Moderna Bivalent (SpikeVax) COVID-19 Vaccine Orientation

September 20, 2022

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Reminder:
This videoconference/webinar will be recorded.

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Acknowledgement

The FNIHB Alberta Region CDC Team has created this training by using the Alberta Health and Alberta Health Services biological pages.

mRNA COVID-19 Vaccine Review

- The Moderna bivalent (SpikeVax) COVID-19 vaccine protects against COVID-19, which is the disease caused by SARS-CoV-2 coronavirus.
- The Moderna bivalent (SpikeVax) COVID-19 vaccine uses the messenger RNA (mRNA) manufacturing platform.
- mRNA (messenger ribonucleic acid) vaccines contain the genetic instructions for making the COVID-19 spike protein. This protein is found on the surface of the virus that causes COVID-19.
- When a person is given the vaccine, their cells will read the genetic instructions like a recipe and produce the spike protein.
- After the protein piece is made, the cell breaks down the instructions and gets rid of them.
- The cell then displays the protein piece on its surface. Our immune system recognizes that the protein doesn't belong there and begins building an immune response and making antibodies.
- mRNA vaccines do not affect, interact with or alter your DNA in any way.

Vaccine Information

- The bivalent COVID-19 vaccine triggers a stronger immune response and provides additional protection against both **Omicron and the original SARS-CoV-2 virus strain**.
- When administered as a second booster dose, Moderna SpikeVax Bivalent (50 mcg) elicited higher neutralizing antibody responses against the original strain, Omicron BA.1 and Omicron BA.4 and BA.5 among individuals with and without prior infection when compared to a second booster dose of Moderna SpikeVax original (50 mcg). This effect was consistent across age groups studied, in individuals 18-65 years of age and individuals >65 years of age. (*Recommendations on the use of Bivalent Omicron-Containing mRNA COVID-19 Vaccines*, National Advisory Committee on Immunization, September 1, 2022)

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Vaccine Information (continued)

- September 1, 2022 – licensed for use in Canada
- September 21, 2022 – Program implementation date in Alberta
- Biological classification: mRNA vaccine
- The manufacturer is Moderna.
- The vial has a royal blue cap and green label.
- Vaccine code: COVMODmRNABA1
- Antigen code: COVID19-17
- Bivalent COVID-19 vaccine will be widely available across Alberta September 21, 2022.

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Use of Vaccine

Licensed Use

- Booster dose for individuals 18 years of age and older at least 4 calendar months after completion of a primary series and/or a previous COVID-19 booster.

Off-License Use

- Booster dose for individuals 18 years of age or older given less than 4 calendar months after completion of a primary series and/or a previous COVID-19 booster.

Note: The bivalent vaccine cannot be used as part of the primary series. The bivalent vaccine can only be given as one of the booster doses.

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Indications Provincially Funded Vaccine

- Booster dose for individuals 18 years of age and older **after completion of a primary series and/or a previous booster dose** of COVID-19 vaccine (regardless of vaccine type).

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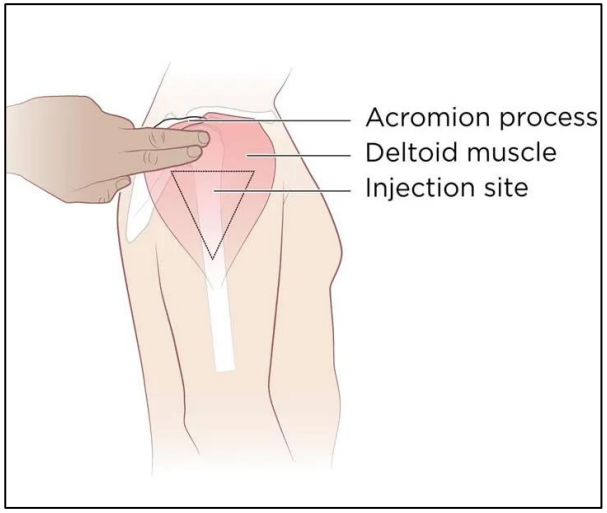
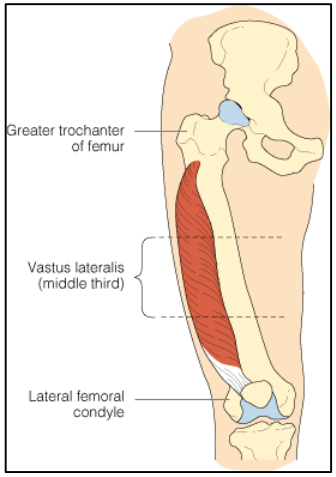
Vaccine Administration

