COVID-19 Vaccine - Janssen
JCOVDEN - Ad26.COV2.S [recombinant]
Revision Date: March 20, 2023

Rationale for Update:
- Updated bivalent booster spacing considerations to 6 months after last dose or infection.

This policy is evergreen and will be updated as new information becomes available.

Please consult the Product Monograph¹ for further information about the vaccine.

<table>
<thead>
<tr>
<th>Janssen</th>
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<tbody>
<tr>
<td>Manufacturer</td>
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<td>Licensed use</td>
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</table>
| Composition/Platform Vaccine Type | • Recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding the SARS-CoV-2 Spike (S) protein.  
• No adjuvants or preservatives. |
| Indications for use of vaccine | Janssen vaccine may be considered for individuals 18 years of age and older.  
Note:  
• A complete primary series and a booster dose with an Omicron-containing bivalent mRNA COVID-19 vaccine is preferentially recommended for individuals in the authorized age group without contraindications to the vaccine.  
• For individuals who refuse an mRNA COVID-19 vaccine or have a contraindication to an mRNA vaccine, the Novavax COVID-19 vaccine is recommended over the Janssen COVID-19 vaccine. |
| Dose | 0.5 mL |
| Route | • Intramuscular injection in the deltoid muscle. |
| Schedule | **Primary Series**  
• 1 dose¹² |
| Notes: | • The Janssen vaccine is currently licensed as a one dose vaccine series.  
• Generally, Janssen should not be used to complete an mRNA, AstraZeneca or Novavax COVID-19 vaccine series.  
  o Individuals with an incomplete primary series and contraindication to other currently available COVID-19 vaccines can receive a Janssen COVID-19 vaccine dose respecting the recommended interval from the previous dose of COVID-19 vaccine. |
| Booster dose indications | • A booster dose of an Omicron-containing bivalent mRNA COVID-19 vaccine is preferentially recommended as a booster dose in the authorized age groups. However, in the event of contraindication or refusal, a single Janssen booster dose can be provided. |
**Individuals 18 years of age and older**

- A single booster dose of the Janssen COVID-19 vaccine may be administered to individuals who have previously received a complete primary series (1 dose) of Janssen vaccine.14

  - **Booster dose:** at least 2 calendar months after the last dose of the primary series.

    - An individual who received one booster dose of Janssen is considered up to date and additional Janssen booster doses are not indicated. However, an individual can receive a one-time Omicron-containing bivalent mRNA COVID-19 booster dose at least 6 calendar months between the last dose of Janssen (or infection).

**Notes:**

- Individuals who received a primary series of Janssen COVID-19 vaccine (one dose) and a first booster dose of any other Health Canada approved COVID-19 vaccine are not eligible for another booster dose of Janssen.

**Interval between previous COVID-19 infection and COVID-19 immunization**

For individuals with a history of COVID-19 infection the following guidance is provided on suggested intervals between infection and COVID-19 immunization.2

**Notes:**

- These suggested intervals are based on immunological principles and expert opinion, and may change as evidence on COVID-19, variants of concern (VOCs), and COVID-19 vaccines emerge. When considering whether or not to administer vaccine doses following the suggested intervals outlined in this table, biological and social risk factors for exposure (e.g., local epidemiology, circulation of VOCs, living settings) and the risk of severe disease should also be taken into account. These intervals are a guide and clinical discretion is advised. Individuals can be immunized at less than the recommended intervals from infection upon request.

- For individuals who have not had any previous doses, they may receive their first dose after acute symptoms of COVID-19 have resolved and they are no longer infectious, or they may follow these suggested intervals (with the exception of those with MIS-C who should wait at least 90 days).

