SCHEDULING STATUS: TBC

COMIRNATY concentrate for dispersion for injection

COVID-19 mRNA vaccine (nucleoside modified)

Contains sugar

Each 0,3 mL dose contains 6 mg sucrose

Read all of this leaflet carefully before you are given COMIRNATY

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- COMIRNATY has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What COMIRNATY is and what it is used for

COMIRNATY is a vaccine used for preventing COVID-19 caused by SARS-CoV-2 virus.

COMIRNATY is given to adults and adolescents from 12 years of age and older.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, so giving protection against COVID-19.

As COMIRNATY does not contain the virus to produce immunity, it cannot give you COVID-19.

2. What you need to know before you receive COMIRNATY

COMIRNATY should not be administered to you:

- if you are hypersensitive (allergic) to COVID-19 mRNA vaccine (nucleoside modified) or any of the other ingredients of COMIRNATY (listed in section 6).

Warnings and precautions

Tell your doctor or health care provider before you are given the vaccine:

- if you have ever had a severe allergic reaction or breathing problems after any other vaccine injection or after you were given COMIRNATY in the past
- if you are feeling nervous about the vaccination process or have ever fainted following any needle injection
- if you have a severe illness or infection with high fever. However, you can have your vaccination if you have a mild fever or upper airway infection like a cold
- if you have a bleeding problem, you bruise easily or you use a medicine to prevent blood-clots
- if you have a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects your immune system

Very rare cases of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have been reported after vaccination with COMIRNATY. The cases have primarily occurred within two weeks following vaccination, more often after the second vaccination, and more often occurred in younger men. Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

As with any vaccine, the 2-dose vaccination course of COMIRNATY may not fully protect all those who receive it and it is not known how long you will be protected.

Due the evolution of SARS CoV2 variants in SA, vaccinated patients are advised to report any COVID or suspected COVID to their doctor to enable collection of virus samples for analysis.

Children

COMIRNATY is not recommended for children aged under 12 years.

Other medicines and COMIRNATY

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before you receive this vaccine.

Driving and using machines

Some of the effects of vaccination mentioned in section 4 (Possible side effects) may temporarily affect your ability to drive or use machines. Wait until these effects have worn off before you drive or use machines.

It is not always possible to predict to what extent COMIRNATY may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which COMIRNATY affects them.

COMIRNATY contains potassium and sodium

COMIRNATY contains less than 1 mmol potassium (39 mg) per dose, that is to say essentially 'potassium-free'.

COMIRNATY contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How COMIRNATY is given

You will not be expected to give yourself COMIRNATY. It will be given to you by a person who is qualified to do so.

COMIRNATY is given after dilution as an injection of 0,3 mL into a muscle of your upper arm.

You will receive 2 injections.

It is recommended to receive the second dose of the same vaccine 3 weeks after the first dose to complete the vaccination course.

If you have the impression that the effect of COMIRNATY is too strong or too weak, tell your doctor or pharmacist.

If you receive more COMIRNATY than you should

Since a health care provider will administer COMIRNATY, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive COMIRNATY

Since a health care provider will administer COMIRNATY, it is unlikely that the dose will be missed.

4. Possible side effects

COMIRNATY can have side effects.

Not all side effects reported for COMIRNATY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking COMIRNATY, please consult your health care provider for advice.

Adverse effects reported in clinical trials.

Tell your doctor if you notice any of the following:

Frequent side effects

- headache
- nausea
- joint pain
- muscle pain

- injection site pain
- tiredness
- chills
- fever
- injection site swelling
- injection site redness

Less frequent side effects

- enlarged lymph nodes
- allergic reactions such as rash or itching, hives or swelling of the face
- decreased appetite
- difficulty sleeping
- feeling weak or lack of energy/sleepy
- excessive sweating
- night sweats
- arm pain
- feeling unwell
- injection site itching
- temporary one-sided facial drooping
- severe allergic reaction

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Post-marketing side effects

- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain
- diarrhoea
- vomiting
- extensive swelling of the vaccinated limb
- swelling of the face (swelling of the face may occur if you have had facial cosmetic injections)

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of COMIRNATY.

5. How to store COMIRNATY

Store all medicines out of reach of children.

The following information about storage, expiry and use and handling is intended for health care providers.

- Store in freezer at -90 °C to -60 °C. Within the 6 months shelf-life unopened vials may be stored and transported at -25 °C to -15 °C for a single period of up to 2 weeks and can be returned to -90 °C to -60 °C.
- Store in the original package in order to protect from light.

