

COVID-19 Vaccine - mRNA Moderna - Frozen Vaccine Biological Page

Section 7:	Biological Product Information	Standard #: 07.204
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Vaccine Name	COVID-19 Vaccine - mRNA Moderna Frozen Vaccine
Manufacturer	Moderna
Biological Classification	<ul style="list-style-type: none"> mRNA (new technology) – nucleoside-modified messenger RNA (modRNA) encoding the viral spike glycoprotein Formulated in lipid nanoparticles (LNPs)
Indications for Provincially Funded Vaccine	Persons 18 years of age and older <ul style="list-style-type: none"> This vaccine is being offered in a staged approach, please follow operational guidelines to assess eligibility
Preferred Use	N/A
Dose	0.5 mL
Route	IM
Schedule	2 doses <ul style="list-style-type: none"> Dose 1 – day 0 Dose 2 – day 21 to 28 Notes: <ul style="list-style-type: none"> Minimum spacing between doses is 21 days Recommended spacing between doses is 21 to 28 days If administration of the second dose of vaccine is delayed, the second dose should be provided as soon as possible. Currently, no data on a maximum interval between doses or on medium or long-term efficacy of COVID-19 vaccines are available. In general, interruption of a vaccine series resulting in a greater than recommended interval between doses does not require restarting the series.
Contraindications/Precautions	Contraindications: <ul style="list-style-type: none"> Persons under 18 years of age. Known severe hypersensitivity to any component of the vaccine. <ul style="list-style-type: none"> One non-medicinal ingredient in the vaccine known to cause type 1 hypersensitivity reactions is polyethylene glycol (PEG). This potential allergen may be found in bowel preparation products for colonoscopy, laxatives, cough syrup, cosmetics, skin products and some food and drinks. Anaphylactic or other allergic reactions to a previous dose of COVID-19 mRNA vaccine. Precautions: <ul style="list-style-type: none"> 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.

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	<ul style="list-style-type: none"> • Timing of administration and potential interference between COVID-19 vaccine and monoclonal products are currently unknown. Medical consultation with primary care physician is advised. • COVID-19 vaccine is generally not recommended for populations who are immunosuppressed due to disease or treatment or those with an auto-immune disorder until further evidence is available as there is a lack of evidence on efficacy and safety in this group. <ul style="list-style-type: none"> ○ However, a complete series of COVID-19 vaccine may be offered in consultation with the individual's physician to individuals in the eligible group in this population if a risk assessment deems the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in this population. ○ Immunocompromised persons may have a diminished immune response to the vaccine.
Possible Reactions	<p>Common:</p> <ul style="list-style-type: none"> • Pain, redness, and swelling at the injection site • Fever, chills • Fatigue • Headache, myalgia, arthralgia • Nausea, vomiting • Lymphadenopathy <p>Rare:</p> <ul style="list-style-type: none"> • Anaphylaxis • Facial swelling • As with any immunization, unexpected or unusual side effects can occur. Refer to product monograph for more detailed information.
Pregnancy	<ul style="list-style-type: none"> • The safety and efficacy of Moderna COVID-19 Vaccine in pregnant women have not yet been established. • Vaccine is generally not recommended for individuals who are pregnant until after completion of pregnancy. <ul style="list-style-type: none"> ○ However, a complete series of COVID-19 vaccine may be offered in consultation with the individual's physician to pregnant individuals in the eligible group if a risk assessment deems that the benefits outweigh the potential risks for the individual and the fetus, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in this population. • It would be prudent to delay pregnancy by 28 days or more after the administration of the complete two-dose vaccine series of an mRNA COVID-19 Vaccine.
Lactation	<ul style="list-style-type: none"> • It is unknown whether Moderna COVID-19 Vaccine is excreted in human milk. A risk to the newborns/infants cannot be excluded. • COVID-19 vaccine is generally not recommended for individuals who are breastfeeding. <ul style="list-style-type: none"> ○ However, a complete series of COVID-19 vaccine may be offered in consultation with an individual's physician to individuals in the eligible group who are breastfeeding if a risk assessment deems that the benefits outweigh the potential risks for the individual and the infant, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in this population.
Composition	<p>Each 0.5 mL dose contains:</p> <p><u>Lipid nanoparticles (these help the mRNA enter the cell):</u></p> <ul style="list-style-type: none"> • PEG2000-DMG LSM-102, 1,2-dimyristoyl-rac-glycero-3-methoxy-polyethyleneglycol • 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]) • Cholesterol • Lipid SM-102

