



TO: DDG: Chief of Operations

Chief Directors: MHS, RHS, STRATEGY

Directors: EMS, FPS, SPC, HIA, Clinical Service Improvement, Medicine Management, Substructures, Districts

Head of Institutions

Director: City Health

Circular/2023

VACCINATION OF CHILDREN 5 -11 YEARS OLD AT RISK OF SEVERE COVID DISEASE

Children 5-11 years old at risk of severe COVID disease have become eligible to receive two doses of the Comirnaty paediatric vaccine®. COVID-19 vaccination for children will be introduced in a phased approach, starting with implementation at selected central, district and regional hospitals followed by expansion to include primary care facilities.

COVID-19 vaccination for children 5 to 11 years will not initially be available in the private sector. Eligible children within the private sector will be able to access vaccination in the public sector.

Eligibility:

Children with chronic heart, respiratory, neurological, kidney, liver, or gastrointestinal conditions, as well as immunosuppression and serious genetic abnormalities that affect a number of systems will be eligible and should be offered vaccination by their healthcare provider (a full list is provided in Annexure A).

Referrals:

A referral letter from a doctor is required for all children 5 -11 years presenting for COVID-19 vaccination. It should contain the patient's details, eligibility criteria and the doctor's practice details. Annexure C may be used as the referral form. The parent/caregiver must present the referral letter or form to the vaccinator.

Depending on capacity at phase 1 and 2 sites, vaccines might only be offered on certain days of the week or on an appointment basis. To avoid unnecessary traveling costs incurred by clients, it is recommended that referring facilities liaise with facilities offering the service regarding vaccine availability and appropriate scheduling of clients.

Consent:

Parent/guardian/caregiver's consent must be recorded on a paper consent form (Annexure B) and this must be filed with the child's health record. Consent will also be captured on EVDS.

Registration on EVDS:

Registration: The parent/guardian/caregiver/healthcare worker must register the child on the registration portal: <https://vaccine.enroll.health.gov.za/#/>

Requirements:

- Child must have a birth certificate.
- Parent/guardian/caregiver must be registered as well.

A new version of EVDS was released to accommodate the introduction of the Comirnaty® paediatric vaccination schedule for at risk children aged 5-11 years old. The system and processes are very similar to how vaccinations were registered and captured previously on EVDS with some minor changes, namely:

- A manual consent form is required (Annexure B)
- Registration of both child and parent/guardian/caregiver is required.
- Child must be linked to the parent/guardian/caregiver on EVDS.

COVID-19 vaccination providers must document vaccine administration in the Electronic Vaccination Data System (EVDS) or on a paper form at the time of administration. If a paper form is used, use the form specific to 5 -11 years old (Annexure D) and back-capture the record into EVDS within 24 hours.

Phased roll-out approach:

COVID-19 vaccination for children will be introduced in a phased approach, starting with implementation at selected central, district and regional hospitals followed by expansion to include primary care facilities. Implementation will take place based on facility readiness, with the following facilities included in phase 1 and 2:

Phase 1: Tygerberg Hospital, Red Cross Children's War Memorial Hospital, TC Newman CDC (on behalf of Paarl Hospital), George Hospital and Worcester Hospital.

Phase 2: Groote Schuur Hospital, New Somerset Hospital, Victoria Hospital, Khayelitsha District Hospital, Mitchells Plain District Hospital, Karl Bremer Hospital and Helderberg Hospital.

Other hospitals and PHC facilities will follow in phase 3 and 4. Further communication to guide this expansion of the services will be issued in due course.

Allocation:

The Western Cape has been allocated an initial tranche of 760 vials (7600 doses) of the Comirnaty® paediatric vaccine. The table below outlines the allocation of the vaccines to the phase 1 and 2 sites as well as the contact persons at the sites:

Phase 1			
Implementation date: June/July 2023			
Hospital	Number of vials allocated	Contact Person	Contact details
Red Cross Children's War Memorial Hospital	153	Mitzi Franken & Christal Bastian	Mitzi.franken@westerncape.gov.za Christal.bastian@westerncape.gov.za
Tygerberg Hospital	178	Granville Marinus Lisa Frigati	Granville.marinus@westerncape.gov.za frigati@sun.ac.za
TC Newman CDC (On behalf of Paarl hospital)	80	Ashton Joseph	Ashton.Joseph@westerncape.gov.za
George Hospital	90	Cynthia Korthom	Cynthia.Korthom@westerncape.gov.za
Worcester Hospital	80	Dr Samantha Camp	Samantha.Camp@westerncape.gov.za
Phase 2			
Implementation date: July/August 2023			
Hospital	Number of vials allocated	Contact Person (To be confirmed)	Contact details
Groote Schuur Hospital	25	Bernadette Eick	Bernadette.eick@westerncape.gov.za
New Somerset Hospital	25	Ebrahim Kriel Deidre Poole	Ebrahim.kriel@westerncape.gov.za Deidre.poole@westerncape.gov.za
Victoria Hospital	25	Ebrahim Kriel Deidre Poole	Ebrahim.kriel@westerncape.gov.za Deidre.poole@westerncape.gov.za
Khayelitsha District Hospital	29	Neshaan Peton	Neshaan.peton@westerncape.gov.za
Mitchells Plain District Hospital	25	Nomtha Bell-Mandla	Nomtha.bell-mandla@westerncape.gov.za
Karl Bremer Hospital	25	Delray Fourie	Delaray.fourie@westerncape.gov.za
Helderberg Hospital	25	Neshaan Peton	Neshaan.peton@westerncape.gov.za

Ordering process:

- All sites storing the vaccines require a Section 22A (15) permit.
- A person responsible for the vaccine ordering is to be identified at the various facilities. The contact details of the person responsible for the ordering of the vaccines is to be forwarded to: Melanie.Holtman@westerncape.gov.za
- Facilities are to place their Comirnaty® paediatric vaccine orders through the Service Priorities Coordination (SPC) Directorate, orders to be sent to Melanie.Holtman@westerncape.gov.za.
- Facilities can place their orders according to their needs
- Melanie Holtman will liaise with and send these orders to the CMD.
- The CMD will capture the orders received from SPC for distribution to the different facilities on their scheduled delivery day.
- Ordering of vaccination cards should be done through the Western Cape Health Warehouse.