Transfers of frozen vials stored at ultra-low temperature (< -60 °C)

- Closed-lid vial trays containing 195 vials removed from ultra-low temperature frozen storage (< -60 °C) may be at temperatures up to 25 °C for up to 5 minutes.
- Open-lid vial trays, or vial trays containing less than 195 vials, removed from ultra-low temperature frozen storage (< -60 °C) may be at temperatures up to 25 °C for up to 3 minutes.
- After vial trays are returned to frozen storage following temperature exposure up to 25 °C, they must remain in frozen storage for at least 2 hours before they can be removed again.

Transfers of frozen vials stored at -25 °C to -15 °C

- Closed-lid vial trays containing 195 vials removed from frozen storage (-25 °C to -15 °C) may be at temperatures up to 25 °C for up to 3 minutes.
- Open-lid vial trays, or vial trays containing less than 195 vials, removed from frozen storage (-25 °C to -15 °C) may be at temperatures up to 25 °C for up to 1 minute.

Once a vial is removed from the vial tray, it should be thawed for use.

- Do not use after the expiry date stated on the label and carton.
- After thawing, the vaccine should be diluted and used immediately. However, in-use stability data have demonstrated that once removed from freezer, the unopened vaccine can be stored for up to 1 month at 2 °C to 8 °C. Within the 1-month shelf-life at 2 °C to 8 °C, up to 12 hours may be used for transportation. Prior to use, the unopened vaccine can be stored for up to 2 hours at temperatures up to 30 °C.
- After dilution, store and transport the vaccine at 2 °C to 30 °C and use within 6 hours. Discard any unused vaccine.
- Once removed from the freezer and diluted, the vials should be marked with the date and time. Once thawed, the vaccine cannot be re-frozen.
- Do not use this vaccine if you notice particulates in the dilution or discolouration.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What COMIRNATY contains

- The active substance is COVID-19 mRNA vaccine. After dilution, the vial contains 6 doses of 0,3 mL with 30 micrograms mRNA in each dose
- The other ingredients are: ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315), 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159), 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC), cholesterol, potassium chloride, potassium dihydrogen phosphate, sodium chloride, disodium phosphate dihydrate, sucrose and water for injections

What COMIRNATY looks like and contents of the pack

The vaccine is a white to off-white frozen dispersion (pH: 6,9 – 7,9) provided in a multidose vial of 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a flip-off plastic cap with aluminium seal.

Pack size: 195 vials

Holder of Certificate of Registration

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton 2196

South Africa

Tel: +27(0)11 320 6000 / 0860 734 937 (Toll-free South Africa)

This leaflet was last revised in

25 January 2022

Registration number

To be advised.

Scan the code with a mobile device to get the package leaflet in different languages.

URL: www.comirnatyglobal.com

The following information is intended for health care providers only:

Due the evolution of SARS CoV2 variants in SA, vaccinated patients should be advised to report any COVID or suspected COVID to their doctor to enable collection of virus samples for analysis.

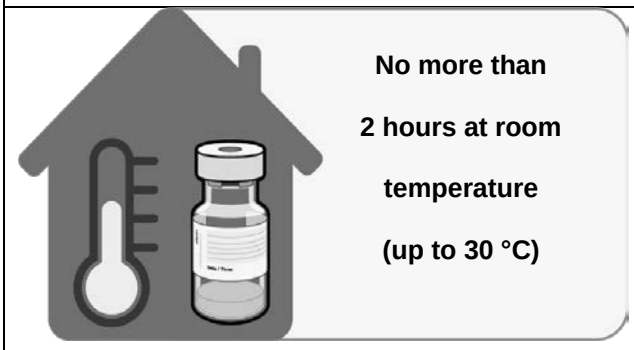
Administer COMIRNATY intramuscularly after dilution as a course of 2 doses (0,3 mL each) 3 weeks apart.

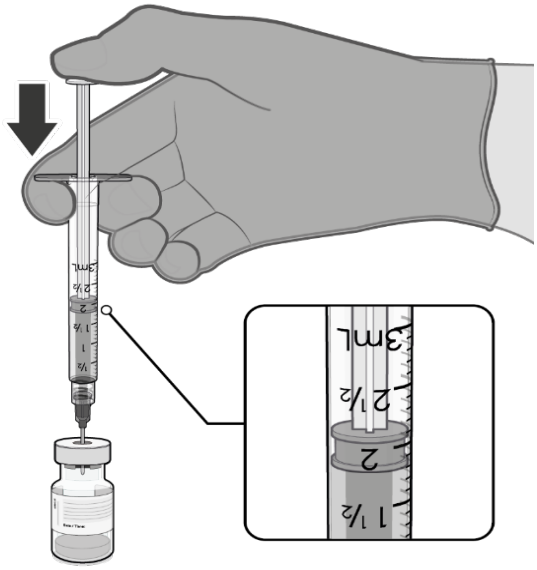
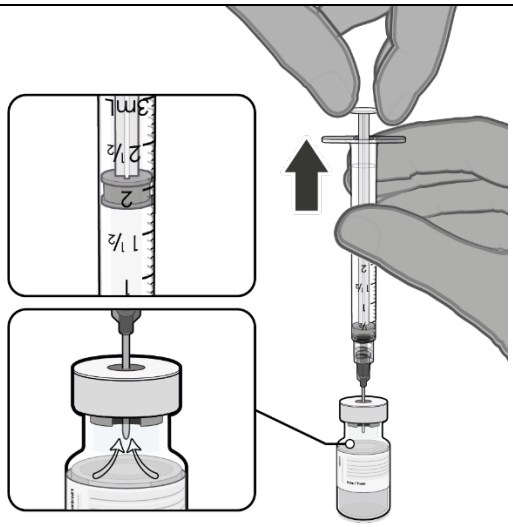
Traceability

