PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

COMIRNATY READY TO USE ADULT VACCINE ADULT 30 micrograms/dose dispersion for injection

COVID-19 mRNA vaccine (nucleoside modified)

Tozinameran

Contains sugar

Each 0,3 mL dose contains 31 mg sucrose

Read all of this leaflet carefully before you are given COMIRNATY READY TO USE ADULT VACCINE

- 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.

What is in this leaflet

1. What COMIRNATY READY TO USE ADULT VACCINE is and what it is used for
2. What you need to know before you receive COMIRNATY READY TO USE ADULT VACCINE
3. How COMIRNATY READY TO USE ADULT VACCINE is given
4. Possible side effects
5. How to store COMIRNATY READY TO USE ADULT VACCINE
6. Contents of the pack and other information

1. What COMIRNATY READY TO USE ADULT VACCINE is and what it is used for

COMIRNATY READY TO USE ADULT VACCINE is a vaccine used for preventing COVID-19 caused by SARS-CoV-2.

COMIRNATY READY TO USE ADULT VACCINE 30 micrograms/dose dispersion for injection 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 READY TO USE ADULT VACCINE does not contain the virus to produce immunity, it cannot give you COVID-19.

2. What you need to know before you receive COMIRNATY READY TO USE ADULT VACCINE

COMIRNATY READY TO USE ADULT VACCINE 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 READY TO USE ADULT VACCINE (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 READY TO USE ADULT VACCINE 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

There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with COMIRNATY READY TO USE ADULT VACCINE (see section 4). These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. 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.

COMIRNATY READY TO USE ADULT VACCINE may not fully protect all those who receive it and it is not known how long you will be protected.

You may receive a third dose of COMIRNATY READY TO USE ADULT VACCINE. The efficacy of COMIRNATY READY TO USE ADULT VACCINE, even after a third dose, may be lower in people who are immunocompromised. In these cases, you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate. Discuss appropriate individual recommendations with your health care provider.

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

Children

COMIRNATY READY TO USE ADULT VACCINE 30 micrograms/dose dispersion for injection is not recommended for children aged under 12 years.

There is a paediatric presentation available for children 5 to 11 years of age. For details, please refer to the Patient information leaflet for COMIRNATY READY TO USE ADULT VACCINE 10 micrograms/dose concentrate for dispersion for injection.

Other medicines and COMIRNATY READY TO USE ADULT VACCINE

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.

COMIRNATY READY TO USE ADULT VACCINE can be used during pregnancy. A large amount of information from pregnant women vaccinated with COMIRNATY READY TO USE ADULT VACCINE during the second and third trimester have not shown negative effects on the pregnancy or the newborn baby. While information on effects on pregnancy or the newborn baby after vaccination during the first trimester is limited, no change to the risk for miscarriage has been seen.

COMIRNATY READY TO USE ADULT VACCINE can be given during breastfeeding.

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 READY TO USE ADULT VACCINE 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 READY TO USE ADULT VACCINE affects them.

3. How COMIRNATY READY TO USE ADULT VACCINE is given

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

COMIRNATY READY TO USE ADULT VACCINE is given 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 are immunocompromised, you may receive a third dose of COMIRNATY READY TO USE ADULT VACCINE at least 28 days after the second dose.

A booster dose of COMIRNATY READY TO USE ADULT VACCINE should be given as early as 3 months after the primary vaccination course with COMIRNATY READY TO USE ADULT VACCINE in individuals 2 years of age and older.

COMIRNATY READY TO USE ADULT VACCINE may also be given as a booster dose to individuals 18 years of age and older who have received a primary vaccination course comprised of another mRNA vaccine or adenoviral vector vaccine. Please check with your healthcare provider regarding eligibility for and timing of the booster dose.

If you have any further questions on the use of COMIRNATY READY TO USE ADULT VACCINE, ask your doctor, pharmacist or nurse.

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

If you receive more COMIRNATY READY TO USE ADULT VACCINE than you should

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

If you forget to receive COMIRNATY READY TO USE ADULT VACCINE

Since a health care provider will administer COMIRNATY READY TO USE ADULT VACCINE, it is unlikely that the dose will be missed.

4. Possible side effects

COMIRNATY READY TO USE ADULT VACCINE can have side effects.

