

FACT SHEET FOR VACCINE RECIPIENTS AND CAREGIVERS

RESTRICTED USE OF COVAXIN™ UNDER CLINICAL TRIAL MODE

THE BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

PRIORITIZED GROUPS OF INDIVIDUALS WHO HAVE BEEN INFORMED BY THE MINISTRY OF HEALTH & FAMILY WELFARE TO ATTEND A BOOTH SPECIFIED FOR COVAXIN™ BASED VACCINATION

You are being offered the Bharat Biotech COVID-19 Vaccine (COVAXIN™) 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 Bharat Biotech COVID-19 Vaccine (COVAXIN™).

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 COVAXIN™ vaccine on 24x7 Toll-Free Number: 18001022245 or at email pvg@bharatbiotech.com. For more information, please read this Information Sheet carefully.

Please read this Fact Sheet for information about the Bharat Biotech COVID-19 Vaccine (COVAXIN™). Talk to Vaccinator/ Officer supervising your vaccination if you have any questions. It is your choice to receive the Bharat Biotech COVID-19 Vaccine (COVAXIN™). The Bharat Biotech COVID-19 Vaccine (COVAXIN™) is administered as a 2-dose series, 4 weeks apart, into the deltoid muscle of the upper arm.

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 of 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 THE BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™)?

The Bharat Biotech COVID-19 Vaccine (COVAXIN™) is a vaccine with approval for restricted use in emergency situation that may prevent COVID-19. The Central Licensing Authority has granted permission for the sale or distribution of COVAXIN for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode.

In phase 1 and phase 2 clinical trials, COVAXIN™ has demonstrated the ability to produce antibodies against COVID-19. However, the clinical efficacy of COVAXIN is yet to be established and it is still being studied in phase 3 clinical trial. Hence, it is important to appreciate that receiving the vaccine does not mean that other precautions related to Covid-19 need not be followed.

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?

The Vaccinator/ Officer supervising your vaccination may include your vaccination information in your state/National Immunization Information System or another designated system. This will ensure that you receive the same vaccine when you return for the second dose. Please also note that privacy and confidentiality pertaining to any information provided by you and archived in the National Immunization Information System will be maintained.

WHAT IS RESTRICTED USE IN EMERGENCY SITUATION?

COVAXIN™ is permitted for restricted use in emergency situation under Clinical Trial Mode. This means that the vaccine offered under this plan will be offered to the restricted prioritized groups only. As you fell under this category, you have been invited to this booth for administration of COVAXIN. This administration will take place under clinical trial mode, which is different from clinical trial as effect of COVAXIN will not be examined against any other intervention through this effort. You will be monitored for any adverse event under this clinical trial mode and supported for medical care under the existing public health program.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE COVAXIN™ COVID-19 VACCINE?

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

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

It is advisable not to take the vaccine in any of these conditions

WHO IS ELIGIBLE TO GET THE BHARAT BIOTECH COVID-19 VACCINE?

CDSCO has authorized the Restricted Use of COVAXIN™ under Clinical Trial Mode. Individuals who are prioritized under the public health program of the Ministry of Health & Family Welfare, Government of India will be covered under this endeavor. Informing the individuals about the offer for vaccination with COVAXIN will rest with the respective Government Program Officials. Those offered COVAXIN at

pre-specified booths will have the options to receive or reject administration of the vaccine.

WHO SHOULD NOT GET BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™)?

You should not get the BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) if you:

- Have any history of allergies.
- Have fever.
- Have a bleeding disorder or are on a blood thinner.
- Are immune-compromised or are on a medicine that affects *your* immune system
- Are pregnant.
- Are breastfeeding.
- Have received another COVID-19 vaccine.
- Any other serious health related issues, as determined by the Vaccinator/Officer supervising vaccination.

WHAT ARE THE INGREDIENTS IN THE BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™)?

The BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) includes the following ingredients: COVAXIN™ contains 6µg of whole-virion inactivated SARS-CoV-2 antigen (Strain: NIV-2020-770), and the other inactive ingredients such as aluminum hydroxide gel (250 µg), TLR 7/8 agonist (imidazoquinolinone) 15 µg, 2-phenoxyethanol 2.5 mg, and phosphate buffer saline up to 0.5 ml. The vaccine (COVAXIN™) thus has been developed by using inactivated/killed virus along with the aforementioned chemicals.

