



SARS-CoV-2 Vaccine (Vero Cell), Inactivated

Please read the instructions carefully and use under the guidance of a physician

Drug Name

SARS-CoV-2 Vaccine (Vero Cell), Inactivated

Composition and Appearance

The SARS-CoV-2 Vaccine (Vero Cell), Inactivated is formulated with SARS-CoV-2 strain which is inoculated on the Vero cells for culturing, virus harvesting, β -propiolactone-inactivation, concentration and purification, then adsorbed with aluminium adjuvant to form the liquid vaccine. The product is a semi-transparent turbid suspension with slight white color, which could be layered due to precipitation, and the precipitation can be easily dispersed by shaking.

Active composition: SARS-CoV-2 (inactivated)

Excipients: Disodium hydrogen phosphate, Sodium chloride, Sodium dihydrogen phosphate, Aluminum hydroxide

Vaccinee

This product is used for people aged 18 years old and above.

Functions

The antibodies against the SARS-CoV-2 can be produced after vaccination, to prevent the COVID-19 disease.

Dosage

Each pre-filled syringe or vial contains 0.5mL of product for each administration by intramuscular injection, each dose contains 6.5U of inactivated SARS-CoV-2 antigen.

Immunization Program

This vaccine will be administered by a healthcare professional of national health authorities and CDC in accordance with the national immunization program and strategies.

Method of Administration: The recommended administration is through intramuscular route, the injection into a muscle will be preferably performed in the upper part of the arm.

Immunization Program and Dosage: Two dose regimen at an interval of 21~28 days, each dose is 0.5mL.

Adverse Reactions

The occurrence rate for ADRs (CIOMS recommendation) can be presented as:

- (1) Very common: Pain at the injection site;
- (2) Common: Transient fever, fatigue, headache, diarrhea; redness, swelling, itching, and hardening at the injection site;
- (3) Uncommon: Skin rash at the injection site; nausea and vomiting, itching at the non-injection site, muscle pain, arthralgia, drowsiness, dizziness, etc.
- (4) No vaccine-related serious adverse reaction was observed.

If there are any adverse reactions not mentioned above during the use of this vaccine, please inform the physician in time.

Contraindications

This vaccine is strictly prohibited in the following cases:

- (1) Individuals who are allergic to any component (active, excipients) of this product, or those who have allergic reactions with this vaccine before.
- (2) Individuals who have serious chronic disease or history of hypersensitivity.
- (3) Vaccination should be postponed if individuals have fever or during the acute phase of disease.

Special Warnings And Precautions For Use

- (1) Intravascular injection is strictly prohibited.
- (2) Drugs and equipment such as epinephrine should be available for emergency treatment in the event of an occasional severe allergic reaction. The vaccinee should be watched for at least 30 minutes after vaccination.
- (3) This vaccine should be used with caution if:
 - ① have blood disorders such as decrease in platelets (thrombocytopenia) or clotting disorders because of the risk of bleeding which may occur during intramuscular administration of the vaccine.
 - ② are taking a treatment that suppresses your immune defences or if you present with immune deficiency, the immune response to the vaccine may be reduced. In such cases it is recommended to postpone vaccination until the end of the treatment or to make sure the subject is well protected. If you have chronic immune deficiency, this vaccine may also be recommended even though the underlying disease may cause a limited immune response.
 - ③ you have uncontrolled epilepsy and other progressive neurological disorders.
- (4) Like all vaccines, this product may not have 100% preventive effect for vaccinee.
- (5) Do not use disinfectant to contact the vaccine when the protective cap is pulled off and injection.
- (6) This vaccine should be used immediately after opening.
- (7) The vaccine should be thoroughly mixed before use. Do not use if any abnormalities are observed such as clots, foreign objects, unclear label, out of expiry and cracks in the syringe or vial, etc.
- (8) Keep away from reach of children.

Drug Interaction

- (1) The clinical trial results of this vaccine in combination with other routine vaccines have not yet been provided.
- (2) If any drugs are being taken or recently taken, including over-the-counter (OTC), please inform the physician in time.

Storage Store and transport in a refrigerated (2℃-8℃) condition, protect from light. Do not freeze.

Packaging Configuration Pre-filled syringe assembly, 1 syringe/box; Vial assembly, 1 vial/box or 3 vials/box.

EXP. 24 months (Tentatively)

Executed Standard *Technical Guidance for Inactivated SARS-CoV-2 Vaccine (Vero Cell) Manufacturing and Testing.*

Manufacturer

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