<table>
<thead>
<tr>
<th>Infection prior to initiation or completion of a primary COVID-19 immunization series</th>
<th>Individuals without certain immunocompromising conditions AND no history of multisystem inflammatory syndrome in children (MIS-C).</th>
<th>8 weeks after a positive test.</th>
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<tbody>
<tr>
<td>Individuals with certain immunocompromising conditions AND no history of MIS-C.</td>
<td>4 to 8 weeks after a positive test.</td>
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<tr>
<td>History of MIS-C (regardless of immunocompromised status).</td>
<td>Receive the vaccine when clinical recovery has been achieved or at least 90 days since the onset of MIS-C, whichever is longer.</td>
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| Infection after primary series completion | Individuals eligible for booster dose. | Janssen booster: 2 months after a positive test or after the last Janssen dose. Bivalent booster: 6 months after a positive test or after last Janssen dose. |
### Contraindications

- Known severe hypersensitivity to any component of the vaccine or component of the container.¹
  - One non-medicinal ingredient in the vaccine that has the potential to cause type 1 hypersensitivity reactions is polysorbate 80. Polysorbate 80 may be found in medical preparations (e.g. vitamin oils, tablets, anticancer agents) and cosmetics.
- Known severe hypersensitivity to any other adenovirus-based vaccine (e.g. AstraZeneca/COVISHIELD).¹
- Previous history of capillary leak syndrome (CLS). CLS is a rare disease characterized by acute episodes of limb edema, hypotension, hemoconcentration and hypoalbuminemia.³
- Experienced previously major venous and/or arterial thrombosis with thrombocytopenia following immunization with Janssen or AstraZeneca/COVISHIELD COVID-19 vaccine.
- Anaphylaxis to previous dose of Janssen COVID-19 vaccine. See [COVID-19 Immunization for Individuals with Allergies and Other Health Conditions](#) for recommendations.

### Precautions

- Individuals receiving anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration.¹
- Administration should be postponed in individuals suffering from acute severe febrile illness.¹,²
- Prior to receiving the Janssen vaccine, individuals should be informed of what is currently known about the risk of the rare but serious events of thrombosis with thrombocytopenia (TTS), venous thromboembolism (VTE), immune thrombocytopenia (ITP), capillary leak syndrome and Guillain-Barre syndrome (GBS) that were reported following immunization the vaccine. This should be part of the benefit-risk discussion to help them make an informed decision.¹,⁴

### Immunocompromised and Auto-Immune Disorders

- Adults with stable/well-controlled HIV infection or adults receiving chronic low-dose (less than 20 mg of prednisone or equivalent) immunosuppressive therapy were included in Janssen COVID-19 Vaccine Phase 3 clinical studies.¹
- Immunocompromised individuals, including those receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.¹
- The mRNA COVID-19 vaccines are preferentially recommended for individuals in the eligible group who are immunosuppressed due to disease or treatment and those with an auto-immune disorder without contraindications to the vaccine. For individuals who refuse an mRNA COVID-19 vaccine or have a contraindication to an mRNA vaccine, the Novavax COVID-19 vaccine is recommended over the Janssen COVID-19 vaccine.
  - It is recommended that individuals consult with their primary health care provider or medical specialist for any vaccine related questions.
  - However, consultation with a primary health care provider or medical specialist is not required to receive COVID-19 vaccine.

  **Exceptions:**
  - SOT clients require consultation with their primary health care provider or medical specialist prior to receiving COVID-19 vaccine.
  - HSCT clients do not require consultation as long as the initial clearance letter has been received to proceed with inactivated vaccines.

Additional resource: [COVID-19 Scientific Advisory Group Rapid Evidence Report](#).
Pregnancy

- mRNA COVID-19 vaccine is preferentially recommended for pregnant individuals in the authorized age group without contraindications to the vaccine.
- For individuals who refuse an mRNA COVID-19 vaccine or have a contraindication to an mRNA vaccine, the Novavax COVID-19 vaccine is recommended over the Janssen COVID-19 vaccine.
- The Janssen vaccine may be offered to individuals in the eligible group who are pregnant if a risk assessment with their primary health care provider or obstetrician determines that the benefits outweigh the potential risks for the woman and fetus.
  - However, the individual may also be immunized without consulting their primary health care provider or obstetrician following their acknowledgment of the absence of evidence on the use of a viral vector COVID-19 vaccine in this population and the preference for an mRNA vaccine due to published safety data and concerns about the complexities of the treatment of Vaccine-Induced Immune Thrombotic Thrombocytopenia in pregnancy should it occur after immunization.

