COVID-19 Vaccine Explainer

24 MARCH 2021[1]

COVID-19 Vaccine Janssen

(Ad26.COV2-S [recombinant])

Manufacturer: Janssen–Cilag International NV

The COVID-19 Vaccine Janssen (Ad26.COV2-S [recombinant]) is a non-replicating adenoviral vector vaccine against coronavirus disease 2019 (COVID-19). The vector virus contained within the vaccine delivers an instruction to host cells to produce the SARS-CoV-2 antigen called the spike protein, which triggers the production of antibodies. This allows the body to generate an immune response and to retain that information in memory immune cells. Efficacy shown in clinical trials in participants who received a single dose of COVID-19 Vaccine Janssen was 66.9% against symptomatic SARS-CoV-2 infection, 76.7% against severe COVID-19 after 14 days and 85.4% after 28 days, and 93.1% against hospitalizations. The data reviewed at this time support the conclusion that the known and potential benefits of COVID-19 Vaccine Janssen outweigh the known and potential risks.

Date of WHO Emergency Use Listing (EUL) recommendation: 12 March 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).

Product characteristics

Presentation	Preservative-free, multi-dose suspension for injection
Number of doses	One vial (2.5 mL) contains 5 doses of vaccine
Vaccine syringe type and needle size	Auto-disable (AD) syringe: 0.5 mL Needle for intramuscular injection 23G x 1” (0.60 × 25 mm)

Schedule and administration

Recommended for age	18 years of age and above
Recommended schedule	One dose
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

[1] Contents will be updated as new information becomes available.

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Schedule and administration contd.

Preparation/ reconstitution/ dilution requirement	**No dilution is required.** **Thaw each vial before use:** Thaw vaccine at room temperature up to 25 °C: • Individual vials take about 1 hour to thaw. • A carton of 10 vials takes about 2 hours to thaw. OR Thaw vaccine in refrigerator at +2 to +8 °C: • Individual vials take about 2 hours to thaw. • A carton of 10 vials takes about 12 hours to thaw. **Once thawed, do not re-freeze.** **Vaccine administration:** 1. Once thawed, the vaccine is ready to use, do not dilute. 2. Inspect the vial visually to make sure that the liquid is colourless to slightly yellow, and clear to very opalescent suspension. If any particulate matter and discoloration are present, do not use. Discard the vial. 3. Swirl the vial gently in an upright position for 10 seconds, do not shake. 4. Record date and time of the first use (first puncture and withdrawal of the dose) on the vial label. 5. Draw up the vaccine dose (0.5 mL) when ready to vaccinate, pre-loading of syringes is not recommended. 6. Before withdrawing each following vaccine dose, swirl the vial gently in an upright position for 10 seconds and do not shake. 7. 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. A maximum of 5 doses can be withdrawn from one vial. Do not combine residual vaccine from multiple vials. Discard any remaining vaccine in the vial after 5 doses have been withdrawn.
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.
Precautions	• All persons should be vaccinated by a health care professional in settings where medical treatment is available in case of allergic reactions. As a precautionary measure, an observation period of at least 15 minutes should be ensured post vaccination. • Vaccination of people suffering from acute severe febrile illness (body temperature higher than 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. • Minor infections such as cold or those with low-grade fever should not delay vaccination.

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Schedule and administration contd.

Special population groups (based on available data as of March 2021)	• For persons with **comorbidities** such as hypertension, chronic lung disease, significant cardiac disease, obesity, diabetes, and human immunodeficiency virus (HIV) infection that have been studied in phase 3 clinical trial and that have been identified as increasing the risk of severe COVID-19, vaccination is recommended. • Vaccination is recommended for older persons as the risk of severe COVID-19 and death increases steeply with age. • Available data on administration in **pregnant women** are insufficient to assess vaccine-associated risks in pregnancy. However, it should be noted that COVID-19 Vaccine Janssen is a non-replicating vaccine. This vaccine and vaccines against other diseases using the same platform have shown no safety issues in pregnant women. Until more data are available, pregnant women should receive COVID-19 Vaccine Janssen only if the benefit of vaccination to the pregnant woman outweighs the potential vaccine risks, such as if the woman is a health worker at high risk of exposure or has comorbidities that place her in a high-risk group for severe COVID-19. Information and, if possible, counseling on the lack of safety data for pregnant women should be provided. WHO does not recommend pregnancy testing prior to vaccination or delaying pregnancy because of vaccination. • COVID-19 Vaccine Janssen efficacy in **lactating women** is expected to be similar as in other adults and it is unknown if the vaccine is excreted in human milk. As this is a non-replicating vaccine, it is unlikely to pose a risk to the breastfeeding child. A lactating woman, who is a part of a group recommended for vaccination, should be offered vaccination. WHO does not recommend discontinuing breastfeeding after vaccination. • Available data are currently insufficient to access vaccine efficacy or vaccine-associated risks in **severely immunocompromised persons**, 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. • **HIV-positive persons** who are well controlled on highly active antiretroviral therapy and are part of a group recommended for vaccination can be vaccinated, given that the vaccine is non-replicating. Available data for HIV-positive persons who are not well controlled on therapy are currently insufficient to allow assessment of vaccine efficacy and safety in this group. Testing for HIV infection prior to vaccine administration is not necessary. • For persons who have received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment, as a precautionary measure, vaccination should be deferred for at least 90 days to avoid interference of treatment with vaccine-induced immune response.
SARS-CoV-2 variants	WHO currently recommends the use of COVID-19 Vaccine Janssen according to the SAGE prioritization roadmap, even if the variants are present in a country. Countries should conduct a benefit-risk assessment according to the local epidemiological situation including the extent of circulating virus variants.

