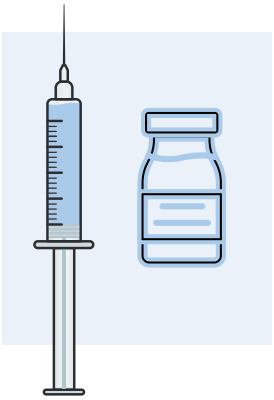
COVID-19 Vaccine Explainer

24 MAY 2021[1]

COVID-19 Vaccine (Vero Cell), Inactivated (Sinopharm)

Manufacturer: Beijing Institute of Biological Products Co., Ltd



The SARS-CoV-2 Vaccine (VeroCell) is an inactivated vaccine against coronavirus disease 2019 (COVID-19) which stimulates the body's immune system without risk of causing disease. Once inactivated viruses get presented to the body's immune system, they stimulate the production of antibodies and make the body ready to respond to an infection with live SARS-CoV-2. This vaccine is adjuvanted (with aluminum hydroxide), to boost the response of the immune system.

A large multi-country phase 3 trial has shown that two doses administered at an interval of 21 days had the efficacy of 79% against symptomatic SARS-CoV-2 infection 14 days or more after the second dose. The trial was not designed and powered to demonstrate efficacy against severe disease. Vaccine efficacy against hospitalization was 79%. The median duration of follow up available at the time of review was 112 days. Two efficacy trials are underway.

The data reviewed at this time support the conclusion that the known and potential benefits of Sinopharm vaccine outweigh the known and potential risks.

Date of WHO Emergency Use Listing (EUL) recommendation: 7 May 2021

Date of prequalification (PQ): currently no information
National regulatory authorities (NRAs) can use reliance approaches for in-country authorization of vaccines based on WHO PQ/EUL or emergency use authorizations by stringent regulatory authorities (SRAs).

Product characteristics

Presentation	Fully liquid, inactivated, adjuvanted, preservative-free suspension in vials and AD pre-filled syringes
Number of doses	Single-dose (one dose 0.5 mL)
Vaccine syringe type and needle size	Two available presentations: 1. Pre-filled AD syringes 2. Vials, for which the following is needed: • Auto-disable (AD) syringes: 0.5 mL • Needles for intramuscular injection 23G × 1" (0.60 × 25 mm)

[1] Contents are updated as new information becomes available.

Schedule and administration

Recommended for age	18 years of age and above Vaccination of children or adolescents below the age of 18 years is not routinely recommended, although the studies are underway.
Recommended schedule	2 doses (0.5 mL each) at a recommended interval of 3 to 4 weeks: Dose 1: at the start date Dose 2: 21 to 28 days after first dose. If the second dose is inadvertently administered earlier than 3 weeks after the first, the dose does not need to be repeated. If the second dose is inadvertently delayed beyond 4 weeks, it should be given at the earliest possible opportunity. It is recommended that all vaccinated individuals receive two doses. According to current recommendation, the same product should be used for both doses.
Route and site of administration	Intramuscular (i.m.) administration The preferred site is deltoid muscle.
Dosage	0.5 mL (single dose)
Diluent	None needed
Mixing syringe	None needed
Preparation/ reconstitution/ dilution requirement	**No dilution is required.** **Vaccine administration:** 1. Vaccine is ready to use, do not dilute. 2. Inspect the vial or monodose pre-filled syringe to make sure that the liquid is opalescent suspension, milky-white in colour. 3. If the stratified precipitate is formed, disperse it by shaking. 4. When using vaccine vials, draw up the vaccine from the vial at the time of administration. Use immediately as this vaccine contains no preservative. During vaccination sessions, vials and/or monodose pre-filled syringes should be kept between +2 and +8 °C and protected from light.
Multi-dose vial policy	Not applicable
Contraindications	• Known history of anaphylaxis to any component of the vaccine. • Persons who developed anaphylaxis after the first dose should not receive a second dose of the Sinopharm vaccine.
Precautions	• All persons should be vaccinated in health-care settings where appropriate medical treatment is available in case of allergic reactions. An observation period of 15 minutes after vaccination should be ensured. • Vaccination of people suffering from acute severe febrile illness (body temperature over 38.5 °C) should be postponed until they are afebrile. • Vaccination of persons with acute COVID-19 should be postponed until they have recovered from acute illness and criteria for discontinuation of isolation have been met.

