

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE PAEDIATRIC

10 micrograms/dose concentrate for dispersion for injection

COVID-19 mRNA vaccine (nucleoside modified)

Tozinameran

Contains sugar

Each 0,2 mL dose contains 10,3 mg sucrose

Read all of this leaflet carefully before you are given COMIRNATY DILUTE TO USE PAEDIATRIC 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 DILUTE TO USE PAEDIATRIC VACCINE is and what it is used for
2. What you need to know before your child receives COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE
3. How COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE will be administered to your child
4. Possible side effects
5. How to store COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE
6. Contents of the pack and other information

1. What COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE is and what it is used for

COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE 10 micrograms/dose, concentrate for dispersion for injection

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

COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE 10 micrograms/dose concentrate for dispersion for injection is given to children from 5 to 11 years of age.

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 DILUTE TO USE PAEDIATRIC VACCINE does not contain the virus to produce immunity, it cannot give your child COVID-19.

2. What you need to know before your child receives COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE

COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE should not be administered:

- if your child is hypersensitive (allergic) to COVID-19 mRNA vaccine (nucleoside modified) or any of the other ingredients of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE (listed in section 6).

Warnings and precautions

Tell your doctor or health care provider before your child is given the vaccine if your child:

- has ever had a severe allergic reaction or breathing problems after any other vaccine injection or after having been given COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE in the past
- is feeling nervous about the vaccination process or have ever fainted following any needle injection
- has a severe illness or infection with high fever. However, your child can have the vaccination if he/she have a mild fever or upper airway infection like a cold
- has a bleeding problem, bruises easily or uses a medicine to prevent blood-clots

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- has a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects your child's 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 DILUTE TO USE PAEDIATRIC 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 DILUTE TO USE PAEDIATRIC VACCINE may not fully protect all those who receive it and it is not known how long your child will be protected.

Your child may receive a third dose of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE. The efficacy of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE, even after a third dose, may be lower in people who are immunocompromised. In these cases, you/your child should continue to maintain physical precautions to help prevent COVID-19. In addition, your/your child's 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 DILUTE TO USE PAEDIATRIC VACCINE is not recommended for children aged under 5 years.

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Other medicines and COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE

Always tell your health care provider if your child is taking, has recently taken, might take any other medicine or has recently received any other vaccine. (This includes all complementary or traditional medicines.)

Pregnancy and breastfeeding

If your child is pregnant or breastfeeding, think your child may be pregnant, please consult your doctor, pharmacist or other health care provider for advice before your child receives this vaccine.

COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE can be used during pregnancy. A large amount of information from pregnant women vaccinated with COMIRNATY DILUTE TO USE PAEDIATRIC 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 DILUTE TO USE PAEDIATRIC VACCINE can be given during breastfeeding.

Driving and using machines

Not applicable.

COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE contains sodium

COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE contains less than 1 mmol sodium (0,9 mg) per dose, that is to say essentially 'sodium-free'.

3. How COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE is given

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You or your child will not be expected to administer COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE. It will be given to you by a person who is qualified to do so.

COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE is given after dilution as an injection of 0,2 mL into a muscle of your upper arm.

Your child 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 your child is immunocompromised, he or she may receive a third dose of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE at least 28 days after the second dose.

If you have the impression that the effect of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE on your child is too strong or too weak, tell your doctor or pharmacist.

If your child receives more COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE than he/she should

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

If your child forgets to receive COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE

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

4. Possible side effects

COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE can have side effects.

Not all side effects reported for COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE are included in this leaflet. Should your child's general health worsen or if he/she experiences any untoward effects while taking COMIRNATY DILUTE TO USE PAEDIATRIC 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

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- 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 (hypoesthesia)
- 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 your child gets 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:

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<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE.

5. How to store COMIRNATY DILUTE TO USE PAEDIATRIC 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.

- Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.
- Store in freezer at -90 °C to -60 °C.
- Store in the original package in order to protect from light.
- The vaccine may be received frozen at -90 °C to -60 °. 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 4 hours or individual vials can be thawed 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 dilution, 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).

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6. Contents of the pack and other information

What COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE contains

- The active substance is COVID-19 mRNA vaccine called tozinameran. After dilution, the vial contains 10 doses of 0,2 mL with 10 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, water for injections

What COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE PAEDIATRIC looks like and contents of the pack

The vaccine is a white to off-white dispersion (pH: 6,9 – 7,9) provided in a multidose vial of 10 doses in a 2 mL clear vial (type I glass), with a rubber stopper and an orange 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

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29 December 2023.

