Issued on June 07, 2021 Version 01

克尔来福® CoronaVac®

COVID-19 Vaccine (Vero Cell), Inactivated

Please read the leaflet carefully and use the vaccine under the doctor guidance.

【NAME OF THE MEDICAL PRODUCT】
Generic Name: COVID-19 Vaccine (Vero Cell), Inactivated
Trade Name: CoronaVac®

【COMPOSITION AND DESCRIPTION】
The product is produced by first inoculating SARS-CoV-2 virus (CZ02 strain) onto African green monkey kidney cells (Vero cells), followed by cultivation, harvest, inactivation, concentration, purification and aluminum hydroxide adsorption. The product is a milky-white suspension. Stratified precipitate may form which can be dispersed by shaking.
Active ingredient: Inactivated SARS-CoV-2 Virus (CZ02 strain) 600SU
Adjuvant: Aluminum hydroxide 0.225mg
Excipients: Phosphate 0.0025mmol (disodium hydrogen phosphate dodecahydrate, sodium dihydrogen phosphate monohydrate), sodium chloride 4.5mg, water for injection q.s.
No preservative in this product.

【TARGET GROUPS FOR VACCINATION】
Adults from 18 to 59 years of age.

【THERAPEUTIC INDICATION】
The product is indicated for active immunization against diseases caused by SARS-CoV-2 virus.

【PRESENTATION】
Each syringe contains 0.5 mL. Single dose of 0.5 mL contains 600SU of inactivated SARS-CoV-2 virus as antigen.

【ADMINISTRATION】
CoronaVac® should be administered by intramuscular injection in the deltoid region of the upper arm. Shake well before use.

【IMMUNIZATION SCHEDULE】
Two doses should be administered for primary immunization. The second dose is preferably given 14-28 days after the first dose. 0.5 mL per dose.
It has not been determined whether this product requires booster immunization.

【ADVERSE REACTIONS】
According to the grading standard of adverse reaction incidence from Council for International Organizations of Medical Sciences (CIOMS), i.e. very common (≥10%), common (1%-10%, 1% was inclusive), uncommon (0.1%-1%, 0.1% was inclusive), rare (0.01%-0.11%, 0.01% was inclusive) and very rare (<0.01%). The safety results have been evaluated based on analysis of pooled data from 4 on-going randomized, blinded, controlled clinical trials in China and Brazil among individuals aged 18 years and older. The most frequently reported adverse reactions were injection-site pain (50.3%), headache (28.0%), fatigue (13.5%), muscle pain (9.7%), diarrhoea (6.8%) and nausea (6.5%). The majority of adverse reactions were mild to moderate in severity and usually resolved within a few days after the vaccination. All adverse reactions were summarized and described as follows.

MedDRA System Organ Class	Frequency	Adverse reactions
Immune system disorders	Uncommon	Hypersensitivity
Metabolism and nutrition disorders	Common	Decreased appetite
Nervous system disorders	Very common	Headache
	Uncommon	Tremor Dizziness Drowsiness
	Rare	Hyposmia
Eye disorders	Rare	Ocular congestion Eyelid oedema
Vascular disorders	Uncommon	Flushing
	Rare	Hot flashes
Respiratory, thoracic and mediastinal disorders	Common	Cough Rhinorrhea Oropharyngeal pain Nasal congestion
	Rare	Nose bleed/epistaxis
Gastrointestinal disorders	Common	Nausea Diarrhoea Abdominal pain
	Uncommon	Vomiting
	Rare	Abdominal distension Constipation
Skin and subcutaneous tissue disorders	Common	Pruritus
	Uncommon	Mucocutaneous rash
Musculoskeletal and connective tissue disorders	Common	Myalgia Arthralgia
	Rare	Muscle spasms
General disorders and administration site conditions	Very common	Vaccination site pain Fatigue
	Common	Vaccination site swelling Vaccination site pruritus Vaccination site erythema Vaccination site induration Chills
	Uncommon	Fever (Axillary temperature ≥ 37.3°C) Vaccination site warmth Oedema

SINOVAC

210mm

克尔来福® CoronaVac®

The following adverse reactions have been observed upon the marketing of other inactivated virus vaccines: 1) local lymphadenopathy at the injection site. 2) allergic reactions caused by any component of the vaccine: hives, allergic rashes and purpura, anaphylactic shock. 3) convulsion (with or without fever) etc. Although the mentioned adverse reactions were not observed in the pre-marketing clinical studies, caution still need to be taken during the use of this vaccine.
In case of any discomfort not mentioned above, please contact your doctor immediately.

