

FACT SHEET FOR VACCINE RECIPIENTS & CAREGIVERS



COVID-19 Vaccine ChAd36-SARS-CoV-2-S (Recombinant) BY BHARAT BIOTECH

Bharat Biotech's COVID-19 Vaccine ChAd36-SARS-CoV-2-S (Recombinant) (iNCOVACC®) 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 iNCOVACC®.

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 Bharat Biotech, who is the manufacturer of iNCOVACC® vaccine on 24x7 Toll-Free Number: 18001022245 or at email at pvg@bharatbiotech.com. For more information, please read this Fact Sheet carefully.

Please read this Fact Sheet for information about iNCOVACC®. Talk to Vaccinator/ Officer supervising your vaccination, if you have any questions. It is your choice to receive iNCOVACC®. iNCOVACC® is administered with a total of 8 drops (0.5 mL per dose), 4 drops into each nostril as a 2-dose series, 4 weeks apart.

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 may experience wide range of symptoms from mild to severe category. 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; loss of taste or smell of recent onset; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS iNCOVACC®?

iNCOVACC® is a nasal vaccine indicated for active immunization against SARS-CoV-2 virus infection.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET iNCOVACC®?

Tell the Vaccinator/ Officer supervising your vaccination about all of your medical conditions, including if you:

- Are on regular medication for any illness, for how long and for which condition.
- Have any allergies
- Have fever
- Have a coagulation/bleeding disorder or are on a blood thinner
- Are immunocompromised or are on a medicine that affects your immune system
- Are pregnant
- Have received another COVID-19 vaccine

WHO SHOULD GET iNCOVACC®?

It has been approved for active immunization against SARS-CoV-2 virus infection for age ≥18 years.

WHO SHOULD NOT GET iNCOVACC®?

You should not get iNCOVACC® 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 iNCOVACC®?

Each 0.5 ml contains: NLT 5x10¹⁰ particles per mL of ChAd36-SARS-CoV-2-S COVID-19 virus (recombinant) including excipients such as Tris (pH 7.4), Sodium Chloride, Magnesium Chloride, Glycerol, Polysorbate- 80

HOW IS iNCOVACC® ADMINISTERED?

iNCOVACC® is administered through the nose, as a 2-dose series, 4 weeks apart. A total of 8 drops (0.5 mL per dose), 4 drops are administered into each nostril.

Booster Dose administration:

Single booster dose to individuals aged 18 years and above, at ≥6 months after completion of primary schedule of Covishield or Covaxin®

HAS iNCOVACC® BEEN LICENSED ?

The CDSCO India has granted permission for the sale or distribution of iNCOVACC® for immunization against SARS-CoV-2 virus infection for age group ≥18 years, for restricted use in emergency situation in public interest

WHAT ARE THE BENEFITS OF iNCOVACC®?

Phase 3 clinical trial done in 3000 participants, iNCOVACC® has been shown to generate good immunity following 2 doses given 4 weeks apart. It is important to appreciate that receiving the vaccine does not mean that other precautions related to COVID-19 need not be followed.

WHAT ARE THE SIDE EFFECTS OF COVID-19 VACCINE iNCOVACC®?

Side effects that have been reported include:

- Headache
- Fever
- Running nose
- Sneezing

A severe allergic reaction may very rarely occur after getting a dose of iNCOVACC®, however no such event was reported in the clinical trial with iNCOVACC®.

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 Bharat Biotech International Limited, who is the manufacturer of iNCOVACC® on 24x7 Toll-Free Number: +1 800 102 2245 or email at pvg@bharatbiotech.com.

WHAT IF I DECIDE NOT TO GET iNCOVACC®?

It is your choice to receive or not receive iNCOVACC®.

CAN I RECEIVE iNCOVACC® WITH OTHER VACCINES?

There is no scientific information yet available on the appropriateness of use of iNCOVACC® along with other vaccines.

WHAT IF I AM PREGNANT?

No data exists with use of iNCOVACC® Vaccine in pregnant women.

WHAT IF I HAVE ALLERGIES?

Individuals who have a known severe allergy to any component of iNCOVACC® are NOT advised to be vaccinated. Each 0.5 ml of iNCOVACC® contains NLT 5x10¹⁰ particles per mL of ChAd36-SARS-CoV-2-S COVID-19 virus (recombinant) including excipients such as Tris (pH 7.4), Sodium Chloride, Magnesium Chloride, Glycerol, Polysorbate- 80

Individuals with a history of severe allergic reactions NOT related to vaccines or injectable medications such as environmental allergies, allergies to food, pet dander, venom, or latex- may still get 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?

Individuals with HIV infection or other immunocompromised conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19. However, data is NOT currently available to establish vaccine safety and efficacy in these groups. Individuals with immunosuppression may not generate a full immune response to COVID-19.

Transplant recipients should be counselled that the vaccine's effectiveness and safety profile for them is not currently known. Transplant recipients may have a weakened immune response compared to the general population. Thus, they should be advised regarding the importance of maintaining all current guidance to protect themselves even after vaccination. Immunocompromised individuals may receive COVID-19 vaccination if they have no contraindications to vaccination.

WILL iNCOVACC® GIVE ME COVID-19?

No, there is no chance of getting COVID-19 post immunization with iNCOVACC®.



Revision Date: 16 November 2022

Manufactured and Marketed by:

Bharat Biotech International Limited Genome Valley, Turkapally, Shamirpet Hyderabad, Telangana. 500078