Schedule and administration

Special population groups (based on available data as of 7 May 2021)	• For persons with **comorbidities**, phase 3 clinical trial data are insufficient to determine vaccine efficacy. Inferring from other inactivated vaccines, in persons with comorbidities other than immune-compromising conditions, vaccine effectiveness is likely to be similar or slightly reduced compared to persons of the same age without comorbidities. However, vaccination is recommended for persons with comorbidities that have been identified as increasing the risk of severe COVID-19. • For **persons aged 60 years or more**, vaccine efficacy and safety profile could not be estimated because of a small number of participants above 60 years of age in the phase 3 trial. However, in older adult age groups seropositivity rates induced by Sinopharm were similar to younger adults, while neutralizing antibody titres 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. There are no theoretical reasons to anticipate a different safety profile in older adults compared to younger, but countries considering the use of this vaccine in older populations should maintain active safety monitoring. • Available data on administration in **pregnant women** are insufficient to assess vaccine efficacy or vaccine-associated risks in pregnancy. However, this is an inactivated vaccine with an adjuvant that is routinely used in many other vaccines and for which a good safety profile has been documented, including in pregnant women. Until data to evaluate safety and immunogenicity in pregnant women are available, WHO recommends the use of Sinopharm in pregnant women when the benefits of vaccination 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 (including, for example, that some pregnant women are at increased risk of infection, or have comorbidities that add to their risk of severe disease), the likely benefits of vaccination in the current epidemiological context, and the current limitations of the safety data in pregnant women. WHO does not recommend pregnancy testing prior to vaccination. WHO does not recommend delaying pregnancy or terminating pregnancy because of vaccination. • There are no data on potential benefits or risks of the vaccine to **breastfed children**. As this is not a live virus vaccine, it is unlikely to pose a risk to the breastfeeding child. Vaccine effectiveness is expected to be similar in lactating women as in other adults. WHO does not recommend discontinuing breastfeeding after vaccination. • Data on administration of the vaccine are currently insufficient to allow assessment of vaccine efficacy for **persons living with HIV**. It is possible that their immune response to the vaccine may be reduced. Persons living with HIV who are a part of a group recommended for vaccination may be vaccinated, given that the vaccine is non-replicating. Where possible, information and counselling should be provided to inform individual benefit-risk assessment. Testing for HIV infection prior to vaccine administration is not necessary. • Available data are currently insufficient to access vaccine efficacy or vaccine-associated risks in **severely immunocompromised persons**, including persons on immunosuppressant therapy, who may have diminished immune response to vaccine. Nevertheless, if part of a recommended group for vaccination, they may be vaccinated, given that the vaccine is non-replicating. Information and, where possible, counselling about vaccine safety and efficacy profiles in immunocompromised persons should be provided to inform individual benefit–risk assessment. • For persons who have received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment, vaccination should be deferred for at least 90 days to avoid interference of treatment with vaccine-induced immune response as a precautionary measure.

Stability and storage

Vaccine storage temperature	Store in the original packaging in a refrigerator at +2 to +8 °C. **Do not store in a freezer.**
Shelf life at different temperatures	**Unopened vials and monodose pre-filled syringes in a refrigerator** between +2 and +8 °C: 24 months or until expiry date stated on the label.
Freeze sensitivity	Do not freeze.
Light sensitivity	Store in the original packaging to protect from light. Avoid exposure to direct sunlight and ultraviolet light.
Conditions before use	Vaccine is ready to use; it may be used if kept cooled at +2 °C to +8 °C.
Wastage rates	Will be dependent on country context.
Buffer stock needed	Will be dependent on country context.

Labelling and packaging

Vaccine Vial Monitor (VVM)	Type 7
Information on label (for vials and pre-filled syringes)	Name and type of vaccine, method of administration, dosage, storage temperature, manufacturing and expiry date, batch number
Information on secondary packaging (for vials and pre-filled syringes)	Name of vaccine, pharmaceutical form, method of administration, dosage, composition (active substance and excipients), manufacturing date, batch number, authorisation number, name and address of manufacturer
Information on tertiary packaging (for vials and pre-filled syringes)	Type of vaccine, name of manufacturer, presentation, batch number, date of expiry, quantity and storage conditions
Secondary packaging dimension and volume	**Single-dose vials:** 1. Carton holding 1 vial/1 dose; 7.2 × 3.9 × 2.2 cm Volume per dose: 61.8 cm^3 2. Carton holding 3 vials/3 doses; 5.45 × 5.3 × 2.2 cm Volume per dose: 21.2 cm^3
	Monodose pre-filled syringes: 1. Carton holding 1 pre-filled syringe in paper holder/1 dose; 10.4 × 4.45 × 2.05 cm Volume per dose: 94.9 cm^3 2. Carton holding 1 pre-filled syringe with blister package/1 dose; 13.5 × 3.7 × 2.5 cm Volume per dose: 124.9 cm^3
Tertiary packaging dimension and volume	**Single-dose vials:** 1. Box with 400 secondary cartons with a total of 400 vials (400 doses); external dimensions 43.0 × 31.0 × 23.5 cm 2. Box with 200 secondary cartons with a total of 600 vials (600 doses); external dimensions 46.0 × 29.0 × 13.0 cm
	Monodose pre-filled syringes: 1. Box with 300 secondary cartons with a total of 300 pre-filled syringes (400 doses); external dimensions 43.0 × 33.0 × 24.5 cm 2. Box with 240 secondary cartons with a total of 240 syringes (240 doses); external dimensions 42.0 × 32.0 × 27.5 cm