Training:

- All vaccinators providing the paediatric vaccine to children need to attend specific online training provided by the People Development Centre (PDC). Previous COVID-19 vaccinator training did not cover vaccination of children 5-11 years old and therefore does not confer competency.
- Access to this course will only be permitted to staff working at facilities offering the paediatric vaccination, in keeping with the phased rollout approach.
- The training course takes 3-5 hours to complete and does not have to be completed in one sitting.
- To access this training course, a staff member needs to create an account on the WCGH People Development Centre, Online School at <https://ktu.traintrack.co.za/auth/register/westerncape>. Staff can then apply to enroll onto this course.
- Names of nominated vaccinators should be sent to mica.jackson@westerncape.gov.za and lene.vanstaden@westerncape.gov.za before vaccinators enroll for the course.

Further details on the vaccination of children 5-11 years at risk of severe COVID-19 disease are contained in the **Standard Operating Procedure: COVID-19 vaccination of children 5-11 years June 2023 (Annexure A)** that is in line with National Department of Health policy.

Other annexures provided include:

Annexure B: Consent form (Compulsory, to be kept on file)

Annexure C: Referral letter (Optional, script/other form of referral can be used)

Annexure D: Record of administration of vaccination (For manual capturing of vaccination if it is not recorded directly onto EVDS)

Annexure E: Anaphylaxis guide

Any related queries can be directed to Hilary.Goeiman@westerncape.gov.za/
[Lene.vanstaden@westerncape.gov.za.](mailto:Lene.vanstaden@westerncape.gov.za)

Yours sincerely



CHIEF DIRECTOR: ECSS
JO ARENDSE

DATE: 3 July 2023

STANDARD OPERATING PROCEDURE: COVID-19 VACCINATION OF CHILDREN 5 – 11 YEARS JUNE 2023

Children 5-11 years old at risk of severe COVID disease have become eligible to receive two doses of the Comirnaty paediatric vaccine®. This document provides guidance on administration of COVID-19 vaccination to children 5 – 11 years of age. It is designed to form an annexure to the "COVID-19 Vaccine Implementation Guide and Toolkit".

COVID-19 vaccination for children will be introduced in a phased approach, starting with implementation at selected central, district and regional hospitals followed by expansion to include primary care facilities.

SERVICE DELIVERY PLATFORM

The majority of children who will be eligible for COVID-19 vaccination have long-term health conditions which require them to attend health services on a regular basis. Within the public sector many of these children are managed at hospital level (central, tertiary, regional and district hospitals), although a substantial portion (primarily children with HIV infection) are managed at Primary Health Care facilities. Any facility providing vaccination must be registered as a vaccination site on the Master Facility List (MFL). The facility may be a primary vaccination or outreach site.

COVID-19 vaccination for children 5 to 11 years will not initially be available in the private sector. Eligible children within the private sector will be able to access vaccination in the public sector. Reimbursement mechanisms for COVID-19 vaccinations administered in the private sector are currently being reviewed, and provision of vaccination of children 5 – 11 years old will be included in any future reimbursement processes.

CLINICAL CONSIDERATIONS

Which children are eligible to be vaccinated?

Only children who are at risk of developing severe COVID-19 disease are eligible to be vaccinated. The conditions which place children at risk of developing severe disease are shown the table below, and all children with these conditions should be offered vaccination.

Disease state	Comment
Respiratory disease	Including those with poorly controlled asthma that requires continuous or repeated use of systemic steroids or with previous exacerbations requiring hospital admission, cystic fibrosis, ciliary dyskinesias, bronchopulmonary dysplasia, bronchiectasis, previous tuberculosis
Chronic heart conditions	<p>Haemodynamically significant congenital and acquired heart disease, or less severe heart disease with other comorbidity. This includes:</p> <ul style="list-style-type: none"> • Single ventricle patients or those palliated with a Fontan (Total Cavopulmonary Connection) circulation • Those with chronic cyanosis (oxygen saturations <85% persistently) • Patients with cardiomyopathy requiring medication • Patients with congenital heart disease on medication to improve heart function • Patients with pulmonary hypertension (high blood pressure in the lungs) requiring medication
Chronic conditions of the kidney, liver or digestive system	Including those associated with congenital malformations of the organs, metabolic disorders and neoplasms, and conditions such as severe gastro-oesophageal reflux that may predispose to respiratory infection as well as renal and liver failure.
Chronic neurological conditions	<p>This includes those with:</p> <ul style="list-style-type: none"> • Neuro-disability and/or neuromuscular condition that may occur as a result of conditions such as cerebral palsy, autism, epilepsy and muscular dystrophy • Hereditary and degenerative condition of the nervous system or muscles, other conditions associated with hypoventilation • Severe or profound multiple learning disabilities (PMLD), Down's syndrome, those on the learning disability register <p>Neoplasm of the brain</p>
Endocrine disorders	Including diabetes mellitus, Addison's and hypopituitary syndrome

Immunosuppression	Immunosuppression due to disease or treatment, including: <ul style="list-style-type: none"> • Those undergoing chemotherapy or radiotherapy, solid organ transplant recipients, bone marrow or stem cell transplant recipients • Genetic disorders affecting the immune system (e.g., deficiencies of IRAK-4 or NEMO, complement disorder, SCID) • Those with haematological malignancy, including leukaemia and lymphoma • Those receiving immunosuppressive or immunomodulating biological therapy including transplant patients • Those treated with or likely to be treated with high or moderate dose corticosteroids • Those receiving any dose of non-biological oral immune modulating drugs e.g., methotrexate, azathioprine, 6-mercaptopurine or mycophenolate • Those with auto-immune diseases who may require long term immunosuppressive treatments. • Those living with Human Immunodeficiency Virus infection. • Children who are about to receive planned immunosuppressive therapy should be considered for vaccination prior to commencing therapy
Asplenia or dysfunction on the spleen	Including hereditary spherocytosis, homozygous sickle cell disease and thalassemia major.
Serious genetic abnormalities that affect a number of systems	Including mitochondrial disease and chromosomal abnormalities

A medical doctor will prescribe the Comirnaty® paediatric vaccine to eligible clients. The timing of COVID-19 vaccination should be determined by the attending specialist or subspecialist. This is particularly relevant for immunosuppressed children such as HIV-infected children with severe immune suppression, recently bone marrow transplanted patients or those on highly immune suppressive therapy regimens. In these patients COVID-19 vaccination should be delayed until there is evidence of immunological reconstitution or until such time that immunosuppressive therapy has been reduced to ensure that they respond to vaccination and are able to mount a protective response after receiving the COVID-19 vaccine. If necessary, consult with an ID subspecialist or clinical immunologist for guidance.

