For use only of a Registered Medical Practitioner or Hospital or Laboratory

COVID-19 Vaccine (ChAd36-SARS-CoV-S (Recombinant))

iNCOVACC®

1. NAME AND DESCRIPTION OF THE MEDICINAL PRODUCT:

COVID-19 Vaccine (ChAd36-SARS-CoV-S (Recombinant)) is a colorless to pinkish liquid, free from extraneous particles, containing NLT $5x10^{10}$ virus particles per mL.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

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

ChAd36-SARS-CoV-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%

For excipients see section 6.1.

3. PHARMACEUTICAL FORM

Vaccine (Liquid)

4. CLINICAL PARTICULARS

4.1 Therapeutic indication

COVID-19 Vaccine (ChAd36-SARS-CoV-S (Recombinant)) is indicated for active immunization against Coronavirus infection (SARS-CoV-2) COVID-19.

iNCOVACC® is indicated for active immunization against SARS-CoV-2 virus infection for age ≥18 years for **restricted use in emergency situation in public interest**.

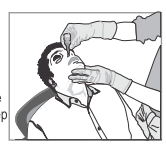
4.2 Posology and method of administration.

iNCOVACC® is an Adenoviral vector-based (expressing a stabilized spike protein) SARS-CoV-2 vaccine for nasal administration only.

Primary Series: iNCOVACC® is administered as 0.5mL per dose in 8 drops, (4 drops in each nostril). The vaccination course consists of two doses administered 28 days apart.

Booster Dose: iNCOVACC® - Administered 0.5mL (8 drops, 4 drops in each nostril) as single booster dose to previously vaccinated with approved Covid-19 Vaccines.

Method of administration for Vial (2 Dose)



1. Blow nose gently to clear.
2. Tilt head back as far as comfortable (See diagram).
3. Insert dropper a little way into nostril and squeeze bulb gently to release 4 drops into nostril and keep head back for 30 seconds.
4. Repeat in another nostril.

In case **iNCOVACC®** partially or completely does not enter the nostril, you may re-administer into the same nostril. In case the recipient prematurely gets up, and the **iNCOVACC®** liquid is seen running from any nostril, you may re-administer to that nostril.

Once opened, Multi-Dose vials should be used within 6 hours and stored at 2 to 8ºC between administrations. Post 6 hours after opening, the vials should be discarded.

iNCOVACC® is presented as a two-dose presentation per vial and for nasal use only. Care should be taken not to contaminate the dropper of the vaccine while administration. Post administration of 8 drops to the recipient, the dropper should be discarded and new dropper should be affixed prior administration to the next recipient. In case, the vaccine is not used immediately for administration to the second recipient, the open vial should be closed with rubber stopper. A new dropper should be placed for the administration of vaccine to the second recipient. The vaccine should not be used beyond 6 hours after the vial is opened.

To facilitate the traceability of the vaccine, the name and the batch number of the administered product must be recorded for each recipient.

4.3 Contraindications

Hypersensitivity to any constituents of the vaccine.

4.4 Special warnings and precautions for use

- Do not administer intramuscularly, intravenously, intradermally, or subcutaneously.
- Like all other vaccines, supervision and appropriate medical treatment should always be available to treat any anaphylactic reactions following immunization. Vaccinees should remain under medical supervision for at least 30 minutes after vaccination.
- Concurrent illness: As with other vaccines, administration of **iNCOVACC®** should be postponed in individuals suffering from an acute severe febrile illness/acute infection.
- Thrombocytopenia and coagulation disorders: **iNCOVACC®** should be given with caution to individuals with thrombocytopenia, coagulation disorder or to persons on anticoagulation therapy.
- **Immunocompromised individuals**
  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 regimen. Immunocompromised individuals may have relatively weaker immune response to the vaccine regimen.
- **Paediatrics population**
  Data are not available for the use of **iNCOVACC®** in paediatric population.

4.5 Interaction with other medicinal products.

No interaction studies have been performed.

