COVID-19 mRNA Vaccine
SPIKEVAX™ Bivalent (Original/Omicron BA.4/5) Supplier: Moderna
(Presentation: 0.1 mg/mL)
Royal Blue Vial Cap
Gray Label Border

INDICATIONS:

- Individuals 6 months of age and older. See COVID-19 Vaccine Eligibility.

The vaccine is not approved for use in those less than 6 years of age or for doses in a primary series.

DOSES AND SCHEDULE:

- Primary series for individuals 6 months to 5 years of age: 2 doses given as 0.25 mL (25 mcg) IM, 8 weeks apart.

- Primary series for individuals 6-11 years of age: 2 doses given as 0.25 mL (25 mcg) IM, 8 weeks apart.

- Primary series for individuals 12 years of age and older: 2 doses given as 0.5 mL (50 mcg) IM, 8 weeks apart.

For individuals who are moderately to severely immunosuppressed (see COVID-19 Vaccine Eligibility), a 3-dose primary series is recommended. The 3rd dose should be provided at least 28 days after the 2nd dose.

- Booster dose for individuals 6-11 years of age: 1 dose given as 0.25 mL (25 mcg) IM, at least 6 months after completion of the primary series. See BOOSTER DOSES.

- Booster dose for individuals 12 years of age and older: 1 dose given as 0.5 mL (50 mcg) IM, at least 6 months after completion of the primary series or a previous booster dose. See BOOSTER DOSES.

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A The minimum age for vaccine receipt is based on age at presentation.
B NACI recommends that Moderna Bivalent vaccine can be used in the primary series in those 6 months of age and older. Informed consent should include a discussion that this vaccine has not yet been approved for use in the primary series or for use in those 6 months to 5 years of age.
C A Moderna vaccine is the preferred product for those who are moderately to severely immunosuppressed due to a potentially greater immune response induced by the Moderna vaccine in these populations; however, if unavailable, or upon client request, an age-appropriate Pfizer COVID-19 mRNA vaccine can be given.
D The recommended 8 week interval is associated with optimal vaccine effectiveness. If administration of the second dose is delayed beyond 8 weeks, the series does not need to be restarted. Clients requesting a shorter interval should be informed that this is not optimal for protection, but their request for an earlier dose should be granted without need for MHO approval, provided the minimum interval between doses has been observed.
E The minimum interval between doses is 28 days. NOTE: there is no ‘4-day grace period’ allowance.
F The minimum interval between doses is 21 days.
G An age-appropriate Pfizer COVID-19 mRNA vaccine is preferred for those 12-29 years of age due to the lower risk of myocarditis/pericarditis with this vaccine (with the exception of those 12-29 years of age who are moderately to severely immunosuppressed due to a potentially greater immune response induced by the Moderna vaccine in these populations). However, if an age appropriate Pfizer COVID-19 mRNA vaccine is unavailable, or upon client request, the Moderna COVID-19 vaccine can be used provided informed consent includes the elevated risk of myocarditis/pericarditis associated with this product.
H For individuals who received a single dose of Janssen vaccine, one additional dose of COVID-19 mRNA vaccine is recommended at least 28 days later.
I The booster dose can be provided at a minimum interval of at least 5 months from completion of the primary series or a previous booster dose. The exception to this is the Janssen vaccine for which the minimum interval is 8 weeks between the single dose of Janssen vaccine and the booster dose.
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ADMINISTRATION:
- No reconstitution required.
- Low dead-volume syringes and/or needles should be used if available to extract the maximum number of doses.

Storage and Handling:
- Note: cartons and vials are labelled “spikevax™ bivalent Original/Omicron BA.4/BA.5”. Refer to the Health Canada Alert for more information.
- The vaccine can be stored at:
  - -50°C to -15°C up to the end of its expiry date, kept in the original packaging and protected from light. Do not store on dry ice or below -50°C.
  - +2°C to +8°C for up to 30 days prior to first use, protected from light.
  - Room temperature (up to +25°C) for up to 24 hours (cumulative).
  - After first vial puncture, the vaccine must be used within 24 hours.
  - The vaccine can be pre-loaded into a syringe for up to 24 hours from first vial puncture.
  - 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:
  - From the freezer to room temperature:
    - 2.5 mL vial requires 45 minutes to thaw
  - From the freezer to the refrigerator:
    - 2.5 mL vial requires 2 hours to thaw
    - Allow at least 15 minutes at room temperature prior to administration.
  - Swirl the vial gently after thawing and between each withdrawal. Do not shake.
- Do not refreeze thawed vials.

BOOSTER DOSES:
No further booster doses following a bivalent COVID-19 mRNA booster dose are recommended at this time, with the exception of the individuals for whom a spring 2023 bivalent booster dose may be recommended. See COVID-19 Vaccine Eligibility, Spring 2023 Eligibility Criteria.

