DISCLAIMER: THIS PRODUCT IS APPROVED UNDER MALAYSIA CONDITIONAL REGISTRATION FOR PHARMACEUTICAL PRODUCTS DURING DISASTER GUIDELINE. THE ADMINISTRATION OF THE PRODUCT IS PURELY BASED ON INDIVIDUAL'S PREFERENCE.

CONVIDECIA

Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) Solution for Injection

What is in this leaflet

What CONVIDECIA is used for

CONVIDECIA is indicated for active immunization to prevent COVID-19 caused by SARS-CoV-2, in individuals 18 years of age and older. The use of this vaccine should be in accordance with official recommendations

How CONVIDECIA works

CONVIDECIA stimulates the body's natural defences (immune system). It causes the body to produce its own protection (antibodies) against the virus. This will help to protect you against COVID-19 in the future. None of the ingredients in this vaccine can cause COVID-19.

Before you use CONVIDECIA

When you must not use it

Do not take CONVIDECIA if you have ever had an allergic reaction to any component of this vaccine or similar vaccines, (see *ingredient* subsection) of this vaccine or similar vaccines.

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

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

If you are not sure, talk to your doctor, pharmacist or nurse.

Pregnant and lactating women.

No data are currently available on the use of CONVINDECIA in Pregnant and lactating women.

Before you start to use it

Caution should be taken when this vaccine is used in the following conditions:

- For patients with thrombocytopenia or haemorrhagic diseases, intramuscular injection of this vaccine may cause bleeding.
- Any confirmed or suspected immunosuppressive or immune-deficient state; asplenia; recurrent severe infections and chronic use (more than 14 days) of immunosuppressant medication within the past 6 months.
- For those with a history of asthma
- For diabetic patients and those with history of convulsions, epilepsy, encephalopathy or mental illness or family history.
- People suffering from acute diseases, acute-outbreak period of chronic diseases, severe chronic diseases, allergies and fever.
- People with positive HIV infection. There is very limited data available for this vaccine in HIV-positive population.
- Those who have been injected with immune globulin should vaccinate at an interval of more than 1 month to avoid decreasing the immune effect.

Taking other medicines

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take, any other medicines or vaccines

How to use CONVIDECIA

How much to use & when to use

CONVIDECIA should be injected into the deltoid muscle of the upper arm as a single dose. Based on the clinical trial results, one dose of vaccination is recommended for one person.

Ad5-nCoV vaccine can be used for both prime and booster immunization. A booster dose (0.5ml) may be administered at least 3-6 months after the first single dose when the potential benefits outweigh any potential risks.

If you forget to use it

If you forget to go back at the scheduled time, ask your doctor, pharmacist or nurse for advice.

If you too much (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 CONVIDECIA Vaccine.

While you are using CONVIDECIA

Things you must do

Not applicable

Things you must not do

Not applicable

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Things to be careful of

Driving and using machines

CONVIDECIA has no known effect on the ability to drive and use machines. However, side effects listed in this leaflet may impact your ability to drive and use machines. If you feel unwell, do not drive or use machines. (see Side effects section)

Side effects

CONVIDECIA can cause the following side effects:

1. Clinical trial

The safety data of participants vaccinated with 5×10^{10}VP in the phase I and phase II clinical trials of this product are summarized and described as follows: Adverse reactions: Adverse reactions within 28 days after one dose of vaccination were as follows:

(1) Local adverse reaction at injection site

Very common (≥10%): pain;

Common (1%~10%, including 1%): redness, induration, swelling, itchy;

Uncommon (0.1%~1%, including 0.1%): bleeding at injection site.

(2) Systemic adverse reactions

Very common (≥10%): fever, muscle pain, fatigue, headache;

Common (1%~10%, including 1%): Nausea, diarrhoea, joint pain, cough, throat pain, vomiting, decreased appetite, dizziness, mucosal abnormality, pruritus;

Uncommon (0.1%~1%, including 0.1%): hypoesthesia, functional GI disorders, joint swelling, somnolence, syncope;

(3) Serious adverse event

No serious adverse event (SAE) related to the vaccine has been observed in the clinical trial participants.

You may report any side effects or adverse reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of CONVIDECIA

Storage

- Keep this medicine out of the sight and reach of children.
- Your doctor, pharmacist or nurse is responsible for storing this vaccine and disposing of any unused product correctly.
- Do not use CONVIDECIA after the expiry date which is stated on the carton.
- Keep vials in outer carton to protect from light.
- Unopened vial should be stored and transported in refrigerated conditions at 2 to 8℃. Do not freeze.
- Opened vial should be used as soon as practically possible and within 6 hours of opening. The vaccine (vial) should be stored between 2°C and 8°C during in-use period.

Disposal

Any unused vaccine that not kept within the recommended conditions or waste material should be disposed of in compliance with the local guidance for genetically modified organisms or biohazardous waste. Spills should be disinfected using agents with activity against adenovirus.

Product Description

What it looks like

0.5 ml sterile colourless or slightly white liquid injection, supplied in single-dose (1 dose) vial of 0.5 ml or multi-dose (3 doses) vial of 1.5 ml.

Ingredients

Active Ingredients

One dose (0.5 ml) contains (Ad5-nCoV* recombinant) ≥ 4×10^{10} viral particles.

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

Inactive Ingredients

- Mannitol
- Sucrose
- Sodium chloride
- Magnesium chloride
- Polysorbate 80
- Glycerin
- N-(2-Hydroxyethyl) piperazine-N'-(2-ethanesulfonic acid) (HEPES)
- Water-For-Injection (as solvent)

MAL number:

MAL21066050AZ

Headquarters

CanSino Biologics Inc.
185 South Avenue, TEDA West District, Tianjin, China 300462

Manufactured and Released By

CanSino Biologics Inc.
Building 020, 6 Xinpeng Road, TEDA West District, Binhai New Area, Tianjin, China, 300462

Product Registration Holder

Solution Biologics Sdn. Bhd.
PT 13796 Jalan Tekno Usahawan 2, Technology Park Malaysia, 57000 Kuala Lumpur, Wilayah Persekutuan, Malaysia

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