

FACT SHEET FOR VACCINE RECIPIENTS & CAREGIVERS
RESTRICTED USE IN EMERGENCY SITUATION OF COVID-19

GEMCOVAC™-19

IN PREVENTION OF COVID-19 DISEASE
IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

The Gennova Biopharmaceuticals COVID-19 Vaccine (GEMCOVAC™-19) is administered 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 Gennova Biopharmaceuticals COVID-19 Vaccine (GEMCOVAC™-19).

REPORTING OF SIDE EFFECTS

As with any new medicine, this vaccine will be closely monitored to allow quick identification of any new safety information. You can help by reporting any side effects you may get after vaccination to Gennova Biopharmaceuticals Limited, who is the manufacturer of GEMCOVAC™-19 vaccine at Safety@gennova.co.in For more information, please read this Information Sheet carefully.

You are being offered the Gennova Biopharmaceuticals Limited GEMCOVAC™-19 Vaccine to prevent COVID-19 caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the GEMCOVAC™-19 Vaccine, which you may receive. Talk to the healthcare provider / doctor if you have questions.

The GEMCOVAC™-19 is a vaccine and may prevent you from getting COVID-19 disease. GEMCOVAC™-19 may not protect everyone.

The GEMCOVAC™-19 vaccination course consists of two separate doses of 0.5 ml each administered 4-weeks apart.

For intramuscular (IM) injection only.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 is an infectious disease caused by a coronavirus called SARS-CoV-2. You can get COVID-19 by coming in contact with an infected person. It predominantly causes a respiratory illness that can affect other organ systems. People with COVID-19 have reported a wide range of symptoms, ranging from mild 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 or difficulty in breathing; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhoea.

WHAT IS THE GENNOVA BIOPHARMACEUTICAL COVID-19 VACCINE (GEMCOVAC™-19)?

GEMCOVAC™-19 is a mRNA-based vaccine using Spike (S)-protein of the virus as antigen. GEMCOVAC™-19 is approved for restricted use in emergency situation that may prevent COVID-19. The vaccine is available as a lyophilized powder.

WHAT SHOULD YOU MENTION TO YOUR HEALTHCARE PROVIDER / DOCTOR BEFORE YOU GET GEMCOVAC™-19 VACCINE?

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

- If you have ever had a severe allergic reaction (anaphylaxis) after any drug, food, any vaccine or any ingredients of GEMCOVAC™-19 vaccine
- If you have fever
- If you have a problem with bleeding or bruising, or if you are taking a blood thinning medicine (anticoagulant)
- If you are immunocompromised or are on a medicine that affects your immune system
- If you are pregnant or plan to become pregnant
- If you are breastfeeding
- If you have received another COVID-19 vaccine

WHO SHOULD GET GEMCOVAC™-19 VACCINE?

GEMCOVAC™-19 Vaccine has been approved for restricted use in emergency situation in individuals 18 years of age and older.

WHO SHOULD NOT GET GEMCOVAC™-19 VACCINE?

You should not get GEMCOVAC™-19 if you:

- Had a severe allergic reaction to any ingredients of the vaccine
- Had a severe allergic reaction after a previous dose of this vaccine
- Currently have an acute infection or fever

WHAT ARE THE INGREDIENTS IN THE GEMCOVAC™-19?

One dose of 0.5 ml contains the mRNA 10 µg, DOTAP 0.3 mg, Squalene 0.376 mg, Sorbitan Monostearate 0.372 mg, Polysorbate-80 0.372 mg, Citric acid monohydrate 1.05 mg and Sucrose 50 mg.

HOW IS THE GEMCOVAC™-19 GIVEN?

GEMCOVAC™-19 will be given to you as an intramuscular (IM) injection only, preferably in the deltoid muscle.

The GEMCOVAC™-19 vaccination course consists of two separate doses of 0.5 ml each. If you receive one dose of the GEMCOVAC™-19 vaccine, then the second dose should be administered 4 weeks after the first dose.

WHAT IF YOU MISSED YOUR SECOND DOSE?

If you forget to get the second dose at the scheduled time, ask your healthcare provider / doctor for advice. It is important that you return for your second dose of GEMCOVAC™-19 vaccine.

HAS THE GEMCOVAC™-19 VACCINE BEEN USED BEFORE?

The GEMCOVAC™-19 has been used in Phase I, II and III clinical trials, a number of participants received one or two doses in Indian trials. Approximately, 3250 individuals have received 2 doses of GEMCOVAC™-19.

WHAT ARE THE BENEFITS OF THE GEMCOVAC™-19 VACCINE?

In an ongoing Phase-II / III clinical trial, GEMCOVAC™-19 has been shown to generate protective immune responses. GEMCOVAC™-19 generates anti-Spike-IgG and neutralising antibodies. However, it is important to note that GEMCOVAC™-19 may not protect everyone who is vaccinated for COVID-19. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE VACCINE?

Side Effects that have been reported with GEMCOVAC™-19 include:

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

- Injection site pain
- Fever
- Headache

Common (may affect up to 1 in 10 people)

- Redness/Erythema
- Swelling/Induration
- Warmth
- Chills
- Malaise
- Fatigue
- Myalgia
- Arthralgia
- Nausea

Uncommon (may affect up to 1 in 100 people)

- Pruritus
- Bruising
- Vomiting
- Influenza like illness

A severe allergic reaction may very rarely occur after getting a dose of GEMCOVAC™-19. These may not be all the possible side effects of GEMCOVAC™-19. Serious and unexpected side effects may occur.

GEMCOVAC™-19 is still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?

If you experience any side effect(s), please contact / visit your health provider / Vaccinator / Officer supervising your vaccination or immediately go to the nearest hospital. In addition, you can report side effects after vaccination to Gennova Biopharmaceuticals Limited, who is the manufacturer of GEMCOVAC™-19 vaccine at Safety@gennova.co.in

WHAT IF I DECIDE NOT TO GET GEMCOVAC™-19?

It is your choice to receive or not receive GEMCOVAC™-19. Should you decide not to receive the GEMCOVAC™-19, it will not change your standard medical care.

CAN I RECEIVE GEMCOVAC™-19 WITH OTHER VACCINES?

There is no scientific information yet available on the appropriateness of use of GEMCOVAC™-19 along with other vaccines.

WHAT IF I AM PREGNANT?

Safety, efficacy and immunogenicity have not been established in pregnant women and nursing mothers. It is unknown if GEMCOVAC™-19 is excreted in human milk. There is currently insufficient information to inform about the associated risks in pregnancy.

WHAT IF I HAVE ALLERGIES?

Individuals who have a known severe allergy to any component of GEMCOVAC™-19 are NOT advised to be vaccinated. Individuals with a history of allergies to oral medications or a family history of allergic reactions, or who might have a mild allergy to vaccines (but no anaphylaxis) may still get vaccinated.

WHAT IF I AM IMMUNOCOMPROMISED?

It is not known whether individuals with impaired immune responsiveness, including individuals receiving immunosuppressant therapy, will elicit the same response as immunocompetent individuals to the vaccine regimen.

WILL THE GENNOVA BIOPHARMACEUTICAL COVID-19 VACCINE (GEMCOVAC™-19) GIVE ME COVID-19?

No. GEMCOVAC™-19 is an mRNA-based vaccine and doesn't contain SARS-CoV-2. There are no chances of getting COVID-19.

HOW CAN I LEARN MORE?

- Ask the vaccination provider/ doctor.
- Contact your local/ state or central health department.

Manufactured and Marketed by:

Gennova Biopharmaceuticals Limited
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