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CoronaVac Suspension for Injection COVID-19 Vaccine (Vero Cell), Inactivated

COVID-19 Vaccine (Vero Cell), Inactivated (600 SU equivalent to 3µg)

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What CoronaVac is used for

CoronaVac is a vaccine used to prevent COVID-19 caused by coronavirus (SARS CoV-2).

CoronaVac is given to adults and adolescents from 12 years of age and older.

A booster dose of CoronaVac may be administered at least 3-6 months after the second dose in individuals 18 years of age and older.

How CoronaVac works

The vaccine stimulates the immune system (the body's natural defences) to produce its own antibodies and blood cells that work against the virus. This will help to increase your protection against COVID-19.

None of the ingredients in this vaccine can cause COVID-19.

Before you use CoronaVac

- When you must not use it

Do not take CoronaVac:

- if you are allergic to CoronaVac or any of the other ingredients of CoronaVac (see section *Product Description*). Signs of an allergic reaction may

include itchy skin rash, shortness of breath and swelling of the face or tongue. Contact your doctor or go to the nearest hospital emergency immediately if you have an allergic reaction

- if you have a history of allergic reactions to other vaccines
- if you have any severe neurological conditions such as spinal cord inflammation and Guillain-Barré syndrome
- if you have uncontrolled severe chronic illnesses
- if you have an infection with high fever (temperature over 38°C)

Pregnancy and lactation

If you are pregnant or breastfeeding, planning to breastfeed, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you receive this vaccine.

There is limited data on the use of CoronaVac in pregnant or breastfeeding women.

Children and adolescents

No dosage adjustment requirement is required in adolescents 12-17 years of age.

If your child is between 12-17 years old, ask your doctor for advice before your child receives this vaccine.

CoronaVac is not recommended for children aged under 12 years as limited safety and efficacy data are available.

Elderly

No dosage adjustment is required in elderly individuals ≥60 years of age. If you are 60 years old or above, ask your doctor for advice before you receive this vaccine.

- Before you start to use it

Talk to your doctor before taking CoronaVac if:

- you have ever had a severe allergic reaction or breathing problems after any other vaccine injection in the past or after you were given the first dose of CoronaVac
- you have ever fainted following any needle injection
- you have bleeding disorders, bruise easily or use a medicine to prevent blood-clots
- you have a weakened immune system, because of a disease such as cancer or HIV infection or you are on medicines that affects your immune system such as corticosteroids, immunosuppressants or cancer medicines
- you have taken or need to take human immunoglobulins. There should be an interval of at least one month between the vaccine and use of immunoglobulins
- you have acute and/or severe chronic illness. Your doctor may need to delay your vaccination.
- you currently have or have a history of seizures, epilepsy, encephalopathy or mental illness
- you are currently having an infection with high fever (temperature over 38°C).

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Your doctor may need to delay your vaccination.

However, you can be vaccinated if you have a mild fever or upper airway infection like a cold.

As with any vaccine, the 2-dose vaccination course of CoronaVac may not fully protect everyone who is vaccinated. A booster dose is recommended as it increases the immune response significantly however it is not known how long and how well you will be protected.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. No interaction studies between CoronaVac and other drugs or vaccines have been performed.

CoronaVac does not contain alcohol or any preservatives

How to use CoronaVac

- How much to use

This vaccine must only be administered intramuscularly.

Adults 18 years of age and older

The vaccine will be given as a 0.5 mL injection into a muscle of your upper arm. You will receive 2 injections, given at least 14 - 28 days apart.

A booster dose (0.5ml) may be administered at least 3-6 months after the second dose.

Children and adolescent 12-17 years of age

The vaccine will be given as a 0.5 mL injection into a muscle of your upper arm. You will receive 2 injections, given at least 28 days apart.

After administration, you will be observed for at least 30 minutes in case of allergic reactions.

- How long to use it

After the first dose (injection) of CoronaVac, you should receive a second dose of the **same** vaccine after at least 14 - 28 days to complete the vaccination course.

The interchangeability of CoronaVac with other COVID-19 vaccines is currently unknown.

Consult your doctor if you have further questions on the use of CoronaVac.

- If you forget to use it

It is important that you return for your second injection of CoronaVac as per your appointment date. If you do miss the second dose, consult your doctor for advice.

