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

INDICATIONS:
• Individuals 18 years of age and older

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 and older who are moderately to 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.

* Moderately to 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 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).
  • Since October 2020, have received or are receiving radiation therapy for cancer.
  • Since March 2020, have received or are receiving systemic therapy for solid tumours as well as hematological cancers (including chemotherapy, molecular therapy, immunotherapy, targeted therapies including CAR-T, monoclonal antibodies, hormonal therapy for cancer).
  • Have combined immune deficiencies affecting T-cells, immune dysregulation (particularly familial hemophagocytic lymphohistiocytosis) or type 1 interferon defects (caused by a genetic primary immunodeficiency disorder or secondary to anti-interferon autoantibodies).
  • Since September 2019, have had a bone marrow or stem cell transplant or are still taking immunosuppressant medications related to transplant.
  • Have a moderate to severe primary immunodeficiency which has been diagnosed by an adult or pediatric immunologist and requires ongoing immunoglobulin replacement therapy (IVIG or SCIG) or the primary immunodeficiency has a confirmed genetic cause (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome).
  • On dialysis (hemodialysis or peritoneal dialysis) or have stage 5 chronic kidney disease (eGFR <15 mL/min) or have glomerulonephritis and receiving steroid treatment.
  • Prior AIDS defining illness or CD4 count ≤ 200/mm³ or CD4 fraction ≤ 15% or detectable plasma viral load since January 2021 or HIV infection and ≥ 65 years old or perinatally acquired HIV infection.

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.
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DOSES AND SCHEDULE (continued):
- Have taken significantly immunosuppressing drugs or treatments including at risk biologics, steroids and other agents:
  - Steroids orally or by injection on an ongoing basis since December 15, 2020.

NOTE: A booster dose with a COVID-19 mRNA vaccine is recommended for certain populations 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:
- Unopened multidose vial:
  - +2°C to +8°C up to the end of its expiry date, 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:
A booster dose of a COVID-19 mRNA vaccine is recommended at least 6 months after the primary series has been completed for those who are:
- Residents of long term care (LTC), assisted living and independent living facilities, and alternate level of care clients awaiting placement in LTC
- Individuals receiving long-term home support

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A A list of these medications can be found on the government of B.C. website.
B Must refer to the expiry date on the orange panel of the carton.
C The minimum interval between completion of the primary series and the booster dose is 8 weeks. This interval may be applied for a minority of individuals for practical reasons, with consideration of the individual benefits and risks, but is not to be used as a routine interval.
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BOOSTER DOSES (continued):
- 70 years of age and older
- Indigenous peoples 18 years of age and older
- Individuals 18 years of age and older in rural and remote communities
- Health care workers who received dose 2 at an interval of less than 42 days from dose 1
- Individuals who are vulnerable or in congregate settings in outbreaks at the direction of the Medical Health Officer

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.
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, 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.

\(^A\) The minimum age for the booster dose 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 Provincial Health Officer recommendations.
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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.

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.
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ADDEDNDUM (continued):

- 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.