A referral letter from a doctor is required for all children 5-11 years presenting for COVID-19 vaccination. It should contain the patient's details, eligibility criteria and the doctor's practice details. Annexure C may be used as the referral form. The parent/caregiver must present the referral letter or form to the vaccinator.

Additional clinical considerations

- Children with a history of myocarditis or pericarditis:
 - If history is prior to COVID-19 vaccination, the child may be vaccinated after the episode of myocarditis or pericarditis has completely resolved.
 - If myocarditis or pericarditis occurred after the first dose of an mRNA vaccine, experts advise no additional doses of any COVID-19 vaccine be administered, including Comirnaty® paediatric vaccine for children 5 through 11 years of age. Administration of the second dose of an mRNA COVID-19 vaccine series can be considered in certain circumstances after the episode of myocarditis or pericarditis has completely resolved.
- Comirnaty® paediatric vaccine may be co-administered with other vaccines without regard to timing, including simultaneous administration.

Contraindications and precautions

The child should be screened for any contraindications and precautions to the vaccines. Contraindications are rare characteristics in vaccinees that increase the risk of a serious adverse reaction if the vaccine is given. In the case of contraindication, do NOT vaccinate. Screen for precautions, which are events or conditions that should be considered in determining if the benefits of the vaccine outweigh the risks. If so, vaccinate with CAUTION.

Contraindications to the vaccine include a history of:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose of this vaccine or to a component of the COVID-19 vaccine
- Known diagnosed allergy to a component of the vaccine.

Precaution of the vaccine include a history of:

- Anaphylaxis after any vaccine other than COVID-19 vaccine or after any injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"])
- Non-severe, immediate (onset less than 4 hours) allergic reaction after a dose of a COVID-19 vaccine of the same type as the Comirnaty®
- An allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the other types of COVID-19 vaccines
- Moderate to severe acute illness, with or without fever
- Multisystem inflammatory syndrome in children (MIS-C)
- Myocarditis or pericarditis after a dose of an mRNA or Novavax COVID-19 vaccine

TRAINING OF VACCINATORS

All vaccinators providing the paediatric vaccine to children need to attend specific online training provided by the People Development Centre (PDC). Previous COVID-19 vaccinator training did not cover vaccination of children 5-11 years old and therefore does not confer competency. Access to this course will only be permitted to staff working at facilities offering the paediatric vaccination, in keeping with the phased rollout approach.

The training course takes 3-5 hours to complete and does not have to be completed in one sitting. To access this training course, a staff member needs to create an account on the WCGH People Development Centre, Online School at <https://ktu.traintrack.co.za/auth/register/westerncape>. Staff can then apply to enroll onto this course.

VACCINE DISTRIBUTION

- The Comirnaty® paediatric vaccine® will be distributed within the current COVID-19 vaccine distribution model, from BIOVAC.
- The vaccine will be distributed to the public sector only, free of charge.
- CMD will place orders with the National Department of Health. Orders will be placed on the Control Tower using NHPVS. Cut-off time is Wednesday at 22h00 for delivery the following week.

The ordered vaccines will be delivered directly to the CMD where they will be stored at the correct temperature.

FACILITY ORDERING PROCESS FOR VACCINES (PHASE 1 AND 2)




- All sites storing the vaccines require a Section 22A (15) permit.
- A person responsible for the vaccine ordering is to be identified at the various facilities.
- The contact details of the person responsible for the ordering of the vaccines is to be forwarded to: Melanie.Holtman@westerncape.gov.za
- Facilities are to place their Comirnaty® paediatric vaccine orders through the Service Priorities Coordination Directorate.
- Orders to be sent to Melanie.Holtman@westerncape.gov.za
- Each multidose vial contains 10 doses of 0.2ml
- Facilities can order single vials according to their need i.e. they do not have to order in multiples of 10 vials (Shippers).
- Melanie Holtman will liaise with and send the orders to the CMD.
- The CMD will capture the orders received from SPC for distribution to the different facilities.
- Distribution takes place as per the normal delivery schedule to sub-structures/sub-districts facilities.
- The cooler boxes are to be returned with the courier on the same day.

ORDERING OF VACCINATION CARDS

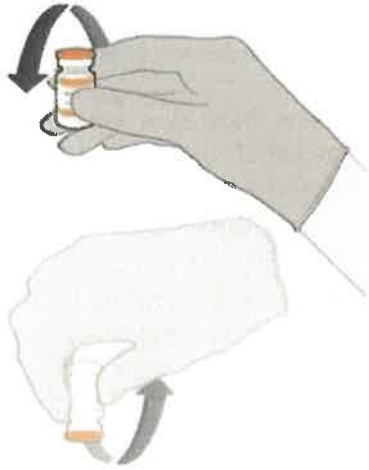
- Ordering of vaccination cards should be done through the Western Cape Health Warehouse.
- Cards are ordered according to the existing processes of either system ordering, or by way of manual log 1 sent to doh.wchw@westerncape.gov.za (ICN 99997044506008).

