120mm

210mm

Issued on March 14, 2022

Version 01

Emergency Use Authorization

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】
Individuals 6 years of age and older.

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

【PRESENTATION】
1) Each vial (syringe) contains 0.5 mL, containing 600SU of inactivated SARS-CoV-2 virus as antigen.
2) Each vial contains 1.0 mL, 2 doses per vial, containing 1200SU of inactivated SARS-CoV-2 virus as antigen.
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 each extraction/injection.

【IMMUNIZATION SCHEDULE】
Two doses should be administered for primary immunization. The second dose is preferably given 4 weeks after the first dose. A third dose at least 6 months after completion of the primary course of 2 doses of the COVID-19 Vaccine Sinovac may be administered in the following populations:
1. Healthcare professionals and workers 18 years of age or older with frequent institutional or occupational exposure to SARS-CoV-2;
2. Individuals who may fail to mount an adequate response to a primary series of vaccines such as senior citizens and patients 18 years of age or older who are diagnosed with immunocompromised conditions;
3. Persons 18 through 60 years of age with comorbidities and at high risk of developing severe COVID-19.

【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%-0.1%, 0.01% was inclusive) and very rare (<0.01%). The safety of COVID-19 Vaccine (Vero Cell) Inactivated has been evaluated based on analysis of pooled data from 5 clinical trials in China and Brazil. The most frequently reported adverse reactions in the clinical trial in Brazil were injection-site pain (60.3%), headache (34.3%), fatigue (16.0%), muscle pain (11.7%), nausea (7.9%) and diarrhoea (7.9%). The majority of adverse reactions were mild to moderate in severity and usually resolved within a few days after the vaccination. The safety profile of booster immunization is equivalent to primary immunization. All adverse reactions were summarized and described as follows.

MedDRA System Organ Class	Frequency	Adverse Reactions
Immune system disorders	Uncommon	Hypersensitivity (containing acute allergic reaction)
Metabolism and nutrition disorders	Common	Loss of appetite
Nervous system disorders	Very common	Headache
	Uncommon	Tremor Dizziness Drowsiness
	Rare	Hyposmia/anosmia Seizure
Eye disorders	Rare	Ocular congestion Eyelid edema Periorbital swelling Conjunctival hyperaemia
Vascular disorders	Uncommon	Flushing
	Rare	Hot flashes
Respiratory, thoracic and mediastinal disorders	Common	Cough Rhinorrhea Oropharyngeal pain Nasal congestion
	Uncommon	Sneezing
	Rare	Nose bleed/epistaxis Larynx irritation
Gastrointestinal disorders	Common	Nausea Diarrhoea Abdominal pain
	Uncommon	Vomiting Odynophagia
	Rare	Abdominal distension Constipation Hiccups Colitis ulcerative Appendicitis
Skin and subcutaneous tissue disorders	Common	Pruritus
	Uncommon	Abnormal skin and mucosa
	Rare	Rash/papule Hyperhidrosis Skin warm
Musculoskeletal and connective tissue disorders	Common	Myalgia Arthralgia
	Rare	Muscle spasms Pain in extremity Back pain Myopathy
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 Vaccination site warmth Edema Discomfort

SINOVAC

克尔来福® CoronaVac®

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. This product has two types of volume including 0.5 mL/vial and 1.0 mL/vial. The specification of 1.0 mL/vial contains 2 doses, which should not be vaccinated for one person. Carefully identify different specifications before use.
2. For the vaccine of 1.0 mL/vial, after the first vaccination, the remaining vaccine shall be stored at room temperature within 1 hour, or between +2℃ and +8℃ within 6 hours according to the actual situation. Before the second vaccination, sterilize the surface of rubber stopper and avoid cross-contamination strictly. The error of administration volume caused by repeat extractions should be minimized. If less than 0.5 mL, the remaining vaccine should be discarded. The remaining vaccine from multiple vials must not be mixed for use.
3. Due to the insufficient data of protection persistence, necessary protective measures should be taken in line with the COVID-19 epidemic.
4. Due to the insufficient data of efficacy in people aged 60 and above, when use CoronaVac® among people aged 60 and above by relevant institutions, the health status and exposure risk of people aged 60 and above shall be considered.
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 vial, spots, stains and scratches on the outer surface of the vial, 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. Appropriate medical treatments, such as adrenaline, should be readily available for immediate use in case of severe anaphylactic reaction following vaccination. Individuals shall be observed for at least 30 minutes on site after injection.
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 acute diseases, acute exacerbation of chronic diseases, severe chronic diseases, allergies and fever should be used with caution; if necessary, delay vaccination after doctor's evaluation.
13. Patients with diabetes and convulsions, epilepsy, encephalopathy or mental illness history or family history should be used with caution.
14. Patients with thrombocytopenia or hemorrhagic diseases, intramuscular injection of this product may cause bleeding, so it should be used with caution.
15. The safety and efficacy data of this product on people with impaired immune function (such as malignant tumor, nephrotic syndrome, AIDS patients) have not been obtained, and the vaccination of this product should be based on individual considerations.
16. The injection of human immunoglobulin should be given at least one month interval to avoid affecting the immune effect.
17. 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.
18. Do not use if there is any adverse reaction of nervous system after inoculation.
19. Like other vaccines, the protective effect may not reach 100% for all recipients.

【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).
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°C and +8°C, and protect from light. Do not freeze. For the vaccine of 1.0 mL/vial, after the first vaccination, the remaining vaccine shall be stored at room temperature within 1 hour or between +2°C and +8°C within 6 hours according to the actual situation.

【PACKAGE】 This product is packaged into vial, which contains 40 vials per box.

【SHELF LIFE】 1) For the presentation of 0.5 mL/vial, the shelf life of vaccines is tentatively schedules as 24 months.
2) For the presentation of 1.0 mL/vial, the shelf life of vaccines is tentatively schedules as 9 months.

【MANUFACTURER】
Manufacturer: SINOVAC LIFE SCIENCES CO., LTD.
Address: No. 21 Tianfu Street, Daxing Biomedicine Industrial Base of Zhongguancun Science Park, Daxing District, Beijing, P.R. China.
Zip Code: 102601
Tel.: 86-10-56897188
Fax: 86-10-56897123
Website: www.sinovac.com
E-mail: sinovac@sinovac.com

SINOVAC

客户名称	北京科兴中维生物技术有限公司		产品名称及版本号	说明书(新型冠状病毒灭活疫苗(Vero细胞)西林瓶出口40瓶装菲律宾) sCX-03-02B-PH(40)	
成品尺寸(mm)	120x210	发送次数	改动内容	制作员	bf
盒型		3	☑文字 ☐版式 ☐尺寸 ☐盒型 ☐颜色 ☐新活	工艺员	
打印日期	2022.3.25			质检员	
请您在确认稿件内容无误后签字确认： ☐颜色 ☐文字 ☐版式 ☐成品尺寸 ☐条形码			客户签字： 日　　期：		
备注：■色样桔色 ■PANTONE 2035C ■K100%				北京宝岛包装印刷有限公司	