COVID-19 Vaccine Explainer

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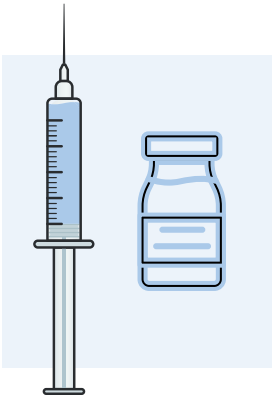
COVID-19 Vaccine (Vero Cell), Inactivated (Sinopharm)

Manufacturer: Beijing Institute of Biological Products Co., Ltd

3 JUNE 2022 UPDATE INCLUDES NEW INFORMATION ON:

- use of COVID-19 Vaccine BIBP in special populations (i.e. pregnant women, persons ≥60 years of age, immunocompromised persons, persons living in HIV, and persons in special settings);
- booster doses and interchangeability with other COVID-19 vaccines;
- co-administration with inactivated influenza vaccine; and
- 2- and 5-dose vial presentation and packaging.

Sections that have been updated are indicated with **.



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. Vaccine efficacy against hospitalization was 79%. Women were underrepresented in the trial. The median duration of follow up available at the time of review was 112 days. To date, a limited number of studies on vaccine efficacy have been published. No specific estimates of vaccine effectiveness against variants are available. The data reviewed by WHO support the conclusion that the known benefits of COVID-19 vaccine BIBP/'Sinopharm' vaccine outweigh the risks that are known or considered possible.

Date of WHO Emergency Use Listing (EUL) recommendation: 7 May of 2021
Date of prequalification (PQ): not applicable
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).

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

World Health Organization

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

Product characteristics**

Presentation	Fully liquid, inactivated, adjuvanted, preservative-free suspension in vials and non-AD prefilled syringes
Number of doses	Each prefilled non-AD syringe and each single dose vial contain one dose of vaccine (0.5 mL) Each 2-dose vial contains 1 mL of vaccine for administration of 2 doses (0.5 mL/dose) Each 5-dose vial contains 2.5 mL of vaccine for administration of 5 doses (0.5 mL/dose)
Vaccine syringe type and needle size	For 1-, 2- and 5-dose vials: • Auto-disable (AD) syringes: 0.5 mL • Needles for intramuscular injection 23G × 1" (0.60 × 25 mm)

Schedule and administration

Recommended for age**	18 years to 59 years WHO SAGE recommends vaccination of persons aged 18 years and older, without an upper age limit (see recommended schedule below). WHO SAGE recommends prioritization of different population groups according to the WHO Prioritization Roadmap
Recommended schedule**	**Primary vaccination series:** 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. **Extended primary series:** WHO SAGE recommends 3 doses (0.5 mL each) for older adults (≥60 years) and immunocompromised persons at intervals: Dose 1: at the start date Dose 2: 21 to 28 days after fist dose Dose 3: • for older adults (≥60 years) 3 to 6 months after second dose, • for immunocompromised persons 1 to 3 months after second dose. If more than 6 months for older adults/3 months for immunocompromised persons have elapsed since the second dose, the third dose should be administered as soon as possible. WHO SAGE recommends a booster dose for the highest and high priority-use groups (i.e. older adults, health workers, persons with comorbidities) to be administered 4 to 6 months after completion of the primary or extended primary series, in accordance with the WHO Prioritization Roadmap. If more than 6 months have elapsed, the booster dose should be given at the earliest opportunity. Evidence suggests that immunogenicity and vaccine effectiveness is superior with a COVID-19 vaccine from a different vaccine platform ('heterologous') compared to the inactivated ('homologous'). WHO SAGE recommends any of the mRNA or viral vectored EUL COVID-19 vaccines to be used as a booster following a primary series of COVID-19 Vaccine BIBP/'Sinopharm'.

Schedule and administration contd.

