

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

INDICATIONS:

- Individuals 18 years of age and older ^{A, B}

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**.

For individuals 12 years of age older who are severely immunosuppressed* 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.

* Severely immunosuppressed individuals who:

- Have had a solid organ transplant (heart, lung, liver, kidney, pancreas or islet cells, bowel or combination organ transplant).
- Since January 2021, have been treated for and/or are receiving active treatment (chemotherapy, targeted therapies, immunotherapy) for malignant hematological disorders (e.g., leukemia, lymphoma, or myeloma).
- Since January 2020, have received treatment with any anti-CD20 agents (i.e., rituximab, ocrelizumab, ofatumumab, obinutuzumab, ibritumomab, tositumomab).
- Since January 2020, have been treated with B-cell depleting agents (i.e., epratuzumab, MEDI-551, belimumab, BR3-Fc, AMG-623, atacicept, anti-BR3, alemtuzumab).
- Have combined immune deficiencies affecting T-cells, immune dysregulation or type 1 interferon defects.
- Since September 2019, have had a bone marrow or stem cell transplant or are still taking immunosuppressant medications related to transplant.

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- Following withdrawal of all available 0.5 mL doses, the residual vaccine from up to three vials may be withdrawn into the same syringe to constitute a full dose provided the vials are from the same manufacturer and the same lot number.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.

^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.

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

ADMINISTRATION (continued):

Storage and Handling:

- Unopened multidose vial:
 - +2°C to +8°C up to the end of its expiry date ^A, kept in the original packaging and protected from light. **Do not freeze.**
 - Room temperature (up to +25°C) for 12 hours.
- Opened multidose vial:
 - After the first dose has been withdrawn, the vaccine is stable at room temperature (up to +25°C) for **3 hours** OR at +2°C to +8°C for **6 hours**. After this time, the vial must be discarded.
 - The vaccine can be pre-loaded into a syringe for up to **3 hours** at room temperature (up to +25°C) OR at +2°C to +8°C for **6 hours**. After this time 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.

BOOSTER DOSES:

No booster doses are recommended at this time.

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.
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.

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 the following populations, a complete COVID-19 vaccine series should be offered to individuals in the authorized age group if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the limited data on the use of COVID-19 vaccine in these populations:
 - immunosuppressed due to disease or treatment
 - those with an autoimmune condition ^B
 - pregnancy and breastfeeding ^C

^A Must refer to the expiry date on the orange panel of the carton.

^B For more information see the [CRA Recommendation on COVID-19 Vaccination in Persons with Autoimmune Rheumatic Disease](#).

^C For more information see the [SOGC Statement on COVID-19 Vaccination in Pregnancy](#).

COVID-19 Vaccine (Ad26.COVS.S [recombinant])

Janssen COVID-19 Vaccine

Supplier: Janssen Inc.

PRECAUTIONS (continued):

- For individuals with suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, consultation with an allergist is advised. If there is a specific concern about a possible allergy to a component of the COVID-19 vaccine being administered, an extended period of observation post-vaccination of 30 minutes may be warranted; alternately, the vaccine can be administered in an emergency room setting, also with a prolonged observation period.
- 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.
- Due to the theoretical risk that viral vector vaccines may temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results, these tests should be administered and read before COVID-19 immunization or delayed for at least 4 weeks after immunization. COVID-19 immunization may take place at any time after all steps of tuberculin skin testing have been completed.

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.

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.

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

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.