



A New Innovation 'INCOVACC'-The Brahmastra for SARS-Cov-2

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ABSTRACT

The covid -19 virus has been spread all over the world. The primary case was declared in 2019, and became virulent disease. As covid 19 disease showed its different variants like Alpha, Beta, Delta, Delta plus and Omicron. To prevent this everyone should practice respiratory etiquette, by coughing into a flexed elbow, stay home and self-isolated until recovery. National institute of health allows some medications and precaution doses like Molnupiravir, Remdesivir as tablet and injectables like Covishield and Covaxin respectively. Throughout this general review we have targeted on the role, drug activity, identification and safety information of the newly developed Nasal vaccine known as 'Incovacc'.

INTRODUCTION

SARS-COV-2 a deadly virus overgrowing from past four years causing an infectious disease named covid 19. The basic symptoms include mild to moderate respiratory illness which can be recovered without requiring special treatment. But in most of the cases people having chronic diseases or low immune system get severely affected which needs emergency medical attention. The primary target of the virus is the respiratory system which gradually affects other major organs. For the prevention of this virus WHO provides some guidelines and protocols to follow.

"INCOVACC" which is designed and developed by one of India's leading pharmaceutical industry named "BHARAT BIOTECH" and is proclaimed as a gamechanger against the SARS-COV-2 virus. The government has also approved it as a booster dose for adults across India. This formulation has excellent potential for vaccination in the nasal route as the immune system of the nasal mucosa is very much organised. Hence, we get better immune response directly at the site of infection which helps in prohibition of infection and transmission of the virus.

OVERVIEW

Covid-19 is an infectious disease caused by the SARS-CoV-2 virus when infects a person shows symptoms which may appear 2-14 days after exposure to the virus like fever, chills, cough, shortness of breath, fatigue, muscle/body aches, headaches, loss of taste or smell, sore throat, congestion, runny nose, nausea/vomiting or diarrhoea. It's predominantly a respiratory illness which can affect other major organs and people having other medical conditions like cardiovascular disease, diabetes, chronic respiratory disease, or cancer are more likely to develop serious illness. The virus can transmit or spread from an infected person's mouth or nose through small liquid droplets when they cough, sneeze, speak or breathe.

So there are some certain steps which can be a barrier to stop the spreadability are as following :

- Maintain distance atleast 1m from others
- Usage of properly fitted mask
- Washing hands frequently and using alcohol based hand sanitizers
- Practicing good respiratory etiquettes (coughing into flexed elbow)
- And majorly to get vaccinated with precautionary dose by following local guidelines for covid-19
- If affected stay home and get self isolated until recovery

DESCRIPTION

Colourless to pinkish liquid, free from extraneous particles, containing NLT 5x10¹⁰ virus particles per ml.

List of excipients – Tris (pH 7.4), sodium chloride, magnesium chloride, glycerol and polysorbate-80.

Incompatibilities- Any other medicinal products or any active immunizing agents should not be mixed with the vaccine.

Shelf life- INCOVACC COVID 19 vaccine [ChAd36-SARS-CoV-2-S (Recombinant)] expiration date indicated on the label or the carton of the vaccine. As per instruction provided on the label it should not be used after the date of expiration. If opened once as soon as practically possible multi dose vial should be used but if kept between +2 to +8°C then it can be used within 6 hours.

ADVANTAGES :

1. It is cost effective as the administration is needle free, there is no requirement of needles and syringe for mass vaccination.
2. Non-invasive administration is painless and eliminates needle related risks like injuries and infections.
3. It is patient reliable.
4. Ease of administration (trained health care workers/nurse/medical practitioner are not required) reducing the dependency.
5. It is more affordable as any category of people can use.
6. The nasal vaccine does not require any expensive equipments for storage and transportation as it can be stored in a normal refrigerator .
7. As the administration of the nasal vaccine is directly at the site of infection it stops the infection and transmission of the virus.

QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each Dose of 0.5 mL, total of 8 drops contains:

ChAd36-SARS-CoV-2-S COVID-19 virus (recombinant)	NLT 5x10 ¹⁰ particles per mL
Tris (pH 7.4)	20 Mm
Sodium Chloride	25 mM
Magnesium Chloride	2 mM
Glycerol	NLT 2.5 %
Polysorbate- 80	0.1%

THERAPEUTIC INDICATION:

The covid 19 vaccine [ChAd36-SARS-CoV-2(Recombinant)] is indicated against SARS-CoV-2 infection for active immunization for age \geq 18 years for restricted use in emergency situation in public interest.

CONTRAINDICATION-

The side effects of the intranasal vaccine incovacc were seen as same as any other vaccine like fever, headache, running nose, sneezing etc. In extremely rare cases allergic conditions may be seen, but no such events were reported in the clinical trials of the vaccine as per Bharat Biotech datasheet.

CLINICAL TRIALS

The company conducted phase I clinical trials recommended by subjects expert committee (SEC) under the Indian drug regulator. 75 volunteers kept under observation and submitted the safety and immunogenicity data for the consideration. The data reviewed by experts on 12th August 2021 and got approval from the drug regulator for phase II/III clinical trials.

They evaluated the immunogenicity and safety of incovacc with BBV154 in healthy people with a positive result.

POSOLOGY

INCOVACC an Adenoviral vector-based (spike protein) covid-19 vaccine for nasal administration only. The spike protein virus is one which attaches to the human cells and infects them, it is stabilized with relevant changes and supports a stable form of delivery which is highly effective in producing immunity or resistance to a virus. Comparatively Covaxin is an inactivated form of vaccine administered through intramuscular injections but Incovacc will be delivered as nasal drop rather than a spray.

Primary series- Incovacc is administered as 0.5ml per dose in 8 drops (4 drops in each nostril). The vaccination course includes two doses which should be administered 28 days apart.

Booster dose- Incovacc is indicated as booster dose for age \geq 18 years at \geq 6 months of completion of the primary schedule of COVISHIELD or COVAXIN.

Authorizations[\[edit\]](#)

See also: [List of COVID-19 vaccine authorizations & iNOVACC](#)

METHOD OF ADMINISTRATION:

1. Blow nose gently to clear.
2. Tilt head back as far as comfortable.
3. Close one nostril with fore finger. Insert dropper a little away into each nostril. Squeeze the dropper to release 4 drops and inhale gently. Keep the head back for 30 secs.
4. Repeat step 3 for another nostril.



Note - Dropper should be replaced for the administration of vaccine to the second recipient.

RESULTS AND DISCUSSIONS:

Incovacc should be administered as four drops in each nostril, a total of eight drops in a slow drip process of delivery rather than a single shot or spray. INCOVACC nasal vaccine has been evaluated and found to have shown satisfactory immune response against SARS-CoV-2 variants such as delta and beta and also cell mediated immune response (both T and B cell) phenotype distribution evaluation against SARS-CoV-2 variants including omicron variants is found to have shown persistent response across variants. Also, the incovacc recipients were denoted with significant levels of mucosal IgA antibody (which was measured in the saliva). This mucosal IgA antibody is found in the upper respiratory tract which may furnish with benefits in reducing the infection and the transmission of the virus.

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