See ‘Safety Information: Risk of Thrombosis with Thrombocytopenia’ section below.


Lactation

- It is unknown whether the Janssen COVID-19 vaccine is excreted in human milk as breastfeeding individuals were excluded from the initial trials. A risk to the newborn/infants cannot be excluded.\(^1,2\)
- The Janssen COVID-19 vaccine can be offered to individuals in the eligible group who are breastfeeding.
  - It is recommended that individuals consult with their primary health care provider or medical specialist for any vaccine related questions or concerns.
  - However, consultation with a primary health care provider or medical specialist is not required to receive the Janssen COVID-19 vaccine. Breastfeeding individuals can be immunized following routine informed consent discussion.

Other Considerations

- Individuals presenting for immunization do not need to be tested for previous COVID-19 infection.
- It is not recommended that serology testing be completed to determine if an immune response to the COVID-19 vaccine has been mounted in individuals, and should not be used as evidence to inform whether vaccine doses have been effective.
- Immunization of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness.
- Individuals with COVID-19-like symptoms, should have their immunization deferred.

Safety Information: Risk of Thrombosis with Thrombocytopenia (TTS), and Immune Thrombocytopenia (ITP), and Venous Thromboembolism (VTE)

- A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely in the U.S. following immunization with the Janssen COVID-19 vaccine.\(^1,4,6\)
- This includes severe cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, mesenteric vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia.
- A causal relationship with the vaccine is considered plausible, but the exact mechanism by which the Janssen vaccine triggers these very rare but serious events is still under investigation. No specific risk factors have been identified at this time.\(^5\)
- Cases of TTS following administration of the Janssen COVID-19 vaccine have been reported in a wide age range of individuals 18 years and older, with the highest reporting rate in females ages 30-49 years. Overall, approximately 15% of TTS cases have been fatal.1
- As of March 18, 2022, approximately 18 million doses of the Janssen vaccine had been administered in the U.S. and 60 confirmed cases of TTS were reported to Vaccine Adverse Event Reporting System (VAERS) with 9 fatalities.13
- Health Canada has assessed the available data on the reported events and has determined that the benefit of the Janssen COVID-19 vaccine outweighs the risk of thrombosis and thrombocytopenia. Health Canada has worked with Janssen Inc. to update the Product Monograph for the Janssen COVID-19 vaccine to include this new safety information to inform Canadians of the possible side effects and to provide information about the signs and symptoms and when to seek prompt medical attention following immunization.4
- Healthcare professionals should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia and be aware of TTS including how to diagnose and treat the condition.4,10
- Those immunized should be instructed to seek immediate medical attention if they develop symptoms of thromboembolism and/or thrombocytopenia between days 4 and 28 following receipt of the Janssen vaccine such as:
  - severe headache that does not go away
  - confusion or seizure
  - difficulty moving part(s) of the body
  - new blurry vision that does not go away
  - difficulty speaking
  - shortness of breath
  - chest pain
  - severe abdominal pain
  - new severe swelling, pain, or colour change of an arm or a leg
  - unusual bruising or spontaneous bleeding
- Cases of Immune Thrombocytopenia (ITP) have been reported very rarely within the first four weeks after receiving the Janssen COVID-19 vaccine and that include serious cases with very low platelet counts.11 If an individual has a history of ITP, healthcare professionals should consider the risk of developing low platelet levels prior to administering the vaccine. In individuals with a history of ITP, it is recommended to monitor platelet levels following immunization with the Janssen COVID-19 vaccine.11
- Cases of Venous thromboembolism (VTE) have also been observed rarely following immunization with Janssen COVID-19 vaccine. The risk of VTE should be considered for individuals with increased risk factors for thromboembolism (blood clots).11

