COVID-19 Vaccine (Vero Cell), Inactivated

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

**NAME OF THE MEDICAL PRODUCT**
CoronaVac

**COMPOSITION AND DESCRIPTION**
The product is produced by first inoculating SARS-CoV-2 virus (C022 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. Striated precipitate may form which can be dispersed by shaking.

Active ingredient: Inactivated SARS-CoV-2 virus (C022 strain) 6000U

Adjuvant: Aluminum hydroxide 0.225mg

Excipients: Sodium chloride 0.3%, edetate disodium 2mg, sodium citrate 4.5mg, water for injection q.s.

No preservative is used in this product.

**TARGET GROUPS FOR VACCINATION**
Adults from 18 to 95 years of age.

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

**PRESENTATION**
Each vial contains 0.5mL. Single dose of 0.5mL contains 6000U of inactivated SARS-CoV-2 Virus as antigen.

**ADMINISTRATION**
CoronaVac should be administered by intramuscular injection in the deltoid region of the upper arm or the thigh, shank before use.

**IMMUNIZATION SCHEDULE**
Two doses should be given, the first dose is preferably given 14-28 days after the first dose. 0.5mL per dose.

It has not been determined whether this product requires booster immunization.

**ADVERSE REACTIONS**

According to the grading standard of adverse events occurrence, the frequency and severity of adverse events are specified as follows:

<table>
<thead>
<tr>
<th>Medical System Organ Class</th>
<th>Frequency</th>
<th>Adverse Reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immune system disorders</td>
<td>Uncommon</td>
<td>Hypersensitivity</td>
</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
<td>Common</td>
<td>Decreased appetite</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Very common</td>
<td>Headache</td>
</tr>
<tr>
<td>Vascular disorders</td>
<td>Uncommon</td>
<td>flushing</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>Common</td>
<td>Cough</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>Common</td>
<td>Diarrhea</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>Common</td>
<td>Pruritus</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>Common</td>
<td>Myalgia</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>Very common</td>
<td>Fatigue</td>
</tr>
</tbody>
</table>

Other adverse reactions may be described as follows:

- Fever (Mild temperature = 37.3°C)
- Vaccination site warmth
- Vomiting

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; 3) allergic reactions caused by the vaccine; 4) purpura, anaphylactic shock, anaphylaxis, and anaphylactic shock (with or without fever) etc. Although the mentioned adverse reactions were not observed in the pre-marketing clinical studies, caution should still be taken during the use of this vaccine.

In case of any discomfort not mentioned above, please contact your doctor immediately.

**CONTRAINDICATIONS**

1. People with a history of severe allergic reactions to CoronaVac or any component of the vaccine.
2. Pregnant women.
3. Children under 18 years of age.

**SPECIAL POPULATION MEDICATION**

1. Liver dysfunction: the use of CoronaVac should be avoided.
2. Renal dysfunction: the use of CoronaVac should be avoided.

**PRECAUTIONS**

1. The product should be stored at room temperature and protected from light.
2. The product should be used within 6 months after opening.
3. The product should be injected into the skin or muscle.
4. The injection site should be disinfected before injection.
5. The injection site should be observed for 30 minutes after injection.
6. After injection, the patient should rest for 30 minutes.
7. The patient should avoid physical exertion for 24 hours after injection.
8. The patient should avoid sexual activity for 48 hours after injection.
9. The patient should avoid alcohol and spicy foods for 24 hours after injection.
10. The patient should avoid fasting for 24 hours before injection.

**SIDE EFFECTS**

1. Local reactions at the injection site: pain, swelling, redness, itching, or warmth.
2. Systemic reactions: fever, myalgia, chills, fatigue, headache, dizziness, nausea, vomiting, coughing, diarrhea, or flatulence.
3. Other reactions: anaphylaxis, angioedema, urticaria, or other allergic reactions.

**DO NOT USE**

1. If the product has been exposed to light or has been opened.
2. If the product has expired.

**STORAGE**

The product should be stored at 2-8°C and protected from light.

**PACKAGING**

The product is packaged in vials, 40 vials per box.

**MANUFACTURER**

Manufacturer: SINOVAC BIOPHARMACEUTICAL CO., LTD.
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北京科兴中维生物技术有限公司 产品名称及版本号
使用说明(新型冠状病毒灭活疫苗(Vero细胞)) SC1039
产品版本 CX-09-013-WHO(40En)