HOW IS THE BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) GIVEN?

The BHARAT BIOTECH COVID-19 VACCINE will be given to you as an injection into the deltoid muscle of the upper arm. The BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) vaccination series is 2 doses given 4 weeks apart.

HAS BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) BEEN USED BEFORE?

The Central Licensing Authority has granted permission for the sale or distribution of COVAXIN™ for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode. In phase 1 and Phase 2 clinical trials, about 680 (300 in Phase 1, and 380 in Phase 2) were administered with 2-doses of COVAXIN™. Phase 3 clinical trial is ongoing in 25,800 participants, and all the participants have received the first dose, as on 06th Jan 2021.

WHAT ARE THE BENEFITS OF BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™)?

In an ongoing clinical trial, the BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) has been shown to generate immunity following 2 doses given 4 weeks apart.

However, the clinical efficacy of COVAXIN is yet to be established and it is still being studied in phase 3 clinical trial. Hence, 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 RISKS OF BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™)?

Side effects that have been reported with the BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) include:

- Injection site pain
- Injection site swelling
- Injection site redness
- Injection site itching
- Stiffness in the upper arm
- Weakness in injection arm
- Body ache
- Headache
- Fever
- Malaise
- Weakness
- Rashes
- Nausea
- Vomiting

There is a remote chance that the BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) could cause a severe allergic reaction. A severe allergic reaction may very rarely occur after getting a dose of the BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™). For this reason, your vaccination provider will ask you to stay for 30 minutes after each dose of vaccination at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty in breathing
- Swelling of your face and throat
- A fast heart beat
- Rash all over your body
- Dizziness and weakness

These may not be all the possible side effects of the BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™). Serious and unexpected side effects may occur. BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) 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.

WHAT IF I DECIDE NOT TO GET THE BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™)?

It is your choice to receive or not to receive the BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™).

CAN I RECEIVE THE BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) WITH OTHER VACCINES?

There is no scientific information yet available on the appropriateness of use of the BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) along with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

If you are pregnant or breastfeeding, you should not get the vaccine as the effect of the vaccine has not been studied in pregnant women and nursing mothers.

WILL THE BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) GIVE ME COVID-19?

No. BHARAT BIOTECH COVID-19 VACCINE (COVAXIN™) is an inactivated (killed) vaccine, and hence, there is no chance of getting COVID-19 because of COVAXIN™ vaccination.

HOW LONG WILL I HAVE TO PARTICPATE IN THIS PROGRAM?

All the Vaccine recipients will be followed-up for a period of 3 months after the 2nd dose of vaccination.

In case of any serious adverse events, Vaccine recipients will be provided medically recognized standard of care in the government designated and authorized centers/hospitals. The compensation for serious adverse event will be paid by sponsor (BBIL) if the SAE is proven to be causally related to the vaccine. The compensation will be determined by the ICMR Central Ethics Committee, as appropriate.

All the recipients need to report to the health care provider/site/sponsor, if they are having signs and symptoms of COVID-19 or diagnosed with COVID-19. If any Vaccine recipient develops symptoms of COVID-19, Vaccine recipient will be provided medically recognized standard of care in the government designated and authorized centers/hospitals. COVID-19 Positive outcomes must be documented in Adverse Event Form. Proof of positive RT-PCR (tests conducted under the existing government program and from approved laboratories) should be provided to establish the diagnosis of COVID-19. Vaccine recipient's verbal recall will not confirm the diagnosis.

**COVID-19 VACCINATION (COVAXIN™)
SCREENING & CONSENT FORM**

The COVID-19 Vaccine, COVAXIN™, is being offered to you as part of a vaccination drive by the Ministry of Health and Family Welfare under restricted use in emergency situation. COVAXIN™ is being offered at this booth in this district.

The Bharat Biotech COVID-19 Vaccine (COVAXIN™) is a vaccine with approval for restricted use in emergency situation that may prevent COVID-19.