【CONTRAINDICATION】
This product is contraindicated in person:
1. People with history of severe allergic reaction to CoronaVac® or other inactivated vaccine, or any component of CoronaVac® (active or inactive ingredients, or any material used in the process);
2. Previous severe allergic reactions to any other vaccines (e.g., acute anaphylaxis, angioedema, dyspnea, etc.).

【SPECIAL POPULATION MEDICATION】
1. CoronaVac® should be used with caution in patients with severe neurological conditions (e.g., transverse myelitis, Guillain-Barré syndrome, demyelinating diseases, etc.).
2. CoronaVac® should be used with caution in patients with episodes of relapse, or unstable severe chronic diseases.
3. Vaccination should be postponed in individuals suffering from an acute severe febrile illness or acute infection. However, the presence of a minor infection and/or low-grade fever should not delay vaccination.
4. Fertility, pregnancy and lactation

Pregnancy
Limited experience exists with use of Sinovac COVID-19 Vaccine in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development. Administration of Sinovac COVID-19 Vaccine in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and foetus.
Breastfeeding
It is unknown whether Sinovac COVID-19 Vaccine is excreted in human milk.
Fertility
Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

【PRECAUTIONS】
1. Traceability: In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.
2. Duration of protection: The duration of protection afforded by the vaccine is unknown as it is still being determined by ongoing clinical trials. Necessary protective measures should be taken in line with the COVID-19 epidemic.
3. Limitations of vaccine effectiveness: Individuals may not be fully protected until 14 days after their second dose. As with all vaccines, vaccination with COVID-19 Vaccine (Vero Cell), Inactivated may not protect all vaccine recipients.
4. Excipients with known effect

Sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per 0.5 ml dose, that is to say essentially "sodium-free".

5. This vaccine is strictly prohibited for intravenous injection. There is no safety and efficacy data of subcutaneous or intradermal injection.
6. Before use, check whether the packaging container, label, appearance and validity period meet the requirements or not. Do not use if there are cracks in the glass needle tube, spots, stains and scratches on the outer surface of the glass needle tube, label is not clear or more than the expiration date and abnormal appearance.
7. Avoid expose CoronaVac® to the disinfectant during use.
8. This product should be stored at places out of reach of children.
9. Adequate treatment provisions, including epinephrine injection and emergency treatment, should be available for immediate use. Individuals should be observed for at least 15 minutes on site after vaccination.
10. Do not mix with other vaccines in the same syringe.
11. Do not freeze. It shall be administered immediately after open.
12. Patients with thrombocytopenia or coagulation disorders, intramuscular injection of this product may cause bleeding, so it should be used with caution.
13. Immunocompromised individuals: The efficacy, safety and immunogenicity of the vaccine have not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy. The efficacy of COVID-19 Vaccine (Vero Cell), Inactivated may be lower in immunosuppressed individuals.
14. The injection of human immunoglobulin should be given at least one-month interval to avoid affecting the immune effect.

【DRUG INTERACTIONS】
1. Concomitant use with other vaccines: no clinical study has been carried out on the evaluation of immune response with other vaccines on the immunogenicity at the same time (before, after or at the same time). Professionals should be consulted when concomitant use.
2. Concomitant use with other drugs: immunosuppressive drugs, such as immunosuppressive drugs, chemotherapy drugs, antimetabolic drugs, alkylating agents, cytotoxic drugs, corticosteroid drugs, etc., may reduce the immune response to this product.
3. Patients undergoing treatment: for patients undergoing treatment, please consult the professional doctors before using CoronaVac® to avoid possible drug interactions.

【CLINICAL TRIALS】 Refer to the data of clinical trials.
【STORAGE】 Store and transport between +2℃ and +8℃, and protect from light. Do not freeze.
【PACKAGE】 This product is packaged into pre-filled syringe, 10 syringes/box.
【SHELF LIFE】 The expiry date of the vaccine is tentatively scheduled as 12 months.

【MANUFACTURER】
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