health
Department:
Health
REPUBLIC OF SOUTH AFRICA

INFORMED CONSENT FORM – COVID-19 Vaccine Janssen

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 COVID-19 vaccine Janssen requires one dose.

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 [COVID-19 vaccine Janssen, Ad26.COV2. S] has been registered for use by the South African Health Products Regulatory Authority (SAHPRA) in terms of the Medicines and Related Substances Act 101 of 1965, subject to certain conditions. It may be used for the active immunisation of people who are 18 years or older for the prevention of COVID-19.

I understand that the majority of adverse reactions are mild to moderate and usually resolve within a few days of vaccination. These could include vaccination site pain/tenderness, fatigue, headache, myalgia, nausea, and pyrexia/fever.

Very rare cases of thrombosis and thrombocytopenia have been observed. This includes severe cases of venous thrombosis at unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis with thrombocytopenia.

To identify possible thromboembolism and/or thrombocytopenia those vaccinated should be seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg swelling, or persistent abdominal pain following vaccination. Additionally, anyone with neurological symptoms including severe or persistent headaches or blurred vision after vaccination, or who experiences skin bruising (petechia) beyond the site of vaccination after a few days, should seek prompt medical attention**.**

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 has been verified by the SAHPRA and that appropriate measures will be taken to prevent, monitor, and manage any unwanted effects of the vaccine on me.

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

PLEASE ANSWER THE FOLLOWING QUESTIONS:

1. **Are you sick today? Y/N**
2. **If Yes, please provide details: _____**

   _____
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 provide the date of vaccination: _____**

b. **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**

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 injection (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. _____**

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

Full Names of vaccine recipient: _____

Vaccinator 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