STEP-WISE GUIDE TO VACCINE ADMINISTRATION

STEP 1. DILUTION AND PREPARATION OF VACCINE

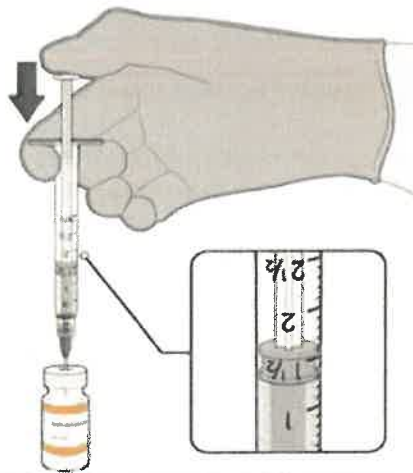
Comirnaty® paediatric vaccine Vial with Orange Cap and Label with Orange Border – VIAL VERIFICATION	
 <p>✓ Orange plastic cap and label with orange border.</p> 	Verify that the vial of Comirnaty® paediatric vaccine has an orange plastic cap and a label with an orange border and states "Children 5y to < 12y."
Comirnaty® paediatric vaccine Vial with Orange Cap and Label with Orange Border – THAWING PRIOR TO DILUTION	
 <p>Store in the refrigerator for up to 10 weeks prior to use.</p>	Thaw vial(s) of Comirnaty® paediatric vaccine before use either by: <ul style="list-style-type: none">• Allowing vial(s) to thaw in the refrigerator [2°C to 8°C].• A carton of 10 vials may take up to 4 hours to thaw, and thawed vials can be stored in the refrigerator for up to 10 weeks.• Allowing vial(s) to sit at room temperature [up to 25°C] for 30 minutes.

Before dilution



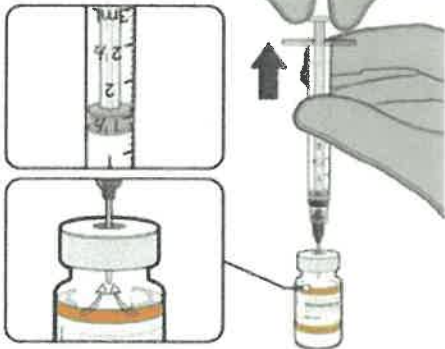
Gently × 10

- Before dilution, mix by inverting vaccine vial gently 10 times.
- Do not shake.
- Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain opaque amorphous particles.
- Do not use if liquid is discolored or if other particles are observed.



Add 1.3 mL of sterile 0.9% sodium chloride injection, USP.

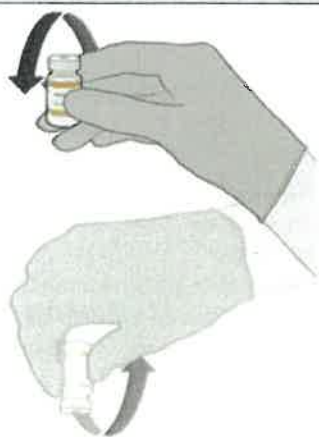
- Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent.
- Using aseptic technique, withdraw 1.3 mL of diluent into a transfer syringe (21-gauge or narrower needle).
- Cleanse the vaccine vial stopper
- Add 1.3 mL of sterile 0.9% Sodium Chloride Injection, USP into the vaccine vial.



Pull back plunger to 1.3 mL to remove air from vial.

- Equalize vial pressure before removing the needle from the vial by withdrawing 1.3 mL air into the empty diluent syringe

After dilution



Gently × 10

- Gently invert the vial containing the Comirnaty® paediatric vaccine 10 times to mix.
- Do not shake.
- Inspect the vaccine in the vial.
- The vaccine will be a white to off-white suspension. Do not use if vaccine is discolored or contains particulate matter



**Record the date and time of dilution.
Use within 12 hours after dilution.**

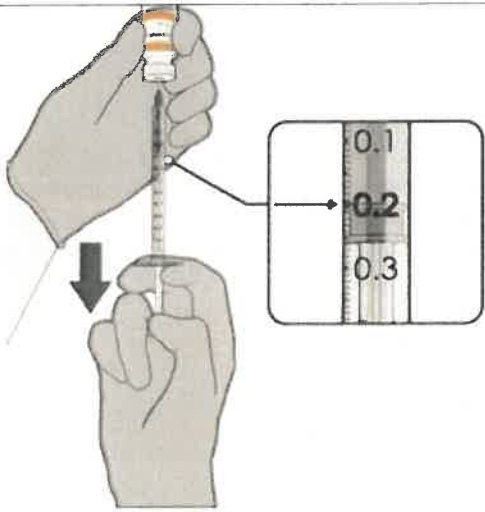
- Record the date and time of dilution on the vial label.
- Store between 2°C to 8°C
- Discard any unused vaccine 12 hours after dilution, or at the end of the immunisation session whichever occurs first

STEP 2: PREPARATION FOR VACCINATION

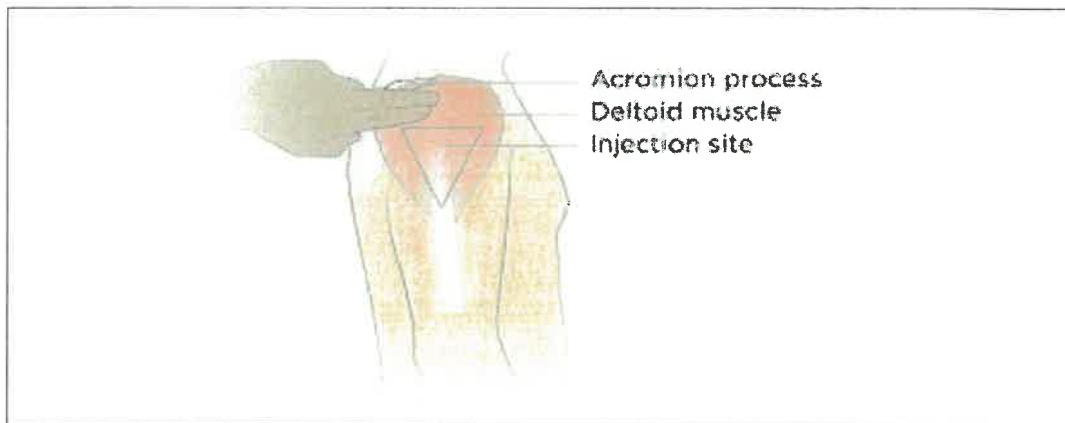
- Confirm that the child 5 through 11 years of age is eligible to be vaccinated (see above).
- Register the child on the EVDS (see details below) **or** on a paper form (see Annexure D).
- Consent should be recorded on a consent form (Annexure B) and should be stored in the child's medical records at the facility.
- Ensure that an emergency trolley is available (See Annexure E for more details).