Not all side effects reported for COMIRNATY READY TO USE ADULT VACCINE are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking COMIRNATY READY TO USE ADULT VACCINE, 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 (more frequently observed after the booster dose)
- 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

- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)
- decreased feeling or sensitivity, especially in the skin (hypoaesthesia)
- 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
- a skin reaction that causes red spots or patches on the skin, that may look like a target or “bulls-eye” with a dark red center surrounded by paler red rings (erythema multiforme)
- extensive swelling of the vaccinated limb
- swelling of the face (swelling of the face may occur if you have had facial dermatological fillers)

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 READY TO USE ADULT VACCINE.

5. How to store COMIRNATY READY TO USE ADULT VACCINE

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 for 9 months.
- Store in the original package in order to protect from light.
- The vaccine may be received frozen at -90 °C to -60 °C. Frozen vaccine can be stored either at -90 °C to

-60 °C or 2 °C to 8 °C upon receipt.

- When stored frozen at -90 °C to -60 °C, 10-vial packs of the vaccine can be thawed at 2 °C to 8 °C for 6 hours or individual vials can be stored at room temperature (up to 30 °C) for 30 minutes.
- Once removed from the freezer, the unopened vial may be stored refrigerated at 2 °C to 8 °C for up to 10 weeks; not exceeding the printed expiry date (EXP). The outer carton should be marked with the new discard date at 2 °C to 8 °C. Once thawed, the vaccine cannot be re-frozen.
- Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between 8 °C and 30 °C.
- Thawed vials can be handled in room light conditions.
- After first puncture, store and transport the vaccine at 2 °C to 30 °C and use within 12 hours, which includes up to 6 hours transportation time. Discard any unused vaccine.
- Do not use this vaccine if you notice particulates in the dilution or discolouration.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What COMIRNATY READY TO USE ADULT VACCINE contains

- The active substance is COVID-19 mRNA vaccine called tozinameran. The vial contains 6 doses of 0,3 mL with 30 micrograms tozinameran 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, trometamol, trometamol hydrochloride, sucrose and water for injections

What COMIRNATY READY TO USE ADULT VACCINE looks like and contents of the pack

COMIRNATY READY TO USE ADULT VACCINE ADULT 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 grey flip-off plastic cap with aluminium seal.

Pack size: 195 vials or 10 vials.

Not all pack sizes may be marketed.

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

To be advised.

Registration number

56/30.2/1179

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

URL: www.COMIRNATY READY TO USE ADULT VACCINEglobal.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 READY TO USE ADULT VACCINE ADULT intramuscularly as a primary course of 2 doses (0,3 mL each) 3 weeks apart.

A booster dose of COMIRNATY READY TO USE ADULT VACCINE ADULT should be given as early as 3 months after the after the primary vaccination course with COMIRNATY READY TO USE ADULT VACCINE ADULT in individuals 12 years of age and older.

A third dose may be given at least 28 days after the second dose to individuals who are severely immunocompromised.

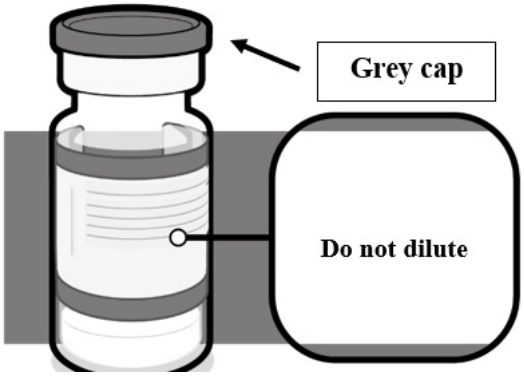
COMIRNATY READY TO USE ADULT VACCINE ADULT may also be given as a booster dose to individuals 18 years of age and older who have received a primary vaccination course comprised of another mRNA vaccine or adenoviral vector vaccine.

