World Health Organization
REGIONAL OFFICE FOR Europe

FACT SHEET FOR HEALTH WORKERS

Sinovac-CoronaVac COVID-19 vaccine

1. GENERAL INFORMATION

- **Vaccine name:** Sinovac-CoronaVac
- **Vaccine platform:** Inactivated whole virus COVID-19 vaccine (Vero Cell)
- **Vaccine characteristics:** The vaccine does not contain human, foetal or animal tissue. Non-live, aluminium-hydroxide-adjuvanted vaccine
- **Age indication:** 18 years of age and older
- **Dosage:** 2 doses (each of 0.5 ml)
- **Route and site of administration:** Intramuscular, in the deltoid muscle of the upper arm

WHO Emergency Use Listing approval: 01 June 2021

2. VACCINE SCHEDULE

- Two doses given with an interval of 2-4 weeks between doses. A series started with this product should be completed with this product. If the second dose is administered <2 weeks after the first dose, the dose does not need be repeated. If administration of the second dose is delayed >4 weeks, it should be given at the earliest possible opportunity.
- There is currently no evidence indicating a need for further doses once an individual has received two doses.

3. CO-ADMINISTRATION WITH OTHER VACCINES

There should be a minimum interval of 14 days between administering SinoVac-CoronaVac and any other vaccine against other conditions.

4. VACCINE EFFICACY (VE) IN CLINICAL TRIALS

- The vaccine was efficacious against symptomatic SARS-CoV-2 infection and against hospitalization at ≥14 days post second dose.

➔ **NOTE:** The clinical trial was not designed to demonstrate: efficacy against asymptomatic infection, efficacy in persons with comorbidities[1], efficacy in pregnancy nor efficacy in persons ≥60 years of age.

VE IN PARTICIPANTS AFTER HAVING RECEIVED COMPLETE SERIES OF VACCINATION (2 DOSES)	
Overall in individuals 18-59 years of age (irrespective of previous SARS-CoV-2 infection)	• 51% VE (95% CI: 36-62%) against symptomatic COVID-19 disease • 100% VE (95% CI: 17-100%) against severe COVID-19 • 100% VE (95% CI: 56-100%) against hospitalization due to COVID-19 ➔ **NOTE:** Data from post-introduction observational trials suggest VE in individuals **≥60 years of age** to be: -- 67.4% VE (95% CI: 64.6–69.6%) against symptomatic COVID-19 disease - 83.3% VE (95% CI 80.4–85.8%) against hospitalizations due to COVID-19 - 83% VE (95% CI: 76.4–87.7%) against death due to COVID-19
With comorbidities[2]: • Any co-morbidity • BMI ≥30 • Hypertension • Type 2 diabetes mellitus	• 48.9% VE (95% CI: 26.6-64.5%) against COVID-19 • 74.9% VE (95% CI: 53.7-86.4%) • 100% VE (95% CI: 28.4-100%) • 48.6% VE (95% CI: -115.6-87.7%)[3]

[1] Immunocompromised individuals were excluded from phase 3 clinical trial.

[2] *Comorbidities included were cardiovascular disease, hypertension, obesity and type 2 diabetes. Comorbidities for which there were too few data to evaluate were asthma, cancer, chronic kidney disease, chronic obstructive pulmonary disorder, HIV infection, immunocompromised, liver disease and neurological conditions.*

[3] The number of participants with type 2 diabetes mellitus was relatively small, with only were few cases of COVID-19 in both the vaccine and the placebo groups thus the confidence interval is very wide.

CI = confidence interval.

NOTE: SARS-CoV-2 viruses undergo evolution. Some new virus variants may be associated with higher transmissibility, disease severity, risk of reinfection, or a change in antigenic composition resulting in lower vaccine effectiveness. Phase III clinical trial was conducted in Brazil when variant from P.2 lineage (Zeta) was predominant. The variant of concern, P.1 (Gamma), was just emerging and not yet frequent. The other variants of concern, such as the B.1.1.7 (Alpha) and the B1.351 (Beta) variants, were not circulating. Vaccine effectiveness against symptomatic infection was maintained in post-introduction observational studies in Brazil, with high circulation of P.1 lineage (Gamma) and against hospitalization and deaths in Chile, with high circulation of B.1.1.7 (Alpha) and P.1 lineage (Gamma). No information is yet available regarding B.1.617 (Delta). As of 24 May 2021 WHO currently recommends the use of Sinovac-CoronaVac to vaccinate target groups according to the national prioritization even if variants are present in a country. WHO will continue to monitor the situation; as new data become available, recommendations will be updated accordingly.

