COVID-19 (mRNA)
COVID-19 mRNA Vaccine mRNA-1273  Supplier: Moderna

INDICATIONS:
- Individuals 12 years of age and older.

The vaccine is not approved for use in those less than 12 years of age.

DOSES AND SCHEDULE:
Individually 12 years of age and older A: 2 doses given as 0.5 mL IM, 28 days apart. B, C, D, E

For individuals 12 years of age older who are severely immunosuppressed*, a 3-dose primary series is recommended F. Moderna COVID-19 vaccine is preferentially recommended for the 3rd dose, which should be provided at least 28 days after the 2nd dose. If Moderna is unavailable, Pfizer-BioNTech can be given.

* Severely immunosuppressed includes individuals who:
  - Have had a solid organ transplant (heart, lung, kidney, pancreas or islet cells, bowel or combination organ transplant).
  - Since January 2021, have been treated for and/or are receiving active treatment (chemotherapy, targeted therapies, immunotherapy) for malignant hematological disorders (e.g., leukemia, lymphoma, or myeloma).
  - Since January 2020, have received treatment with any anti-CD20 agents (i.e., rituximab, ocrelizumab, ofatumumab, obinutuzumab, ibrutinumab, tositumomab).
  - Since January 2020, have been treated with B-cell depleting agents (i.e., epratuzumab, MEDI-551, belimumab, BR3-Fc, AMG-623, atacicept, anti-BR3, alemtuzumab).
  - Have combined immune deficiencies affecting T-cells, immune dysregulation or type 1 interferon defects.
  - Since September 2019, have had a bone marrow or stem cell transplant or are still taking immunosuppressant medications related to transplant.

A The minimum age for vaccine receipt is based on year of birth (i.e., the vaccine may be offered to individuals who will be turning 12 years of age within the current calendar year), per Provincial Health Officer recommendations.
B The vaccine series should be completed with the same COVID-19 vaccine product. If it is not possible to determine what product was used for the first dose, or if the same product is unavailable, the second dose may be given with an available mRNA product.
C This is the schedule authorized by Health Canada. In BC, the preferred interval between doses is 6-8 weeks, except in outbreak communities at the direction of the Medical Health Officer and for individuals who meet approved criteria for an expedited dose 2. As of August 9th, 2021, invitations to book dose 2 will be sent out at 4 weeks after the first dose as outlined on the government of B.C. website. If administration of the second dose is delayed beyond 8 weeks, the series does not need to be restarted.
D The minimum interval between doses is 21 days. For optimal response, immunizers should observe recommended intervals as much as possible, however, doses given earlier than recommended may still be considered valid and need not be repeated if minimum intervals are observed.
E NACI recommends that mRNA vaccine (Pfizer BioNTech or Moderna) can be offered as a second dose to individuals who received a first dose of the AstraZeneca/COVISHIELD vaccine, unless contraindicated.
F For individuals who received a single dose of Janssen vaccine, one additional dose of Moderna COVID-19 vaccine is recommended at least 28 days later.
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ADMINISTRATION:
• No reconstitution required.
• If there is enough vaccine left in the vial for a complete 0.5 mL dose after 10 or 14 A doses have been removed from the vial, another dose can be drawn and administered. This depends, in part, on the type of syringes and needles used to withdraw doses from the vials; low dead-volume syringes and/or needles should be used if available, as standard syringes and needles may not facilitate the extraction of an additional dose from a single vial.
• Following withdrawal of all available 0.5 mL doses, the residual vaccine from up to three vials may be withdrawn into the same syringe to constitute a full dose provided the vials are from the same manufacturer and the same lot number. See addendum for more information.