Dose and Route:

Booster Dose:

- 0.5 ml (50mcg)
- Intramuscular (IM) injection in the deltoid or vastus lateralis muscle.





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Schedule

Schedule:

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- Booster Dose
  - At least **5 calendar months after the last dose of COVID vaccine received, whether that was the final dose in the primary series or a booster dose** (regardless of vaccine type).

Notes:

- A shortened interval of at least 3 calendar months between the last dose and the bivalent booster may be considered in certain situations: seniors congregate care facilities, requirement for travel or employment, increased risk for infection based on local transmission, and the degree of individual risk of exposure.
- The benefit of protection of a booster dose may be affected by the interval between doses. A longer interval may result in a better response after a booster dose, as this allows time for the immune response to mature in breadth and strength. A longer interval may, however, also increase the chance of a period with waning (lower) protection while awaiting a next dose. These need to be considered in situations mentioned above.
- The schedule for individuals with immunocompromising conditions is the same as the schedule for the general population.

Interval between previous COVID-19 Infection and COVID-19 Immunization

- It is expected that individuals who have been infected with SARS-CoV-2 may optimize their benefit from future vaccine doses by timing them according to the interval since infection, using similar immunological principles to those informing intervals between vaccine doses.
- Emerging evidence indicates that a longer interval between SARS-CoV-2 infection and immunization is associated with improved immune responses to COVID-19 vaccines.
- Previously infected individuals are **recommended to receive a booster dose 5 months after symptom onset or positive test (if asymptomatic) AND 5 months after the last COVID-19 vaccine dose**.
- A shortened interval of at least 3 months after symptom onset or positive test (if asymptomatic) AND 3 calendar months after the last COVID-19 vaccine dose may be considered in certain situations: seniors congregate care facilities, requirement for travel or employment, increased risk for infection based on local transmission and the degree of individual risk of exposure.

Vaccine Contraindications

- Less than 18 years of age.
- Known hypersensitivity to any component of the vaccine.
- Two non-medicinal ingredients in the vaccine that have been associated with allergic reactions in other products:
  1. Polyethylene glycol (PEG). The potential allergen may be found in bowel preparation products for colonoscopy, laxatives, cough syrup, cosmetics, contact lens care solutions, skin products and some food and drinks.
  2. Tromethamine (trometamol or Tris) – component found in contrast media, oral and parenteral medications.
- Anaphylaxis to a previous dose of COVID-19 mRNA vaccine may not be an absolute contraindication. See COVID-19 Immunization for Individuals with Allergies and Other Health Conditions for recommendations

Vaccine Precautions

- Individuals who have had a serious allergic reaction to another vaccine, drug or food should talk to their health care provider before receiving the vaccine.
- 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.
- There were no vaccine-related cases of myocarditis or pericarditis in the bivalent vaccine clinical trial. However, given the number of participants enrolled in the bivalent clinical trial it is unlikely that rare adverse events would be detected.

Myocarditis/Pericarditis

- Very rare cases of myocarditis and/or pericarditis following immunization with original mRNA COVID-19 vaccines have been reported during post-authorization use. However, the risk of myocarditis and/or pericarditis following a first and second booster dose of an original mRNA COVID-19 vaccine appears to be lower than the risk following the second dose of the primary series.
- **Anyone receiving a mRNA COVID-19 vaccine should be informed of the risk of myocarditis and pericarditis and advised to seek medical attention if they develop related symptoms including shortness of breath, chest pain, or the feeling of a rapid or abnormal heart rhythm.**
- Healthcare professionals are advised to consider the possibility of myocarditis and/or pericarditis in their differential diagnosis if individuals present with chest pain, shortness of breath, palpitations or other signs and symptoms of myocarditis and/or pericarditis following immunization with an mRNA COVID-19 vaccine.
- Generally, deferral of COVID-19 immunization is not required for those with a prior history of myocarditis or pericarditis that is unrelated to COVID-19 mRNA vaccines.
    - If these individuals have questions or concerns about their prior history of myocarditis or pericarditis and immunization, it is recommended that individuals consult with their clinician. However, consultation with a clinician is not required to receive COVID-19 vaccines.