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.** **Single dose vials and prefilled syringes:** 1. Vaccine is ready to use, do not dilute. 2. Check the VVM and ensure that the inner square is lighter in colour than the outer circle. If the inner square is not lighter in colour than the outer circle, discard the vial. 3. Inspect visually the vial or pre-filled syringe to make sure that the liquid is opalescent suspension, milky-white in colour. 4. If the stratified precipitate is formed, disperse it by shaking. 5. When using vaccine vials, draw up the vaccine from the vial at the time of administration. Use immediately as this vaccine contains no preservative. **Two- and five-dose vials:** 1. Vaccine is ready to use, do not dilute. 2. Check the VVM and ensure that the inner square is lighter in colour than the outer circle. 3. Inspect visually the vial to make sure the liquid is opalescent suspension, milky-white in colour. 4. If the stratified precipitate is formed, disperse it by shaking. 5. Record date and time of the first use (first puncture and withdrawal of the dose) on the vial label. 6. Draw up the vaccine dose (0.5 mL) when ready to vaccinate, pre-loading of syringes is not recommended. 7. Before withdrawing each following vaccine dose, if the precipitate has formed, disperse it by shaking. 8. Preferably, use the vaccine immediately after first puncture or within 6 hours afterwards. Discard if vaccine is not used within this time or at the end of the session, whichever comes first. During vaccination session, vials and/or monodose pre-filled syringes should be kept between +2 and +8 °C and protected from light. Do not combine residual vaccine from multiple vials. When a full 0.5 mL dose cannot be extracted, discard any remaining vaccine in the vial.
Multi-dose vial policy**	After the first dose has been withdrawn, keep between +2 °C and +8 °C during the in-use period, and discard any unused vaccine in the vial after 6 hours, or at the end of the immunization session, whichever comes first. Keep opened vaccine vial in the foam pad of the vaccine carrier.
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 COVID-19 Vaccine BIBP/'Sinopharm'.
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 contd.

Special population groups**
(based on available data as of 7 May 2021)

- For persons with **comorbidities** that have been identified as increasing the risk of severe COVID-19 such as diabetes, hypertension, obesity, and neurodevelopmental and neurodegenerative conditions, vaccination is recommended.
- For **persons aged ≥60 years**, currently available evidence, despite its limitations, suggests lower immunogenicity. As the risk of severe disease and death due to COVID-19 increases steeply with age, WHO SAGE recommends an additional or the third dose as an extended primary vaccination series (see recommended schedule above).
- Available data on administration in **pregnant women** are insufficient to assess vaccine efficacy or safety of the COVID-19 Vaccine BIBP/'Sinopharm' 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 COVID-19 Vaccine BIBP/ '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, increased risk of intensive care unit admission and invasive ventilation, preterm birth and of neonates requiring neonatal intensive care), 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 (PLWH)**. It is possible that their immune response to the vaccine may be reduced. PLWH that is well controlled (i.e. current CD4 count >200 cells/µL and/or viral suppression) who are a part of a group recommended for vaccination may be vaccinated with the standard primary series of 2 doses, 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 for WHO EUL COVID-19 vaccine products suggest that vaccine effectiveness and immunogenicity is lower in **moderately and severely immunocompromised persons (ICP)** (i.e. transplant recipients, persons with active cancer, immunodeficiency, on active treatment with immunosupressives and persons living with HIV (PLWH) with CD4 count of <200 cells/µL) compared to persons without such conditions. Based on the emerging evidence, WHO SAGE recommends including an additional (third) dose for ICP aged 18 years and older, included in the extended primary vaccination series (see recommended schedule above). Given the limited vaccine effectiveness in this population, a booster dose may be considered to be administered 3 to 6 months after the third dose. WHO SAGE recommends a heterologous booster (i.e. not inactivated COVID-19 vaccine) as a fourth homologous dose does not appear to further increase immunogenicity.
- For persons who have received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment, vaccination does not need to be delayed.
- Persons in special settings such as refugee and detention camps, prisons, slums and other settings with high population densities where physical distancing is not implementable, should be prioritized for vaccination, taking into account national epidemiological data, vaccine supply and other relevant considerations.