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

CONTRAINDICATIONS:
1. History of anaphylactic reaction to any component of the vaccine is generally considered a contraindication, however for more details on the administration of COVID-19 vaccines to individuals with allergies to components of the COVID-19 vaccines, please see the PRECAUTIONS section.

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A 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.
B 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.
C Alternatively, such individuals may be offered Novavax COVID-19 vaccine if they are age-eligible.
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PRODUCT COMPONENTS:
Other components: cholesterol; 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC); acetic acid; lipid SM-102; sodium acetate trihydrate; sucrose; tromethamine (trometamol); tromethamine hydrochloride (trometamol hydrochloride).

PRECAUTIONS:
• For individuals with a history of anaphylactic reaction to a previous dose of an mRNA COVID-19 vaccine, re-vaccination (i.e., administration of a subsequent dose in the series when indicated) may be offered with the same vaccine or the same mRNA platform if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent is provided. Prior to re-vaccination, consultation with an allergist or another appropriate physician (e.g., Medical Health Officer) is advised. If re-vaccinated, vaccine administration should be done in a controlled setting with expertise and equipment to manage anaphylaxis, with an extended period of observation of at least 30 minutes after re-vaccination.**

• For individuals with suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, the vaccine should be administered in a controlled setting with expertise and equipment to manage anaphylaxis, with an extended period of observation post-vaccination of at least 30 minutes.

• Wait until symptoms of an acute illness are resolved before vaccinating with COVID-19 vaccine to differentiate symptoms of illness from vaccine side effects.

• 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.

• Additional doses of a COVID-19 vaccine should be deferred in individuals who experienced a physician-diagnosed myocarditis or pericarditis event following a previous dose of a COVID-19 mRNA vaccine. However those with a history compatible with pericarditis who had no cardiac workup or had normal investigations may proceed to further vaccination once symptoms have resolved and 90 days have passed since receipt of the dose associated with the event. For those with confirmed myocarditis (with or without pericarditis), an individual risk/benefit discussion between the patient and their healthcare provider should occur so that the patient (with their parent/guardian as applicable) can make an informed decision about proceeding with a subsequent dose. If another dose is offered, the Pfizer-BioNTech COVID-19 vaccine should be offered because of the lower rate of myocarditis/pericarditis compared to the Moderna vaccine. Informed consent should include the unknown rates of recurrence of myocarditis and/or pericarditis following receipt of additional doses of the Pfizer-BioNTech COVID-19 vaccine, as well as the need to seek immediate medical assessment and care should symptoms develop. Deferral is 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. For more information refer to the NACI summary.

** Alternatively, such individuals may be offered Novavax COVID-19 vaccine if they are age-eligible.
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SPECIAL CONSIDERATIONS:
- COVID-19 vaccines can be administered concomitantly or at any time before or after the administration of another inactivated or live vaccine.
- Deferral of COVID-19 vaccination is no longer recommended for individuals who have received anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma for treatment or prevention of COVID-19.
- COVID-19 vaccine may be offered to individuals without contraindications who have recovered from 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.

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.
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 internationally and in Canada (see Public Health Agency of Canada reports). Of reported events to the Public Health Agency of Canada to April 15, 2022 meeting the Brighton Case Definition Levels 1-3, the frequency of occurrence has been 1.7 per 100,000 doses administered following any dose of the Moderna 100 mcg vaccine, and 1.1 per 100,000 doses administered following any dose of the Pfizer-BioNTech 30 mcg vaccine. This event is seen more often after the second dose, and in males 12-29 years of age. The reported rates within 7 days of immunization among males 18-29 years of age after the second vaccine dose are 16.36 per 100,000 for the Moderna vaccine and 3.14 per 100,000 for the Pfizer-BioNTech vaccine. In US data reported to VAERS, the reported rates of myocarditis occurring within 7 days of vaccination among 5-11 year old males in association with the 2nd dose of Pfizer-BioNTech vaccine (10 mcg formulation) are one-eighth the rate reported in 12-15 year old males (30 mcg formulation) with a rate of 2.7 cases per million doses. Most cases recover fully. In BC, information to support health care provider recognition and reporting of this event in association with the mRNA vaccines has been issued. The exact cause of these events is not known but is thought to be related to the immune response to the spike protein which is also important in immunity against COVID-19 virus. Rates of myocarditis and pericarditis following Moderna Bivalent COVID-19 mRNA vaccination are unknown at this time, but expected to be very low.

REFERENCES:
1. Moderna SPIKEVAX™ Bivalent (Original / Omicron BA.4/5) vaccine product monograph
2. National Advisory Committee on Immunization: Guidance on an additional COVID-19 booster dose in the spring of 2023 for individuals at high risk of severe illness due to COVID-19
3. National Advisory Committee on Immunization: Interim guidance on the use of bivalent Omicron-containing COVID-19 vaccines for primary series