STEP 3: ADMINISTER THE VACCINE

- Ensure that the vaccine vial has been correctly prepared and stored.
- Draw up the correct dose (Primary Series: 0.2 mL of the monovalent vaccine, 2 doses 21 days apart).

Comirnaty® paediatric vaccine Vial with Orange Cap and Label with Orange Border -WITHDRAWAL OF INDIVIDUAL 0.2 mL DOSES	
 <p>Withdraw 0.2 mL dose of vaccine.</p>	<ul style="list-style-type: none">• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.2 mL of the Comirnaty® paediatric vaccine preferentially using a low dead-volume syringe and/or needle.• 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.• Administer immediately

- Administer the vaccine.
 - Administer Comirnaty® paediatric vaccine by intramuscular (IM) injection)
 - The deltoid muscle is the preferred injection site. The Vastus lateralis muscle in the anterolateral thigh can also be used.
 - Needle gauge and length: Use a 22-25 gauge, 1 inch



STEP 4: RECORD THE VACCINATION

COVID-19 vaccination providers must document vaccine administration in the Electronic Vaccination Data System (EVDS) or on a paper form at the time of administration. If a paper form is used, use the form specific to 5-11 yr olds (Annexure D) and back capture the record into EVDS within 24 hours.

A new version of EVDS was released to accommodate the introduction of the paediatric Cominarty vaccination schedule for at risk children aged 5-11 years old. The system and processes are very similar to how vaccinations were registered and captured previously on EVDS with some minor changes, namely:

- A manual consent form is required (Annexure B)
- Registration of both child and parent/guardian/caregiver is required.
- Child must be linked to the parent/guardian/caregiver on EVDS.
- The **schedule** for 5-11 year olds offers 2 paediatric Cominarty (Pfizer) doses 21 days apart.
 - A child who is vaccinated after turning 12 years old should receive the normal Cominarty dose – NOT the paediatric dose, even if they registered at age 11 years.
 - If they have received 1st paediatric Cominarty dose and subsequently turn 12, they will still be eligible for the 2nd paediatric Cominarty dose.

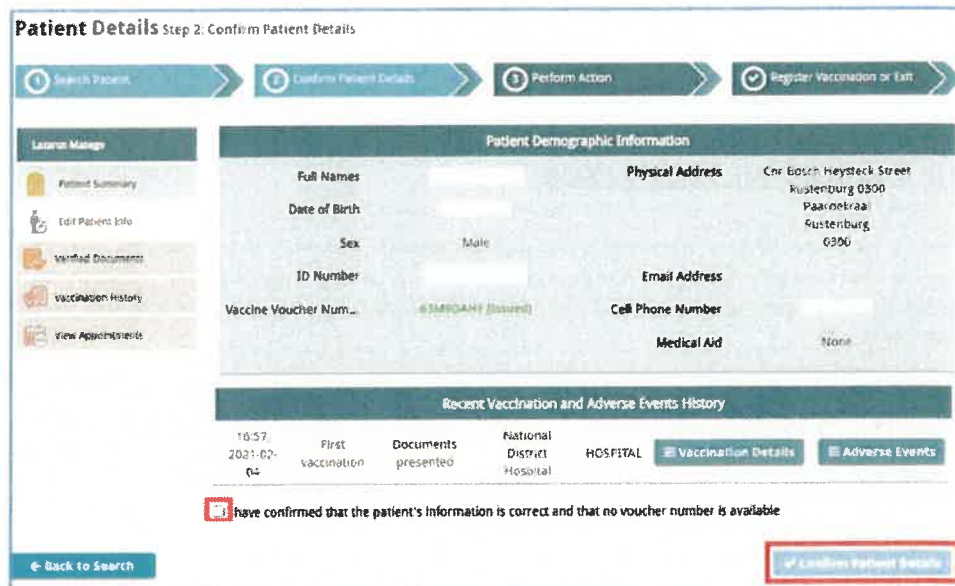
Registration: The parent/guardian/caregiver must register the child on the registration portal: <https://vaccine.enroll.health.gov.za/#/>

Requirements:

- Child must have a birth certificate.
 - Parent/guardian/caregiver must be registered as well.
- Parent/guardian/caregiver's consent must be recorded on a paper consent form (Annexure B) and this must be filed with the child's health record.
 - Proof of identity:
 - **Child: A birth certificate must be presented.**
 - Adult: An identity document must be provided by the accompanying adult (parent/guardian/caregiver). This may be a South African ID number, a foreign passport number, a Section 22 (asylum seeker) permit number, a Section 24 (legal refugee) permit number or a refugee identification number.

Recording the vaccination on the EVDS

- Both the parent/guardian/caregivers' and the child's details, including identity numbers, must be recorded on the EVDS. EVDS will link the child and the adult.
- Search for the child on the EVDS.
- Search for the caregiver/guardian of the child by using the identity document number presented by the accompanying adult.
- Confirm both individuals' details, click on the record to continue and confirm that the information presented is correct. Edit the information if it is not correct.



