FDA Philippines EUAs Release Date: August 19, 2021

Product Information of SinoPharm COVID-19 Vaccine (Vero Cell), Inactivated COVILO

This product is approved for marketing with conditions. Please read the package insert carefully and administer under the guidance of your physician.

【Drug Name】 Generic name: COVID-19 Vaccine (Vero Cell), Inactivated

Brand name: COVILO

English name: SinoPharm COVID-19 Vaccine (Vero Cell), Inactivated

【Ingredients】 This product is prepared by inoculating African green monkey kidney cells (Vero cells) with SARS-CoV-2 WIV04 strain, followed by culturing, harvesting, virus inactivation, concentration, purification, and adding aluminum hydroxide adjuvant. It doesn't contain any antibiotic or preservative.

Active ingredient: inactivated antigen of SARS-CoV-2 WIV04 strain.

Adjuvant: aluminum hydroxide.

Auxiliary materials: sodium chloride, disodium hydrogen phosphate, sodium dihydrogen phosphate.

【Characteristics】 This product should be a slightly milky white suspension, which can be layered due to precipitation and is easy to disperse on shaking, and there should be no lump that cannot be dispersed on shaking.

【Eligible】 Population aged 18 and above.

The protective efficacy data from the interim analysis of overseas Phase III clinical trials show that this product has protective effect on the population aged 18-59 years. The proportion of subjects aged 60 and above in the clinical trials is relatively low (1.57%), which will be increased in the subsequent clinical trials to further obtain direct evidence for the protective effectiveness on the population. Existing clinical trial data show that population aged 60 and above produce neutralizing antibodies to a certain extent after vaccination with this product. For the population aged 60 and above, it's necessary for the relevant institutions for disease prevention and control to consider their health status and exposure risks to evaluate the necessity of vaccination with this product.

【Function and Use】

This product is used to prevent COVID-19 caused by SARS-CoV-2 infection. It has been conditionally approved for marketing based on the results of the second interim analysis of overseas Phase III clinical study of efficacy, and the final analysis data have not been obtained yet. Its efficacy and safety need to be further confirmed.

【Specification】

0.5 mL per vial / prefilled syringe. 0.5 mL per single human dose, containing 200 WU of inactivated SARS-CoV-2 antigen.

【Administration and Dosage】

Two doses at an interval of 21-28 days for primary immunization, and a single human dose is 0.5 mL.

Intramuscular injection is recommended, and the best injection site is the deltoid muscle of the upper arm. Shake well before injection.

The necessity for booster immunization has not been determined yet.

【Adverse Reactions】

The safety of this product was evaluated in two clinical trials conducted in China and abroad. The first was a randomized, double-blind, placebo-controlled Phase I/II clinical trial in China, which preliminarily evaluated the safety and immunogenicity of this product in the population aged 18 and above. The second is an international, multicenter, randomized, double-blind, placebo-controlled Phase III clinical trial to evaluate the efficacy, safety, and immunogenicity of this product. Systematic safety follow-up observation was carried out 0-7 days after vaccination of each dose, and adverse events were collected by means of active reporting by subjects and regular follow-up by investigators on D8-14/21/28, while attention is paid to the serious adverse events occurred within 12 months after the full course of immunization.

General description of adverse reactions in clinical trials of this product

According to the classification of adverse reaction incidence recommended by the Council for International Organizations of Medical Sciences (CIOMS): very common (≥10%), common (1% ~ 10%, including 1%), occasional (0.1% ~ 1%, including 0.1%), rare (0.01% ~ 0.1%, including 0.01%), very rare (< 0.01%), the safety data of the subjects studied in Phase I/II and Phase III clinical trials of this product are summarized as follows:

(1) Local adverse reactions

Very common: pain;

Common: swelling and redness;

Occasional: induration, rash, itching;

Rare: hypoesthesia, erythema, discoloration, discomfort, fever;

Very rare: sclerosis, bruise, paresthesia.