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**	**Monodose pre-filled syringes:** 1. Carton holding 1 pre-filled syringe in paper holder/1 dose; 10.4 × 4.5 × 2.1 cm Volume per dose: 98.3 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 **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; 5.5 × 5.3 × 2.2 cm Volume per dose: 21.4 cm^3 3. Carton holding 10 vials/10 doses; 10 × 4.5 × 5.1 cm Volume per dose: 23 cm^3 **Two-dose vials:** 1. Carton holding 1 vial/2 doses; 7.2 × 3.9 × 2.2 cm Volume per dose: 30.9 cm^3 2. Carton holding 3 vials/6 doses; 5.5 × 5.3 × 2.2 cm Volume per dose: 10.7 cm^3 3. Carton holding 10 vials/20 doses; 10 × 4.5 × 5.1 cm Volume per dose: 11.6 cm^3 **Five-dose vials:** 1. Carton holding 1 vial/5 doses; 7.2 × 3.9 × 2.2 cm Volume per dose: 12.4 cm^3 2. Carton holding 3 vials/15 doses; 5.5 × 5.3 × 2.2 cm Volume per dose: 4.3 cm^3 3. Carton holding 10 vials/50 doses; 10 × 5.3 × 5.1 cm Volume per dose: 5.4 cm^3

Labelling and packaging contd.

Tertiary packaging dimension and volume**

Monodose pre-filled syringes:
1. Box with 300 secondary cartons with a total of 300 pre-filled syringes (300 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

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
3. Box with 100 secondary cartons with a total of 1000 vials (1000 doses); external dimensions 42.5 × 27.5 × 24.0 cm

Two-dose vials:
1. 1. Box with 400 secondary cartons with a total of 400 vials (800 doses); external dimensions 43.0 × 31.0 × 23.5 cm
2. Box with 200 secondary cartons with a total of 600 vials (1200 doses); external dimensions 46.0 × 29.0 × 13.0 cm
3. Box with 100 secondary cartons with a total of 1000 vials (2000 doses); external dimensions 42.5 × 27.5 × 24.0 cm

Five-dose vials:
1. Box with 400 secondary cartons with a total of 400 vials (2000 doses); external dimensions 43.0 × 31.0 × 23.5 cm
2. Box with 200 secondary cartons with a total of 600 vials (3000 doses); external dimensions 46.0 × 29.0 × 13.0 cm
3. Box with 100 secondary cartons with a total of 1000 vials (5000 doses); external dimensions 43.5 × 28.0 × 28.0 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 (≥1/1000 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

*From clinical trials.

Safety information* contd.

Co-administration of vaccines/medicines**	Limited evidence, mainly derived from co-administration studies with other COVID-19 vaccines, suggests that COVID-19 Vaccine BIBP/'Sinopharm' can be co-administered with inactivated influenza vaccines. When administering both vaccines during the same visit, use different arm for each vaccine injection. 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 with vaccines other than inactivated influenza vaccines 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. With the emergence of Omicron SARS-CoV-2 variant, reinfection after prior infection appear to be common. Hybrid immunity (i.e. from vaccination and from disease) is superior to immunity induced by vaccine or infection alone. The optimal time interval between infection and vaccination is not yet known. Persons with laboratory-confirmed SARS-CoV-2 infection before primary series vaccination may choose to delay vaccination for 3 months. Persons with breakthrough infections following any dose could also consider delaying the next dose by 3 months. When more data on duration of immunity after infection become available, the length of this time period may be revised as well as the number of doses needed. No data are currently available on vaccine-induced protection against Omicron.

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 subsequent dose. 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 tests

COVID-19 Vaccine BIBP/'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 vaccination with COVID-19 Vaccine BIBP/'Sinopharm'.

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