

COVID-19 Vaccine (Ad26.COV2.S [recombinant]) Janssen COVID-19 Vaccine Supplier: Janssen Inc.

INDICATIONS:

- Individuals 18 years of age and older ^{A, B}
- See [COVID-19 Vaccine Eligibility](#)

The vaccine is not approved for use in those less than 18 years of age.

DOSES AND SCHEDULE:

Adults 18 years of age and older: 1 dose given as 0.5 mL **IM**. ^C

For individuals who are moderately to severely immunosuppressed (see [COVID-19 Vaccine Eligibility](#)) and received Janssen COVID-19 vaccine, an additional dose of COVID-19 mRNA vaccine is recommended for completion of a 2-dose primary series. Moderna COVID-19 vaccine is preferentially recommended for the 2nd dose, which should be provided at least 28 days after the 1st dose. If Moderna is unavailable, Pfizer-BioNTech can be given.

NOTE: A booster dose with a COVID-19 mRNA vaccine is recommended for individuals 18 years of age and older who have already received a primary COVID-19 vaccine series. A second booster dose may be offered to certain individuals. See [BOOSTER DOSES](#).

ADMINISTRATION:

- No reconstitution required.
- Carefully mix contents of the vial by swirling gently in an upright position for 10 seconds; **do not shake**.

Storage and Handling:

- The vaccine can be stored at:
 - -25°C to -15°C up to the end of its expiry date printed on the vial and carton after “EXP”, kept in the original packaging and protected from light.
 - +2°C to +8°C for up to 11 months, not exceeding the original expiry date ^D, kept in the original packaging and protected from light.
 - Room temperature (up to +25°C) for 12 hours (cumulative).
 - After the first dose has been withdrawn, the vaccine may either be kept at room temperature (up to +25°C) for **3 hours** OR at +2°C to +8°C for **6 hours**. After these times, the vial must be discarded.

^A mRNA vaccines are the preferred COVID-19 vaccines for the primary series and booster dose. Viral vector vaccines should only be offered to individuals for whom all other authorized COVID-19 vaccines are contraindicated or have been refused, due to the reduced effectiveness and the possible adverse effects specifically associated with viral vector vaccines (e.g., Thrombosis with Thrombocytopenia Syndrome [TTS]). Informed consent should include the risk and symptoms of TTS versus the individual's risk of serious illness from COVID-19, as well as the need to seek immediate medical care should symptoms develop.

^B The minimum age for vaccine receipt is based on age at presentation (i.e., the vaccine may be offered to individuals on or after their 18th birthday).

^C Janssen COVID-19 vaccine (Ad26.COV2.S [recombinant]) may be given as a second dose if AstraZeneca/COVISHIELD vaccine is not available; recipients should be advised that mRNA vaccine is preferable for a 2nd dose for those without a contraindication to mRNA vaccine because of improved protection against COVID-19.

^D Refer to the updated expiry date written on the carton and disregard the manufacturer date printed on the vial. Retain the carton until all vials from the carton have been used.

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ADMINISTRATION (continued):

- The vaccine can be pre-loaded into a syringe and may either be kept at room temperature (up to +25°C) for **3 hours** OR at +2°C to +8°C for **6 hours**. After these times the syringe must be discarded.
- Ensure that the vial/syringe is clearly labelled with the date and time of first vial entry.
- During use, vials/syringes may be handled in room light conditions.
- Product should be thawed/held prior to use in one of the following ways:
 - From the freezer to the refrigerator:
 - A carton of 10 vials will take approximately 13 hours to thaw.
 - Individual vials will take approximately 2 hours to thaw.
 - From the freezer to room temperature:
 - A carton of 10 vials will take approximately 4 hours to thaw.
 - Individual vials will take approximately 1 hour to thaw.
- Do not refreeze thawed vials.

BOOSTER DOSES:

A first booster dose of a COVID-19 mRNA vaccine is recommended for individuals 18 years of age and older at least 2 months after the 1-dose Janssen primary series has been completed.

A second booster dose of a COVID-19 mRNA vaccine *should be* offered to the following individuals at least 6 months after the first booster dose: ^A

- Residents of LTC and alternate level of care clients awaiting placement in LTC
- Residents of assisted living facilities 70 years of age and older (Indigenous persons 55 years of age and older)
- Individuals 80 years of age and older in the community

A second booster dose of a COVID-19 mRNA vaccine *may be* offered to the following individuals at least 6 months after the first booster dose: ^A

- Individuals 70-79 years of age in the community
- Indigenous persons 55-79 years of age in the community

If COVID-19 mRNA vaccines are contraindicated or if the client refuses an mRNA vaccine, a 0.5 mL booster dose of Novavax or Janssen COVID-19 vaccine may be provided. If Janssen vaccine is provided, such clients should be informed that the Janssen vaccine provides lower protection against infection with COVID-19, and that it is associated with rare but serious adverse effects (e.g., TTS, thrombocytopenia and Guillain-Barré syndrome) which have not been seen with the mRNA vaccines or Novavax vaccine.

