COVID-19 Vaccine – Ad26.COV2.S [recombinant] Janssen Vaccine Biological Page

Section 7:	**Biological Product Information**		**Standard #: 07.206**
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	Janssen COVID-19 Vaccine
Manufacturer	Janssen (Johnson & Johnson)
Biological Classification	• Recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding the SARS-CoV-2 Spike (S) protein.
Indications for Provincially Funded Vaccine	**Persons 18 years of age and older** **Notes:** • Janssen vaccine may be considered for individuals 18 years of age and older. • A complete series and a booster dose with an mRNA COVID-19 vaccine are 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, Novavax COVID-19 vaccine is recommended over Janssen COVID-19 vaccine.
Preferred Use	N/A
Dose	0.5 mL
Route	IM in the deltoid or vastus lateralis muscle
Schedule	Primary Series: • 1 dose **Notes:** • The Janssen vaccine is currently licensed as a one dose vaccine series and individuals are considered fully immunized 14 days following the immunization at this time. However, there is a possibility that in the future individuals who received one dose of the Janssen vaccine may need an additional dose to be considered fully immunized • Generally, Janssen should not to be used to complete a mRNA or AstraZeneca or Novavax COVID-19 vaccine series. ○ Individuals with an incomplete primary series and a contraindication to other currently available COVID-19 vaccines can receive Janssen COVID-19 vaccine respecting the recommended interval from the previous dose of COVID-19 vaccine. Individuals with one dose of Janssen COVID-19 vaccine would be considered fully immunized at this time.
Booster Dose Indications	• A booster dose of mRNA vaccine is recommended to provide better protection. However, in the event of contraindication or refusal, Janssen can be provided. **Individuals 18 years of age and older** • A single booster dose of Janssen COVID-19 vaccine may be administered to individuals who have previously received a complete primary series (1 dose) of Janssen vaccine. • **Booster dose**: at least 2 calendar months after the last dose of the primary series.

<table>
<tr><th></th><th colspan="3">Janssen COVID-19 Vaccine</th></tr>
<tr><td></td><td colspan="3">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.
Janssen vaccine is not authorized for use as a second booster dose. Eligible individuals may receive Pfizer, Moderna or Novavax COVID-19 vaccine as their second booster dose.</td></tr>
<tr><td rowspan="5">Interval Between Previous COVID-19 Infection and COVID-19 Immunization</td><td colspan="3">For individuals with a history of COVID-19 infection the following guidance is provided on suggested intervals between infection and COVID-19 immunization.
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 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).</td></tr>
<tr><td rowspan="3">Infection prior to initiation or completion of a primary COVID-19 immunization series.</td><td>Individuals without certain immunocompromising conditions AND no history of multisystem inflammatory syndrome in children (MIS-C)</td><td>8 weeks after symptom onset or positive test (if asymptomatic)</td></tr>
<tr><td>Individuals with certain immunocompromising conditions (as listed above) AND no history of MIS-C</td><td>4 to 8 weeks after symptom onset or positive test (if asymptomatic)</td></tr>
<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></tr>
<tr><td>Infection after primary series</td><td>Individual eligible for booster dose</td><td>3 months after symptom onset or positive test (if asymptomatic) and at least 2 months after the last dose</td></tr>
<tr><td>Contraindications/ Precautions</td><td colspan="3">Contraindications:
Persons under 18 years of age
Known severe hypersensitivity to any component of the vaccine or component of the container
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). See COVID-19 Immunization for Individuals with Allergies and Other Health Conditions for recommendations.</td></tr>
</table>

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	• Previous history of capillary leak syndrome (CLS). CLS is a rare disease characterized by acute episodes of limb edema, hypotension, hemoconcentration and hypoalbuminemia. • 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. • Administration should be postponed in individuals suffering from acute severe febrile illness. • 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 of the vaccine. This should be part of the benefit-risk discussion to help them make an informed decision.

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.
	• Immunocompromised individuals, including those receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.
	• 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, Novavax COVID-19 vaccine is recommended over 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.
	  ▪ Response for immunizers if individual has not consulted with their primary health care provider: “Vaccine studies are not complete on the use of this vaccine in immunocompromised individuals or those with auto-immune disorders. Emerging data has not detected any safety issues related specifically to those who are immunocompromised. We recommend you speak to your physician regarding the timing of immunization based on your treatment or if you have questions about the immunization, but it is not required to receive the vaccine.”
	  Exceptions:
	  ▪ SOT client 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 vaccine.
	• Additional resources:
	  ○ COVID-19 Scientific Advisory Group Rapid Evidence Report.