4.6 Pregnancy and Lactation

Not applicable.

4.7 Effects on ability to drive and use machine

: No studies for the effect of **iNCOVACC®** on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Clinical Trial Experience

Safety of the **iNCOVACC®** (**BBV154**)vaccine was evaluated in the Phase 1, Phase 2 and Phase 3 trials of adults age ≥18 years.

Phase 1 clinical trial

The phase 1 study was conducted in India with a total of 175 subjects, 70 in group A (Single dose), 70 in group B (Double dose) and 35 in group C (Placebo). Among 70 subjects in group A, 57 (81.43%) were males and 13 (18.57%) were females. In group B, among 70 subjects, 57 (81.43%) were males and 13 (18.57%) were females. In group C, among 35 subjects, 30 (85.71%) were males and 5 (14.29%) were females.

	Total number of subject N= 175					
	Group A (Single dose N=70)		Group B (double dose N=70)		Group C (placebo N=35)	
	Male	female	Male	female	Male	female
	57(81.43%)	13(18.57%)	57(81.43%)	13(18.57%)	30(85.71%)	5 (14.29%)
Total Solicited Adverse events reported 8	Total 3 (4.29%) events were reported of which 2 events of headache, 1 event of fever		Total 5 (7.14%) events were reported of which 3 events of fever, 2 events of sneezing		No adverse events	

A total of 8 solicited adverse events were reported during the study. 3 adverse events were reported from group A, 5 adverse events were reported from group B and no adverse events were reported from group C.

In group A, 3 solicited adverse events (2 events of headache and 1 event of Fever) were reported in 3 subjects (4.29%). In group B, 5 solicited adverse events (3 events of Fever and 2 events of Sneezing) were reported in 5 subjects (7.14%).
No serious adverse event was reported in the study.

Groups	Total number of subjects N=200 age group between 18 to 60		
	Male	Female	Total Solicited Adverse event reported 6
Group 1(N=160) Vaccine	118 (73.75%)	42 (26.25%)	Total 5 (3.12%) event were reported of which 2 events of running nose, 3 events of headache
Group 2 (N= 40) Placebo	30 (75.00%)	10 (25.00%)	1 event of headache (2.5%)

Phase 2 clinical trial:

A Phase 2, Randomized, Double Blinded, Multi-centric Study to evaluate the Immunogenicity, Reactogenicity and Safety of an Intranasal COVID-19 Vaccine (ChAd36-SARS-CoV-S (Recombinant)) was conducted in 200 Healthy Volunteers of ages 18 to 60. A total of 200 subjects participated in the study, of which 148 (74.00%) were male and 52 (26.0%) were female. Among 160 subjects in vaccine, 118 (73.75%) were male and 42 (26.25%) were females. In placebo group, among 40 subjects, 30 (75.00%) were males and 10 (25.00%) were females.

iNCOVACC® is well tolerated in both the treatment groups. A total of 6 solicited adverse events were reported during the study. 5 solicited adverse events were reported in group-1 (2 events of running nose and 3 events of headache) were reported in 5 subjects (3.12%). 1 adverse event (Headache) was reported in 1 subject (2.5%) in group-2.All 6 adverse events were mild in severity and resolved. Majority of the adverse events, within 1 day. These 6 adverse events were reported in 6 volunteers, which is about 3% of the total volunteers.
No serious adverse event was reported in the study.

Phase 3 clinical trial

A Phase 3 randomized open label multi-centric study to compare immunogenicity and safety of **iNCOVACC®** with COVAXIN®, and to assess Lot to Lot consistency of **iNCOVACC®** in healthy volunteers is ongoing in 3160 subjects of 18 years and above. The data is analyzed till day 90 for a total of 3141 subjects. Percentage of male subjects enrolled in the study are 69.24% and the female subjects are 30.76%.