Registration number

57/30.2/0022.

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



URL: www.COMIRNATY DILUTE TO USE PAEDIATRIC 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 DILUTE TO USE PAEDIATRIC VACCINE PAEDIATRIC intramuscularly after dilution as a course of 2 doses (0,2 mL each) 3 weeks apart.

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

Traceability

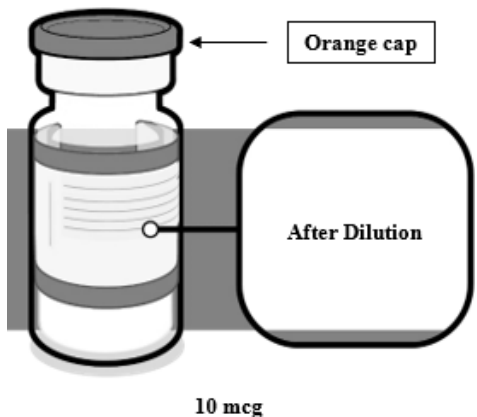
In order to improve the traceability of biological medicines, the name and the batch number of the administered medicine should be clearly recorded.

Handling instructions

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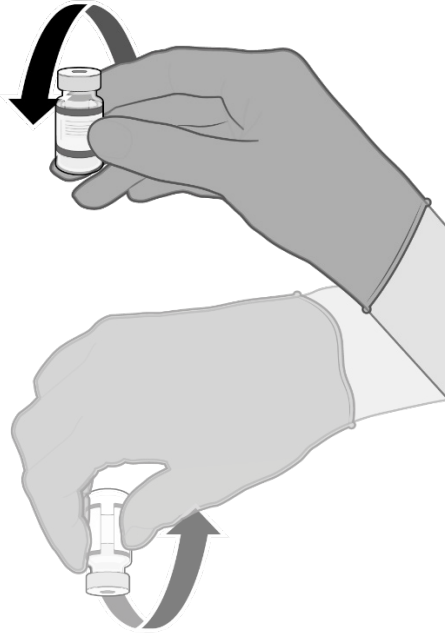
COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE PAEDIATRIC should be prepared by a health care provider using aseptic technique to ensure the sterility of the prepared dispersion.

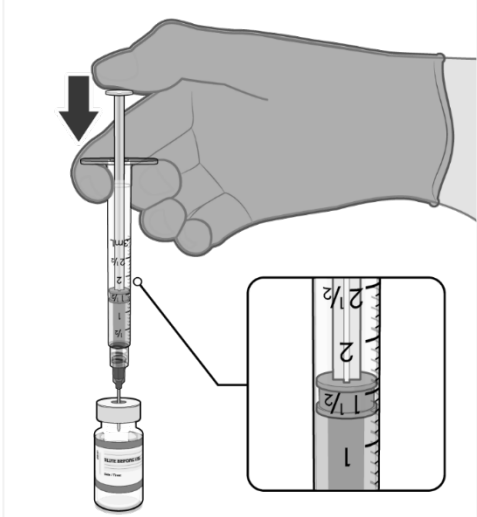
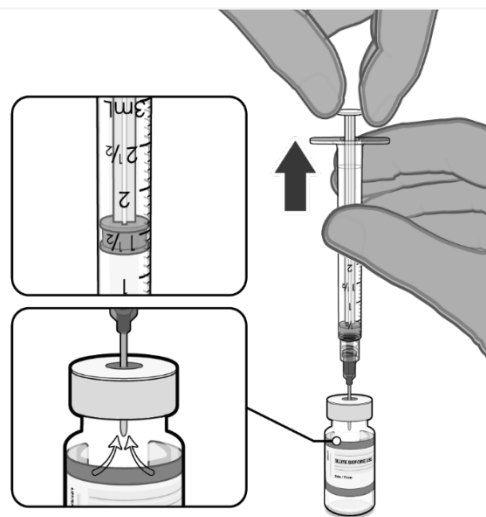
VIAL VERIFICATION OF COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE PAEDIATRIC 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (CHILDREN 5 TO 11 YEARS)	
 <p>The diagram illustrates the components for vial verification. On the left is a vial with a white body and a grey band, topped with an orange cap. An arrow points from the text 'Orange cap' to the cap. Below the vial is the label '10 mcg'. To the right of the vial is a rounded rectangular container labeled 'After Dilution'.</p>	<ul style="list-style-type: none"> • Verify that the vial has an orange plastic cap. • 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 a grey plastic cap, please make reference to the professional information for COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE ADULT 30 micrograms/dose dispersion for injection.
HANDLING PRIOR TO USE OF COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE PAEDIATRIC 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (CHILDREN 5 TO 11 YEARS)	
	<ul style="list-style-type: none"> • 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 4 hours to thaw. Ensure vials are