SEROLOGICAL TESTING:

Serological testing is not recommended before or after immunization.

^A The minimum interval between the booster doses is 4 months. Clients requesting a shorter interval should be informed that this is not optimal for protection, but their request for an earlier dose should be granted without need for MHO approval, provided the minimum interval between doses has been observed.

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CONTRAINDICATIONS:

1. History of anaphylactic reaction to a previous dose of an adenovirus vector COVID-19 vaccine or to any component of the Janssen COVID-19 vaccine. These individuals should be offered an mRNA COVID-19 vaccine and observed for at least 30 minutes after immunization.
2. History of thrombosis with thrombocytopenia following a previous dose of an adenovirus vector COVID-19 vaccine. These individuals should be offered an mRNA vaccine pending advice of the involved hematologist.
3. History of capillary leak syndrome.

PRODUCT COMPONENTS:

Potential allergens: polysorbate 80.

Other components: 2-hydroxypropyl- β -cyclodextrin (HBCD), citric acid monohydrate, ethanol, sodium hydroxide, hydrochloric acid, trisodium citrate dihydrate.

PRECAUTIONS:

- For individuals with suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, the vaccine should be administered in a controlled setting with expertise and equipment to manage anaphylaxis, with an extended period of observation post-vaccination of at least 30 minutes.
- Individuals who have experienced a previous cerebral venous sinus thrombosis (CVST) with thrombocytopenia, unrelated to adenovirus vector COVID-19 vaccination, or heparin-induced thrombocytopenia (HIT) should only receive this vaccine if the benefits outweigh the potential risks and an mRNA vaccine is unavailable.
- Wait until symptoms of an acute illness are resolved before vaccinating with COVID-19 vaccine to differentiate symptoms of illness from vaccine side effects.
- Individuals diagnosed with Multisystem Inflammatory Syndrome in Children (MIS-C) or Adults (MIS-A) should delay COVID-19 vaccination until they have recovered from illness and for 90 days after the date of diagnosis of MIS-C or MIS-A.
- Additional doses of a COVID-19 vaccine should be deferred in those who experienced a physician-diagnosed myocarditis or pericarditis event following a previous dose of a COVID-19 mRNA vaccine. For guidance on how to proceed with further COVID-19 vaccination, see the PRECAUTIONS section of the [Pfizer-BioNTech](#) and [Moderna](#) product pages. Deferral is not required for those with a prior history of myocarditis or pericarditis that is unrelated to COVID-19 mRNA vaccines and are no longer being followed by a medical professional for heart issues.
- In individuals with a history of immune thrombocytopenia (ITP), the risks of developing low platelet levels should be considered before vaccination.
- In individuals with a pre-existing increased risk for thromboembolism, the possible increased risk of venous thromboembolism (VTE) should be considered before vaccination.

SPECIAL CONSIDERATIONS:

- COVID-19 vaccines can be administered concomitantly or at any time before or after the administration of another inactivated or live vaccine.
- Deferral of COVID-19 vaccination is no longer recommended for individuals who have received anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma for treatment or prevention of COVID-19.

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SPECIAL CONSIDERATIONS (continued):

- COVID-19 vaccine may be offered to individuals without contraindications who have recovered from SARS-CoV-2 infection.
- COVID-19 booster doses may be deferred in those who have tested positive for COVID-19 (by PCR or rapid antigen test) until 3 months from symptom onset or, for asymptomatic cases, from the time of the positive test. For more information refer to the [NACI](#) statement.
- Recipients should practice public health measures for prevention of SARS-CoV-2 infection and transmission regardless of vaccination with COVID-19 vaccine.

ADVERSE EVENTS:

Local: pain, redness, swelling.

Systemic: headache, fatigue, myalgia, nausea, fever.

Very rare cases of Guillain Barré syndrome, immune thrombocytopenia (ITP) and capillary leak syndrome have been reported.

Rare cases of venous thromboembolism (VTE) have been reported.

A potential increased risk of serious blood clots has been observed with most cases having onset 4 to 28 days following receipt of the Janssen vaccine. This adverse event is being referred to as Thrombosis with Thrombocytopenia Syndrome (TTS) and is estimated to occur in approximately 1 in 100,000 vaccine recipients. Symptoms warranting medical attention include: headache beginning beyond 4 days after vaccination, blurred vision, difficulty speaking, seizure, difficulty moving parts of the body, shortness of breath, chest pain, new severe swelling, pain or colour change of an arm or a leg, persistent abdominal pain, abnormal bruising, reddish or purple spots or blood blisters under the skin, or bleeding beyond the site of vaccination.

REFERENCES:

1. [Janssen product monograph](#)
2. [National Advisory Committee on Immunization: Recommendations on the use of COVID-19 Vaccine\(s\)](#)