



# health

Department:  
Health  
REPUBLIC OF SOUTH AFRICA

## INFORMED CONSENT FORM:

**Vaccine:** \_\_\_\_\_ **Number of Doses in Schedule:** \_\_\_\_\_

The COVID-19 vaccination will reduce the chance of you suffering from COVID-19 disease. Like all medicines, no vaccine is completely effective and it takes a few weeks for your body to build up protection from the vaccine. Some people may still get COVID-19 despite being vaccinated, but vaccination should lessen the severity of COVID-19 infection.

The vaccine cannot give you COVID-19 infection, and you have to complete the vaccination schedule for this vaccine to reduce your chance of becoming seriously ill. You will still need to follow the guidance in your workplace and public areas, including wearing the correct personal protection equipment and taking part in any screening programmes. Like all medicines, vaccines can cause side effects. Most of these are mild and short-term, and not everyone gets them.

This 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  $\geq 18$  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, these expected side effects have been described.** I confirm that I have been fully informed and all my questions answered.

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 this Section 21- approved vaccine.

**Vaccine recipient:** \_\_\_\_\_

**Please answer the following questions:**

1. Are you sick today? Y/N

2. If Yes, please provide details: \_\_\_\_\_

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

a. If Yes, please indicate what vaccine: \_\_\_\_\_

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

a. If Yes, please clarify Date: \_\_\_\_\_

b. and where (which clinic): \_\_\_\_\_

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

a. 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

a. 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 injectable medication (a shot 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 completing the vaccination schedule for this vaccine, however, if I choose not to receive the 2<sup>nd</sup> dose if required 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: \_\_\_\_\_

**THIS INFORMATION MUST BE CAPTURED ON EVDS**

# Covid-19 vaccine eConsent