Safety information*

Possible events (by frequency)	• Observed events were mostly mild to moderate and short lived **Local events** **Very common (≥1/10):** Pain at the injection site **Uncommon (≥1/1 000 to <1/100):** Redness, swelling, induration, itching **Systemic events** **Very common (≥1/10):** Headache **Common (≥1/100 to <1/10):** Fever, fatigue, myalgia, arthralgia, cough, dyspnoea, nausea, diarrhoea, pruritus **Uncommon (≥1/1 000 to <1/100):** Dizziness, anorexia, oropharyngeal pain, dysphagia, running nose, constipation, hypersensitivity **Rare (≥1/10 000 to <1/1 000):** 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 (<1/10 000):** 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):** Anaphylaxis
Co-administration of vaccines/medicines	There should be a minimum interval of 14 days between administration of this and any other vaccine against other diseases, until data on co-administration become available.

*From clinical trials.

Important reminders

Vaccination session and vaccine administration

Before, during, and after vaccination, all people should continue to follow current guidance for protection from COVID-19 in their area (e.g. wearing a mask, keeping physical distance, hand hygiene).

Vaccination should be offered regardless of a person's history of symptomatic or asymptomatic SARS-CoV-2 infection. Viral or serological testing is not recommended for the purpose of decision-making about vaccination. Based on current data, symptomatic reinfection is uncommon within 6 months after an initial natural infection, and in the context of limited vaccine supply, persons with PCR-confirmed SARS-CoV-2 infection in the preceding 6 months may choose to delay vaccination until near the end of this period. However, emerging data indicate that symptomatic reinfection may occur in settings where variants with evidence of immune escape are circulating, and in these settings, earlier vaccination after infection may be advisable. The length of this time period may be revised when more data on duration of immunity after natural infection become available.

The presence of a minor infection such as a cold or low-grade fever should not delay vaccination.

A person with acute PCR-confirmed COVID-19 should not be vaccinated until after they have recovered from acute illness and the criteria for discontinuation of isolation have been met. The optimal minimum interval between a natural infection and vaccination is not yet known.

Before vaccination, advise vaccine recipient about possible post-vaccination symptoms and observe post-vaccination for at least **15 minutes**.

To alleviate post-vaccination symptoms, antipyretic or analgesics may be taken (routine prophylaxis to prevent the symptoms is not recommended due to lack of information on impact on immune response).

Encourage a vaccine recipient to complete the vaccination series to optimize protection and schedule the time for the second dose. The same vaccine product should be used for both doses. When scheduling vaccination for occupational groups (e.g. health workers) consideration should be given to the reactogenicity profile observed in clinical trials, occasionally leading to time off work in the 24-48 hours following vaccination.

SARS-CoV-2 variants

As SARS-CoV-2 viruses undergo evolution, new variants may be associated with higher transmissibility, disease severity, risk of reinfection, or a change in antigenic composition. Sinopharm vaccine efficacy has not yet been evaluated in the context of widespread circulation of variants of concern. WHO currently recommends the use of Sinopharm even if the variants are present in the country. There is an urgent need for a coordinated approach for surveillance and evaluation of variants and their potential impact on vaccine effectiveness. Countries using the vaccine in the presence of variants are encouraged to monitor vaccine effectiveness and study eventual breakthrough infections due to variants.

SARS-CoV-2 tests

Sinopharm contains inactivated SARS-CoV-2 virus which elicits immunological response to the spike and nucleocapsid protein. As currently available antibody tests for SARS-CoV-2 assess levels of IgM and/or IgG to the spike or the nucleocapsid protein, a positive test could indicate either prior infection or prior vaccination. Antibody testing is not currently recommended to assess immunity to COVID-19 following Sinopharm vaccination.

Resources and more information at:

https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-COVID-19-vaccine-BIBP

https://extranet.who.int/pqweb/vaccines/who-recommendation-covid-19-vaccine-bibp