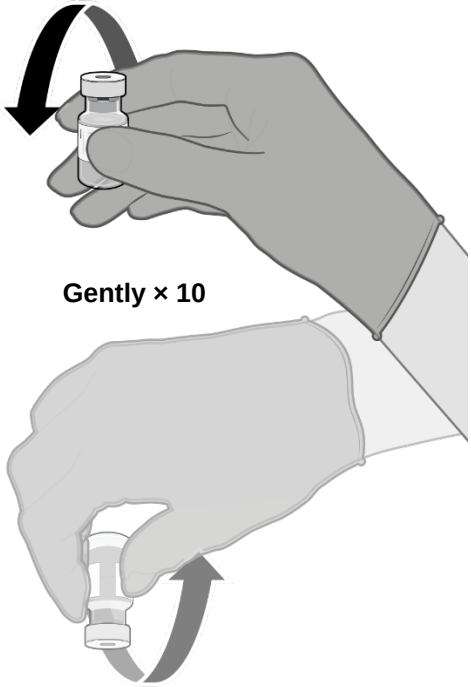
In order to improve the traceability of biological medicines, the name and the batch number of the administered medicine should be clearly recorded.

Handling instructions

COMIRNATY should be prepared by a health care provider using aseptic technique to ensure the sterility of the prepared dispersion.

<table>
<tr><td colspan="2">THAWING PRIOR TO DILUTION</td></tr>
<tr><td> 
</td><td>• The multidose vial is stored frozen and must be thawed prior to dilution. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 195-vial pack may take 3 hours to thaw. Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 30 °C for immediate use.
• The unopened vial can be stored for up to 1 month at 2 °C to 8 °C. Within the 1-month shelf-life at 2 °C to 8 °C, up to 12 hours may be used for transportation.
• Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake.
• Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.</td></tr>
<tr><td colspan="2">DILUTION</td></tr>
<tr><td></td><td>• The thawed vaccine must be diluted in its original vial with 1,8 mL sodium chloride 9 mg/mL (0,9 %) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.</td></tr>
</table>

 **1,8 mL of 0,9 % sodium chloride injection**	
 **Pull back plunger to 1,8 mL to remove air from vial**	• Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1,8 mL air into the empty diluent syringe.
	• Gently invert the diluted dispersion 10 times. Do not shake. • The diluted vaccine should present as an off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.



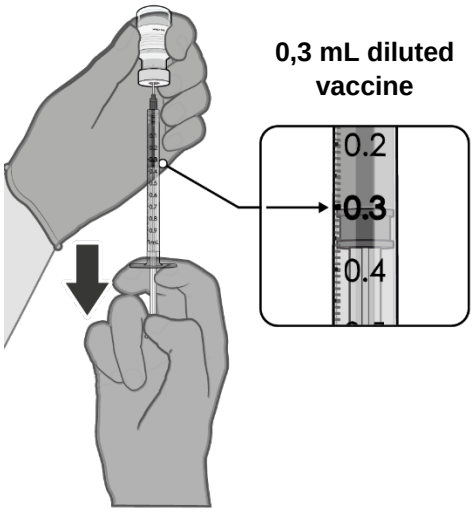
Gently × 10

Record appropriate date and time.

Use within 6 hours after dilution

- The diluted vials should be marked with the appropriate date and time.
- After dilution store at 2 ºC to 30 ºC and use within 6 hours, including any transportation time.
- Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.

PREPARATION OF INDIVIDUAL 0,3 mL DOSES OF COMIRNATY

	• After dilution, the vial contains 2,25 mL from which 6 doses of 0,3 mL can be extracted. • Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. • Withdraw 0,3 mL of COMIRNATY. Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. • Each dose must contain 0,3 mL of vaccine. • If the amount of vaccine remaining in the vial cannot provide a full dose of 0,3 mL, discard the vial and any excess volume. • Discard any unused vaccine within 6 hours after dilution.

Disposal

Any unused medicine or waste material should be disposed of in accordance with local requirements.