SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Whole Virion Inactivated Corona Virus Vaccine

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

This is a single or multidose vial and injected in intra-muscular route.

Each Single human dose (0.5 mL) contains

Whole Virion Inactivated Corona Virus Antigen 6 micrograms. produced using a Vero cell-based platform, that propagates the virus, expressing the viral spike (S) protein of SARS-CoV-2.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

The vaccine is a white translucent liquid and free from extraneous particulate matter containing 6 µg of Whole Virion Inactivated Corona Virus Antigen (strain: NIV-2020-770) for injection (sterile), pH: 7.00 - 8.00.

4. CLINICAL PARTICULARS

It is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 18 years of age and older. The use of this vaccine should be in accordance with official recommendations. This vaccine is permitted for restricted use in Emergency situation in Clinical Trial mode, as per provisions of New Drugs and Clinical Trials Rules, 2019, under Drugs & Cosmetics Act 1940.

4.1 Therapeutic indication

COVAXIN™ is indicated for active immunization against SARS-CoV-2 Virus infection for age ≥18years.

4.2 Posology and method of administration.

COVAXIN™ should be administered as two doses on Day 0 and Day 28.
Method of administration: intramuscular injection (IM).

4.3 Contraindications

- Hypersensitivity to any constituents of the vaccine.
- Pregnant and lactating mothers.
- During fever or severe infection.
- Individuals below 18 years.

4.4 Special warnings and precautions for use

- Do not administer intravenously, intradermally, or subcutaneously.
- Like all other vaccines, supervision and appropriate medical treatment should always be available to treat any anaphylactic reactions following immunization.
- The vaccine should remain under medical supervision for at least 30 minutes after vaccination.

Before use, COVAXIN™ should be shaken well to obtain a uniform, whitish translucent suspension. Vial should be visually checked for the presence of any particulate matter or other coloration, if any, prior to its administration. If in doubt, do not use the contents of the vial.

COVAXIN™ should not be mixed with other vaccines.

4.5 Interaction with other medicinal products.

Chloroquine and Corticosteroids as they may impair the antibody response.

4.6 Pregnancy and Lactation

Safety and effectiveness have not been established in pregnant women and in nursing mothers.

4.7 Effects on ability to drive and use machines

No studies on the effect of COVAXIN™ on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Clinical Trial Experience

Safety of the COVAXIN™ vaccine was established in Phase 1 and Phase 2 studies.

Phase 1 clinical trial was conducted in India in 375 adult healthy volunteers. The most common local adverse event reported was Injection site Pain. The most common systemic adverse events reported were headache, followed by fatigue, fever, body ache, abdominal pain, nausea, and vomiting. The other less common adverse events were dizziness/giddiness, tremor, sweating, cold, cough, and injection site swelling. No vaccine related serious adverse events (SAE) were reported.

A Phase 2 clinical trial was conducted in India in 380 adolescents and adult healthy volunteers. Similar adverse events were reported in the phase 2 clinical trial. No serious adverse events (SAE) were reported.

A Phase 3 efficacy study is on-going in 25,800 participants and administered with 1st dose of vaccination with COVAXIN™, no vaccine related adverse events were observed.

4.9 Immune Response

COVID-19 disease is caused due to SARS-CoV-2 virus infection.

In Phase 1 clinical trial a total of 375 healthy participants were enrolled across the three groups and received three vaccine formulations, BBV152A (3µg with Algel-IMDG (Aluminium hydroxide gel- Imidazo quinolin gallamide (IMDG); a TLR 7/8 agonist), BBV152B (6µg with Algel-IMDG), and BBV152C (6µg with Algel). None of the participants had detectable neutralizing antibodies at baseline analyzed by MNT_{50}. The proportion of participants seroconverted post 2 weeks after 2nd dose was 87.9%, 91.9%, and 82.8% in the BBV152A, B, and C groups, respectively.

In Phase 2 clinical trial a total of 380 healthy participants were enrolled among two groups and received two vaccine formulations, BBV152 A and BBV152B. None of the participants had detectable neutralizing antibodies at baseline analyzed by MNT_{50}. The proportion seroconverted participants of Group 1 and Group 2, post 4 weeks of 2nd dose was 88.0% and 96.6% respectively.

4.10 Overdose

No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

COVID-19 disease is caused due to SARS-CoV-2 virus infection. **COVAXIN™** is a whole virion inactivated SARS-CoV-2 virus vaccine, has been studied in Phase 1 and 2 clinical studies for safety and immunogenicity and found to be safe and immunogenic. **COVAXIN™** has been shown to prevent COVID-19 following 2 doses given 4 weeks apart. The duration of protection against COVID-19 is currently unknown.

5.2 Pharmacokinetic properties

Evaluation of pharmacokinetic properties is not required for vaccines.

5.3 Preclinical safety data

All the formulations were tested for immunogenicity in mice, rats, and rabbits. Mice, rats, and rabbits were vaccinated on days 0, 7, and 14 (n+1 doses). Further these formulations are tested for immunogenicity, safety, and protective efficacy in Syrian Hamster challenge model and Non-Human Primates (*Rhesus macaque*) challenge model. The Hamsters were vaccinated on Days 0, 14, and 35 (n+1 doses), the live SARS-CoV-2 virus was challenged through intranasal route on Day 50. Likewise, the Rhesus macaques were vaccinated on Days 0 and 14, and live SARS-CoV-2 virus was challenged through intranasal and intratracheal routes on Day 28. All the formulations were found to be safe, immunogenic, and provided effective protection to both upper and lower respiratory tract.

