

The Sinopharm COVID-19 Vaccine (also known as SARS-CoV-2 Vaccine (Vero Cell), Inactivated) has been granted authorization under the Health Sciences Authority (“HSA”) of Singapore’s Special Access Route (SAR) scheme for unauthorized COVID-19 vaccine use in Singapore under the direction of the Ministry of Health. This SAR scheme applies only to COVID-19 vaccines that are granted Emergency Use List (EUL) by the World Health Organization (WHO).

Read the information in this information sheet carefully. Consult your doctor or our clinic if you have questions.

1. What is the Sinopharm COVID-19 Vaccine and what is it used for?

The Sinopharm COVID-19 Vaccine is a form of vaccine categorised as “inactivated vaccines” which is reported to simulate the body’s immune system without the risk of causing diseases. Once inactivated viruses are presented to the body’s immune system, they stimulate the production of antibodies which prepares the body to respond to the future live SARS-CoV-2 (the “COVID-19 virus”) infections¹. The World Health Organization (WHO) Strategic Advisory Group of Experts on Immunization (SAGE)² has also completed its review of the Sinopharm COVID-19 Vaccine and assessed the vaccine to be safe for use, with its benefits far outweighing its risk for individuals aged 18 to 59 years old³. The Sinopharm COVID-19 Vaccine consists of two doses with the second dose due in three to four weeks after the initial dose.

As Sinopharm COVID-19 Vaccine recipients, you will need to receive both doses of the vaccine to achieve vaccine protection and for the vaccine protection to have a lasting effect. Please note, however, the Sinopharm COVID-19 vaccine does not guarantee full immunity against COVID-19.

In addition, the WHO Explainer¹ has cited the results of a large multi-country phase 3 trial, which has shown that two doses of the vaccine helps your immune system to produce protective responses and had the efficacy of 79% against hospitalization and symptomatic COVID-19 virus infection 14 days or more after the second dose. The WHO further reported that efficacy trials are underway for further evaluation of the efficacy of Sinopharm COVID-19 Vaccine, to determine long term protectivity induced by this vaccine.

2. What you need to know before and after you receive Sinopharm COVID-19 Vaccine?

You should NOT get vaccinated with the Sinopharm COVID-19 Vaccine if you:

- have a known history of allergic reaction(s) to the Sinopharm COVID-19 Vaccine or other inactivated vaccines or any components of Sinopharm COVID-19 vaccine (i.e., active/ inactive ingredients[#], or any materials used in the manufacturing process of the Sinopharm COVID-19 Vaccine.;
- had a previous severe allergic reaction to vaccine (e.g., acute anaphylaxis, angioneurotic edema, dyspnoea, etc.); after the first dose;
- had uncontrolled epilepsy or other progressive nervous system diseases, and with a history of Guillain-Barre syndrome;
- have uncontrolled severe chronic disease;
- have a body temperature over 38.5°C should postpone vaccination until they no longer have a fever.

Tell your doctor or nurse before getting this vaccine if you:

- have and/or had a fever in the past 24 hours;
- received another vaccine in the past 14 days;
- are pregnant, or think you may be pregnant, and/or lactating;
- previously received another form/type of COVID-19 Vaccine;
- are on active treatment for cancer or are immunocompromised, or taking treatment that affects your immune system or have active or recent treatment for cancer, organ or stem cell transplantation;
- had contracted COVID-19 before.

If any of the above scenarios apply to you, the doctor or nurse will assess your suitability and advise if you can proceed to receive the Sinopharm COVID-19 Vaccine.

Precautions³

- Like all vaccines, the protective effect may not reach 100% for all recipients, please note that the Sinopharm COVID-19 Vaccine does not guarantee full immunity against COVID-19.
- Due to insufficient data of long-term persistence of protection induced by this Sinopharm COVID-19 Vaccine, the recommendations are based on interim data and necessary protective measures should continue to be taken in line with preventive and control precautions related to the COVID-19 endemic.