Patient Details Step 2: Confirm Patient Details

1 Search Patient → 2 Confirm Patient Details → 3 Perform Action → 4 Register Vaccination or Exit

Lazarus Menu

- Patient Summary
- Edit Patient Info
- Verified Documents
- Vaccination History
- View Appointments

Patient Demographic Information

Full Names	Physical Address	Cnr Bosh Heystek Street Rustenburg 0300 Paansekraai Rustenburg 0300
Date of Birth		
Sex	Male	
ID Number	Email Address	
Vaccine Voucher Num...	Cell Phone Number	
STIMQAHY (Issued)	Medical Aid	None

Recent Vaccination and Adverse Events History

16-57	2021-02-02	First vaccination	Documents presented	National District Hospital	HOSPITAL	Vaccination Details	Adverse Events
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I have confirmed that the patient's information is correct and that no voucher number is available

← Back to Search Confirm Patient Details

- Identity documents:
 - Select *Verified documents* on the left to add an identity document. Ensure that the child and adult's documents are be listed here.
 - Add a new identity document by clicking on *Add* and select the type of document from the list provided. Enter the identification number printed on the document.
- Select the **Patient Summary** to confirm vaccine eligibility
- Click on the *Register Vaccination* button at the bottom
- EVDS will initiate the registration process and you will now capture the patient's health background, consent and vaccine information.
- Complete the EVDS health background screen.

Vaccination Registration Step 4: Register or Exit

1 Search Patient → 2 Confirm Patient Details → 3 Perform Action → 4 Register or Exit → Registration Complete

Patient: Madikizela Arnes

Back capture? Date of vaccination* 2021-03-19 Time of vaccination* 14:37

Obtain Health Background

Record Informed Consent

Register Vaccination

← Back to Patient Summary X Cancel Register Vaccination

- Complete the EVDS consent screen using the information on the paper consent form.

Record Informed Consent

Please select the administered vaccine *

Paediatric Comirnaty

The COVID-19 vaccination will reduce the chance of those who receive the vaccine suffering from COVID-19 disease. Like all medicines, no vaccine is completely effective. It takes a few weeks for your body to build protection after vaccination. Although some people may still get COVID-19 after receiving the vaccine, vaccination should lessen the severity of COVID-19 infection. The vaccine cannot give you COVID-19 infection. The COMIRNATY™ vaccine primary schedule requires two doses.

Like all medicines, vaccines can cause side effects. Most of these are mild and should resolve within 2-3 days, and not everyone gets them.

This vaccine, (Comirnaty DTU paediatric vaccine), has been authorised for use by the South African Health Products Regulatory Authority (SAHPRA). It may be used for the active immunisation of individuals who are 5 years or older for the prevention of coronavirus disease 2019 (COVID-19).

Stanley Mkhutidisi has read and explained the above to the child's parent or caregiver.

Obtain patient consent:

I, Rachel Mathipa, confirm that I

Understand that the majority of adverse reactions are mild to moderate in severity and usually resolve within a few days of vaccination. Adverse reactions could include, but are not limited to: injection site pain or swelling, fatigue, headache, myalgia and chills, arthralgia and pyrexia.

Very rare cases of myocarditis and pericarditis have been observed following vaccination. These cases have primarily occurred within 14 days following vaccination, more often after the second vaccination, and more often in younger men.

To identify possible myocarditis or pericarditis those vaccinated should seek immediate medical attention if they develop symptoms such as (acute or persisting) chest pain, shortness of breath, or palpitations following vaccination. Healthcare professionals should follow the EML Standard Treatment Guidelines to diagnose and treat myocarditis and pericarditis if they occur.

I confirm that I have been fully informed and my questions have been answered by Stanley Mkhutidisi

2. Have been informed that

- The quality, effectiveness and safety of this vaccine has been verified by the South African Health Products Regulatory Authority (SAHPRA); and that
- Appropriate measures will be taken to prevent, monitor and manage the unwanted effects of the vaccine.

Has consent been given for Eligible Vaccine to be vaccinated?

No Yes

- Register the vaccination **AFTER** you have administered the vaccine
- Check that all items are complete and select **Paediatric Comirnaty**.
- Enter the vaccine batch number, serial number (if available) and vaccine expiry date.
- Click on the *Register Vaccination* button at the bottom right.

Patient: Syncope Malunga

Back capture? Date of vaccination* 2021-05-06 Time of vaccination* 16:03

Obtain Health Background

Record Informed Consent

Register Vaccination

Please ensure that you administer the vaccine to the patient before completing the information in the next section.

I confirm that the vaccine has been administered to the patient.*

Which document did the patient present to verify his/her identity?*

FSA ID Below: 5084065272087
 Affidavit to Verify South African ID Number
 Affidavit to Verify Foreign Passport Number

If you cannot find the document:

Select a reason for Vaccination*

Vaccination 1st date

Select vaccine manufacturer*

Pfizer

Select vaccine batch number*

Select vaccine batch number

Vaccine serial number

Vaccine expiry date Vaccine manufacturing date

- The child or caregiver should also be provided with a vaccination record card, which includes the following information: date of vaccination, product name/manufacturer, lot number, and name and location of the administering clinic and healthcare professional. The vaccinator must sign the vaccination record card.

STEP 5: OBSERVE THE CHILD FOLLOWING VACCINATION

- Procedures for observation are outlined in Chapter 7 of the COVID-19 Vaccine Implementation Guide and Toolkit
- Vaccination providers should observe patients after vaccination to monitor for allergic reactions and syncope:
 - 30 minutes for persons with:
 - An allergy-related contraindication to a different type of COVID-19 vaccine
 - A history of non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of COVID-19 vaccine
 - A history of anaphylaxis after non-COVID-19 vaccines or injectable therapies
 - 15 minutes: All other persons
- Syncope may occur in association with injectable vaccines, in particular among adolescents. Procedures should be in place to avoid falling injuries and manage syncopal reactions.

- Have a written protocol to manage medical emergencies following vaccination. Recommendations, including equipment and medications can be found in Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination
- Healthcare personnel who are trained and qualified to recognize the signs and symptoms of anaphylaxis as well as administer intramuscular epinephrine should be available at the vaccination location at all times.

STEP 6: MANAGE AND REPORT ADVERSE EVENTS

Adverse events following immunisation should be managed and reported as outlined in the "COVID-19 Vaccine Implementation Guide and Toolkit" (Chapter 8: Vaccine Safety Surveillance).

