# Package Insert

Version 1.0

First Approval Date: June 10, 2021

**Recombinant Novel Coronavirus Vaccine**
**(Adenovirus Type 5 Vector)**

Convidecia™

## 1.DRUG NAME

Proprietary Name: Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector)

Short name: Ad5-nCoV

Trade Name: Convidecia or CONVIDECIA

## 2.DESCRIPTION

This COVID-19 vaccine is non-replicate, recombinant human type 5 Adenovirus vector expressing S protein of SARS-CoV-2. It is made through the process that HEK293SF-3F6 cells are infected with replication-defective recombinant human type 5 Adenovirus expressing S protein of SARS-CoV-2, then a liquid formulation is obtained through culture, amplification, harvest, purification and adding with appropriate excipients. No preservatives or antibiotics are used in this vaccine.

**Active Ingredient:** Replication-defective recombinant human type 5 Adenovirus expressing S protein of SARS-CoV-2.

**Excipients:** Mannitol, sucrose, sodium chloride, magnesium chloride, polysorbate 80, glycerin, and N-(2-Hydroxyethyl) piperazine-N'-(2-ethanesulfonic acid) (HEPES) and Water-For-Injection as solvent.

## 3. INDICATIONS AND USAGE

This Ad5-nCoV vaccine is intended to use to prevent the COVID-19 disease caused by the SARS-CoV-2 virus for adults age 18 years and older.

## 4. DOSAGE FORM AND PRESENTATION

Each dose contains 0.5 mL sterile colorless or slightly white liquid injection, supplied in a single-dose glass vial, a single-dose prefilled syringe, or a three-dose vial, containing ⩾ $4\times10^{10}$VP/dose of replication-defective recombinant human type 5 adenovirus expressing S protein.

## 5. DOSAGE AND ADMINISTRATION

A single dose for intramuscular injection in the deltoid muscle of the upper arm.

It has not been determined whether this vaccine requires a booster immunization.

It is recommended a 23G or 25G, 1.5 inch needle to be used for extraction of the vaccine from the bottom of the vial.

## 6. ADVERSE REACTIONS

The safety of Ad5-nCoV vaccine has been evaluated in three clinical trials carried out in China and internationally:

1) A randomized, opened phase I clinical trial in adults aged 18-60 years in China;

2) A randomized, double-blind, placebo-controlled phase II clinical trial in people aged 18 years and older in China;

3) A randomized, double-blind, placebo-controlled, multi-center phase III efficacy clinical trial in people aged 18 years and older in Pakistan, Mexico, Russia, Chile and Argentina.

In the Phase I and Phase II clinical trials, adverse events within 28 days after vaccination and severe adverse events (SAE) within 6 months after vaccination were collected for all subjects. In the phase III clinical trial, all subjects were regularly followed up by the investigator to collect Medically Attended Adverse Events (MAE) and SAE within 12 months. Adverse events within 28 days after vaccination were systematically collected in the safety extended cohort (3000 people), which has not yet been completed currently.

According to the classification of the incidence of adverse reactions recommended by the Council for International Organizations of Medical Sciences (CIOMS): very common (⩾ 10%), common (1%~10%, including 1%), uncommon (0.1%~1%, including 0.1%), rare (0.01%~0.1%, including 0.01%), very rare (<0.01%), the safety data from clinical trials and the experience of emergency use of Ad5-nCoV vaccine are summarized as follows:

**(1) Local adverse reaction at injection site**

Very common: pain;

Common: swelling, itch, redness, induration;

Uncommon: bleeding, rash, cellulitis.

**(2) Systemic adverse reactions**

Very common: fever, headache, fatigue, myalgia, drowsiness, nausea, diarrhea;

Common: joint pain, cough, oropharyngeal pain, vomiting, loss of appetite, dizziness, mucosal disease, pruritus;

Uncommon: hypoesthesia, gastrointestinal dysfunction, joint swelling, syncope, difficulty breathing, acute bronchospasm, itching (non-vaccination site), acute allergic reaction.

**Severity of adverse reactions**

The severity of adverse reactions observed in clinical trials of Ad5-nCoV vaccine is mainly grade 1 (mild), and the incidence of grade 3 and above adverse reactions is 7.40%.

The adverse reactions at the injection site of grade 3 and above are pain, swelling, and redness; the systemic adverse reactions of grade 3 and above are fever, headache, drowsiness, nausea, and myalgia.

**(4) Serious adverse event**

Investigators have judged all the serious adverse events (SAE) observed in clinical trials as unrelated or possible unrelated to vaccination till January 10, 2021.

## 7. CONTRAINDICATIONS

(1) Allergic reaction to any component of this vaccine or similar vaccines.

(2) People who have experienced severe allergic reactions to vaccines in the past (such as acute allergic reactions, angioedema, dyspnea, etc.).

(3) People with uncontrolled epilepsy and other progressive neurological diseases, and the history of Guillain-Barré syndrome.

(4) Pregnant and lactating women.