- If necessary, please note that the doctor or nurse may require you to postpone and/or cancel your appointment to receive the Sinopharm COVID-19 Vaccine. Please seek your doctor's advice on your suitability for the Sinopharm COVID-19 Vaccine and used with caution as necessary if you have or is suffering from:
 - acute diseases, acute onset of chronic diseases, severe chronic diseases, atopy and/or fever or
 - diabetes, or history of convulsions, epilepsy, encephalopathy, or mental illness or family history of these disease, or
 - thrombocytopenia or haemorrhagic diseases, intramuscular injection of the Sinopharm COVID-19 vaccine may cause bleeding.
- The safety and efficacy data of the Sinopharm COVID-19 vaccine on people with impaired immune function (such as malignant tumor, nephrotic syndrome, AIDS patients) have not been obtained and the vaccination should be based on individual considerations.
- Please do not received a second dose and/or subsequent dose of the Sinopharm COVID-19 Vaccine if you experience any adverse reaction to the nervous system after receiving the initial dose of the Sinopharm COVID-19 Vaccine.
- People injected with immunoglobulin should be vaccinated with the Sinopharm COVID-19 Vaccine at least one month apart, so as not to affect the immune efficacy.
- *Interactions with other drugs/ COVID-19 Vaccines:*
 - patients undergoing treatments: for patient undergoing medical treatment(s), please consult your doctor before using the Sinopharm COVID-19 Vaccine to avoid possible drug interaction;
 - concomitant use with other drugs: immunosuppressive drugs, such as immunosuppressive agents, chemotherapy drugs, anti-metabolic drugs, alkylating agents, cytotoxic drugs, corticosteroids, etc. may reduce the body's immune response to this product;
 - concomitant use with other vaccines: Clinical trials of the Sinopharm COVID-19 vaccine used in combination with other vaccines have not yet been conducted to evaluate immune response with other vaccine on the immunogenicity at the same time.
- *Women of childbearing age:* The data collected from clinical trials on women with unexpected pregnancies after vaccination are very limited, and such data is insufficient to determine conclusively, the risk of adverse pregnancy outcomes after vaccination.
- *Pregnant or lactating women^{1,3}:* Pregnant women with COVID-19 are at higher risk of developing severe disease than non-pregnant women of reproductive age. The available clinical data of pregnant and lactating women are not available at present to assess vaccine efficacy or vaccine-associated risk in pregnancy. Animals' developmental and reproductive toxicology (DART) studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/ foetal development, parturition or postnatal development. In addition, the Sinopharm COVID-19 Vaccine is an inactivated vaccine with an adjuvant that is routinely used in many other vaccines with a documented good safety profile, including in pregnant women. On the basis of previous experience with use of other inactivated vaccines during pregnancy, the effectiveness of the Sinopharm COVID-19 Vaccine in pregnant women is expected to be comparable to that observed in non-pregnant women of similar age. In the interim, the WHO recommends the use of the Sinopharm COVID-19 Vaccine in pregnant and/or lactating women when the benefits of vaccination outweigh the potential risks. To help pregnant and/or lactating women make this assessment, she 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 safety data in pregnant women. The WHO does not recommend pregnancy testing prior to vaccination. WHO does not recommend delaying pregnancy or terminating pregnancy or discontinuing breastfeeding because of vaccination.
- *For persons aged below the age of 18 years or aged 60 years or more^{1,3}* – Phase I and II data on individual 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 due to small sample size. However, WHO SAGE, reported that in older adult age groups, seropositivity rates induced by the vaccine were similar to younger adults, while neutralizing antibody titers were substantial although lower in the older age group; preliminary and not yet peer-reviewed post-introduction observational data from Bahrain suggest a vaccine effectiveness across all age groups of more than 80%, including persons aged ≥ 60 years. According to the WHO, there are currently no efficacy or safety data for children or adolescents below the age of 18 years, although a phase II paediatric study is underway. Until such data are available, routine vaccination of individuals below 18 years of age with the Sinopharm COVID-19 vaccine is not recommended.
- You will be required to observe a 15 minutes post-vaccination period. This is to see whether any negative reaction occurs after vaccination.

In general, it is advisable to stay well-hydrated and not to skip meals before coming for vaccination. Individuals who are dehydrated or fasting may be more prone to fainting after the vaccination.

It is also advisable to avoid possible actions that may stimulate a serious allergic reaction after receiving the Sinopharm COVID-19 Vaccine or unless otherwise advised by your doctor:

- avoid strenuous exercise or physical exertion for 12-24 hours after getting vaccinated
- avoid drinking alcohol for 12-24 hours after getting vaccinated
- avoid taking non-steroidal anti-inflammatory drugs (NSAIDs) for pain or fever after vaccination. (NSAIDs include medications like ibuprofen, naproxen, and diclofenac.)

3. How is the Sinopharm Covid-19 Vaccine administered?

The Sinopharm COVID-19 Vaccine is administered as an injection into the muscle of your upper arm. You should return for your second dose of the same vaccine on the stipulated appointment given to complete the prescribed dosage of the Sinopharm COVID-19 Vaccine.

4. What are the possible side effects? How do I manage the side effects?

Like most vaccines, the Sinopharm COVID-19 Vaccine may cause side effects. Most side effects are mild or moderate, and usually improves within a few days. The table below list some potential side effects that have been reported by persons who had received the Sinopharm COVID-19 Vaccine and some suggestions on how to manage such symptoms.