5. VACCINE SAFETY FROM CLINICAL TRIALS

- The most frequently reported adverse reactions included injection site pain, swelling, pruritus, redness, induration headache, fatigue and myalgia.
- Adverse reactions (aside from injection-site reactions), tended to be less frequent with the second dose.
- Adverse reactions were generally milder and less frequent in the older age group (≥65 years) compared to the younger age group (18–59 years).

6. POST VACCINATION ADVICE

- To relieve symptoms of reactogenicity, health care providers may advise the patient the following:
  - Take analgesic and/or anti-pyretic medicinal products to relieve pain, discomfort or fever.
  - Apply a clean, cool, wet washcloth over the injection site and try to use or exercise the affected arm to reduce pain and discomfort on the injection site.
  - Drink plenty of fluids and dress lightly to reduce discomfort from fever.

Encourage patients to continue to practice prevention measures, such as wearing face masks, following physical distancing and ventilation guidelines and washing their hands often.

7. CONTRAINDICATIONS AND PRECAUTIONS

Contraindications

- History of anaphylaxis to any component of the vaccine. If anaphylaxic reaction occurred after the first dose, the second dose should not be administered

Precautions

- Acute febrile illness (body temperature ≥38.5 ^{0}C)
- Individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following intramuscular administration

8. SPECIAL CONDITIONS AND GROUPS FOR WHICH EVIDENCE IS LIMITED

CONDITION/GROUP	SAGE RECOMMENDATION
Pregnancy	• WHO recommends the use of Sinovac-CoronaVac in pregnant women when the benefits of vaccination to the pregnant woman outweigh the potential risks. To help pregnant women make this assessment, they should be provided with information about the risks of COVID-19 in pregnancy, the likely benefits of vaccination in the local epidemiological context, and the current limitations of the safety data in pregnant women. • Pregnancy testing before vaccination is not recommended. • Delaying or terminating a pregnancy because of vaccination is not recommended.
Breastfeeding	• WHO recommends the use of Sinovac-CoronaVac in lactating women as in other adults. • WHO does not recommend discontinuing breastfeeding after vaccination.
Immunocompromised persons	• Immunocompromised persons who are part of a group recommended for vaccination may be vaccinated with Sinovac-CoronaVac. • Immune response may be reduced.
Persons living with HIV	• Given that the vaccine is nonreplicating, persons living with HIV who are part of a group recommended for vaccination may be vaccinated. • Immune response may be reduced. • Testing for HIV infection before vaccination is not recommended.

Persons ≥ 60 years of age	• Vaccination is recommended. • For very frail older persons with a life expectancy anticipated to be <3 months, an individual risk–benefit assessment will need to be conducted.
Persons < 18 years of age	• Vaccination in individuals <18 years old is not routinely recommended.
Persons with current acute COVID-19	• Persons with acute PCR-confirmed COVID-19 should not be vaccinated until they have recovered from acute illness and criteria for discontinuation of isolation have been met. • The optimal minimum interval between a natural infection and vaccination is not yet known.
Persons who have previously had SARS-CoV-2 infection	• Vaccination should be offered regardless of a person's history of symptomatic or asymptomatic SARS-CoV-2 infection. • Viral or serological testing for prior infection is not recommended for the purpose of decision-making about vaccination.
Persons who previously received passive antibody therapy as part of a COVID-19 treatment	• As a precautionary measure, vaccination should be deferred for at least 90 days to avoid interference of the antibody treatment with vaccine-induced immune responses.

PCR = polymerase chain reaction

SAGE = Strategic Advisory Group of Experts on Immunization

9. SOURCES

1. Interim recommendations for use of the inactivated COVID-19 vaccine, CoronaVac, developed by Sinovac: Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-Sinovac-CoronaVac-2021.1 , accessed 26 July 2021).
2. Background document on the inactivated vaccine Sinovac-CoronaVac against COVID-19: Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-Sinovac-CoronaVac-background-2021.1 , accessed 26 July 2021).
3. Annexes to the recommendations for use of the Sinovac-CoronaVac vaccine against COVID-19: Grading of evidence, Evidence to recommendation tables: Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-Sinovac-CoronaVac-annexes-2021.1, accessed 26 July 2021).
4. WHO recommendation of Sinovac COVID-19 vaccine (Vero Cell [Inactivated]) – CoronaVac; Geneva: World Health Organization; 2021 (https://extranet.who.int/pqweb/vaccines/who-recommendation-sinovac-covid-19-vaccine-vero-cell-inactivated-coronavac, accessed 26 July 2021).

WHO/EURO: 2021-2913-42671-59457