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	<p><u>pH stabilizers (help maintain the PH of the vaccine)</u></p> <ul style="list-style-type: none"> • acetic acid • sodium acetate • tromethamine • tromethamine hydrochloride <p><u>Other:</u></p> <ul style="list-style-type: none"> • sucrose (protects the nanoparticles when frozen) <p>No adjuvants, preservatives or antibiotics</p>
Blood/Blood Products	Contains no human blood/blood products
Bovine/Porcine Products	Contains no animal-derived materials
Latex	Does not contain latex
Interchangeability	<ul style="list-style-type: none"> • Currently, no data exists on the interchangeability of COVID-19 vaccines. • The vaccine series should be completed with the same COVID-19 vaccine product. • If the vaccine product used for a previously received dose is not known, or not available, attempts should be made to complete the vaccine series with a similar type of COVID-19 vaccine (e.g., mRNA vaccine). The previous dose may be counted, and the series need not be restarted.
Administration with Other Products	<ul style="list-style-type: none"> • In the absence of evidence, COVID-19 vaccines should not be given simultaneously with other live or inactivated vaccines due to the potential for immune interference and the need to be able to monitor for potential symptoms of COVID-19 and COVID-19 vaccine adverse events without potential confounding from adverse events following other vaccines. • If a COVID-19 vaccine is inadvertently administered at the same time as another vaccine, neither dose should be repeated. • In the absence of evidence, it would be prudent to wait for a period of at least 28 days between the administration of the complete two-dose schedule of COVID-19 vaccine and the administration of another vaccine (except in the case where another vaccine is required for post-exposure prophylaxis). • In the absence of evidence, it would be prudent to wait for a period of at least 14 days after the administration of another vaccine before administering a COVID-19 vaccine.
Appearance	<ul style="list-style-type: none"> • Frozen and thawed: white to off-white solution
Storage	<ul style="list-style-type: none"> • Can be stored in a freezer between -25°C to -15°C storage. • Vaccine can be thawed in two ways: <ul style="list-style-type: none"> ○ 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 and 30 minutes from frozen state. Let vial stand at room temperature for 15 minutes before administering. • Do not refreeze after thawing. • Thawed, unpunctured vials <ul style="list-style-type: none"> ○ Thawed unpunctured vials can be stored at +2°C to +8°C up to 30 days, ○ Thawed unpunctured may be stored at +8°C to +25°C for up to 12 hours. • Thawed, punctured vials <ul style="list-style-type: none"> ○ Thawed punctured vials (first dose is withdrawn), the vial can be stored at +2°C to +25°C for 6 hours ○ Discard after 6 hours. • Protect from light • Do not store on DRY ice or below -40°C
Packaging	<p>Vaccine:</p> <ul style="list-style-type: none"> • 10 doses per vial <ul style="list-style-type: none"> ○ Box 51 mm long, 126 mm wide, 60 mm high

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	<ul style="list-style-type: none"> 12 boxes/carton (1200 doses/carton) Carton 267 mm long, 169 mm wide, 135 mm high 100 doses per package
Preparation/ Reconstitution	<p>The Moderna COVID-19 Vaccine multiple dose vial contains a frozen suspension that does not contain preservative and must be thawed and diluted prior to administration.</p> <ul style="list-style-type: none"> 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. <p><u>Thawed pre-puncture</u></p> <ul style="list-style-type: none"> Stored at +2°C to +8°C for 30 days Stored at +8°C to +25°C for 12 hours <p><u>Thawed post-puncture</u></p> <ul style="list-style-type: none"> 6 hours at +2°C to +25°C Discard after 6 hours
Vaccine Code	COVMODmRNA
Antigen Code	COVID-19-2
Licensed for	Individuals 18 years of age and older
Notes: <ul style="list-style-type: none"> Licensed for use in Canada December 23, 2020 	
Related Resources <ul style="list-style-type: none"> Alberta Health Services Website (2020). COVID-19 Vaccine Information. 	
References <ul style="list-style-type: none"> Alberta Health, Health System Accountability and Performance Division, Alberta Immunization Policy (2020, December). COVID-19 Vaccine-mRNA: Moderna – Frozen vaccine. Moderna (2020 December 23) Moderna COVID-19 Vaccine, mRNA-1273 SARS-CoV-2 vaccine, Suspension for intramuscular injection: <i>Product Monograph</i>. https://covid-vaccine.canada.ca/info/pdf/moderna-covid-19-vaccine-pm1.pdf National Advisory Committee on Immunization (2020 December 23). Recommendations on the use of COVID-19 Vaccines. 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 	