COVID-19 Vaccine – mRNA
Moderna (SpikeVax) Bivalent Frozen Vaccine
Biological Page

Section 7:	**Biological Product Information**		**Standard #: 07.217**
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	COVID-19 Vaccine – mRNA Bivalent Frozen Vaccine
Manufacturer	Moderna
Biological Classification	• mRNA (new technology) – nucleoside-modified messenger RNA (modRNA) encoding the viral spike glycoprotein • Formulated in lipid nanoparticles (LNPs)
Indications for 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).
Preferred Use	N/A
Dose	**Booster** 0.5 mL (50mcg)
Route	IM in the deltoid or vastus lateralis muscle
Schedule	**Booster dose** • At least 5 calendar months after the last dose of COVID-19 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 (or infection) and the bivalent booster may be considered (e.g. for individuals at higher risk for severe outcomes). • A longer interval of at least 5 calendar months leads to a better immune response against COVID-19 that is also expected to last longer, because it allows time for the immune system to mature in breadth and strength. This needs to be considered in situations where individuals request an interval shorter than 5 months. However, individuals should not be turned away if they still choose a shortened interval. • 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 calendar months after symptom onset or positive test (if asymptomatic) AND 3 calendar months after the last COVID-19 vaccine dose may be considered (e.g. for individuals at higher risk for severe outcomes). Although a longer interval leads to a better immune response against COVID-19 that is also expected to last longer, individuals should not be turned away if they choose a shortened interval.

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Contraindications/ Precautions	**Contraindications:**
	• Known severe hypersensitivity to any component of the vaccine.
	  ○ Two non-medicinal ingredients in the vaccine that have been associated with allergic reactions in other products:
	  ▪ Polyethylene glycol (PEG). This potential allergen may be found in bowel preparations products for colonoscopy, laxatives, cough syrup, cosmetics, contact lens care solutions, skin products and some food and drinks.
	  ▪ 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 contraindications. See COVID-19 Immunization for Individuals with Allergies and Other Health Conditions for recommendations.
	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 injections 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.

Myocarditis/ Pericarditis	• 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.
	• 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 an 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.
	• Individuals with a history compatible with pericarditis within 6 weeks of receiving a dose of an 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

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	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, consultations with a primary health care provider or obstetrician is not required to receive COVID-19 vaccine.
	Additional resources:
	• Society of Obstetricians and Gynecologists of Canada 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.

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) or paraesthesia (tingling, itching or prickling sensation) • Dizziness **Rare:** • Anaphylaxis • Allergic reaction • Facial swelling/Bell's Palsy* • Myocarditis/pericarditis* • Erythema multiforme* • As with any immunization, unexpected or unusual side effects can occur

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	*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). Refer to product monograph for more detailed information
Composition	Each 0.5 mL 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]) 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
Blood/Blood Products	Contains no human blood/blood products
Bovine/Porcine Products	Contains no animal-derived materials
Latex	Does not contain latex
Interchangeability	N/A
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 unadjuvated vaccines) to individuals 18 years of age and older. • Currently there is no data on the impact of the COVID-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. o 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. o 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.

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	○ 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 conserved 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 infections and COVID-19 immunization outlined in the document would still apply to individuals who got the monoclonal antibodies or convalescent plasma for their infection. • Individuals who are to receive Evushled (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	• Frozen and thawed: white to off-white solution
Storage	• Can be stored in a freezer between -25ºC to -15 ºC. • Vaccine can be thawed in two ways: ○ From the freezer to room temperature (between +15°C to +25°C), thaw for 1 hour from frozen state. ○ 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. • Thawed, unpunctured vials ○ Thawed unpunctured vials can be stored at +2 ºC to +8 ºC up to 30 days. ○ Thawed unpunctured vials may be stored at +8 ºC to +25 ºC for up to 24 hours. • Thawed, punctured vials ○ Thawed punctured vials (first dose is withdrawn), the vial can be stored at +2 ºC to +25 ºC 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. • Protect from light. • Do not store on DRY ice or below -50°C.
Packaging	Canadian Packaging: • 5 doses/vial • 50 doses per package
Preparation/ Reconstitution	The Moderna 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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	Thawed pre-puncture • Stored at +2°C to +8°C for 30 days • Stored at +8°C to +25°C for 24 hours Thawed post-puncture • 24 hours at +2°C to +25°C • Discard after 24 hours
Vaccine Code	COVMODmRNABA1
Antigen Code	COVID19-17
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.

Program Notes

- 2022 September 1: Licensed for use in Canada.
- 2022 September 21: Implemented in Alberta.

Related Resources:

- Alberta Health Services Website (2022). COVID-19 Vaccines - mRNA Information Sheet.

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10. 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