

**EQUINE ANTI COVID ANTIBODY
FRAGMENTS F(ab')₂
VINCOV-19™
(3 mL liquid vial)**

NAME OF THE MEDICINAL PRODUCT:

VINCOV-19™, Equine Anti Covid Antibody Fragments F(ab')₂ (Liquid Injection 3 mL).

DESCRIPTION:

VINCOV-19™ is an Equine Anti Covid Antibody Fragments F(ab')₂ for passive immunotherapy for the SARS-Cov-2.

COMPOSITION:

Each 1 mL contains:

Equine Anti Covid Antibody Fragments F(ab')₂ neutralizing titers of NLT 10000.

Cresol B.P. ≤ 0.25% v/v

Sodium Acetate B.P.,

Sodium Chloride B.P.,

Polysorbate-80 B.P

PHARMACEUTICAL DOSAGE FORM:

Sterile Liquid Solution for Intravenous injection.

THERAPEUTIC INDICATIONS:

VINCOV-19™ is indicated for the treatment of SARS-Cov-2 in human subjects of age group between 18 - 65 years exposed to the SARS-Cov-2 virus.

Patient who are positive for COVID-19 by RT - PCR or Rapid antigen method has to be administered VINCOV-19™ as soon as possible after the diagnosis and administration must always be performed under medical supervision. VINCOV-19™ can be safely used along with routine standard of care for treatment of COVID-19.

POSOLGY AND METHOD OF ADMINISTRATION:

One vial (3 mL) to be administered intravenously mixed in 100 mL of normal saline over a period of 100 minutes (1 mL/min) and second dose to be repeated after 24 hours.

WARNINGS AND PRECAUTION:

- VINCOV-19™ alone is not a treatment for COVID-19 and has to be administered along with Standard of Care treatment.
- In view of heterologous nature of equine Covid immunoglobulin fragments, the risk of undesirable effects should always be assessed. A clear history should be verified regarding prior injections of heterologous proteins or allergy to such products. Allergies induced by contact with horses should also be investigated.
- Administration of VINCOV-19™ should be performed under strict medical supervision in order to prevent any possible anaphylactic shock.
- Keep the emergency medicines ready before administration of the product to treat anaphylactic shock, if any.

CAUTION FOR USAGE:

Those who are allergic to equine serum should not use this drug.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:

This product should not be mixed with other medicinal product in the same syringe.

SIDE/ADVERSE/UNDESIRABLE EFFECTS:

Immediate or delayed allergic type reactions can occur after the use of heterologous proteins.

The immediate reactions observed are anaphylactic reactions with hypotension, dyspnoea, rash or urticaria. In very rare cases anaphylactic shock or Quincke's oedema may occur. Delayed Serum sickness like reactions may occur 6 to 10 days after administration of heterologous proteins. Clinical symptoms and signs like fever, pruritus, erythema, urticaria, arthralgia or adeno-pathy may be seen.

No Serious Adverse Events were reported during the clinical study.

OVERDOSE:

The recommended dose should not be exceeded.

PHARMACOLOGICAL/MECHANISM OF ACTION:

The Antibody fragments (F(ab')₂) specifically neutralizes the circulating virus in the blood and reduce the viral infectivity of the target organs in humans.

PHARMACOTHERAPEUTIC GROUP:

Immunotherapeutic / Passive Immunotherapy.

SHELF-LIFE:

Proposed shelf-life is 24 months (Stored at 2°C - 8°C).

STORAGE CONDITION:

Store between +2°C and +8°C (in a refrigerator). Do not freeze. Protect from light.

PRESENTATION:

Vial containing 3 mL Sterile Solution for IV injection.

DISPOSAL:

Left over product and used vial should be discarded as Biomedical waste.

Manufactured by:



VINS BIOPRODUCTS LIMITED

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Kothur (M), Rangareddy (Dist.),
Telangana, India.