Storage and Handling: B
• The vaccine can be stored at:
  o -20°C (-25°C to -15°C) up to the end of its expiry date C, kept in the original packaging and protected from light. Do not store on dry ice.
  o +2°C to +8°C for up to 30 days prior to first use, protected from light.
  o Room temperature (up to +25°C) for up to 24 hours (cumulative).
  o After first vial puncture, the vaccine must be used within 24 hours.
  o The vaccine can be pre-loaded into a syringe for up to 24 hours from first vial puncture.
  o Ensure that the vial/syringe is clearly labelled with the date and time of first vial entry.
• Product should be thawed/held prior to use, in one of the following ways:
  o From the freezer to room temperature:
    ▪ 10-dose vial requires 1 hour to thaw
    ▪ 14-dose vial requires 1 hour and 30 minutes to thaw
  o From the freezer to the refrigerator:
    ▪ 10-dose vial requires 2 hours and 30 minutes to thaw
    ▪ 14-dose vial requires 3 hours to thaw
    ▪ Allow at least 15 minutes at room temperature prior to administration. D
  o Swirl the vial gently after thawing and between each withdrawal. Do not shake.
• Do not refreeze thawed vials.

BOOSTER DOSES:
No booster doses are recommended at this time.

SEROLOGICAL TESTING:
Serological testing is not recommended before or after immunization.

A Moderna vaccine is available in 10-dose and 14-dose vials. The U.S. labelled product yields at least 14 doses and contains a different carton and vial label. Continue to reference the Canadian Product Monograph for all product information for use in Canada. Note: to consistently extract 14 doses, a minimum ratio of 7 low-dead-volume syringes and 7 non-low-dead-volume syringes are recommended.
B For more information on storage and handling and temperature monitoring refer to Appendix E: Management of Biologicals and Guidance for Receiving and Handling the Moderna COVID-19 mRNA Vaccine.
C The expiry date is not printed on the US-labelled product. The expiry date for the corresponding lots can be found in the ‘Products affected’ section of the Health Canada alert.
D The recommendation to allow the vaccine to sit for at least 15 minutes at room temperature prior to administration is intended for patient comfort only, and is not a requirement.
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CONTRAINDICATIONS:
1. History of anaphylactic reaction to a previous dose of an mRNA COVID-19 vaccine or to any component of the vaccine. These individuals should be offered an adenovirus vector COVID-19 vaccine and observed for at least 30 minutes after immunization.

PRODUCT COMPONENTS:
Other components: cholesterol; 1,2-distearoyl-sn-glycerophosphocholine (DSPC); acetic acid; lipid SM-102; sodium acetate; sucrose; tromethamine; tromethamine hydrochloride.

PRECAUTIONS:
• For the following populations, a complete COVID-19 vaccine series should be offered to individuals in the authorized age group if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the limited data on the use of COVID-19 vaccine in these populations:
  o immunosuppressed due to disease or treatment
  o those with an autoimmune condition A
  o pregnancy and breastfeeding B C
• For individuals with suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, consultation with an allergist is advised. If there is a specific concern about a possible allergy to a component of the COVID-19 vaccine being administered, an extended period of observation post-vaccination of 30 minutes may be warranted; alternately, the vaccine can be administered in an emergency room setting, also with a prolonged observation period.
• Wait until symptoms of an acute illness are resolved before vaccinating with COVID-19 vaccine to differentiate symptoms of illness from vaccine side effects.
• There is insufficient evidence on the receipt of COVID-19 vaccine following receipt of anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma for treatment or prevention of COVID-19. Therefore, COVID-19 vaccination should be deferred for at least 90 days to avoid potential interference of the antibody therapy with vaccine-induced immune response. Deferral is not required following treatment with tocilizumab or sarilumab.
• Individuals diagnosed with Multisystem Inflammatory Syndrome in Children (MIS-C) or Adults (MIS-A) should delay COVID-19 vaccination until they have recovered from illness and for 90 days after the date of diagnosis of MIS-C or MIS-A.
• Due to the theoretical risk that mRNA vaccines may temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results, these tests should be administered and read before COVID-19 immunization or delayed for at least 4 weeks after immunization. COVID-19 immunization may take place at any time after all steps of tuberculin skin testing have been completed.
• The 2nd dose of mRNA COVID-19 vaccine should be deferred in those who experienced a physician-diagnosed myocarditis or pericarditis event following the first dose with no other cause identified, until further information about the risk of recurrence is available. Deferral is

A For more information see the CRA Recommendation on COVID-19 Vaccination in Persons with Autoimmune Rheumatic Disease.
B For more information see the SOGC Statement on COVID-19 Vaccination in Pregnancy.
C A recent study in the United States supports the safety of mRNA COVID-19 vaccines among pregnant people.
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PRECAUTIONS (continued):  
not required for those with a prior history of myocarditis or pericarditis that is unrelated to COVID-19 mRNA vaccines and are no longer being followed by a medical professional for heart issues.

