
- Manufacturer recommends that Comirnaty should not be mixed with other vaccines/products in the same syringe.

FERTILITY, PREGNANCY, AND LACTATION

Pregnancy

There is limited evidence available on the use of Comirnaty in pregnant women. In pre-clinical studies there was no direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition, or post-natal development. Consider vaccination with Comirnaty in pregnancy only if the potential benefit outweighs any risk to the mother and foetus. Administration of Comirnaty in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus. However, preliminary data published by Centre for Disease Control and Prevention in United states of America showed that patterns of reporting of both most frequently reported reactions and reactogenicity after second dose were similar to patterns observed among nonpregnant women.

Breast-feeding

There is no data available as to whether Comirnaty is excreted in human milk or not. However, current data suggests that children of mothers who received Comirnaty vaccine may develop; irritability, poor sleep, increased drowsiness, fever, and up respiratory tract infection. Please inform the patients to notify healthcare providers as soon as possible if their children experience the above-mentioned signs and symptoms or any other discomfort.

Fertility

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

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

ADVERSE VACCINE REACTIONS FROM CLINICAL STUDIES

The following adverse events 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), not known (cannot be estimated from available data).

Blood and lymphatic system disorders	
Uncommon:	Lymphadenopathy
Immune system disorders	
Not Known:	Anaphylaxis; hypersensitivity
Nervous system disorders	
Very common:	Headache
Rare:	Acute peripheral facial paralysis

ADVERSE VACCINE REACTIONS FROM CLINICAL STUDIES (CONTINUED)

Musculoskeletal and connective tissue disorders	
Very common:	Arthralgia (Joint pain); myalgia
General disorders and administration site conditions	
Very common:	Fatigue; chills; pyrexia Injection-site pain;
Common: Uncommon:	Redness at injection site; injection site swelling Malaise
Gastrointestinal disorders	
Common	Nausea

POST-AUTHORISATION SAFETY DATA

Globally there are 246 684 adverse reactions (Adverse Events Following Immunisation, AEFIs) reported as of 15th July 2021.
Of all the reported AEFIs, 18.4 % 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.
The common reported (AR) is headache at 27.7 % followed by pyrexia, myalgia, fatigue and least reported is dyspnoea. The occurrence rate of specific ARs for Comirnaty Vaccine is similar to other vaccines.

ADVERSE EVENTS OF SPECIAL INTEREST (AESI)

There are reports of myocarditis/ pericarditis amongst young adults ≤30 years old. It must be noted that most symptom appear after the second dose. In addition, it is more predominate in males compared to females. Therefore, HCPs must advise adolescence and young adults to refrain from strenuous exercise and sporting activities for about 2 weeks after receiving Comirnaty vaccine.

REPORTING OF ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFIS)

HCPs should educate patients about AEFIs and encourage them to visit their nearest healthcare facility if they get any AEFIs or they are concerned about 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 AEFI 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

MANUFACTURER

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

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