APPROVED FOR RESTRICTED USE IN EMERGENCY SITUATION
OF SARS-CoV-2 rS Protein (COVID-19) Nanoparticle Vaccine

SARS-CoV-2 rS Protein (COVID-19) recombinant spike protein Nanoparticle Vaccine

COVOVAX™

This vaccine has been given restricted use in emergency situation for prevention of COVID-19. It does not have a marketing authorization, however, this approval for the restricted use in emergency situation grants permission for the vaccine to be used for active immunization of individuals aged 7 years and older for the prevention of coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 in individuals 7 years of age and older.

Reporting of side effects

As with any new medicine, this vaccine will be closely monitored to allow quick identification of new safety information. You can help by reporting any side effects, you may get after vaccination to the Serum Institute of India Pvt. Ltd. who is the manufacturer of **COVOVAX™** vaccine on 24 x 7 Toll-Free Number: 1800 1200124 or at **pharmacovigilance@seruminstitute.com.**
For more information read this fact sheet carefully.

You are being offered the Serum Institute of India Pvt. Ltd. (SIIPL) **COVOVAX™** Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the **COVOVAX™** Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The **COVOVAX™** is a vaccine and may prevent you from getting COVID-19 disease.

Read this Fact Sheet for information about the **COVOVAX™** Vaccine. Talk to the healthcare provider / doctor if you have questions. It is your choice to receive the **COVOVAX™** Vaccine.

The **COVOVAX™** vaccination course consists of two separate doses of 0.5 ml each. The second dose should be administered at 3 weeks after the first dose.

For intramuscular (IM) injection only.

The **COVOVAX™** may not protect everyone.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19 ?

COVID-19 disease is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE SIIPL COVOVAX™ VACCINE ?

The **COVOVAX™** vaccine is approved for restricted use in emergency situation that may prevent COVID-19 caused by a coronavirus called SARS-CoV-2 in individuals 7 years of age and older.

WHAT SHOULD YOU MENTION TO YOUR HEALTHCARE PROVIDER / DOCTOR BEFORE YOU GET COVOVAX™ VACCINE ?

Tell the healthcare provider / doctor about all of your medical conditions, including:

- If you have ever had a severe allergic reaction (anaphylaxis) after any drug, food, any vaccine or any ingredients of **COVOVAX™** vaccine
- If you have fever
- If you have a problem with bleeding or bruising, or if you are taking a 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.

Vaccination in patients with bleeding disorders or receiving a blood thinning medicine (anticoagulants):
As with other intramuscular injections, **COVOVAX™** should be given with caution to individuals with a problem with bleeding or bruising, or those taking a blood thinning medicine (anticoagulant) because bleeding or bruising may occur following an intramuscular injection in these individuals.
A fine-gauge needle (23-gauge or smaller caliber) should be used for the vaccination in such individuals, followed by firm pressure on the injection site, without rubbing, for at least 2 minutes. 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.

Patients with weak immune system or receiving immunosuppressive medicines:
Currently there is no data available in individuals with a weakened immune system or who are taking chronic treatment that suppresses or prevents immune responses. People with weakened immune systems due to other illnesses or medications might be at increased risk for severe COVID -19. They may receive **COVOVAX™**. However, people with weakened immune systems should also be aware of the potential for reduced immune responses to **COVOVAX™**, as well as the need to continue following all current guidance to protect themselves against COVID-19 (see below).

WHO SHOULD GET THE COVOVAX™ VACCINE ?

COVOVAX™ Vaccine has been authorized for restricted use in emergency situation in individuals 7 years of age and older caused by SARS-CoV-2.

WHO SHOULD NOT GET THE COVOVAX™ VACCINE ?

You should not get the **COVOVAX™** Vaccine if you have ever had a serious allergic reaction (including anaphylaxis) to:

- a previous dose of **COVOVAX™**
- any ingredient of **COVOVAX™** (listed below)

If you are not sure, talk to your doctor, pharmacist or nurse.

Signs of an allergic reaction may include pain at injection site and/or tenderness, fatigue, malaise, swelling at injection site, pyrexia, chills, headache, nausea or vomiting. Contact your doctor or healthcare professional immediately or go to the nearest hospital emergency room right away if you have an allergic reaction. It might get worsen if not treated immediately.

People with a history of severe allergic reactions not related to vaccines or injectable medications such as food, pets, environmental, or latex allergies may get vaccinated. People with a history of allergies to oral medications or a family history of severe allergic reactions may also get vaccinated.

WHAT ARE THE INGREDIENTS IN THE COVOVAX™ VACCINE ?

The **COVOVAX™** Vaccine includes the following ingredients:
SARS-CoV-2 rS Protein DS
Adjuvant Matrix-M1
Disodium hydrogen phosphate heptahydrate
Sodium dihydrogen phosphate monohydrate
Sodium chloride
Polysorbate 80
Water for injections

HOW IS THE COVOVAX™ GIVEN ?

