PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

CORONAVAC 600 SU (3 µg) suspension for injection

Inactivated SARS-CoV-2 Virus (Vero Cell)

Sugar free and preservative free

Read all of this leaflet carefully before you receive CORONAVAC

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What CORONAVAC is and what it is used for

CORONAVAC is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 to 59 years of age.

2. What you need to know before you receive CORONAVAC

CORONAVAC should not be administered to you

- If you are hypersensitive (allergic) to inactivated SARS-CoV-2 virus or any of the other ingredients of CORONAVAC (listed in section 6).

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- If you had an allergic reaction to the first dose of CORONAVAC.
- If you feel anxious or stressed before receiving the injection.
- If you suffer from acute illness, acute infection with fever.
- If you suffer from a mental illness or disease (such as Guillain-Barré syndrome).
- If you have impaired immune function (such as HIV) or receiving immunosuppressant therapy.
- If you suffer from thrombocytopenia or any coagulation disorder (such as haemophilia) as the intramuscular injection of CORONAVAC may cause bleeding or bruising.

Children and adolescents

You should not receive CORONAVAC if you are under 18 years of age.

Other medicines and CORONAVAC

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

No interaction studies have been performed. Concomitant administration of CORONAVAC with other vaccines has not been studied.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving CORONAVAC.

Safety in pregnancy and breastfeeding has not been established.

Driving and using machines

CORONAVAC has no or negligible influence on the ability to drive and use machines. However, some of the side effects mentioned under possible side effects include dizziness and drowsiness which may temporarily affect your ability to drive or use machines.

3. How to receive CORONAVAC

You will not be expected to give yourself CORONAVAC. It will be given to you by a person who is qualified to do so.

CORONAVAC is for intramuscular use only.

CORONAVAC should be administered by intramuscular injection in the deltoid muscle of the upper arm.

Usual dose for people aged 18 to 59 years:

CORONAVAC is administered as a course of two doses of 0,5 ml each.

Dose 1: at the start date.

Dose 2: 14 to 28 days after first dose.

If the second dose is inadvertently administered earlier than 2 weeks after the first, the dose does not need to be repeated.

If the second dose is inadvertently delayed beyond 4 weeks, it should be given at the earliest possible opportunity.

It is recommended that all vaccinated individuals receive two doses. According to the current recommendation, the same product should be used for both doses.

People living with HIV/AIDS

The efficacy, safety and immunogenicity of the vaccine has only been evaluated in a limited number of individuals living with HIV/AIDS in China and Brazil. The vaccine was safe in these populations, but the efficacy of the vaccine may be lower.

If you receive more CORONAVAC than you should

Since a health care provider will administer CORONAVAC, he/ she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of CORONAVAC

Since a health care provider will administer CORONAVAC, it is unlikely that the dose will be missed.

4. Possible side effects

CORONAVAC can have side effects.

Not all side effects reported for CORONAVAC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving CORONAVAC, please consult your health care provider for advice.

If any of the following happens, stop receiving CORONAVAC and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to CORONAVAC. You may need urgent medical attention or hospitalisation.

The following side effects have been reported in clinical trials of CORONAVAC:

Very common side effects:

- headache
- tiredness
- pain at the site of the injection

Common side effects:

- loss of appetite
- blocked nose
- runny nose
- cough
- sore throat
- nausea
- diarrhoea
- stomach pain
- itching
- muscle pain
- joint pain
- feeling of coldness
- swelling, itching, warmth, reddening of the skin or hardening of the skin at the injection site

Uncommon side effects:

- allergic reaction
- trembling
- dizziness
- drowsiness

- reddening of the face
- vomiting
- abnormal skin and lining of the mouth
- fever
- water retention

Rare side effects:

- eyelid swelling
- eye congestion
- hot flushes
- nosebleed
- constipation
- bloating
- muscle spasms
- reduced ability to smell
- hearing loss
- nausea, vomiting, headache, confusion, drowsiness, unsteady walk, weakness in the arms and legs, numbness, trouble with vision, fever
- sudden weakness in the facial muscles
- brain bleeding
- Guillian Barré syndrome (muscle weakness, tingling in the hands and feet, decreased reflexes in the arms and legs)
- small, raised areas of bleeding underneath the skin
- swelling of the larynx
- purple spotted skin rash, stomach pain, upset stomach, inflammation in the joints, swelling and pain

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions & Quality Problem Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

Alternatively contact Curanto Pharma (Pty) Ltd at +27 12 004 0913 or send an email to regulatory@curantopharma.co.za

By reporting side effects, you can help provide more information on the safety of CORONAVAC.

5. How to store CORONAVAC

Store all medicines out of reach of children.

- Store in a refrigerator (2 - 8 ºC).
- Store in the original package in order to protect from light.
- Do not freeze.
- After first opening, the vaccine should be used immediately.
- Do not use after the expiry date stated on the label / carton.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CORONAVAC contains

- The active substance is: Inactivated SARS-CoV-2 Virus (CZ02 strain)

  Each 2 ml vial or 1 ml pre-filled syringe contains 0,5 ml.

  A single dose of 0,5 ml contains 600 SU (3 µg) of inactivated SARS-CoV-2 virus produced in Vero cells, adsorbed on aluminium hydroxide (0,225 mg).

  Sugar free and preservative free.

- The other ingredients are: aluminium hydroxide, disodium hydrogen phosphate, monosodium dihydrogen phosphate, sodium chloride and water for injection.

What CORONAVAC looks like and contents of the pack

CORONAVAC is an opalescent aqueous suspension (pH: 6,8 – 7,8).

CORONAVAC is presented as follows:

Pre-filled syringe: Single dose 1 ml pre-filled syringe (type I glass barrel) with a rubber plunger stopper, stainless steel needle and plastic tip cap.

Vial: Single dose 2 ml vial (type I glass) with a rubber stopper and aluminium-plastic combination cap.

Pack size: 10 pre-filled syringes or 40 vials per cardboard box.

Holder of Certificate of Registration

Curanto Pharma (Pty) Ltd

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Centurion, 0157

Manufactured by:

Sinovac Life Sciences Co., Ltd.

No. 21, Tianfu Street, Daxing Biomedicine Industrial Base of Zhongguancun Science Park,

Daxing District, Beijing, P.R. China.

Marketed by:

Numolux Group (Pty) Ltd

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Centurion, 0157

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Access to the corresponding Professional Information

To be confirmed.