In phase 1 and phase 2 clinical trials, COVAXIN™ has demonstrated the ability to produce antibodies against COVID-19. However, the clinical efficacy of COVAXIN is yet to be established and it is still being studied in phase 3 clinical trial. Hence, it is important to appreciate that receiving the vaccine does not mean that other precautions related to Covid-19 need not be followed.

The Central Licensing Authority has granted permission for the sale or distribution of COVAXIN for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode.

In case of any adverse events or serious adverse events, you will be provided medically recognized standard of care in the government designated and authorized centers/hospitals.

The compensation for serious adverse event will be paid by sponsor (BBIL) if the SAE is proven to be causally related to the vaccine.

HOW CAN YOU LEARN MORE IF YOU WISH BEFORE PROVIDING CONSENT?

- Ask the Vaccinator/ Officer supervising your vaccination.
- Visit at <https://www.mygov.in/covid-19/>

I FUTURE EMPHASIZE THAT ANY INFORMATION PROVIDED BY ME PRIOR TO TAKING THE VACCINE WILL BE ARCHIVED IN THE DATABASE MAINTAINED BY THE IMMUNIZATION PROGRAM OF THE GOVERNMENT & PRIVACY AS WELL AS CONFIDENTIALITY OF THE INFORMATION PROVIDED BY YOU WILL BE MAINTAINED.

Recipient Name:		
DOB: Age:	Gender: Male..... Female.....Third Gender.....	Marital Status:
ID Number / Aadhaar Number/Registration Number:		
Address of the recipient:		
Mobile/Phone Number:		
Name:		
Mobile/Phone Number:		
Name and Address of Clinic/Office Site Where Vaccine is Administered:		
Name and contact mobile number of the Vaccinator/ Officer supervising your vaccination:		

S. No.	Questionnaire			
1.	Are you feeling sick today?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
2.	In the last 14 days, have you had a COVID-19 test or been told by a health care provider or health department to isolate or quarantine at home due to COVID-19 infection or exposure?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
3.	Have you been treated with antibody therapy for COVID-19 in the past 90 days (3 months)? If yes, when did you receive the last dose as furnished on document?(please tell me)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
4.	Have you ever had a serious allergic reaction?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
5.	Have you had any vaccines in the past 28 days (4 weeks)? If yes, how long ago was your most recent vaccine?(please tell me)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
6.	Are you pregnant or considering becoming pregnant?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
7.	Are you a nursing mother?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
8.	Are you on any medication for a long-standing disease? a) If yes please tell me the name of the disease	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown
9.	Are you taking radiotherapy?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown

INFORMED CONSENT

I have been provided and have read, or had been explained to me, the Fact sheet about the COVID-19 vaccination. I understand that this vaccine requires two doses for it to be effective and two doses need to be administered. I have been allowed to ask questions which were answered to my satisfaction. I understand the benefits and risks of the vaccination as described. I request that the COVID-19 vaccination be given to me.

Name	Vaccine recipient (Signature/Thumb impression)	Date/Time

If vaccine recipient is illiterate, consent should be taken in the presence of Impartial Witness and also please include Impartial Witness Signature.

Name	Impartial Witness (Signature)	Date/Time

Area Below to be Completed by Vaccinator					
Vaccine Name	Vaccine Dose	Date of administration	Time of Administration	Route of Administration	Manufacturer & Lot Number
COVAXIN™	<input type="checkbox"/> First Dose				
	<input type="checkbox"/> Second Dose				

Administration Site:	<input type="checkbox"/> Left Deltoid	<input type="checkbox"/> Right Deltoid
Dosage:	<input type="checkbox"/> 0.5ml	Intra Muscular

I have reviewed the details of side effects with the vaccine recipient.

I confirm that the vaccine recipient was allowed to ask questions about the vaccination, and all the questions asked by the vaccine recipient have been answered correctly, and to the best of my ability.

Name of the Vaccinator: _____

Vaccinator Signature: _____

Location Name (Vaccination Site): _____

Please contact your vaccination supervising officer at this numberand your vaccinator (contact number) in case of any need related to vaccination or difficulty faced even after going back home following vaccination.