

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

GEMCOVAC[®]-OM



AS A BOOSTER FOR THE PREVENTION OF
COVID-19 DISEASE IN INDIVIDUALS 18 YEARS OF
AGE AND OLDER WHO HAVE RECEIVED EITHER
COVAXIN[®] OR COVISHIELD[™] AS PRIMARY VACCINATION

Gennova Biopharmaceuticals Limited's COVID-19 Vaccine (GEMCOVAC[®]-OM) 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 GEMCOVAC[®]-OM.

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 observe after vaccination of GEMCOVAC[®]-OM at safety@gennova.co.in or the toll free number 18002090801. For more information, please read this Information Sheet carefully.

You are being offered the Gennova Biopharmaceuticals Limited's GEMCOVAC[®]-OM 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[®]-OM, which you may receive. Talk to the healthcare provider / doctor if you have questions.

GEMCOVAC[®]-OM is an intradermal vaccine and may prevent you from getting COVID-19 disease. However, GEMCOVAC[®]-OM may not protect everyone.

GEMCOVAC[®]-OM vaccination consists of a single dose of 0.1 mL administered intradermal using a Needle-free Tropis[®] Injection system (PharmaJet, Colorado, USA).

This vaccine is for intradermal (ID) 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, vomiting, or diarrhoea.

WHAT IS GEMCOVAC[®]-OM?

GEMCOVAC[®]-OM is a mRNA-based vaccine which uses spike protein of the omicron variant (BA.1) of the SARS-CoV-2 as an antigen. GEMCOVAC[®]-OM is approved for restricted use in emergency situation as a booster in individuals 18 years of age and older who have received either COVAXIN[®] or COVISHIELD[™] as primary vaccination. GEMCOVAC[®]-OM 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[®]-OM 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[®]-OM 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[®]-OM?

GEMCOVAC[®]-OM has been authorized for emergency use as a booster in individuals 18 years of age and older who have received either COVAXIN[®] or COVISHIELD[™] as primary vaccination.

GEMCOVAC[®]-OM is indicated as a single booster dose in individuals aged ≥ 18 years administered at least 4 months after completion of primary vaccination with either COVISHIELD[™] or COVAXIN[®].

WHO SHOULD NOT GET GEMCOVAC[®]-OM?

You should not get GEMCOVAC[®]-OM if you:

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

WHAT ARE THE INGREDIENTS IN GEMCOVAC[®]-OM?

One dose of vaccine (0.1 mL) contains the mRNA 10 µg, DOTAP 0.3 mg, Squalene 0.38 mg, Sorbitan Monostearate 0.37 mg, Polysorbate-80 0.37 mg, Citric Acid Monohydrate 1.05 mg and Sucrose 10 mg.

HOW IS GEMCOVAC[®]-OM GIVEN?

GEMCOVAC[®]-OM will be given to you as an intradermal (ID) injection only, using a Needle-free Tropis[®] Injection system (PharmaJet, Colorado, USA).

HAS GEMCOVAC[®]-OM BEEN USED BEFORE?

GEMCOVAC[®]-OM has been used in a Phase II/III clinical trial conducted in India in which a number of participants received it as a single booster dose. Approximately, 3070 individuals have received a booster dose of GEMCOVAC[®]-OM at least 4 months after completion of primary vaccination with either COVISHIELD[™] or COVAXIN[®].

WHAT ARE THE BENEFITS OF GEMCOVAC[®]-OM?

In an ongoing Phase-II / III clinical trial, GEMCOVAC[®]-OM has been shown to generate protective immune responses. GEMCOVAC[®]-OM generates anti-Spike-IgG which have shown to neutralize the SARS-CoV-2 virus. However, it is important to note that GEMCOVAC[®]-OM may not protect everyone who is vaccinated from COVID-19. The duration of protection against COVID-19 is currently unknown.

Therefore, you should follow all the standard measures recommended by the Government Authorities.

WHAT ARE THE RISKS OF GEMCOVAC[®]-OM?

A severe allergic reaction may very rarely occur after getting a dose of GEMCOVAC[®]-OM. Additionally, serious and unexpected side effects may occur. The safety of GEMCOVAC[®]-OM 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[®]-OM vaccine at [Safety@gennova.co.in](mailto:safety@gennova.co.in) or the toll free number 18002090801.

WHAT IF I DECIDE NOT TO GET GEMCOVAC[®]-OM?

It is your choice to receive or not receive GEMCOVAC[®]-OM. Should you decide not to receive the GEMCOVAC[®]-OM, it will not change your standard medical care.

CAN I RECEIVE GEMCOVAC[®]-OM WITH OTHER VACCINES?

There is no scientific information yet available on the appropriateness of use of GEMCOVAC[®]-OM 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[®]-OM 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[®]-OM 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.

WILL THE GEMCOVAC[®]-OM GIVE ME COVID-19?

No. GEMCOVAC[®]-OM 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:

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