A vaccination reminder card will be given to you after your first dose (injection). The patient reminder card will contain the scheduled date for your second dose and other important information.

Keep the vaccination reminder card safe so you always know what to do.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have been given an extra dose of this vaccine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

The use of this vaccine should be in accordance with official recommendations.

Tell all the doctors, dentists and pharmacists treating you that you have received CoronaVac.

There is no data on the simultaneous administration of CoronaVac with other vaccines or products. Tell your doctors, dentists and pharmacists if you are taking, have recently taken or might take, any other medicines or vaccines.

- Things you must not do

Concomitant administration of CoronaVac with other vaccines or products has not been studied. Therefore, do not take any new medicines after receiving CoronaVac without consulting your doctor.

- Things to be careful of

Driving and using machines

CoronaVac has no known effect on the ability to drive and use machines. However, some of the side effects (see section *Side Effects*) may temporarily impact your ability to drive and use machines. If you feel unwell, do not drive or use machines. Wait until these

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effects have worn off before you drive or use machines.

Side effects

Like all medicines, CoronaVac may cause side effects, although not everybody gets them.

Consult your doctor or pharmacist immediately if you experience any side effects after receiving CoronaVac.

Side effects for both primary vaccination schedule and booster dose that occurred during clinical trials with CoronaVac were as follows:

- *Very common (may affect more than 1 in 10 people):*

- injection site: pain

- *Common (may affect up to 1 in 100 people):*

- injection site: swelling,
- tiredness
- muscle pain
- nausea
- diarrhoea
- joint pain
- cough
- shivering
- runny nose
- sore throat
- stuffy nose
- fever
- headache

- *Uncommon (may affect up to 1 in 1,000 people):*

- injection site: burning sensation, skin discolouration, itching, redness, hardening and numbness
- vomiting
- hypersensitivity
- abnormal skin and mucous membrane condition
- trembling
- flushing

- swelling
- dizziness
- drowsiness
- stomach ache
- bloating
- loss of appetite
- redness
- itching
- papule

- *Rare (may affect up to 1 in 10,000 people):*

- muscle cramps
- swelling of eyelids
- nose bleeds
- constipation
- diminished sense of smell
- pink eye
- hot flashes
- hiccups
- eye redness

If you experience any of these side effects that do not go away, tell your doctor.

If you are concerned about any side effects that you may be experiencing or if you notice any side effects not listed in this leaflet, please inform your doctor, pharmacist or nurse.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

By reporting side effects, you can help provide more information on the safety of this vaccine.

Storage and Disposal of CoronaVac

- Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label. The expiry date refers to the last day of that month.

Store and transport between +2°C to +8°C. Store in original package and protect from light.

Do not freeze this product. Shake well before use. Do not use if there are clumps that do not disperse after shaking.

For multi-dose (2 doses) vial, after opening, the vaccine must be stored at 2°C to 8°C and used within 6 hours or stored at room temperature (maximum 37°C) and used within 1 hour.

Discard any unused vaccine if it is not kept within the recommended conditions.

When opening the vial, do not expose the vaccine to disinfectants.

Do not use if the vaccine vial is cracked, spotted or stained, if the label is unclear or if you notice foreign particulates in the vial.

Do not combine CoronaVac with other vaccines in the same syringe.

- Disposal

This vaccine should not be disposed of via wastewater or household waste.

Any unused medicinal product or waste material should be disposed of in

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accordance with local requirements.

These measures will help to protect the environment.

Product Description

- What it looks like

CoronaVac is a milky-white (opalescent) aqueous suspension provided in a vial. Precipitation may occur within the vial but is dispersed upon shaking.

CoronaVac is available in the following presentations:

- Single-dose (1 dose) vial of 0.5 mL
- Multi-dose (2 doses) vial of 1.0 mL

Each dose (0.5 mL) contains 600SU (equivalent to 3µg) of SARS-CoV-2 antigen

- Pack Size

Box of 40 vials

Box of 10 vials

Not all packaging will be marketed.

- Ingredients

- Active ingredient:

- SARS-CoV-2 antigen

- Inactive ingredients:

- aluminium hydroxide
- disodium hydrogen phosphate
- monosodium dihydrogen phosphate
- sodium chloride
- water for injection

- MAL Number

MAL21046125ACSZ

**Manufacturer / Product
Registration Holder**
**Pharmaniaga LifeScience Sdn
Bhd**

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