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Pregnancy	• mRNA COVID-19 vaccine is preferentially recommended for pregnant indivduals in the authorized age group without contraindications to the vaccine. • For individulas who refuse an mRNA COVID-19 vaccine or have a contraindication to an mRNA vaccine, Novavax COVID-19 vaccine is recommended over Janssen COVID-19 vaccine. • 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. o 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 pregnant women to receive 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. o Response for immunizers if individual has not consulted with their primary health care provider: "The vaccine studies have not tested whether this vaccine is safe or effective for you. We recommend that you do not receive the immunization until you have discussed the potential risks and benefits with your doctor. However, it is your choice whether to proceed without consulting your doctor." • Additional resources: o Society of Obstetricians and Gynecologists of Canada Statement on COVID-19 Immunization in Pregnancy.
Lactation	• It is unknown whether Janssen COVID-19 vaccine is excreted in human milk as breastfeeding individuals were excluded from the initial trials. A risk to the newborns/infants cannot be excluded. • Janssen COVID-19 vaccine can be offered to individuals in the eligible group who are breastfeeding. o It is recommended that individuals consult with their primary health care provider or medical specialist for any vaccine related questions or concerns. o However, consultation with a primary health care provider or medical specialist is not required to receive Janssen COVID-19 vaccine. Breastfeeding individuals can be immunized following routine informed consent discussion. o Response for immunizers if individual has not consulted with their primary health care provider: "Vaccine studies are not complete on the use of this vaccine in breastfeeding women. Early information has not identified any safety issues speficially related to lactation. If you have questions about the immunization, we recommend you speak to your physician but it is not required to receive the vaccine."
Other Considerations	• Individuals presenting for immunization do not need to be tested for previous COVID-19 infection. • Immunization of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness. o However, individuals with COVID-19-like symptoms should not go to an immunization/venue in order to minimize the risk of COVID-19 transmission. o Individuals within facilities who are isolated due to COVID-19-like symptoms can be provided COVID-19 vaccine as long as they are well enough to be immunized. • It is not recommended that serology testing be completed to determine if an immune response to COVID-19 vaccine has been mounted in

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	immunocompromised individuals. It is still unknown what antibody level correlates with protection against COVID-19, and serology testing in many labs may also not detect antibodies developed as a response to vaccine. Serology testing should not be used as evidence to inform whether vaccine doses have been effective.
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 US following immunization with Janssen COVID-19 Vaccine.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 combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely in the U.S. following immunization with Janssen COVID-19 vaccine. • This includes severe cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thromboise, 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. • 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. • As of March 18, 2022, approximately 18 million doses of 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. • Health Canada has assessed the available data on the reported events and has determined that the benefit of Janssen COVID-19 vaccine outweigh the risk of thrombosis and thrombocytopenia. Health Canada has worked with Janssen Inc. to update the Product Monograph for 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. • 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. • 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: o severe headache that does not go away o confusion or seizure o difficulty moving part(s) of the body o new blurry vision that does not go away o difficulty speaking o shortness of breath o chest pain o severe abdominal pain o new severe swelling, pain, or colour change of an arm or a leg o unusual bruising or spontaneous bleeding • Cases of Immune Thrombocytopenia (ITP) have been reported very rarely within the first four weeks after receiving Janssen COVID-19 vaccine and that include serious cases with very low platelet counts. 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

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	recommended to monitor platelet levels following immunization with the Janssen COVID-19 vaccine. • 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).
Possible Reactions	**Very Common or Common** • Pain, redness, and swelling at the injection site • Fever, chills • Fatigue • Headache, myalgia, arthralgia, • Nausea **Uncommon** • Rash • Muscle weakness • Feeling weak • Arm/leg pain • Malaise • Dizziness **Rare:** • Anaphylaxis • Urticaria • Seizures • Vertigo • Tinnitius • Vomiting/Diarrhea • Paresthesia, hypoesthesia • Lymphadenopathy • Thrombosis with thrombocytopenia syndrome (TTS) • Venous Thromboembolism (VTE) • Immune Thrombocytopenia (ITP) • Capillary Leak Syndrome (CLS) • Guillain-Barre Syndrome (GBS) • Asthenia • Transverse myelitis (TM) • Unexplained bleeding • As with any immunization, unexpected or unusual side effects can occur. Refer to product monograph for more detailed information.
Composition	Each 0.5 mL dose contains: Suspension, (5×10^{10} virus particles), adenovirus type 26 (Ad26) vectored COVID-19 vaccine encoding the SARS-CoV-2 Spike (S) protein in a stabilized confirmation • 2-hydroxypropyl-β-cyclodextrin (HBCD) • Citric acid monohydrate • Ethanol • Hydrochloric acid • Polysorbate 80 • Sodium chloride • Sodium hydroxide • Trisodium citrate dihydrate • Water for injection No adjuvants or preservatives

