科興 Sinovac

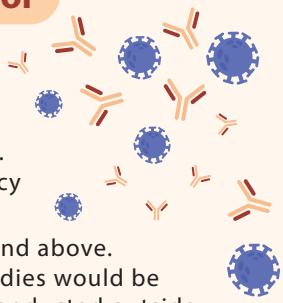
新型冠狀病毒滅活疫苗（Vero細胞）
COVID-19 Vaccine (Vero Cell), Inactivated

CoronaVac「克爾來福」

接種須知
Vaccination Fact Sheet

衞生防護中心 Centre for Health Protection
衞生署 Department of Health

1 What is CoronaVac and what it is used for[1]



CoronaVac is indicated for active immunization against COVID-19 disease caused by SARS-CoV-2 virus.

The vaccine is authorized for use under the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K). It has not been registered in Hong Kong under the Pharmacy and Poisons Ordinance (Cap. 138).

CoronaVac is indicated for susceptible people aged 18 and above. Data from clinical trials showed that neutralizing antibodies would be induced after vaccination. In the phase III clinical trial conducted outside China, only 5.10% participants enrolled was 60 years and above, hence, the efficacy evidence of people aged 60 and above is insufficient. The subsequent clinical trials will be carried out for further evaluation of efficacy in this population. When using CoronaVac among people aged 60 and above by relevant medical institutions, the health status and exposure risk shall be considered.

> *Please note, to expedite the availability of CoronaVac to Hong Kong, some of the textual information (include English name; dosing interval and expiry date) in the sales pack/label and the drug insert of the initial shipment of CoronaVac are different from the version provided by the vaccine supplier upon its authorization for emergency use under Cap 599K. As there might be a chance of the product information updated from time to time, you may also wish to visit the below link for latest information: https://www.fhb.gov.hk/download/our_work/health/201200/e_evaluation_report_CoronaVac.pdf*

2 What you need to know before you receive CoronaVac[1]

CoronaVac should not be given to

- People with history of allergic reaction to CoronaVac or other inactivated vaccine, or any component of CoronaVac (active* or inactive* ingredients, or any material used in manufacturing process);
- People with previous severe allergic reactions to vaccine (e.g. acute anaphylaxis, angioedema, dyspnea, etc.);
- People with severe neurological conditions (e.g. transverse myelitis, Guillain-Barré syndrome, demyelinating diseases, etc.);
- Patients with uncontrolled severe chronic diseases;
- Pregnant and lactating women.

*Including inactivated SARS-CoV-2 Virus (CZ02 strain), aluminium hydroxide, disodium hydrogen phosphate dodecahydrate, sodium dihydrogen phosphate monohydrate, and sodium chloride.

[1]Following information provided by drug company

Precautions

- Due to the insufficient data of persistence of protection induced by this vaccine, necessary protective measures should be taken in line with prevention and control of the COVID-19 epidemic.
- For patients with acute diseases, acute exacerbation of chronic diseases, severe chronic diseases, atopy and fever, the vaccine should be used with caution; if necessary, delay vaccination after doctor's evaluation.
- For patients with diabetes, or history of convulsions, epilepsy, encephalopathy or mental illness, or family history of these diseases, the vaccine should be used with caution.
- For patients with thrombocytopenia or hemorrhagic diseases, intramuscular injection of this product may cause bleeding, so it should be used with caution.
- The safety and efficacy data of this product on people with impaired immune function (such as malignant tumor, nephrotic syndrome, AIDS patients) have not been obtained, and the vaccination of this product should be based on individual considerations.
- People who inject human immunoglobulin should receive this vaccine at least one month apart to avoid affecting the immune effect.
- Do not use it again if there is any adverse reaction of nervous system after vaccination.
- Like other vaccines, the protective effect may not reach 100% for all recipients.
- Observe for 30 minutes after vaccination.

Women of childbearing age

The data collected from clinical trials on women with unexpected pregnancy after vaccination are very limited, and it is insufficient to decide the risk of adverse pregnancy outcomes after vaccination.

Pregnant or lactating women

The clinical data of pregnant and lactating women are not available at present.

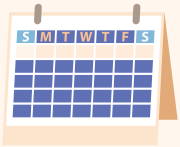
People aged 60 and above

The benefit of using CoronaVac generally exceeds the risk of not using any vaccines in persons aged 60 and above. Phase I and II data on individuals aged 60 and above showed that the vaccine is safe and immunogenic. There is limited phase III efficacy data for individuals aged 60 and above because of small sample size.