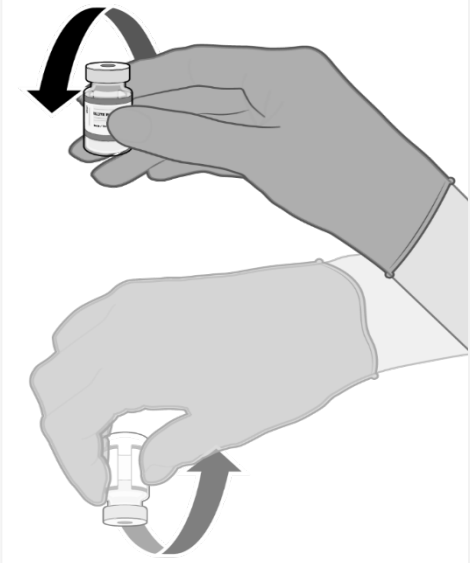

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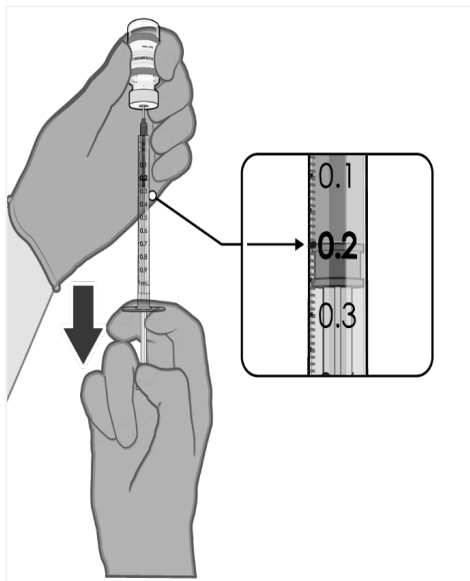
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 <p>Store for up to 10 weeks at 2 °C to 8 °C</p>	<p>completely thawed prior to use.</p> <ul style="list-style-type: none">• Upon moving vials to 2 °C to 8 °C storage, update the expiry date on the carton.• Unopened vials can be stored for up to 10 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.
<p>MIXING PRIOR TO DILUTION OF COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE PAEDIATRIC 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (CHILDREN 5 TO 11 YEARS)</p>	

 <p>Gently x 10</p>	<ul style="list-style-type: none">• 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.
<p>DILUTION OF COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE PAEDIATRIC 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (CHILDREN 5 TO 11 YEARS)</p>	
	<ul style="list-style-type: none">• The thawed vaccine must be diluted in its original vial with 1,3 mL sodium chloride 9 mg/mL (0,9 %) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.

 <p>1,3 mL of 0,9 % sodium chloride injection</p>	
 <p>Pull back plunger to 1,3 mL to remove air from vial.</p>	<ul style="list-style-type: none">• Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1,3 mL air into the empty diluent syringe.
	<ul style="list-style-type: none">• Gently invert the diluted dispersion 10 times. Do not shake.

 <p>Gently × 10</p>	<ul style="list-style-type: none">• The diluted vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.
 <p>Record appropriate date and time. Use within 12 hours after dilution.</p>	<ul style="list-style-type: none">• The diluted vials should be marked with the appropriate date and time.• After dilution, store at 2 °C to 30 °C and use within 12 hours.• Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.
<p>PREPARATION OF INDIVIDUAL 0,2 mL DOSES OF COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE PAEDIATRIC 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (CHILDREN 5 TO 11 YEARS)</p>	



0,2 mL diluted vaccine

- After dilution, the vial contains 2,6 mL from which 10 doses of 0,2 mL can be extracted.
- Using aseptic technique, cleanse the vial stopper with a single use antiseptic swab.
- Withdraw 0,2 mL of COMIRNATY DILUTE TO USE PAEDIATRIC VACCINE PAEDIATRIC for children aged 5 to 11 years.

Low dead-volume syringes and/or needles should be used in order to extract 10 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 ten doses from a single vial.

- Each dose must contain 0,2 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0,2 mL, discard the vial and any excess volume.
- Discard any unused vaccine within 12 hours after dilution.

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Disposal

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