

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 12 years of age and older 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. 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**.
- Following withdrawal of all available 0.5 mL doses, the residual vaccine from up to three vials may be withdrawn into the same syringe to constitute a full dose provided the vials are from the same manufacturer and the same lot number. See [addendum](#) for more information.

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 6 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).

^A Informed consent should include the risk and symptoms of Thrombosis with Thrombocytopenia Syndrome (TTS) versus the individual’s risk of serious illness from COVID-19, as well the need to seek immediate medical care should symptoms develop.

^B The minimum age for vaccine receipt is based on year of birth (i.e., the vaccine may be offered to individuals who will be turning 18 years of age within the current calendar year), per BC Government recommendations.

^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):

- 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.
- 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 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. If COVID-19 mRNA vaccines are contraindicated or if the client refuses an mRNA vaccine, a 0.5 mL booster dose of the Janssen COVID-19 vaccine may be provided; however, 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., Thrombosis with Thrombocytopenia Syndrome [TTS], thrombocytopenia and Guillain-Barré syndrome) which have not been seen with the mRNA vaccines.

SEROLOGICAL TESTING:

Serological testing is not recommended before or after immunization.

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.

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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.
- There is insufficient evidence on the receipt of COVID-19 vaccine following receipt of anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma for treatment or prevention of COVID-19. Therefore, COVID-19 vaccination should be deferred for at least 90 days to avoid potential interference of the antibody therapy with vaccine-induced immune response. Deferral is not required following treatment with tocilizumab or sarilumab
- 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 with no other cause identified, until further information about the risk of recurrence is available. 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.
- A complete series of COVID-19 vaccine may be offered to individuals without contraindications who have recovered from PCR-confirmed SARS-CoV-2 infection.
- Recipients should practice public health measures for prevention of SARS-CoV-2 infection and transmission regardless of vaccination with COVID-19 vaccine, at this time.

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.

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ADVERSE EVENTS (continued):

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\(s\)](#)

ADDENDUM: Pooling residual vaccine from up to three vials to constitute an extra dose

Following withdrawal of all available 0.5 mL doses, a full 0.5 mL dose may be constituted from the residual vaccine volume from up to three separate vials, provided the vials are from the **same manufacturer** and **same lot number**. In order to minimize the risk of microbial contaminants and maintain product quality, the following processes should be followed:

- Only vials containing *residual* vaccine volume are to be used to prepare a full dose when using multiple vials to constitute a single dose. Residual volume should *not* be combined with contents from a different vial that still contains at least one full dose of the vaccine (to minimize the chance of contaminating the contents of a vial that still contains multiple doses of the vaccine).
- Given this vaccine does not contain preservative, and therefore has a short timeline for its use following first vial puncture, pooling of residual vaccine from two or three vials must occur as soon as possible - it is *not* recommended to save multiple vials with residual volume for use at one time (e.g., the end of the clinic).
- Perform hand hygiene before handling the vaccine. Strictly adhere to aseptic technique while handling the vaccine and minimize the number of vial punctures.
- Firmly and briskly wipe the surface of the rubber stopper with an alcohol swab for initial *and subsequent uses*, being sure to apply friction, and allow it to dry for at least 10 seconds.
- To assist with the withdrawal of residual vaccine from the vial, invert the vial and ensure the end of the needle is below fluid level and situated in the groove of the vial stopper.
- Once the residual vaccine is withdrawn, keep the needle in the vial when expelling air bubble(s) to minimize vaccine wastage.
- Check the syringe to ensure it contains the total 0.5 mL dose prior to administration.
- If not administered immediately, the syringe should be clearly labeled with the date and time of the vial with the shortest timeframe for use.