## 8. WARNINGS AND PRECAUTIONS

(1) The protection persistency data of Ad5-nCoV vaccine has not yet been obtained. Necessary self-protection measures against COVID-19 still should be taken after vaccination.

(2) This vaccine is strictly prohibited by intravascular injection. There are no data on the safety and efficacy of this vaccine by subcutaneous or intradermal injection.

(3) Before use, check whether the packaging container, label, appearance, and expiration date meet the requirements. It should not be used under following circumstances: damage or crack, spots, stains, scratches on the outer surface of the vaccine container, unclear label, expired vaccine, or abnormal appearance.

(4) Avoid vaccine exposure to disinfectant when opening the vaccine vial and injection.

(5) Keep the product out of reach of children.

(6) People who are vaccinated should be observed on site according to the local general vaccination practice (at least 30 minutes). The vaccination clinic should be equipped with first-aid drugs and equipment such as epinephrine to deal with the emergency such as severe acute allergic reaction.

(7) Ad5-nCoV vaccine cannot be mixed with other vaccines in the same syringe.

(8) For Ad5-nCoV vaccine in single dose presentation, it Ad5-nCoV vaccine should be used immediately after opening.

(9) People suffering from acute diseases, acute-outbreak period of chronic diseases, severe chronic diseases, allergies and fever should be used with caution. If necessary, the vaccination shall be delayed after the doctor’s evaluation.

(10) Cautionary use for diabetic patients and those with history of convulsions, epilepsy, encephalopathy or mental illness or family history.

(11) Cautionary use for those with a history of asthma.

(12) Cautionary use for patients with thrombocytopenia or any coagulation dysfunction since intramuscular injection may cause bleeding.

(13) The safety and efficacy data for people with impaired immune function (such as malignant tumors, nephrotic syndrome) is limited. Those people should be vaccinated based on individualized considerations.

(14) Those who have been injected with immune globulin should vaccinate Ad5-nCoV vaccine at an interval of more than 1 month to avoid decreasing the immune effect.

(15) People who have any neurological adverse reactions after vaccination of Ad5-nCoV vaccine are prohibited from re-vaccination.

(16) There is no evidence of the efficacy of Ad5-nCoV vaccine for people with SARS-CoV-2 infection history at this point.

(17) People with positive HIV infection. There is very limited data available for this vaccine in HIV-positive population. It is recommended that the use of this vaccine in people with positive HIV infection should be strictly under physicians' guidance.

(18) Same as other vaccines, Ad5-nCoV vaccine may not produce 100% efficacy in the vaccinated population.

## 9. SYMPTOMS AND TREATMENT OF OVERDOSE

Only one single dose is used for administration for each person. No overdose should occur. No symptoms and treatment of overdose is applicable for Ad5-nCoV vaccine.

## 10. EFFECTS ON ABILITY TO DRIVE AND OPERATE MACHINERY

Based on available clinical trial results, no effect on ability to drive and operate machinery caused by Ad5-nCoV has been found.

## 11. SPECIAL POPULATION

(1) Women of childbearing age: The data collected in clinical trials for women who have unintended pregnancy after Ad5-nCoV vaccination is very limited. It is not enough to assess the risk of adverse pregnancy outcomes (including spontaneous abortion) after vaccination with Ad5-nCoV.

(2) Pregnant or lactating women: There is no clinical trial data of Ad5-nCoV vaccine for pregnant and lactating women.

(3) People age 60 years and older: The safety and efficacy data of people aged 60 years and above are limited in the clinical trials.

## 12. DRUG INTERACTIONS

1. Simultaneous vaccination with other vaccines: No undergone clinical trial for

simultaneous vaccination with other vaccines.

2. Concomitant use with other drugs: no relevant data is available for immunosuppressants, chemotherapeutics, antimetabolites, alkylating agents, cytotoxic drugs, corticosteroids, etc., which may reduce the immune response of Ad5-nCoV.

   **For people who received or are receiving drug therapy, the consultancy of professional physician is required to avoid possible drug interactions.**

## 13. STORAGE AND HANDLING

It should be stored and transported in refrigerated conditions under 2-8 °C.

For three-dose vaccine, the vaccine vial should be stored in refrigerated conditions under 2-8 °C prior to and after each puncture. After the first dose has been withdrawn, hold the vial between 2° to 8°C for up to 6 hours. Discard the vial if vaccine is not used within these times.

## 14. SHELF-LIFE

Tentatively 12 months.

## 15. PACKAGE

Single dose:

One glass vial (0.5ml/vial) in one small box.

Or one prefilled syringe (0.5ml/syringe) in one small box .

Multi-dose:

One glass vial (1.5 ml/vial) contains 3 doses of 0.5 ml in one small box.

## 16. DEVELOPERS

Beijing Institute of Biotechnology
No.20 Dongdajie Street, Fengtai District, Beijing, China, 100071

CANSINO BIOLOGICS INC.
185 South Ave., TEDA West District, Tianjin, China, 300462

**17. MANUFACTURER**

CANSINO BIOLOGICS INC.

185 South Ave., TEDA West District, Tianjin, China, 300462