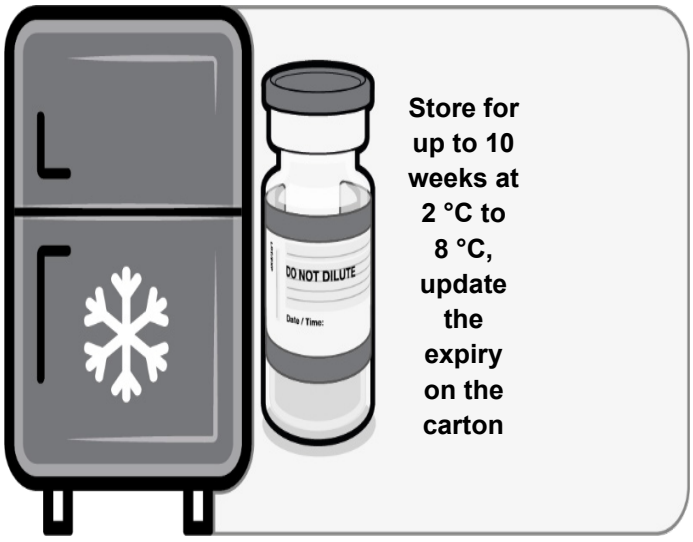
Traceability

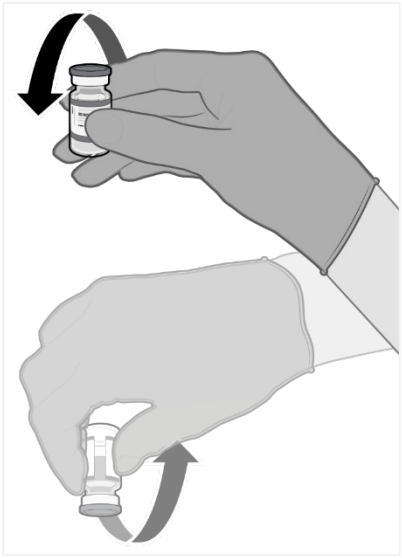
In order to improve the traceability of biological medicines, the name and the batch number of the administered medicine should be clearly recorded.

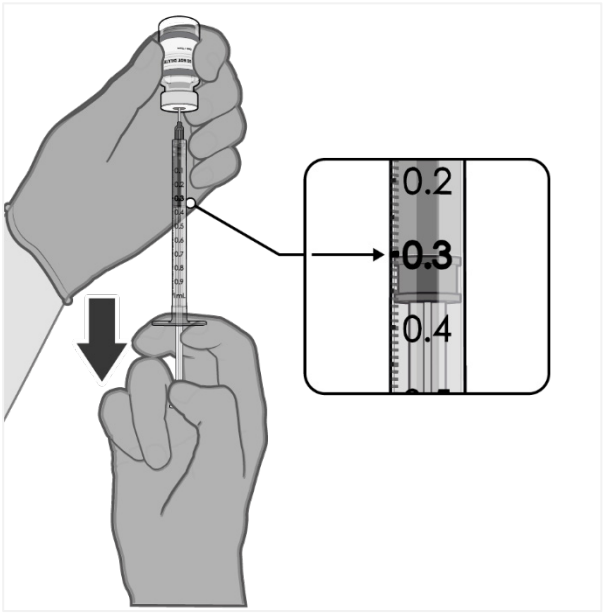
Handling instructions

COMIRNATY READY TO USE ADULT VACCINE ADULT should be prepared by a health care provider using aseptic technique to ensure the sterility of the prepared dispersion.

VIAL VERIFICATION OF COMIRNATY READY TO USE ADULT VACCINE ADULT 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION (12 YEARS AND OLDER)	
	• Verify that the vial has a grey plastic cap and a grey border around the label and the product name is COMIRNATY READY TO USE ADULT VACCINE ADULT 30 micrograms/dose dispersion for injection.

	• If the vial has a purple plastic cap, please make reference to the professional information for COMIRNATY 30 micrograms/dose concentrate for dispersion for injection. • If the vial has an orange plastic cap, please make reference to the professional information for COMIRNATY READY TO USE ADULT VACCINE PAEDIATRIC 10 micrograms/dose concentrate for dispersion for injection.
HANDLING PRIOR TO USE OF COMIRNATY READY TO USE ADULT VACCINE ADULT 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION (12 YEARS AND OLDER)	
	• If the multidose vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 10-vial pack may take 6 hours to thaw. Ensure vials are completely thawed prior to use. • Upon moving vials to 2 °C to 8 °C storage, update the expiry date on the carton. • Unopened vials can be stored for up to 10 weeks at 2 °C to 8 °C not exceeding the printed expiry date (EXP).

	• Alternatively, individual frozen vials may be thawed for 30 minutes at temperatures up to 30 °C. Prior to use, the unopened vial can be stored for up to 12 hours at temperatures up to 30 °C. Thawed vials can be handled in room light conditions.
 **Gently x 10**	• Gently mix by inverting vials 10 times prior to use. Do not shake. • Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles. • After mixing, the vaccine should present as an off-white dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.
PREPARATION OF INDIVIDUAL 0,3 mL DOSES OF COMIRNATY READY TO USE ADULT VACCINE ADULT 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION (12 YEARS AND OLDER)	
	• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. • Withdraw 0,3 mL of COMIRNATY READY TO USE ADULT VACCINE ADULT.



0,3 mL vaccine

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 12 hours after first puncture. Record the appropriate date/time on the vial.

Disposal

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