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Myocarditis/Pericarditis (continued)

- Individuals with a history compatible with pericarditis within 6 weeks of receiving a dose of a mRNA COVID-19 vaccine, who either had no cardiac workup or who had normal cardiac investigations, can be re-immunized when they are symptom free and at least 90 days have passed since previous immunization.
- In most circumstances, further doses of mRNA COVID-19 vaccines should be deferred among people who experienced myocarditis (with or without pericarditis) within 6 weeks of receiving a previous dose of an mRNA COVID-19 vaccine.
    - However, further doses may be offered if individuals with confirmed myocarditis or pericarditis with abnormal cardiac investigation choose to receive another dose of vaccine after discussing the risks and benefits with their clinician.
- Informed consent should discuss the unknown risk of recurrence of myocarditis and/or pericarditis following additional doses of COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of mRNA COVID-19 vaccine.

Pregnancy

- The safety and efficacy of this bivalent COVID-19 mRNA vaccine in pregnant women have not yet been established in the clinical trials. However, data available so far on monovalent mRNA vaccines administered in pregnancy did not detect safety signals from post-marketing surveillance.
- **The Bivalent COVID-19 mRNA vaccine can be offered to pregnant individuals as they are more at risk for severe illness from COVID-19 compared with non-pregnant individuals.**
  - It is recommended that individuals consult with their primary health care provider or obstetrician for any vaccine related questions or concerns.
  - However, consultation with a primary health care provider or obstetrician is not required to receive COVID-19 vaccine.

Additional resource:

SOGC Statement on COVID-19 Vaccination in Pregnancy

Lactation

- It is unknown whether this vaccine is excreted in human milk as breastfeeding individuals were excluded from the initial trials. A risk to the newborns/infants cannot be excluded
- However, based on how this vaccine works, **the bivalent COVID-19 mRNA vaccine is not expected to be a risk to lactating individuals or their breastfed newborns/infants.**
- **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 COVID-19 vaccine.

Additional resource:
SOGC Statement on COVID-19 Vaccination in Pregnancy

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.
  - 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.

Possible Reactions

Common:

- Pain, redness, swelling, and induration at the injection site
- Fever, chills
- Fatigue
- Headache, myalgia, arthralgia
- Nausea, vomiting
- Lymphadenopathy
- Hypoaesthesia (decreased sense of touch or sensation, numbness)
- Paraesthesia (tingling, itching or prickling sensation)
- Dizziness
- Erythema multiforme*
- As with any immunization, unexpected or unusual side effects can occur.
  - Refer to product monograph for more detailed information.

Rare:

- Anaphylaxis
- Allergic reaction
- Facial swelling/Bell's Palsy*
- Myocarditis/pericarditis*

*There were no cases of facial swelling/Bell's palsy, myocarditis/pericarditis, or erythema multiforme following SpikeVax Bivalent immunization during the study period, however these were reported post-market following SpikeVax (Original).

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Vaccine Composition

Each 0.5ml dose contains:

- Elasomeran (mRNA) encoding the pre-fusion stabilized Spike glycoprotein of 2019 novel Coronavirus (SARS-CoV-2)
- Imelasomeran (mRNA) encoding the pre-fusion stabilized conformation variant (K983P and V984P) of the SARS-CoV-2 Spike glycoprotein (Omicronvariant B.1.1.529 [BA.1])
- Does not contain human blood/blood products
- Does not contain animal-derived materials
- Does not contain latex

Non-medicinal ingredients:

- Acetic acid, Cholesterol, DSPC (1,2-distearoyl-sn-glycero-3- phosphocholine), Lipid SM-102, PEG2000-DMG (1,2-dimyristoyl-racglycerol,methoxy-polyethyleneglycol), Sodium acetate trihydrate, Sucrose, Trometamol, Trometamol hydrochloride, Water for injection

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Administration with other products

- No participants in the bivalent clinical trial were concurrently administered other vaccines. Data with regard to the safety and immunogenicity of other authorized COVID-19 vaccines (including original monovalent mRNA vaccines) when given concurrently with other vaccines, are currently limited. However, no specific safety concerns have been identified to date.
- **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 18 years of age and older.**
- Currently there is no data on the impact of the COVID-19 mRNA 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.
  - 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, 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.

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Administration with other products (continued)

- **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.
  - 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
  - There was no correlation between interval to COVID-19 immunization and neutralizing titres in recent monoclonal antibody recipients
  - 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

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Administration with other products (continued)

- **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 health care provider or medical specialist should be consulted on a case-by-case basis.
- mRNA COVID-19 vaccines may be given at any time before or after an **immunoglobulin** preparation (including RhIg) or blood product has been administered. There is no recommended minimum interval between these products and COVID-19 vaccine.

Appearance and Storage

Appearance

- Frozen and thawed: a white to off-white solution
- Canadian packaging has 5 doses/vial

Storage

- At the vaccine depot, it is stored in a freezer between -25°C to -15°C.
- Vaccine can be thawed in two ways:
  1. From the freezer to room temperature (between +15°C to +25°C), thaw for 1 hour from frozen state.
  2. From the freezer to a vaccine fridge +2°C to +8°C; thaw for 2 hours. Let vial stand at room temperature for 15 minutes before administering.
- Do not refreeze after thawing.
- Protect from light
- Do not store on DRY ice or below -50°C.

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Appearance and Storage (continued)

Storage

Thawed, unpunctured vials:

- Thawed unpunctured vials can be stored at **+2°C to +8°C up to 30 days**.

  (Please keep this in mind when ordering vaccines)

- Thawed unpunctured vials may be stored at **+8°C to +25°C for up to 24 hours**.

Thawed, punctured vials

- Thawed punctured vials (first dose is withdrawn), the vial can be stored at +2°C to +25°C for 24 hours.
- Discard after 24 hours.
- Vials can be punctured to a maximum of 20 times and any remaining vaccine after 20 punctures must be discarded.

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Preparation/Reconstitution

- The Moderna bivalent COVID-19 vaccine multiple dose vial contains a frozen suspension that does not contain preservative and must be thawed prior to administration.
- **No reconstitution required**
- The product should be thawed as indicated in the *Storage* section
- Swirl vial gently after thawing and between each withdrawal. **Do not shake.**

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Ordering

- The COVID-19 mRNA bivalent vaccine is available for ordering through the AVI (Alberta Vaccine Inventory) system.
  - Found in the COVID-19 vaccine order set
  - Vaccine: COVID-19 bivalent, mRNA 1273 – mRNA
  - Vaccine Name: SpikeVax Bivalent 5 dose/vial

- Reminders:
  - Vials can only be stored in a vaccine fridge under cold chain for 30 days. Please take this into consideration when ordering.
  - The bivalent vaccine can only be given to individuals who have already had a primary series, which will affect the number of eligible individuals.

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Informed Consent

- Clients must give informed consent before immunization
- Prior to immunizing, the immunizer must:
  - Determine that the client is eligible (based on current phase and/or eligibility requirements)
  - Review the disease being prevented
  - Review vaccine
  - Discuss:
    - risks and benefits of getting the vaccine and not getting the vaccine
    - side effects and after care
    - how the vaccine is given
  - Provide the opportunity to ask questions
  - Affirm verbal consent

COVID-19 Vaccines

There are many different COVID-19 vaccines, different ages, different doses – need to be diligent to avoid errors.