Adverse events following immunisation can be recorded on:

- MedSafety app
- National Health Hotline (0800 299 999)
- At any health facility or the appropriate sub-district or district within 24 hours of presentation to the health facility.
- To the provincial office (Communicable Disease Control- EPI) office to: charelene.lawrence@westerncape.gov.za / Felencia.daniels@westerncape.gov.za

An EPID number will be issued and an AEFI Case Reporting Form (CRF) and/or Case Investigation Form (CIF) will need to be completed.

Which adverse events should be recorded?

- Vaccine administration errors (whether associated with an adverse event [AE] or not).
- Serious AEs (irrespective of attribution to vaccination).
- Multisystem inflammatory syndrome (MIS) in adults or children - Adverse event of special interest
- Cases of myocarditis (for mRNA vaccines) – Adverse event of special interest
- Cases of pericarditis (for mRNA vaccines) – Adverse event of special interest
- Cases of COVID-19 that result in hospitalization or death.
- Any additional adverse events following immunisation of concern.
- Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event.

See **Provincial Circular H72/2022** for more information on reporting of AEFIs.



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

COMIRNATY® PAEDIATRIC VACCINE: CHILDREN 5 – 11 YEARS CONSENT FORM

COVID-19 vaccination has been recommended for your child by a clinician. COVID-19 vaccination will reduce your child's chance of suffering from COVID-19 disease. The vaccine, COMIRNATY®, COVID-19 mRNA paediatric vaccine, has been authorised for use by the South African Health Products Regulatory Authority (SAHPRA) for the active immunisation of individuals 5 to 11 years of age for the prevention of COVID-19. The COMIRNATY® paediatric vaccine schedule requires two doses given at least 21 days (three weeks) apart.

Like all medicines, no vaccine is completely effective. It takes a few weeks for your child's body to build protection after vaccination. Although your child may still get COVID-19 after receiving the vaccine, vaccination should lessen the severity of COVID-19 infection. The vaccine cannot give your child COVID-19 infection. Like all medicines, vaccines can cause side effects. Not everyone gets side effects, and most side effects are mild and should resolve within 2-3 days. Side effects can include, but are not limited to: injection site pain, fatigue, headache, myalgia and chills, arthralgia, pyrexia, and injection site swelling.

Cases of myocarditis and pericarditis have very rarely been observed following vaccination. These cases have primarily occurred within 14 days following vaccination, more often after the second vaccination, and more often in younger men. Please bring your child to a health facility if they develop symptoms such as (acute or persisting) chest pain, shortness of breath, or palpitations following vaccination.

PLEASE FILL IN THE SECTION BELOW

I, _____ parent/caregiver of _____
Parent/guardian/caregivers' name and surname Child's name and surname

Child's date of birth: _____ Age: _____

Please tick in the appropriate box (Tick only one box)

I AGREE that my child should receive the COVID-19 paediatric vaccine (Comirnaty® vaccine) and that the vaccine administration is recorded on the Electronic Vaccination Data System (EVDS).

I DO NOT AGREE for my child to receive the COVID-19 paediatric vaccine (Comirnaty® vaccine).

Signature: _____ Date: _____ Cell no: _____

REFERRAL LETTER**COVID-19 VACCINATION: REQUEST FOR ADMINISTRATION OF PAEDIATRIC DOSE (5-11 years old)****DETAILS OF VACCINEE**

Name	
Date of birth	
ID number	
Address	
Mobile number of parent/guardian	

I, (insert name of referring doctor), confirm that this individual is eligible to receive the Comirnaty® paediatric dose based on the eligibility criteria shown below.

INDIVIDUALS WITH THE FOLLOWING CONDITIONS	
Respiratory disease	
Chronic conditions of the kidney, liver or digestive system	
Endocrine disorders	
Asplenia/spleen dysfunction	
Chronic heart conditions	
Chronic neurological disease	
Immunosuppression	
Multi-system genetic conditions	
Other (specify):	

DATE THAT VACCINES SHOULD BE ADMINISTERED

FIRST DOSE	SECOND DOSE

DETAILS OF REQUESTING DOCTOR:

Full name	
HPCSA or practice number	
Institution of practice	
Contact number	
Date	
Signature	



health

Department: Health REPUBLIC OF SOUTH AFRICA

COVID-19 VACCINATION PAPER-BASED RECORD OF ADMINISTRATION OF PAEDIATRIC DOSE (5-11 years old)

DETAILS OF VACCINEE (CHILD)

All personal particulars like names, surname, date of birth should be official particulars that appear on the child's birth certificate.

Form for child details including fields for First Name/s, Surname, Date of birth, Gender, ID number, Address, Medical Aid Scheme, and Medical Aid Number.

DETAILS OF PARENT/GUARDIAN

All personal particulars like names, surname, date of birth should be official particulars that appear on the persons ID or passport

Form for parent/guardian details including fields for First Name/s, Surname, Date of birth, Gender, ID number, Relationship to child, Address, Mobile number, and Email.

DETAILS OF VACCINATION SITE

To be completed by the Vaccinator

Form for vaccination site details including fields for Vaccination site UID, Vaccination site name, and District.



PRE-VACCINATION QUESTIONS

To be completed by the Vaccinator

Is the child sick today?	Yes		No	
Has the child received any other COVID-19 vaccine at any time?	Yes		No	
- If yes, which vaccine?				
- Date of administration				
Has the child ever had an anaphylactic reaction or other severe symptoms after receiving another vaccination or injection (a shot given intravenously, intramuscularly, or subcutaneously)? If Yes, please describe the symptoms	Yes		No	
Does the child have a history of an anaphylactic reaction to anything other than a vaccine or injectable medication? If Yes, please describe the reaction from the symptom list below:	Yes		No	
- Trouble breathing	Yes		No	
- Broke out in hives	Yes		No	
- Facial or tongue swelling	Yes		No	
- Low blood pressure	Yes		No	
Does the child have any chronic conditions?	Yes		No	

VACCINE INFORMATION

To be completed by the Vaccinator

Vaccine name																
Vaccine manufacturer																
Batch no:																
Expiry date	Y	Y	Y	Y	M	M	D	D								
Dose (tick one)	First dose				Second dose				Other dose							