(2) Systemic adverse reactions

Very common: headache and fatigue/acratia;

Common: muscle pain (non-injection site), diarrhea, cough, oropharyngeal pain, fever, runny nose, dyspnea, arthralgia, pruritus (non-injection site), nausea, dizziness, and constipation;

Occasional: flu-like symptoms, lethargy, vomiting, abdominal pain, nasopharyngitis, chest pain, nasal obstruction, expectoration, dysphagia, sneezing, anorexia, sputum increase, acute allergic reaction, epigastric pain, skin and mucosal abnormalities, insomnia, limb pain, throat irritation, chest discomfort, hypoesthesia, back pain, chills, fever, hyperhidrosis, anorexia, abdominal discomfort, palpitation, and limb discomfort;

Rare: loss of taste, abdominal distension, eye congestion, dry throat, erythema (non-injection site), eye irritation, hypothermia, erythema of the pharynx, dysphonia, pain in the waist and ribs, hypersensitivity, loss of smell, musculoskeletal rigidity, neck pain, itchy rash, eye pain, earache, facial swelling, gastrointestinal flatulence, erythematous rash, rhinitis, sleep disorder, increased appetite, elevated blood pressure, hot flashes, nasal congestion, discomfort (non-injection site), excessive sleep, dry mouth, muscle spasm, bone pain, dry skin, conjunctivitis, blurred vision, vertigo, abnormal sensation, taste disorder, taste inversion, lower abdominal pain, macular rash, urticaria, acne-like rash, and anxiety;

Very rare: wheezing, respiratory symptoms, swelling of the pharynx, peripheral swelling, axillary pain, head discomfort, poor sleep quality, abdominal stiffness, bad breath, dry lips, hypoesthesia in the mouth, swollen lips, gastroesophageal reflux disease, mucous stool, allergic dermatitis, skin irritation, papular rash, skin lesions, blisters, maculopapular, skin depigmentation, dermatitis, papules, water herpes, petechiae, folliculitis, laziness, dry eye, eye pruritus, periorbital swelling, eye secretion, hyperappetite, increased body temperature, hypotension, lymphadenopathy, lymphadenitis, muscle strain, flushing, cold feeling, and eye swelling.

(3) Severity of adverse reactions

The severity of adverse reactions observed in the clinical trials of this product was mainly Grade 1 (mild), the incidence rate of solicited adverse reactions of Grade 3 and above was 0.68%, and no Grade 4 adverse reaction related to vaccination with this product was reported. In the clinical trial reports, the Grade 3 local adverse reactions were pain, induration and swelling, and the Grade 3 systemic adverse reactions were fever, diarrhea, constipation, anorexia, vomiting, muscle pain (non-injection site), arthralgia, headache, cough, dyspnea, pruritus (non-injection site) and fatigue/acratia.

(4) Serious adverse events (SAE)

As of December 31, 2020, the serious adverse events observed in clinical trials were judged by the investigators as being or as being possibly irrelevant to the vaccination. Please see the full version of package insert for the occurrence of adverse reactions in domestic and overseas clinical trials of this product.

【Contraindications】

1. Those who are allergic to any ingredient contained in this product (including auxiliary materials).
2. Those who have had severe allergic reactions to vaccines in the past (such as acute allergic reactions, angioneurotic edema, dyspnea, etc.).
3. Patients with uncontrolled epilepsy and other progressive nervous system diseases, and patients with a history of Guillain-Barre syndrome.
4. Pregnant and lactating women.

【Precautions】

1. The protection persistence data of this product has not been obtained yet, and necessary protective measures should be taken according to the needs of epidemic prevention and control after vaccination.
2. No direct evidence for the protective effect of this product on the population aged 60 and above has been obtained yet, therefore, it's necessary for the relevant institutions for disease prevention and control to consider their health status and exposure risks to evaluate the necessity of vaccination with this product.
3. Check the packaging container, label, appearance, and validity period before use. The product can't be used if the glass container has cracks or there is any spot, stain or scratch on the outer surface, or the label is unclear, or the product expires, or the appearance is abnormal.

