

COVID-19 Vaccine (Vero Cell), Inactivated

Please read the leaflet carefully and use the vaccine under the guidance of a physician.

[Name of the Medical Product]

Generic Name: COVID-19 Vaccine (Vero Cell), Inactivated
Trade Name: CoronaVac
English Name: COVID-19 Vaccine (Vero Cell), Inactivated

[Composition and Character]

The product is manufactured by inoculation of SARS-CoV-2 virus (CZ02 Strain) into African Green Monkey Kidney Cell (Vero Cell), then the virus is incubated, harvested, inactivated, concentrated, purified and adsorbed by aluminum hydroxide. The vaccine is an opalescent suspension, stratified precipitate may form which can be dispersed by shaking.
Active ingredient: Inactivated SARS-CoV-2 Virus.
Excipients: Aluminum hydroxide, disodium hydrogen phosphate, sodium dihydrogen phosphate, sodium chloride.
This product contains no preservatives.

[Object of Vaccination]

This product is suitable for people (aged 18 years and over) susceptible to virus.

[Usage]

Vaccination of this product stimulates body to induce immunity against the disease caused by SARS-CoV-2 virus.

[Dosage]

Each dose (0.5mL) contains SARS-CoV-2 antigen of 600 SU.

[Route of Administration]

The recommended route of administration is via intramuscular injection at deltoid of upper arm. Shake well before use.

[Immunization Schedule]

For emergency vaccination, the basic immunization schedule is 2 doses at 2-week interval. The routine immunization schedule is 2 doses at 1-month interval, each inoculation dose is 0.5 mL.
Whether the immunity of product needs to be strengthened is not yet determined.

[Adverse Reactions]

According to the adverse reaction occurrence rate from Council for International Organization of Medical Sciences (CIOMS), the grading can be classified as: Very common ($\geq 10\%$), common ($1\% - 10\%$, 1% is inclusive), uncommon ($0.1\% - 1\%$, 0.1% is inclusive), rare ($0.01\% - 0.1\%$, 0.01% is inclusive), very rare ($< 0.01\%$). The specific results are based on clinical trial data.

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 studies, they still need to be paid attention to during the use of this vaccine.
In case of any discomfort not mentioned above, please contact your doctor immediately.

[Contraindications]

This product is contraindicated in person:

1. Who is known to be allergic to any of the components of this vaccine.
2. Who is febrile, patient in the acute illness period and acute attack of chronic disease.

[Precautions]

1. Intravascular injection of this vaccine is strictly prohibited.
2. Epinephrine injection and other appropriate agents and devices should be available to control immediate serious allergic reactions. Recipients should be observed on site for at least 30 minutes after vaccination.
3. Under the following circumstances, the use of this vaccine should be carefully used:
 - 1) In patients with thrombocytopenia or bleeding disorders, intramuscular injection of this vaccine may cause bleeding.
 - 2) Patients who are receiving immunosuppressive therapy or with immunodeficiency, the immune response to the vaccine may be weakened. Vaccination should be deferred until the end of treatment or ensured patients to be well protected. The vaccine should be recommended for patients with chronic immune deficiency, even if the underlying disease may lead to a limited response.
 - 3) Patients with uncontrolled epilepsy and other progressive neurological disorders, such as Guillain-Barre Syndrome.
4. As with any vaccine, vaccination with this product may not protect 100% of individuals.
5. The vaccine must be kept out of reach of children.
6. Do not expose the disinfectant to the vaccine when opening the vaccine vial and injection.
7. Shake well when using. Do not use if the vaccine bottle is cracked, poorly marked or ineffective, or if there is a foreign matter in the vaccine bottle.
8. Do not combine this product with other vaccines in the same syringe.
9. Do not freeze this product. The vaccine should be used immediately after it is open.

[Drug Interactions]

Concomitant administration of other vaccines: there has been no clinical studies on the effect of concomitant (pre, post or simultaneous) administration of other vaccines on the immunogenicity of this vaccine. There is no data available to assess the effect of simultaneous administration of this product with other vaccines.
Immunosuppressive drugs: immunity inhibitor, chemotherapy drug, antimetabolites, alkylating agents, cytotoxic drugs, corticosteroids etc. may reduce the body's immune response to this vaccine.
Patients who are receiving treatment: for those who are using the drug, it is recommended to consult a professional physician before receiving the vaccine to avoid possible drug interactions.

[Clinical Trial]

Referring to the data of clinical trials.

[Storage]

Store between +2°C and +8°C and protect from light. Do not freeze.

[Packaging]

This product is packaged into vial, 40 vials per box.

[Expiry Date]

The expiry date of the vaccine is tentatively scheduled as 36 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