Other medications and CoronaVac

- Concomitant use with other vaccines: no clinical study has been carried out on the evaluation of immune response with other vaccines on the immunogenicity at the same time (before, after or at the same time).
- Concomitant use with other drugs: immunosuppressive drugs, such as immunosuppressive drugs, chemotherapy drugs, antimetabolic drugs, alkylating agents, cytotoxic drugs, corticosteroid drugs, etc., may reduce the immune response to this product.
- Patients undergoing treatment: for patients undergoing treatment, please consult the medical professional before using CoronaVac to avoid possible drug interactions.

3 How CoronaVac is given[1]



- **Two doses** should be administered for primary immunization. The second dose is preferably given **28 days after** the first dose. 0.5 mL per dose.
- CoronaVac should be administered by intramuscular injection in the deltoid region of the upper arm.
- It has not been determined whether this product requires booster immunization.

4 Possible side effects[1]

	Side effects	may affect
Very common	• injection site: pain • headache • fatigue	**⩾ 10% people**
Common	• injection site swelling, pruritus, erythema, induration • myalgia • nausea • diarrhea • arthralgia • cough • chills • pruritus • loss of appetite • rhinorrhea • sore throat • nasal congestion • abdominal pain	**1% -10% people**
Uncommon	• burn at injection site • vomit • hypersensitivity • abnormal skin and mucosa • fever • tremor • flushing • edema • dizziness • drowsiness	**0.1% -1% people**
Rare	• muscle spasms • eyelid edema • nosebleeds • abdominal distension • constipation • hyposmia • ocular congestion • hot flashes • hiccup • conjunctival congestion	**0.01% - 0.1% people**
Serious	• No serious adverse event related to vaccination was identified up to 3 February 2021.	

5 Reporting of adverse events after immunization

The Department of Health ("DH") has an adverse drug reaction ("ADR") reporting system which receives adverse events following immunization (AEFIs) reports to monitor the safety of COVID-19 vaccines.

If you have any suspected adverse event occurred after immunization, please alert healthcare professionals (e.g. doctors, dentists, pharmacists, nurses and Chinese medicine practitioners), when seeking their advice, to report the AEFIs to the DH if they consider that the AEFIs may be associated with the vaccination.

For continuously monitoring of the safety and clinical events associated with COVID-19 vaccination, your personal data collected for vaccination and your clinical data held by the Hospital Authority and the relevant private healthcare facilities and healthcare professionals, may be accessed and used by DH and relevant organizations collaborated with the Government (including the University of Hong Kong) insofar as such information is necessary for the monitoring.

In situations when pain or redness at the injection site increases after 24 hours from injection; or your side effects are worrying you or do not seem to be going away in a few days, please contact your doctor.

If you do seek medical attention, make sure you tell the healthcare professionals about your vaccination details and show them your vaccination record card if available. Healthcare professionals will then make proper assessment and, if necessary, report any AEFI that is deemed medically significant to DH for further action and assessment.

Please allow the healthcare professional to report the AEFI, with your consent to passing the adverse event case information, personal and clinical data to DH for continuous monitoring the safety and clinical events associated with COVID-19 vaccination.

Message to the healthcare professionals:

Please conduct medical assessment and if you consider the AEFI associated with the vaccine is deemed medically significant, please report it to the Drug Office of the Department of Health via online reporting at the webpage

https://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/adr_reporting/index.html

If the vaccine recipient experiences serious adverse event following immunization, please refer the recipient to hospital.

☐ I have read and understood all information as provided in the factsheet and the Statement of Purpose of Collection of Personal Data, and I consent to the administration of COVID-19 Vaccination to me / my child / my ward* under the COVID-19 Vaccination Programme; and the Department of Health and the relevant organizations (collaborated with the Government (including the University of Hong Kong))'s access to and use of (i) my / my child / my ward's* personal data contained herein and (ii) my / my child / my ward's* clinical data held by the Hospital Authority and the relevant private healthcare facilities and healthcare professionals, for the purpose of continuously monitoring the safety and clinical events associated with COVID-19 Vaccination by the Department of Health insofar as such access and use are necessary for the purpose.

* Please delete as appropriate

For further information on vaccine information and side effects, please visit the website at

www.covidvaccine.gov.hk

English

हिन्दी

नेपाली

اردو

ไทย

Bahasa Indonesia

Tagalog

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বাংলা ভাষা

Tiếng Việt

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