Vaccine	Age	Colour Cap
Moderna (Spikevax)	6 months – 5 years	Blue
Moderna (Spikevax)	6 years – 11 years 12 years and older	Red
Moderna (Spikevax) Bivalent	**18 years and older** (following a primary series)	**Royal blue cap and green label**
Pfizer (Comirnaty)	5 – 11 years	Orange
Pfizer (Comirnaty)	12 years and older	Purple

Additional Information – Novavax & Janssen

In planning for the roll-out of the COVID-19 mRNA bivalent vaccine booster doses, several questions came forward regarding plans for additional booster doses of Novavax and Janssen vaccine for individuals who do not want to receive a mRNA vaccine.

- **Novavax:** Albertans can continue to receive a second booster dose with Novavax, however a third booster dose of Novavax is not allowed at this time.
- **Janssen:** Only a single booster dose is licensed at this time (and there is no permissive off-label statement from NACI). An additional booster dose of Janssen vaccine will not be offered this fall.

- **Novavax and Janssen vaccines are not being administered in First Nations health centres. Individuals should contact Alberta Health Services or a pharmacy for Novavax or Janssen vaccine.**

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Questions?

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References

- Alberta Health (2022). *COVID-19 Vaccine-mRNA: Moderna Bivalent (Original and Omicron BA.1) – Frozen vaccine (SpikeVax)* implementation dated September 21, 2022. Retrieved from https://open.alberta.ca/dataset/58d31634-61d9-469d-b95f-f714719b923e/resource/57bf69b2-ddb5-4f51-ab93-8ff9aacdff21/download/aip-bp-covid-19-moderna-bivalent-original-omicron-ba1.pdf
- Alberta Health Services (2022). *COVID-19 Vaccine – mRNA Moderna (SpikeVax) Bivalent Frozen Vaccine Biological Pag*e dated September 21, 2022. Retrieved from https://www.albertahealthservices.ca/assets/info/hp/cdc/if-hp-cdc-ipsm-covid-19-moderna-bivalent-bio-pg-07-217.pdf
- Benschop, et al. (2021 December 16). *The effect of anti-SARS-CoV-2 monoclonal antibody, bamlanivimab, on endogenous immune response to COVID-19 vaccination*. medRxiv. Preprint. https://doi.org/10.1101/2021.12.15.21267605
- Centers for Disease Control and Prevention. (2021 April 28) *Information about COVID-19 Vaccines for People who are Pregnant or Breastfeeding*. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html.
- Health Canada. Recalls and safety alerts. (2020 December 12) *Pfizer-BioNTech COVID-19 vaccine: Health Canada recommendations for people with serious allergies*. https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/74543a-eng.php
- National Advisory Committee on Immunization. (2021). *Canadian Immunization Guide (Evergreen ed.)*. Ottawa, ON: Public Health Agency of Canada https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html
- National Advisory Committee on Immunization. (2022 September 1). *Recommendations on the use of bivalent Omicron-containing mRNA COVID-19 vaccines*. https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-bivalent-Omicron-containing-mrna-covid-19-vaccines.pdf

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References

- National Advisory Committee on Immunization. (2022 January 14). *Summary of NACI advice on vaccination with COVID-19 vaccines following myocarditis (with or without pericarditis)*. https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/summary-advice-vaccination-covid-19-vaccines-following-myocarditis-with-without-pericarditis.html
- National Advisory Committee on Immunization. (2022 February 4). *NACI rapid response: Updated guidance on COVID-19 vaccination timing for individuals previously infected with SARS-CoV-2*. https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/rapid-response-guidance-covid-19-vaccination-timing-individuals-previously-infected-sars-cov-2.html
- Shimabukuro, T., Kim, S., et al. *Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons.* The New England Journal of Medicine. (2021 April 21) https://www.nejm.org/doi/full/10.1056/NEJMoa2104983[5] Centers for Disease Control and Prevention. (updated 2022 July 14) *Information about COVID-19 Vaccines for People who are Pregnant or Breastfeeding*. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html
- SPIKEVAX™ Bivalent (Original / Omicron) (2022 September 1) COVID-19 mRNA vaccine, Bivalent (Original and Omicron B.1.1.529 (BA.1) Variant), Dispersion for intramuscular injection: *Product Monograph*. https://covid-vaccine.canada.ca/info/pdf/spikevax-bivalent-en.pdf

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