	Janssen COVID-19 Vaccine
Blood/Blood Products	Contains no human blood/blood products.
Bovine/Porcine Products	Contains no bovine/porcine products.
Latex	Does not contain latex.
Interchangeability	• Currently, no data exists on the interchangeability of COVID-19 vaccines. • There are no data available on the use of the Janssen COVID-19 vaccine to complete a series initiated with another COVID-19 vaccine.
Administration with Other Products	• In the absence of evidence, COVID-19 vaccines may be co-administered with, or at any time before or after other vaccines (including live, inactivated, adjuvanted or unadjuvanted vaccines). • Currently there is 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. o If tuberculin skin testing or an IGRA test is required for baseline screening, it should be administered and read before administration of any COVID-19 vaccine or delayed for at least 28 days after a dose of COVID-19 vaccine. o Immunization with COVID-19 vaccines may take place at any time after all steps of tuberculin skin testing (including read) have been completed. o If tuberculin skin testing is required for other reasons (e.g., contact tracing, immigrants, query LTBI), testing should not be delayed, as these are theoretical considerations. However, re-testing (at least 28 days after a dose of COVID-19 vaccine) of individuals with negative results for whom there is high suspicion of TB infection may be prudent in order to avoid missing cases due to potentially false-negative results. • 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. o 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. o 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. o There was no correlation between interval to COVID-19 immunization and neutralizing titres in recent monoclonal antibody recipients. o Intervals between previous COVID-19 infection and COVID-19 immunization outlined in this document would still apply to individuals who received 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. **Note:** Anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma should not be administered concomitantly with COVID-19 vaccines (i.e. administer on different days). • Timing of administration and potential interference between COVID-19 vaccine and monoclonal products not used for treatment or prophylaxis of COVID-19 infection are currently unknown and the primary care provider or medical specialist should be consulted on a case-by-case basis.

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	• 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.
Appearance	• The solution is colourless to slightly yellow, clear to very opalescent.
Storage	• Can be stored at -25° to -15° until expiry date • Can be stored in a refrigerator between +2°C to +8°C for a single period of up to 11 months, not exceeding the original expiry date. • Unpunctured vials of Janssen may be stored at room temperature (up to +25°C) for up to 12 hours. • Punctured vials (first dose is withdrawn) can be stored at +2°C to +8°C for up to 6 hours or at room temperature (up to +25°C) for 3 hours. Discard if not used within this time. • Protect from light. • Do not freeze. **Notes:** • It will take a carton of 10 vials approximately 4 hours to thaw and an individual vial will take approximately 1 hour to thaw at room temperature. • It will tak a carton of 10 vials approximately 13 hours to thaw and and individual vial will take approximately 2 hours to thaw at +2°C to +8°C. • Do not refreeze once thawed.
Packaging	**Vaccine:** • 5 doses per vial. • Multi-dose Type 1 glass vial with a latex-free rubber stopper (chlorobutyl), aluminum seal and flip-off blue plastic cap. • 10 multidose vials per package. • Carton size 93mm x 38mm x 54mm.
Preparation/ Reconstitution	• No reconstitution is required. • Carefully mix the contents of the multi-dose vial by swirling gently in an upright position for 10 seconds. • Do not shake. • Discard any remaining vaccine in the multi-dose vial after 5 doses have been extracted.
Vaccine Code	COVJANVec
Antigen Code	COVID-19-6
Licensed for	• 18 years of age and older.
Program Notes: • 2021 March 5: Licensed for use in Canada. • 2021 November 12: Available for use in Alberta; updated to include recommendation for booster dose of mRNA vaccine 6 months following single dose. • 2021 December 8: 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. • 2021 January 10: Updated to include recommendation for booster dose of mRNA vaccine 5 months following single dose. • 2022 February 14: Clarified wording on individuals with history of COVID-19 infection. • 2022 March 2: Updated to incorporate NACI interim guidance on suggested interval between previous COVID-19 infection and COVID-19 immunization. • 2022 April 6: Updated to clarify NACI interim guidance on suggested interval between previous COVID-19 infection and COVID-19 immunization.	

- 2022 April 11: Included link to “COVID-19 Immunization for Individuals with Allergies and Other Health Conditions”.
- 2022 July 11: Addition of single booster dose; update of possible reactions; storage and handling to align with most recent product monograph.
- 2022 July 19: Updated recommendations for timing of COVID-19 vaccines and receipt of anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma for treatment or prophylaxis of COVID-19.

Related Resources:

- Alberta Health Services Website (2022). COVID-19 Viral Vector-Based Vaccines Information Sheet.

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