ADVERSE EVENTS FOLLOWING IMMUNISATION

To be completed by the Vaccinator

Did any adverse event occur?	No		Yes											
If yes, was it recorded on the AEFI system?	No		Yes											

VACCINATOR DETAILS

To be completed by the Vaccinator

First Name/s															
Surname															
ID number															
Job Title															
Professional body	SANC				HPSCA										
Registration no:															
Mobile number															
Signature															
Date:	Y	Y	Y	Y	M	M	D	D							

COVID-19 vaccination:

Children 5-11 years old Anaphylaxis guide for vaccination units



Western Cape Government
FOR YOU



Any medicine carries a very small risk of anaphylaxis (a severe and often sudden allergic reaction). Anaphylaxis is very rare with vaccines. It is important to clinically tell the difference between minor reactions, like anxiety associated fainting, which are more common, and anaphylaxis, as this can be life threatening.

CHECK THE EMERGENCY KIT AND FOLLOW STANDARD VACCINE PRECAUTIONS

Medications	Equipment
<ul style="list-style-type: none"> Adrenaline (epinephrine) injection (1:1000) solution – 5 ampoules Sodium chloride 0.9% IV fluid (1L) - 2 bags Sodium chloride 0.9% ampoules – 1 ampoule Salbutamol inhaler - 1 inhaler Promethazine injection (25mg/mL) - 2 ampoules Hydrocortisone injection (100mg) -2 vials, + diluent¹ 	<ul style="list-style-type: none"> Syringe 2mL and 22G IM needle – 4 sets Syringe 5mL and 22G IM needle – 2 sets IV catheters (20G + 22G) - 2 sets Burette with rapid giving set – 2 sets Adhesive dressing Bandage Micropore Inhaler spacer Nebuliser chamber and paediatric size face mask Paediatric size oxygen face mask Blood pressure cuffs (child and small adult cuffs) Baumanometer (BP machine) Pulse oximeter

¹Sterile water for injection

- Adverse Events Following Immunisation (AEFI) reporting form: available via NICD website.
- Check location/access to bag-valve-mask (Ambu bag) on nearby emergency trolley.



Give urgent attention and inform a doctor if child has any of:

Skin/mucosa	Respiratory	Cardiovascular	Gastrointestinal
<ul style="list-style-type: none"> Itchiness Skin rash (hives) Swelling of eyes, lips, tongue, face, hands/feet Widespread redness Nasal congestion 	<ul style="list-style-type: none"> Wheeze or cough Throat tightness/stridor Shortness of breath Hoarseness Oxygen saturation < 92% Trouble swallowing or drooling 	<ul style="list-style-type: none"> Systolic BP < 90 Dizziness Collapse Chest pain/palpitations 	<ul style="list-style-type: none"> Nausea Vomiting Diarrhoea Cramps/bloating

Treat as anaphylaxis when signs or symptoms are:

- Generalised (i.e. generalised hives or ≥ 2 body systems involved) or
- Serious or life-threatening, even if only single body system (e.g. shock, any difficulty breathing, or significant swelling of the tongue)

IM adrenaline is safe. When in doubt, treat as anaphylaxis

COVID-19 vaccination:

Children 5-11 years old Anaphylaxis guide for vaccination units



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FOR YOU

Health



Treat suspected anaphylaxis

First
Line
priority

1. Allow child to sit or lie down as they feel most comfortable. Raise legs if possible. Avoid standing/walking. Give 100% face mask **oxygen** at 15L/min.
 - Avoid lying child flat if difficulty breathing.
2. Give immediately **adrenaline** IM into mid-outer thigh (see dosing table).
 - Repeat every 5 minutes if no response.
3. Attach pulse oximeter monitor, if available.
4. Assess for signs of shock (cold hands/feet, weak/fast pulse > 120, capillary refill time (CRT) > 2 seconds or decreased level of consciousness): if present, give **IV fluid bolus** rapidly (see dosing table).
 - Repeat until signs of shock have resolved. Stop if breathing worsens.
5. If wheeze persists, give **salbutamol** 400-600mcg (4-6 puffs) with metered dose inhaler (MDI) and large volume (500mL) spacer. Give each puff separately: press down once and allow 6 deep breaths, then remove inhaler and spacer and wait for 30 seconds before repeating.
 - Repeat every 5-10 minutes if no response.
6. If stridor, encourage carer to keep child calm: give **adrenaline** (1:1000) 1mL in 1mL sodium chloride 0.9% via **nebuliser** (oxygen 8L/minutes) every 15 minutes until stridor disappears.
7. Give **hydrocortisone** IM/slow IV (see dosing table).
8. If generalised itch/rash or face/tongue swelling, give **promethazine** IM/slow IV (see dosing table).

DOSING TABLE

Age	Adrenaline injection 1:1000 1mg/mL	IVI fluid bolus Sodium chloride 0.9% or Ringer's Lactate	Promethazine	Hydrocortisone	Weight
5-6 years	0.2mL	200mL	5mg	100mg	± 20kg
7-8 years	0.3mL	250mL	7mg	125mg	± 25kg
9-10 years	0.3mL	300mL	10mg	150mg	± 30kg
11 years	0.4mL	400mL	15mg	175mg	± 35-40kg

Refer all cases of suspected anaphylaxis:

If delay in referral, take blood, within 2 hours of symptoms onset, to confirm vaccine-related anaphylaxis (tryptase sampling): collect blood in 2x yellow topped tubes (SST) and send with child. If delay > 4 hours, store tubes on ice.

Report

- Report electronically using the Med Safety app or
- Complete a NDoH Case Reporting Form (CRF) for an AESI* if anaphylaxis, or an AEFI** if other allergic reaction, and send to aefi@health.gov.za.
- Report to sub-district/district office and provincial EPI manager within 24 hours.

*AESI - Adverse Event of Special Interest | ** AEFI - Adverse Event Following Immunisation

REPLACE ALL MEDICATIONS/EQUIPMENT USED AND SEAL EMERGENCY KIT.