PHARMACEUTICAL PARTICULARS

6.1 List of excipients and composition

Each 0.5 mL (single human dose) contains

Whole Virion Inactivated Corona Virus Antigen …….6 µg

Aluminium hydroxide gel equivalent to Al^{+3}……...250 µg

TLR 7/8 Agonist……15 µg

2-phenoxyethanol……...2.5 mg

Phosphate buffered saline……..q.s. to 0.5 mL

Note: TLR 7/8 agonist is an Imidazo quinolin gallamide (IMDG)

6.2 Incompatibilities

The product should not be mixed with any other medicinal products or active immunizing agents.

6.3 Shelf life

The expiry date of COVAXIN™ is indicated on the label and carton of the product. Do not use the product after the expiration date shown on the label and carton of the product.

6.4 Special precautions for storage

Store at +2° to +8 °C, do not freeze. Discard if frozen.

Shake well before use. Keep out of reach of children. Protect from light.

Do not use the vaccine after the expiration date as shown on the label.

6.5 Nature and contents of container

COVAXIN™ is presented as Single dose (0.5 mL) and multidose (5 mL and 10 mL) in transparent vial (type I glass) with a stopper (butyl rubber) and a flip-off plastic cap with aluminium seal. Each vial of single dose contains 0.5 mL, each vial of multidose contains 10 doses (5 mL) and 20 doses (10 mL) respectively.

6.6 Handling of multi-dose vials

Opened vials should be used as soon as possible and within 6 hrs when kept between 2 - 8 ºC.

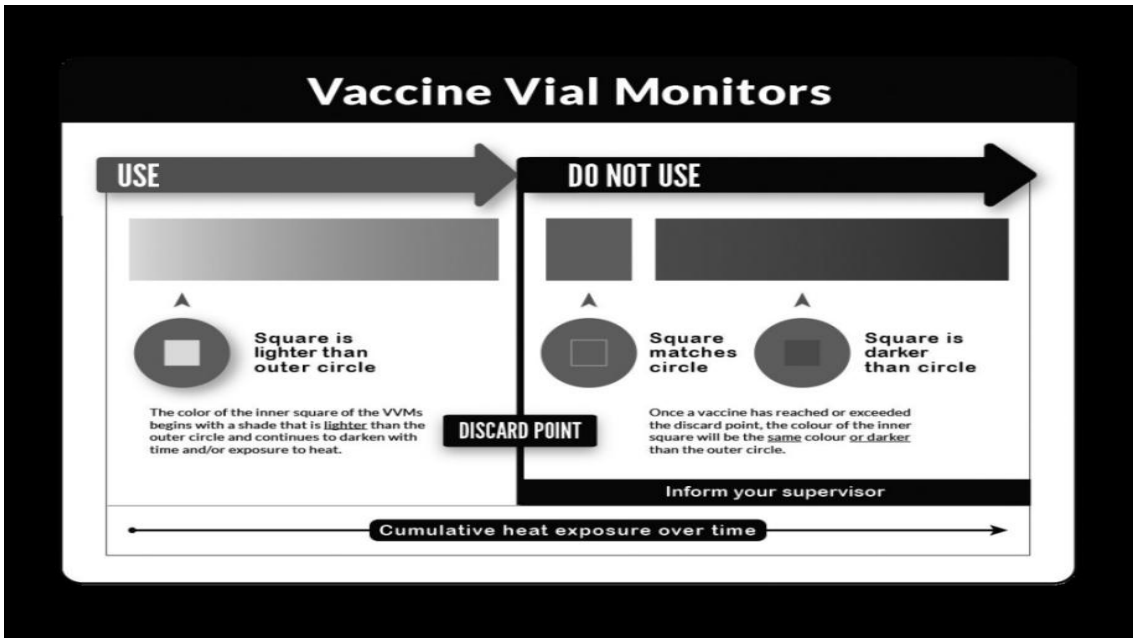
Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. THE VACCINE VIAL MONITOR (OPTIONAL)

Presentation available with or without vaccine vial monitor

Vaccine Vial Monitors (VVM7) dot is a part of the label on **COVAXIN™** vials supplied through Bharat Biotech. VVM7 are supplied by TEMPTIME Corporation, USA. This is a time-temperature sensitive dot that provides an indication of the cumulative heat to which the vial has been exposed. It warns the end user when exposure to heat is likely to have degraded the vaccine beyond an acceptable level.



The interpretation of the VVM7 is simple: Focus on the central square; its colour will change progressively. As long as the colour of this square is lighter than the colour of the ring, the vaccine can be used. As soon as the colour of the central square is the same colour as the ring or of a darker colour than the ring, the vial should be discarded.

8. MARKETING AUTHORISATION NUMBER(S)

MF/BIO/21/000002, dated 3rd Jan, 2021

9. MARKETING AUTHORISATION HOLDER

Manufactured and Marketed by:

Bharat Biotech International Ltd.

Sy. No. 230, 231 and 235, Genome Valley, Turkapally, Shamirpet Mandal, Medchal-Malkajgiri District - 500 078, Telangana State, India.
E-mail: feedback@bharatbiotech.com; Website: www.bharatbiotech.com
For complaints and suggestions about the product, and any adverse event,
please email to feedback@bharatbiotech.com or call on Toll-free number: 1800 102 2245

10. DATE OF CREATION / REVISION OF THE TEXT

15th January, 2021