	MAY AFFECT*	SIDE EFFECTS³
VERY COMMON	≥ 10% people	Injection site: pain; Headache
COMMON	1%-10% people	Fever, fatigue, myalgia, arthralgia, cough, dyspnea, nausea, diarrhea, pruritus
UNCOMMON	0.1%-1% people	Injection site: Redness, swelling, induration, itching Dizziness, anorexia, oropharyngeal pain, dysphagia, running nose, constipation, hypersensitivity
RARE	0.01%-0.1% people	Lethargy, drowsiness, difficulty falling asleep, sneezing, nasopharyngitis, nasal congestion, dry throat, influenza, hypoesthesia, limb pain, palpitations, abdominal pain, rash, abnormal skin mucosa, acne, ophthalmodynia, ear discomfort, lymphadenopathy
VERY RARE	<0.01% people	Chills, taste dysfunction, loss of taste, paresthesia, tremor, attention disorder, epistaxis, asthma, throat irritation, tonsillitis, physical discomfort, neck pain, jaw pain, neck lump, mouth ulcers, toothache, oesophagus disorders, gastritis, faecal discoloration, ophthalmodynia, blurred vision, eye irritation, earache, tension, hypertension, hypotension, urinary incontinence, delayed menstruation
NOT KNOWN	cannot be estimated from available data ¹	Anaphylaxis

*According to the classification of adverse reactions recommended by the International Committee of Medical Science Organizations (CIOMS).

Observed side effects events are mostly mild to moderate and short lived. Those with fever are advised to self-isolate at home until the fever subsides, or/and take one to two tablets of Paracetamol every six hours or dose according to each individual's weight. Consult your doctor in situations when the side effects persist or get worsens, or if your fever persist for more than 48 hours and/or if respiratory systems such as cough, runny nose, sore throat, shortness of breath or loss of sense or taste and smell develops. **If you experience a severe allergic reaction, seek medical attention immediately. Call 995 or go to the nearest A&E immediately.** Please note that the above is a non-exhaustive list and may not contain all possible side effects of Sinopharm COVID-19 Vaccine. If you experience side effects not listed above, please consult your doctor.

5. How do I report side effects?

You should contact your doctor for further advice. Your doctor will be able to advise you and if appropriate, he/she will report the side effects to HSA immediately or within the allocated time frame of becoming aware of any such serious adverse reactions arising from the use of Sinopharm COVID-19 Vaccine. You may also report side effects directly to HSA on a form by scanning this QR code.



6. What is the Special Access Route (SAR)?

The HSA SAR applies only to COVID-19 vaccines that are granted Emergency Use List (EUL) by the WHO and have not been authorised under the Pandemic Special Access Route (PSAR) by HSA, i.e., non-PSAR authorised vaccines. Non-PSAR authorised vaccines are not covered under the Vaccine Injury Financial Assistance Programme, which supports people who suffer adverse effects from their Covid-19 jabs.

According to the HSA's guidelines, please note that:

- the Sinopharm Covid-19 Vaccine has not been evaluated for the required quality, safety and efficacy standards for import and supply in Singapore by HSA;
- the Sinopharm Covid-19 Vaccine is not subject to HSA's enforcement and compliance checks on whether they are adulterated, counterfeit or substandard; and pursuant to the Ministry of Health (MOH)'s directive, recipients of the Sinopharm COVID-19 Vaccine will not be eligible for the Vaccine Injury Financial Assistance Programme for COVID-19 Vaccination (VIFAP) should any serious adverse events occur; and may not be treated in the same manner as those vaccinated with Pandemic Special Access Route ("PSAR")-authorised vaccines for the purpose of public health measures such as travellers and pre-event testing concessions

For more information on the HSA's SAR scheme, please refer to the HSA's website at: <https://www.hsa.gov.sg/therapeutic-products/register/special-access-routes/SAR-covid19>

References/ Footnotes:

Following information provided by Vaccine manufacturer³ that the ingredients include and not limited to inactivated SARS-CoV-2 Virus (19nCoV-CDC-Tan-HB02 strain), aluminium hydroxide, disodium hydrogen phosphate, sodium chloride and sodium dihydrogen phosphate.

1. The WHO COVID-19 Vaccine Explainer: Sinopharm [Vero Cell]- Inactivated, COVID-19 vaccine (2021, May 23). Retrieved August 10 2021 from World Health Organisation website: <https://www.who.int/publications/m/item/sinopharm-vero-cell---inactivated-covid-19-vaccine>
2. Wilder-Smith, A., Hombach, J., Marti, M., & O'Brien, K. (2021, May 24). Interim recommendations for use of the inactivated COVID-19 vaccine BIBP developed by China National Biotec Group (CNBG), Sinopharm. Retrieved July 27, 2021, from World Health Organisation website: https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BIBP-2021.1
3. Sinopharm COVID-19 Vaccine Package Insert, last updated on June 2021. Retrieved August 10 2021, from World Health Organisation website <https://extranet.who.int/pqweb/key-resources/documents/who-package-insert-covid-19-vaccine-bibp-9-june-21>

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