Total subjects	3160 subjects	
Data analyzed till day 90	3141 subjects	
	Male	69.24%
	Female	30.76%
Total 248 Adverse event till day 90	**iNCOVACC®**	**COVAXIN®**
	197 subjects	51 subjects
Solicited local adverse events	3.28% running nose, sneezing, nasal congestion, nasal pain, sore throat, lacrimation.	21.73% Injection site pain, injection site swelling and injection site redness.
Common Solicited systemic events reported	Fever, Headache, Myalgia, Fatigue, Nausea and Vomiting.	Fever, Headache, Nausea
No Serious Adverse Events were seen in both groups		

All the subjects in both the groups were followed up till day 90.
A total of 248 adverse events, 197 in **iNCOVACC®** group and 51 in COVAXIN® group were reported in the study till day 90.

Solicited local adverse events reported in a total of 3.28% of subjects in **iNCOVACC®** group and in a total of 21.73% of subjects in COVAXIN® group. The local events were different for **iNCOVACC® (BBV154) and COVAXIN® (BBV152).**

Common solicited local events seen in **iNCOVACC®** are running nose, sneezing, nasal congestion, nasal pain and sore throat.

Common solicited local events seen in COVAXIN® are injection site pain, injection site swelling and injection site redness.

Common solicited systemic events reported in both the groups were fever, nausea and vomiting.

All these common events were reported in a very less percentage of subjects in **iNCOVACC®** group compared to COVAXIN® group.

No SAEs were observed in both the groups COVAXIN® and **iNCOVACC®**.
No cases of Covid-19, Thrombocytopenia, Guillian Barre syndrome, Myocarditis were reported in the study.

The safety profile was excellent in **iNCOVACC®** group as compared to COVAXIN® group.

Phase 2 Heterologous Clinical trial:

A total of 608 subjects participated in the Phase 2 randomized, multi-centric, Clinical Trial of Heterologous Prime-Boost Combination of SARS-CoV-2 Vaccines to evaluate the immunogenicity and safety of BBV152 (COVAXIN®) with **iNCOVACC®** (Adenoviral Intranasal COVID-19 vaccine) in Healthy Volunteers of which 470 (77.3%) were male and 138 (22.70%) were female with 152 subjects in each group:

	Group1 (COVAXIN®+ COVAXIN®)	Group2 (COVAXIN®+ iNCOVACC®)	Group3 (iNCOVACC® + COVAXIN®)	Group4 (iNCOVACC® + iNCOVACC®)
Solicited Systemic adverse events	Fever, headache, nausea, vomiting, body pain	Fever, headache, body pain, fatigue	Cough, fever, headache, body pain	Fever, headache, fatigue, vomiting
Solicited local adverse events	Injection site pain, injection site redness	Injection site pain, injection site swelling, running nose	Nasal pain, Injection site pain	Nasal pain, nose irritation, running nose
Unsolicited adverse events	Dizziness, fever, malaise, oral ulcer, rashes, reduced appetite, cold, cough, ASOM, syncope	Cough, dizziness, fever, headache, haematochezia, stomach pain, right rib pain	malaise, rashes, watery eyes, dengue fever, cold, cough	Fever, ASOM, cold, cough, headache, malaise, reduced hearing, body pains
No SAEs were seen in Phase 2 Heterologous study				

Total 54 Solicited local adverse events and 172 Solicited systemic adverse events were seen in 144 subjects. Total 45 Unsolicited adverse events were seen in 31 subjects.

All the adverse events were mild and resolved within 24 hours
No SAEs were reported during the study

Phase 3 Heterologous Clinical trial:

A total of 875 subjects participated in the Phase 3, Randomized, Multi-Centric, Open-labeled study to evaluate immunogenicity and safety of **iNCOVACC®** Booster Dose in participants previously vaccinated with EUA vaccines of which 565 (64.57%) were male and 310 (35.43%) were female. Among 250 subjects in group-1, 161 (64.40%) were males and 89 (35.60%) were females. In group 2, among 125 subjects, 77 (61.60%) were males and 48 (38.40%) were females. In group 3, among 250 subjects, 165 (66.00%) were males and 85 (34.00%) were females. In group 4, among 125 subjects, 88 (70.40%) were males and 37 (29.60%) were females and in group 5, among 125 subjects, 74 (59.20%) were males and 51 (40.80%) were females.