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Stability and storage

Vaccine storage temperature	If the vaccine is received frozen, store in the original carton in a freezer at -25 to -15 °C. Do not store on dry ice or below -40 °C. If the vaccine is received thawed at +2 to +8 °C, store refrigerated at +2 to +8 °C in the original carton. Do not refreeze.
Shelf life at different temperatures	**Frozen unopened** vaccine vial in freezer at -25 and -15 °C: 24 months, or from receipt until expiry date printed on the vial and outer carton. **Thawed unopened** vaccine vial in refrigerator at +2 to +8 °C: once removed from the freezer, for a single period of up to 3 months. • The expiry date must be updated when the vaccine is removed from the freezer and before it is stored in the refrigerator. • If a 3-month period is within the original expiry date printed on the outer carton, cross out the original expiry date on the outer carton to mark as not valid. Write down the new expiry date which would be 3 months from the date you removed the vaccine from the freezer. • If a 3-month period is longer than the original expiry date printed on the outer carton, respect the original expiry date. **Thawed opened vial** (after first puncture) at +2 to +8 °C: up to 6 hours after the first dose has been withdrawn.
Freeze sensitivity	**Never** refreeze thawed vials. Do not store in insulated passive container with dry ice or ultra-low temperature phase-change material (PCM), or in freezer below -40 °C.
Light sensitivity	Store in the original outer carton to protect from light. Avoid exposure to direct sunlight and ultraviolet light.
Conditions before use	After thawing, visual inspection, and gentle swirling of the vial, vaccine is ready for use.
Wastage rates	Will depend on country context.
Buffer stock needed	Will depend on country context.

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Labelling and packaging*

Vaccine Vial Monitor (VVM) (if yes, location and type)	Initial pandemic supply will not include a VVM.
Information on vial label	Lot number, expiry date, blank box/space to fill in the updated expiry date, after the first puncture of the vial at +2 to +8 °C
Information on secondary packaging	Lot number, expiry date
Information on tertiary packaging	To be finalized
Secondary packaging dimension and volume	Carton box holding 10 vials/50 doses; 9.3 × 3.8 × 5.4 cm Volume per dose: 3.82 cm^3/dose
Tertiary packaging dimension	Carton containing 48 secondary packaged carton boxes with a total of 480 vials (2400 doses)* External dimensions 39.3 × 24.8 × 13.1 cm *Tertiary packaging and pallet configuration may vary according to the mode of transport.

*Labelling and packaging may be subject to change, depending on supply source.

Safety information*

Possible events (by frequency)	• Most adverse events occurred 1 to 2 days following vaccination, were mild to moderate in severity and usually resolved within 1 to 2 days. • Observed events were generally milder and less frequently reported in older adults (≥60 years) than in younger adults. **Very common (≥1/10):** Headache, nausea, myalgia, pain at the injection site, fatigue **Common (≥1/100 to <1/10):** Swelling or redness at the injection site, chills, arthralgia, cough, fever (≥38 °C) **Uncommon (≥1/1 000 to <1/100):** Rash, muscle weakness, arm or leg pain, feeling weak and generally unwell, sneezing, sore throat, back pain, tremor, hyperhidrosis (abnormal sweating) **Rare (≥1/10 000 to < 1/1 000):** Allergic reaction, hives **Not known (cannot be estimated from available data):** Severe allergic reaction (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 studies.

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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).

A person presenting with COVID-19 symptoms should not be vaccinated. Vaccination may be offered to people who have recovered from symptomatic or asymptomatic COVID-19.

Testing is not recommended for the purpose of decision-making about vaccination, however, based on current data, 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.

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 analgesic products (e.g. paracetamol-containing products) may be used, if required.

When scheduling vaccination for occupational groups (e.g. health workers) consideration should be given to the reactogenicity profile of this vaccine observed in clinical trials, occasionally leading to time off work in the 24-48 hours following vaccination.

Any unused COVID-19 Vaccine Janssen or waste material should be disposed of in accordance with local requirements. If content of the vial leaks out, spills should be disinfected with an appropriate antiviral disinfectant.

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.

In the US, where newly emerging variants of concern were not predominant at the time of the vaccine trial, vaccine efficacy for moderate to severe/critical COVID-19 was 72.0% (58.2, 81.7), and efficacy for severe/critical COVID-19 was 85.9% (-9.4, 99.7). In South Africa, despite the fact that the 20H/501Y.V2 variant (B.1.351 lineage) was the predominant strain, similar efficacies were observed as in the US: efficacy for moderate to severe/critical COVID-19 was 64.0% (95% CI: 41.2, 78.7) and efficacy for severe/critical COVID-19 was 81.7% (95% CI: 46.2, 95.4). In Brazil, where a variant from the P.2 lineage was the predominant strain, vaccine efficacy for moderate to severe/critical COVID-19 was 68.1% (95% CI: 7.8, 99.7) and for severe/critical COVID-19 87.6% (95% CI: 48.8, 80.7) (https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-Ad26.COV2.S-2021.1).

There is an urgent need for a coordinated approach for surveillance and evaluation of variants and their potential impact on vaccine effectiveness. WHO will continue to monitor the situation; as new data become available, recommendations will be updated accordingly.

Resources and more information at:

https://www.fda.gov/media/146304/download

https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssen-epar-product-information_en.pdf

https://extranet.who.int/pqweb/vaccines/who-recommendation-janssen-cilag-international-nv-belgium-covid-19-vaccine-ad26cov2-s

https://apps.who.int/iris/bitstream/handle/10665/340203/WHO-2019-nCoV-vaccines-SAGE-recommendation-Ad26.COV2.S-2021.1-eng.pdf?sequence=1&isAllowed=y