The **COVOVAX™** Vaccine will be given to you as an intramuscular (IM) injection only, preferably in the deltoid muscle.

The **COVOVAX™** vaccination course consists of two separate doses of 0.5 ml each.
If you receive one dose of the **COVOVAX™** vaccine, then the second dose should be administered at 3 weeks after the first dose.

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™** vaccine.

HAS THE COVOVAX™ VACCINE BEEN USED BEFORE ?

The **COVOVAX™** is used in clinical trials, a large number of participants received two doses in clinical studies.

WHAT ARE THE BENEFITS OF THE COVOVAX™ VACCINE ?

In ongoing clinical trials, the **COVOVAX™** Vaccine has been shown to prevent COVID-19 following 2 doses given between 3 weeks apart. The duration of protection against COVID-19 disease is currently unknown.

Protection against COVID-19 starts from approximately 7 days after the second dose of **COVOVAX™**. Individuals may not be fully protected until 7 days after the second dose is administered. However, please note that as with any vaccine, **COVOVAX™** may not protect everyone who is vaccinated from COVID-19.

WHAT ARE THE RISKS OF THE COVOVAX™ VACCINE ?

Like all medicines, this vaccine can cause side effects, although not everybody gets them.
Get urgent medical attention from your doctor if you get symptoms of a severe allergic reaction. 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.

Side effects that have been reported with the **COVOVAX™** Vaccine include:

Very Common (may affect more than 1 in 10 people)

- Injection site pain
- Injection site tenderness
- Feeling tired (fatigue)
- Malaise
- Headache
- Fever
- Soreness of muscles
- Joint pain
- Nausea or vomiting

Common (may affect up to 1 in 10 people)

- Chills
- Injection site redness
- Injection site swelling
- Injection site induration (hardness)
- Pain in extremity (legs or arms)
- Body ache

Uncommon (may affect up to 1 in 100 people)

- Asthenia (weakness or lack of energy)
- Injection site pruritus (itching)
- Injection site rash
- Rash
- Skin redness
- Itching
- Hives
- Enlarged lymph nodes
- Back pain

Rare (may affect up to 1 in 1000 people)

- Dizziness (feeling dizzy)
- Sleepiness
- Diarrhoea
- Decreased appetite

Adverse reactions were usually mild to moderate in severity with a median duration of less than or equal to 2 days for local injection site reactions and less than or equal to 1 day for systemic reactions following vaccination.

When compared with Dose 1, local and systemic adverse reactions were more frequently reported after Dose 2.
In case you need medical advice, kindly consult your healthcare provider / doctor.

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

If you experience unusually high or prolonged fever, or other symptoms, alternative causes should be considered and contact your healthcare provider / doctor to seek further medical advice.

WHAT SHOULD I DO ABOUT SIDE EFFECTS ?

If you experience a severe allergic reaction, call or go to the nearest hospital.

Call the healthcare provider / doctor if you have any side effects that bother you or do not go away.

In addition, you can report side effects after vaccination to Serum Institute of India Pvt. Ltd. who is the manufacturer of **COVOVAX™** vaccine as below:

- 24x7 Call Center Toll-Free Number **(For Reporting of Adverse Events Only)**: 1800 1200124
- **pharmacovigilance@seruminstitute.com**

WHAT IF I DECIDE NOT TO GET THE COVOVAX™ VACCINE ?

It is your choice to receive or not receive the **COVOVAX™** Vaccine. You may prefer to consult your healthcare provider / doctor.

CAN I RECEIVE THE COVOVAX™ VACCINE WITH OTHER VACCINES ?

There is no information on the use of the **COVOVAX™** Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

You may discuss your options with the healthcare provider / doctor.

WILL THE COVOVAX™ VACCINE GIVE ME COVID-19 INFECTION ?

No. The **COVOVAX™** is spike protein based COVID-19 Vaccine, does not contain SARS-CoV-2 virus and cannot give you COVID-19 infection.

KEEP YOUR VACCINATION CARD

When you get your dose, please discuss with your healthcare provider / doctor regarding the option of your vaccination record on digital platform, if available.

AFTER VACCINATION, DO I NEED TO CONTINUE TAKING PRECAUTIONS TO PREVENT COVID-19 INFECTION ?

People who get vaccinated should continue to follow all current guidance to protect themselves against COVID-19 after they are vaccinated.

That means:

- Wearing a mask
- Staying at least six feet away from others
- Avoiding crowds
- Washing hands with soap and water or using hand sanitizer

HOW CAN I LEARN MORE ?

- Ask the healthcare provider / doctor.
- Contact your local or state public health department.

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