Parent Vaccine	COVAXIN®	
Booster Vaccine	**Group-1 iNCOVACC®**	**Group-2 COVAXIN®**
Solicited systemic adverse events	Fever, headache, fatigue	Fever, headache, fatigue, nausea, sneezing, vomiting
Solicited local adverse events	Nasal pain, sneezing	Injection site pain, injection site redness, injection site swelling, injection site induration
Unsolicited adverse events	Chest pain. cold, fatigue, fever, itching in eyes	weakness
No SAEs were seen in Phase 3 Heterologous study		

Parent Vaccine	COVISHIELD		
Booster Vaccine	**Group-3 iNCOVACC®**	**Group-4 COVAXIN®**	**Group-5 COVISHIELD**
Solicited systemic adverse events	Fever, headache, fatigue, joint pain, weakness	Fever, fatigue, joint pain, muscle pain, body pain	Body pain, chills, headache, fever, fatigue, vomiting
Solicited local adverse events	Running nose	Injection site pain	Injection site pain
Unsolicited adverse events	Breathlessness, cough, fatigue	Runny nose, sore throat	Cold, weakness
No SAEs were seen in Phase 3 Heterologous study			

A total of 105 adverse events were reported in 76 subjects which is 8.69% of the total population. Among the 105 adverse events, 83 events were solicited and 22 events were unsolicited.

In group 1, 10 solicited adverse events and 8 unsolicited events were reported.
In group 2, 19 solicited adverse events and 2 unsolicited events were reported.
In group 3, 16 solicited adverse events and 6 unsolicited events were reported.
In group 4, 15 solicited adverse events and 3 unsolicited events were reported.
In group 5, 23 solicited adverse events and 3 unsolicited events were reported.

All the adverse events were mild and resolved within 24 hours and No SAEs were reported during the study

4.9 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. **iNCOVACC®** has been studied in a Phase 1 and 2 and an ongoing Phase 3 clinical studies for safety and immunogenicity and found to be safe and immunogenic.

Immune Response and Efficacy
Immunogenicity studies in humans:
Phase 1 clinical trial
In Phase 1, GMTs using MNT_{50} were calculated for all the three Arms. This was calculated for baseline Day 0 titres and post vaccination Day 28 and 42.

At baseline, geometric mean titres were 17.97 (95% CI 11.73, 27.51), 16.75 (95 % CI 11.6, 24.19) and 15.05 (95% CI 9.84, 23.02) in group A, B and C respectively. On Day 28, geometric mean titres were 47.9 (95% CI 30.44, 75.38), 44.01 (95 % CI 28.3, 68.44) and 17.36 (95% CI 10.68, 28.21) in group A, B and C respectively. On Day 42, geometric mean titres were 65.58 (95% CI 41.27, 97.94), 150.7 (95 % CI 108.6, 209.1) and 23.89 (95% CI 13.44, 42.46) in group A, B and C respectively.

Days	Statistics	Group A	Group B	Group C
Day 0	GMT 95 % CI	17.97 (11.73, 27.51)	16.75 (11.6, 24.19)	15.05 (9.84, 23.02)
Day 28	GMT 95 % CI	47.9 (30.44, 75.38)	44.01 (28.3, 68.44)	17.36 (10.68, 28.21)
Day 42	GMT 95 % CI	65.58 (41.27, 97.94)	150.7 (108.6, 209.1)	23.89 (13.44, 42.46)

Phase 2 clinical trial
In Phase 2, the GMTs of $PRNT_{50}$ at day 0 were 3.1 (95% CI 1.65, 5.67) and at day 42 were 286.8 (95% CI 190.32, 432.09) for iNCOVACC® and 3.7 (95%CI 1.01, 13.73) at day 0 and 47.1 (95% CI 12.34,179.58) at day 42 for placebo.

