health
Department:
Health
REPUBLIC OF SOUTH AFRICA

INFORMED CONSENT FORM – COMIRNATY™ (COVID-19 mRNA vaccine)

The COVID-19 vaccination will reduce your chance of 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. You will still need to follow the usual precautions in your workplace or public areas, including wearing a mask. The **COMIRNATY™**vaccine 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™, COVID-19 mRNA vaccine**, has been authorised for use by the South African Health Products Regulatory Authority, in terms of Section 21 of the Medicines and Related Substances Act (Act 101 of 1965) for the active immunisation of individuals ≥12 years old for the prevention of coronavirus disease 2019 (COVID-19)

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

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 be 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

_____ **Vaccinator**

I have also been informed that:

- the quality, effectiveness, and safety of this vaccine have been verified by the South African Health Products Regulatory Authority (SAHPRA).
- appropriate measures will be taken to prevent, monitor, and manage the unwanted effects on me of the Section 21- approved vaccine.

This section to be read by the vaccinator. The vaccinator will then check a box on the EVDS to confirming that he/she has read and explained this section to the vaccinee.

PLEASE ANSWER THE FOLLOWING QUESTIONS:

1. **Are you sick today? Y/N**

   If Yes, please provide details: _____

2. **Have you received any vaccinations in the past two weeks? Y/N**

If Yes, please indicate what vaccine: _____

3. **Have you received any other COVID-19 vaccine at any time? Y/N**

   If Yes, please provide the date of vaccination: _____

4. **Where did you receive the vaccine (e.g which clinic):_____**

5. **Have you been diagnosed with COVID-19 infection in the last 90 days? Y/N**

   If Yes, what date did you test positive: _____

6. **Do you have a history of an anaphylactic reaction to anything other than a vaccine or injectable medication Y/N**

   If Yes, please describe: _____

7. **Have you ever had an anaphylactic reaction:**

Reaction	**Yes**	**No**
Trouble breathing		
Broke out in hives		
Facial or tongue swelling		
Low blood pressure		
Other severe symptoms after receiving another vaccination or injection (a shot was given intravenously, intramuscularly, or subcutaneously)?		

8. **Female vaccine recipients only: Do you suspect that you might be pregnant today? Y/N**
9. **If Yes or unknown, please indicate when you had your last menstrual period. _____**

I understand that I will only be protected after receiving 2 doses of the COMIRNATY™ vaccine, however, if I choose not to receive the 2nd dose I will inform my healthcare professional accordingly.

The vaccinator will ask the vaccinee each of these questions, and record the answers on the EVDS.

Full Names of vaccine recipient: _____

_____

Vaccinator / Admin to conducting informed consent:

_____

Signature of vaccine recipient/ recipient unique ID:

_____

Vaccinator to ask vaccinee for consent to administer the vaccine.

Vaccinee's response will be captured by the vaccinator on the EVDS.

Full Name of the vaccinator: _____

Date: _____