4. Do not inject intravenously. There has been no data on the safety and effectiveness of subcutaneous or intradermal injection of this product yet.

5. The subjects should be observed on site for at least 30 minutes after vaccination. Vaccination clinics should keep epinephrine and other drugs for first aid in case of severe allergic reactions.

6. It should be used with caution for the patients with acute disease, severe chronic disease, allergic physique, fever, or at acute attack period of chronic disease; When necessary, they can have postponed immunization according to doctor's evaluation.

7. It should be used with caution for patients with diabetics, and those with a history or family history of convulsion, epilepsy, encephalopathy or mental illness.

8. It should be used with caution for patients with thrombocytopenia and any coagulation dysfunction, as they may bleed during the intramuscular injection.

9. Safety and efficacy data of this product for those with impaired immune function (such as patients with malignant tumor, nephrotic syndrome and AIDS) have not yet been obtained. Vaccination with this product for them should be based on individualized considerations.

10. Vaccination should be deferred for at least 1 month following administration of immunoglobulin, so as not to affect the immune effect.

11. Those with any neurological reaction after vaccination with this product are forbidden to be administered again.

12. There has been no evidence of protective efficacy of this product for patients with SARS-CoV-2 infection or patient with a history of SARS-CoV-2 infection yet.

13. Like the other vaccines, it is impossible to ensure that this product protects all the vaccinees.

【Use for Special Population】

1. Women of childbearing age: The data collected among women who had unplanned pregnancy after vaccination in the clinical trials are very limited, which is not sufficient for evaluating the risk of adverse pregnancy outcomes (including spontaneous abortion) after vaccination.

2. Pregnant or lactating women: No clinical trial data of pregnant and lactating women has been obtained for this product.

3. Population aged 60 and above: The immunogenicity and safety data of this population vaccinated with this product have been obtained in domestic Phase I/II

clinical trial, but no direct evidence of protective efficacy has been obtained in overseas Phase III clinical trial.

【Drug interactions】

1. Coadministration with other vaccines: Impact of co-administration (before, after or at the same time) of other vaccines on the immunogenicity of this product has not been studied in the clinical trials.

2. Concomitant use of other drugs: Drugs with immunosuppressive effect, including immunosuppressants, chemotherapy drugs, antimetabolic drugs, alkylating agents, cytotoxic drugs, corticosteroids, etc., may reduce the body's immune response to this product.

If you are using or have recently used any other vaccine or drug, you should consult your physician before vaccination with this product to avoid possible drug interaction,.

【Storage】 Store and ship at 2-8 ℃. Freezing is strictly forbidden.

【Shelf Life】 6 months

【Package】 Pre-filled syringe assembly (with needle),1 syringe/box.

Injection vial, 1 vial/box, 3vials/box.

【Implementation Standard】YBS00192021

【License Number】GYZZS20210005，GYZZS20210006

【License Number】

【Marketing Authorization Holder in China】

Company Name: SinoPharm/China National Pharmaceutical Group/Wuhan Institute of Biological Products Co., Ltd.

Address： No.1, Huangjin Industrial Park Road, Zhengdian, Jiangxia District, Wuhan, Hubei Province, P.R.China

【Manufacturer】

Company Name: SinoPharm/China National Pharmaceutical Group/Wuhan Institute of Biological Products Co., Ltd.

Address: No.1, Huangjin Industrial Park Road, Zhengdian, Jiangxia District, Wuhan, Hubei Province, P.R.China

Post code: 430207

Tel: 0086-27-88913353

Fax: 0086-27-88913353

Website: http://www.wibp.com.cn

【EUA Holder/Importer/Distributor in Philippines]

Conpany: 2World Traders Inc., 285 Elgrande Avenue BF Homes Paranaque City, M.M.

Tel.: 02 88792926, Fax: 02 88792926

Email: QPPV2world@gmail.com Website: 2worldinternational.com

Sinopharm / WIBP