Drug	Statistics	Day 0	Day 42
BBV154/ iNCOVACC®	GMT 95 % CI	3.1 (1.65, 5.67)	286.8 (32, 432.09)
Placebo	GMT 95 % CI	3.7 (1.01,13.73)	47.1 (12.34,179.58)

Phase 3 clinical trial
In Phase 3 study, the GMTs of $PRNT_{50}$ at day 0 were 26.1 (95% 18.7, 36.6) and at day 42 were 768.5 (95% CI 665.1, 888.0) for **iNCOVACC®** and 37.0 (95%CI 21.0, 65.4) at day 0 and at day 42, 531.0 (95% CI 425.9, 662.1) for COVAXIN®, as comparator.

Drug	Statistics	Day 0	Day 42
BBV154/ iNCOVACC®	GMT 95 % CI	26.1 (18.7, 36.6)	768.5 (665.1, 888.0)
BBV152/ COVAXIN®	GMT 95 % CI	37.0 (21.0, 65.4)	531.0 (425.9, 662.1)

Heterologous Clinical Trial
Phase 2 clinical trial
In Phase 2, at baseline, IgG titres were 20.34 (13.03, 31.76), 19.31(11.94, 31.23), 19.72 (12.69, 30.64) and 25.95 (15.6, 43.17) in group-1, group-2, group-3, and group-4 respectively.

On Day 56, IgG titres were 285.11 (199.38,407.7), 464.54 (335.12, 643.95), 303 (226.71, 406.57) and 430.2 (286.77, 645.35), in group-1, group-2, group-3 and group-4 respectively.

Days	Statistics	Group - 1 (COVAXIN®+ COVAXIN®)	Group - 2 (COVAXIN®+ iNCOVACC®)	Group - 3 (iNCOVACC® + COVAXIN®):	Group - 4 (iNCOVACC®+ iNCOVACC®
Day 0	GMT (95% CI)	20.34 (13.03, 31.76)	19.31 (11.94, 31.23)	19.72 (12.69, 30.64)	25.95 (15.6, 43.17)
Day 56	GMT (95% CI)	285.11 (199.38, 407.7)	464.54 (335.12, 643.95)	303.6 (226.71, 406.57)	430.2 (286.77, 645.35)

Phase 3 clinical trial
In Phase 3, at baseline, IgG titres were 289.63 (95% CI 204.84, 409.53), 388.65 (95 % CI 243.83, 619.5), 372.19 (95% CI 270.15, 512.76), 320.88 (95% CI 185.08, 556.31) and 451.56 (95% CI 289.71, 703.83) in group-1, group-2, group-3, group-4 and group-5 respectively.

On Day 28, IgG titres were 365.47 (95% CI 272.01, 491.05), 409.11 (95 % CI 287.58, 581.99), 518.09 (95% CI 403.35, 665.46), 368.84 (95% CI 238.91, 569.43) and 363.25 (95% CI 227.04, 581.16) in group-1, group-2, group-3, group-4 and group-5 respectively.

On Day 56, IgG titres were 564.06 (95% CI 479.09, 664.11), 578.05 (95 % CI 436.86, 764.89), 655.49 (95% CI 533.25, 805.75), 625.39 (95% CI 474.68, 823.96) and 650.07 (95% CI 519.74, 813.09) in group-1, group-2, group-3, group-4 and group-5 respectively.

Day	Statistics	COVAXIN®		COVISHIELD		
Day0	GMT (95%CI)	319.55 (242.13, 421.72)		376.4 (296.95, 477.12)		
		iNCOVACC® (Group -1)	COVAXIN® (Group -2)	iNCOVACC® (Group - 3)	COVAXIN® (Group - 4)	COVISHIELD (Group - 5)
Day 0	GMT (95%CI)	289.63 (204.84, 409.53)	388.65 (243.83, 619.5)	372.19 (270.15, 512.76)	320.88 (185.08, 556.31)	451.56 (289.71, 703.83)
Day 28	GMT (95%CI)	365.47 (272.01, 491.05)	409.11 (287.58, 581.99)	518.09 (403.35, 665.46)	368.84 (238.91, 569.43)	363.25 (227.04, 581.16)
Day 56	GMT (95% CI)	564.06 (479.09, 664.11)	578.05 (436.86, 764.89)	655.49 (533.25, 805.75)	625.39 (474.68, 823.96)	650.07 (519.74, 813.09)