SPECIAL CONSIDERATIONS:  
- COVID-19 vaccines can be administered concomitantly or at any time before or after the administration of another inactivated or live vaccine.
- A complete series of COVID-19 vaccine may be offered to individuals without contraindications who have recovered from PCR-confirmed SARS-CoV-2 infection.
- Recipients should practice public health measures for prevention of SARS-CoV-2 infection and transmission regardless of vaccination with COVID-19 vaccine, at this time.

ADVERSE EVENTS:  
Local: pain, swelling, redness, axillary lymphadenopathy. Delayed injection site reactions, with onset on or after day 8 following vaccination, may occur in a small percentage of vaccine recipients, mostly after the first dose.
Systemic: fatigue, headache, myalgia, chills, arthralgia, fever, nausea and vomiting.

Rare cases of facial paralysis/Bell’s palsy have been reported.

Pericarditis and myocarditis in association with the mRNA vaccines have been observed in Israel and the US, where these vaccines have been used in younger people longer than in Canada, especially after the second dose. In the US data, they have noted that the observed rates exceed what would be expected (given that these are inflammatory disorders of the lining of the heart and heart muscle, respectively, and occur for a variety of reasons including in association with viral infections). These events have occurred more frequently after the second dose at a rate of about 1 per 100,000 second doses, and have been observed mostly in males under 30 years of age. Most cases recover fully with conservative treatment. In BC, we have ensured that health care providers are aware of this observation and the possibility of it being causally linked to the vaccine, and how to diagnose and report this event when it occurs after mRNA vaccine, which is yet to be detected as occurring above the expected frequency in our safety reports in BC and Canada. This is an emerging safety signal and will need to be studied further.

REFERENCES:  
1. Moderna vaccine product monograph  
2. National Advisory Committee on Immunization: Recommendations on the use of COVID-19 Vaccine(s)
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ADDENDUM: Pooling residual vaccine from up to three vials to constitute an extra dose

Following withdrawal of all available 0.5 mL doses, a full 0.5 mL dose may be constituted from the residual vaccine volume from up to three separate vials, provided the vials are from the same manufacturer and same lot number. In order to minimize the risk of microbial contaminants and maintain product quality, the following processes should be followed:

- Only vials containing residual vaccine volume are to be used to prepare a full dose when using multiple vials to constitute a single dose. Residual volume should not be combined with contents from a different vial that still contains at least one full dose of the vaccine (to minimize the chance of contaminating the contents of a vial that still contains multiple doses of the vaccine).
- Given this vaccine does not contain preservative, and therefore has a short timeline for its use following first vial puncture, pooling of residual vaccine from two or three vials must occur as soon as possible - it is not recommended to save multiple vials with residual volume for use at one time (e.g., the end of the clinic).
- Perform hand hygiene before handling the vaccine. Strictly adhere to aseptic technique while handling the vaccine and minimize the number of vial punctures.
- Firmly and briskly wipe the surface of the rubber stopper with an alcohol swab for initial and subsequent uses, being sure to apply friction, and allow it to dry for at least 10 seconds.
- To assist with the withdrawal of residual vaccine from the vial, invert the vial and ensure the end of the needle is below fluid level and situated in the groove of the vial stopper.
- Once the residual vaccine is withdrawn, keep the needle in the vial when expelling air bubble(s) to minimize vaccine wastage.
- Check the syringe to ensure it contains the total 0.5 mL dose prior to administration.
- If not administered immediately, the syringe should be clearly labeled with the date and time of the vial with the shortest timeframe for use.