<table>
<thead>
<tr>
<th>Interchangeability</th>
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<tbody>
<tr>
<td>Currently, no data exists on the interchangeability of COVID-19 vaccines.2</td>
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<tr>
<td>There are no data available on the use of the Janssen COVID-19 vaccine to complete a series initiated with another COVID-19 vaccine.1</td>
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<th>Administration with Other Products</th>
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<tbody>
<tr>
<td>COVID-19 vaccines may be co-administered with, or at any time before or after other vaccines (including, live, inactivated, adjuvanted, or unadjuvanted vaccines) to individuals 6 months of age or older.2</td>
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<tr>
<td>Currently there are no data on the impact of the COVID-19 vaccines on tuberculin skin testing or IGRA (QFT) test results. There is a theoretical risk that COVID-19 vaccines may temporarily affect cell-mediated immunity, resulting in false-negative tuberculin skin testing or IGRA (QFT) test results.2</td>
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In the absence of data, and acknowledging the importance of both timely tuberculosis testing and immunization, immunization with COVID-19 vaccines can take place at any time before, after or at the same visit as the TST or IGRA test.\(^2\)

However, repeat tuberculin skin testing or IGRA (at least 4 weeks post-COVID-19 immunization) of individuals with negative TST or IGRA results for whom there is high suspicion of latent tuberculosis may be considered in order to avoid missing persons with TB infection.\(^2\)

- Deferral of COVID-19 immunization is not recommended for individuals who have received anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma provided for treatment or prophylaxis of COVID-19 just because they received these pharmacological interventions. This applies to people who received these before receiving any COVID-19 vaccine dose or between doses.
  - A study among nursing home residents and staff demonstrated that recipients of a SARS-CoV-2 monoclonal antibody (bamlanivimab), mounted a robust immune response to mRNA immunization, regardless of age, risk category or vaccine type.\(^15\)
  - Although antibody response was numerically lower in people who received monoclonal antibodies, they were still considered to be high and the clinical significance of the reduction is unknown.\(^15\)
  - There was no correlation between interval to COVID-19 immunization and neutralizing titres in recent monoclonal antibody recipients.\(^15\)
  - Intervals between previous COVID-19 infection and COVID-19 immunization outlined in this document would still apply to individuals who got the monoclonal antibodies or convalescent plasma for their infection.

- Individuals who are to receive Evusheld (tixagevimab and cilgavimab) as pre-exposure prophylaxis should wait at least 2 weeks following COVID-19 immunization to minimize interference.

- Viral vector COVID-19 vaccines may be given at any time before or after an immunoglobulin preparation (including RhIg) or blood product not specific to COVID-19 treatment has been administered. There is no recommended minimum interval between these products and COVID-19 vaccine.

**Program Notes**

- March 5, 2021 - licensed for use in Canada
- November 12, 2021 – updated to include recommendation for booster dose of mRNA vaccine 6 months following single dose
- December 8, 2021 - Individuals with a contraindication to currently available COVID-19 vaccines can receive Janssen COVID-19 vaccine with a minimum of 28 days from any previously received COVID-19 vaccine.
- December 22, 2021 - interval for booster dose changed from at least 6 months to at least 5 months after last dose of the primary series for all individuals 18 years of age and older.
- February 14, 2022 - Clarified wording on individuals with history of COVID-19 infection.
- March 2, 2022 - Updated to incorporate NACI interim guidance on suggested interval between previous COVID-19 infection and COVID-19 immunization.
- April 6, 2022 - Updated to clarify NACI interim guidance on suggested interval between previous COVID-19 infection and COVID-19 immunization.
- July 11, 2022 – Addition of a single booster dose, and update of possible reactions, and storage and handling to align with most recent product monograph.
- January 20, 2023 – Removed the following sections: Possible Reactions, Appearance, Storage and Handling, Packaging, Non-Medicinal Ingredients and Preparation/Reconstitution and updated booster dose recommendation.
- March 01, 2023 – Updated booster dose recommendations.
- March 20, 2023 - Updated bivalent booster spacing considerations to 6 months after last dose or infection.
References