Effectiveness against SARS-CoV-2 Variants
iNCOVACC® nasal vaccine has been evaluated and shown satisfactory immune response against several variants of such as Delta, Beta and Omicron including the recent variant BA.5. Cell mediated immune response, both T and B cell phenotype distribution is evaluated against SARS-CoV-2 variants including omicron variants found the response is persistent across variants.

5.2 Pharmacokinetic properties
Evaluation of pharmacokinetic properties is not required for vaccines.

5.3 Preclinical safety data
Safety and immunogenicity in Mice, Rats, Hamsters and Rabbits
Repeated dose intranasal immunogenicity and safety study with **iNCOVACC®** in laboratory animals (BALB/c mice, Swiss Albino mice, Wistar rats, Syrian Hamsters and New Zealand Rabbits) was conducted based on the New Drugs and Clinical Trials Rules, 2019 and WHO guidelines on Nonclinical Evaluation of Vaccines.

Treatment with **iNCOVACC®** did not show treatment related changes in clinical signs, body weights, feed consumption, body temperature, clinical pathology, terminal fasting body weights, organ weights and gross pathology in both sexes. There was no treatment related microscopic findings observed in animals treated with **iNCOVACC®**.

No mortality was observed throughout the study period. No clinical signs of toxicity were observed in all the treated animals.

No adverse effect on body weight and body weight gain was observed for treated animals. No significant change in the body temperature was observed of all the treated animals. No adverse effects on feed consumption were noted for all the treated animals.

Local reactogenicity was assessed prior to study, on day of each dosing and followed by 24 hours as per Draize scoring system. No skins reactions were observed.

There were no treatment related changes observed in clinical pathology parameters, terminal fasting body weights and organ weights in any of the groups in both sexes.

Animals immunized through intranasal route with **iNCOVACC®**, at a given antigen concentrations were found to be immunogenic, eliciting high levels of IgG and IgA antibodies specific to SARS-CoV-2 S1 antigen. High neutralization antibody titers were observed in **iNCOVACC®** immune serum.

In conclusion, treatment with **iNCOVACC®** even at high dose (5×10^{11} VP/animal) did not produce any treatment related changes when administered with full Human Single Dose (HSD) of multiple doses (n+1).

Challenge Studies of ChAd36-SARS-CoV-2-S Carried out at Washington University.

Introduction
ChAd36-SARS-CoV-2-S is an adenoviral based SARS-CoV-2 intranasal vaccine (ChAd36-SARS-CoV-2-S) expressing a prefusion stabilized spike (S) protein developed by Michael Diamond's group (Washington University, Saint Louis, USA).

Brief summary of challenge studies
Challenge studies were performed in three different animal models, K18-hACE2 transgenic mice, Syrian hamster and non-human primates.

(i) K18-hACE2 transgenic mice
Mice were immunized with ChAd-SARS-CoV-2-S, in two different routes. Both, Intranasal or intramuscular administration of ChAd-SARS-CoV-2-S, prevents SARS-CoV-2 lung infection and pneumonia in mice. In particular, intranasal delivered ChAd-SARS-CoV-2-S uniquely prevents both upper and lower respiratory tract infections, potentially protecting against SARS-CoV-2 infection and transmission (*Hassan et al. 2020*).

(ii) Syrian Hamsters
Similarly, intranasal administration of ChAd36-SARS-CoV-2-S in Syrian hamster showed superiority over intramuscular vaccination, in terms of neutralizing antibodies and in preventing SARS-CoV-2 infection in both the upper and lower respiratory tracts (Bricker et al. 2020).

