

PATIENT INFORMATION LEAFLET FOR
SARS-CoV-2 rS Protein (COVID-19) recombinant spike protein Nanoparticle
Vaccine
COVOVAX

SCHEDULING STATUS: S2

COVOVAX (5 micrograms SARS-CoV-2 spike protein Nanoparticle per 0,5 mL dispersion
for injection)
SARS-CoV-2 spike protein
Sugar free

Read all of this leaflet carefully because it contains important information for you

- COVOVAX is available without a doctor's prescription, for you to protect against COVID-19. Nevertheless, you still need to use COVOVAX carefully to get the best results from it.
- You are being offered the COVOVAX to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2.
- This leaflet contains information to help you understand the risks and benefits of the COVOVAX, which you may receive because there is currently a pandemic of COVID-19.
- 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. It is your choice to receive the COVOVAX vaccine.

What is in this leaflet

1. What COVOVAX is and what it is used for
2. What you need to know before you take COVOVAX
3. How to take COVOVAX
4. Possible side effects
5. How to store COVOVAX
6. Contents of the pack and other information.

1. What COVOVAX is and what it is used for

COVOVAX belongs to a class of medicine known as Biological Antigens. The COVOVAX is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older.

2. What you need to know before you take COVOVAX

COVOVAX should not be administered to you:

- if you are hypersensitive (allergic) to SARS-CoV-2 spike protein or any of the other ingredients of COVOVAX (listed in **section 6**).
- if you have fever
- if you have a problem with bleeding or bruising, or if you are taking blood thinning medicines (anticoagulant)
- if you have a problem with liver related disorder and/or inflammation of the gall bladder
- if your immune system does not work properly (immunodeficiency) or you are taking medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants or cancer medicines)

- if you are pregnant or plan to become pregnant
- if you are breastfeeding
- if you have received another COVID-19 vaccine

If you have any of the above conditions, you should consult your healthcare provider/doctor before deciding to take the vaccine.

Warnings and Precautions

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

Special care should be taken with COVOVAX:

- if you experience hypersensitivity (allergic reaction) to any of the ingredients in the COVOVAX such as pain at the injection site and/or tenderness, fatigue, malaise, swelling at injection site, pyrexia, chills, headache, nausea or vomiting.
- if you experience anxiety-related or stress-related reactions to the needle injection. it is important that precautions are in place to avoid injury from fainting.
- if you are currently suffering from an acute infection, the vaccination should be postponed.
- if you have a pre-existing bleeding disorder or are receiving a blood thinning medicine
- if you have a weak immune system or are receiving immunosuppressive medicines
- once you have taken the vaccine you should continue to follow all current guidance to protect yourself against COVID-19 such as wearing a mask, staying at least six feet away from others, avoiding crowds and washing of hands with soap and water or using hand sanitizer.

Children and adolescents

Do not given COVOVAX SARS-CoV-2 rS Protein Nanoparticle Vaccine to children and adolescents less than 12 years as the safety and efficacy has not yet been established.

Other medicines and COVOVAX

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Ask your doctor or healthcare professional for advice before you are given the COVOVAX if you are also taking blood thinning medicines or immunosuppressants.

If possible, vaccination could be scheduled prior to the use of these medications, so that the patients' risk of bleeding is not increased by their therapeutic action.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before you are given COVOVAX.

Driving and using machinery

COVOVAX is not expected to have any effect on your ability to drive and use machines.

It is not always possible to predict to what extent COVOVAX may interfere with the daily activities of a patient. Some of the effects mentioned under possible side effects may temporarily affect your ability to drive and use machines.

3. How to take COVOVAX

Always take COVOVAX exactly as your doctor or pharmacist or nurse have told you. Check with your doctor or pharmacist or nurse if you are not sure.

The COVOVAX will be given to you as an intramuscular (IM) injection only, preferably in the

deltoid muscle.

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

The COVOVAX vaccination course consists of two separate doses of 0.5 mL each.

If you receive one dose of the COVOVAX, then the second dose should be administered between 3 weeks after the first dose.

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

If you miss your second dose

If you forget to go back at the scheduled time, ask your healthcare provider/doctor for advice. It is important that you return for your second dose of COVOVAX.

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

Children:

Not recommended.

4. Possible Side Effects

COVOVAX can have side effects

Not all side effects reported for COVOVAX are included in this leaflet. Should your general health worsen or if you experience any untoward effects following the vaccination, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following symptoms of a severe allergic reaction occurs, tell your doctor immediately or go to the casualty department at your nearest hospital:

Such reactions may include a combination of any of the following symptoms:

- Feeling faint or light-headed
- Pain in a muscle or group of muscles
- Physical discomfort
- Swelling and extreme pain at injection site

After vaccination, you may have more than one side effect at the same time. If any of your symptoms are persistent, please seek advice from your healthcare provider/doctor.

Tell your doctor if you notice any of the following:

Frequent side effects:

- injection site pain
- injection site tenderness
- feeling tired (fatigue)
- malaise
- headache
- fever
- soreness of muscles
- joint pain
- nausea or vomiting
- chills
- injection site redness
- injection site swelling
- injection site induration (hardness)
- bodyache
- pain in legs or arms

Less frequent side effects:

- asthenia (weakness or lack of energy)
- injection site pruritus (itching)
- injection site rash
- back pain
- skin redness
- hives
- enlarged lymph nodes

Side effects with unknown frequency:

- dizziness (feeling dizzy)
- sleepiness

These may not be all the possible side effects of the COVOVAX. Serious and unexpected side effects may occur. If you notice any side effects not mentioned in this leaflet, please inform your healthcare provider/doctor.

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 Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8> or by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free) . By reporting side effects, you can help provide more information on the safety of COVOVAX.

5. How to store COVOVAX

- Store at or between 2 °C to 8°C (in a refrigerator)
- Do not freeze
- Keep vials in outer container to protect from light
- Do not use the vaccine if the contents has been frozen

Opened multidose vial (after the first use)

Once opened (first needle puncture) multi-dose vials should be used as soon as practically possible and within 6 hours when kept between 2 °C - 8°C. All opened (punctured) multidose vials of COVOVAX should be discarded at the end of immunization session or six hours after the first needle puncture, whichever comes first.

6. Contents of the pack and other information

What COVOVAX contains

The active substance is 5 micrograms SARS-CoV-2 spike protein per dose.

The other ingredients are adjuvant Matrix-M1, disodium hydrogen phosphate heptahydrate, polysorbate 80, sodium dihydrogen phosphate monohydrate, sodium chloride, water for injections.

What COVOVAX looks like and contents of the pack

COVOVAX is colourless to slightly yellow, clear to mildly opalescent, free to practically free from visible particles.

COVOVAX is supplied as ready to use liquid in rubber-stoppered (bromobutyl) single and multidose vial in below listed presentations:

0.5 mL single-dose vials or 5 mL multi-dose vials.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

To access corresponding Professional Information, scan the QR Code below.

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