(iii) Rhesus macaques
Single-dose intranasal immunization of ChAd-SARS-CoV-2-S, in Rhesus macaques induces neutralizing antibodies and T cell responses against SARS-CoV-2. ChAd-SARS-CoV-2-S vaccine protected Rhesus monkeys against SARS-CoV-2 infection (Hassan et al. 2021).

Protection against SARS-CoV-2 Variants
Further, assessment of durability, dose response, and cross-protective activity of ChAd-SARS-CoV-2-S against SARS-CoV-2 variants following single intranasal dose induced durable high neutralizing antibodies along with S-specific IgG and IgA secreting long-lived plasma cells in the bone marrow. Protection against a historical SARS-CoV-2 strain was observed across a 100-fold vaccine dose range and over a 200-day period. At 6 weeks or 9 months after vaccination, serum antibodies neutralized SARS-CoV-2 strains, B.1.351, B.1.1.28, and B.1.617.1 spike protein and conferred almost complete protection in the upper and lower respiratory tracts after challenge with variant viruses. Thus, in mice, intranasal immunization with ChAd-SARS-CoV-2-S provides durable protection against historical and emerging SARS-CoV-2 strains (Hassan et al. 2021b).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Tris (pH 7.4), Sodium Chloride, Magnesium Chloride, Glycerol and Polysorbate-80.

6.2 Incompatibilities
The vaccine should not be mixed with any other medicinal products or active immunizing agents.

6.3 Shelf life
The expiry date of **iNCOVACC®** COVID-19 Vaccine (ChAd36-SARS-CoV-S (Recombinant)) is indicated on the label and carton of the vaccine.

Do not use the vaccine after the expiration date shown on the label and carton of the vaccine.

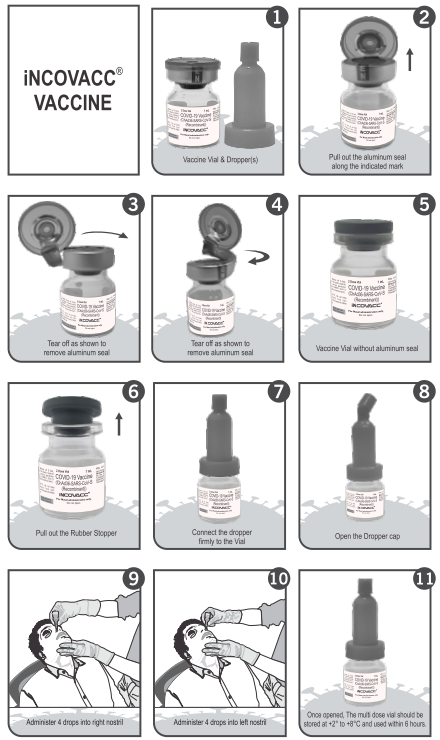
Once opened, Multi dose vial should be used as soon as practically possible and within 6 hours when kept between +2 to+8°C.

iNCOVACC® should be discarded at the end of the immunization session or within 6 hours whichever comes first.

6.4 Special precautions for storage
Store at +2° to +8 °C.
Do not freeze.
Discard if frozen.
Shake gently before use.
Keep out of reach of children.
Protect from light.
Store vials in the original carton till the vial is used.

7. PRESENTATION
iNCOVACC® COVID-19 Vaccine (ChAd36-SARS-CoV-S (Recombinant)) is presented in USP type 1-glass vials
- Multi dose vial - 1mL (2 dose)

8. INSTRUCTIONS FOR USE, HANDLING AND DISPOSAL
8.1. Vial (2 Dose) Administration Procedure :



iNCOVACC® contains genetically modified organisms (GMOs). Any unused vaccine or waste material should be disposed of in accordance with local requirements. Spills should be disinfected with an appropriate antiviral disinfectant (e.g. Hydrogen peroxide-based disinfectants).

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Manufactured & Marketed by:

BHARAT BIOTECH
Lead Innovation

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