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

INDICATIONS:  

A A booster dose for individuals 18 years of age and older.  
B A booster dose for individuals 12-17 years of age who are moderately to severely immunocompromised. See COVID-19 Vaccine Eligibility.

The vaccine is not approved for use in those less than 18 years of age or for doses in a primary series.  

DOSES AND SCHEDULE:  

- Fall booster dose: 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.  

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: the carton label is “spikevax™ 0 (Zero) / O” (Omicron) while the vial label is “spikevax™ 0 / O”. Refer to the Health Canada Alert for more information.
- The vaccine can be stored at:  
  o -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.  
  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:  
    - 2.5 mL vial requires 45 minutes to thaw  
  o From the freezer to the refrigerator:  
    - 2.5 mL vial requires 2 hours to thaw

A The minimum age for vaccine receipt is based on age at presentation.  
B A Moderna Bivalent vaccine is the preferred product for those who are moderately to severely immunosuppressed; however, if unavailable, or upon client request, the Pfizer Bivalent vaccine can be given.  
C NACI recommends that a booster dose of the Moderna Bivalent vaccine may be offered to individuals 12-17 years of age who are moderately to severely immunosuppressed.  
D A minimum interval of at least 3 months between completion of the primary series or a previous booster dose and the fall booster may be considered in the context of heightened epidemiologic risk or for operational considerations. 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.  
E 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.
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ADMINISTRATION (continued):
- Allow at least 15 minutes at room temperature prior to administration. A
  - 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 the bivalent COVID-19 mRNA vaccine fall booster dose are recommended at this time.

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. B

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. B
- For individuals with suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, the vaccine should be administered in a controlled setting with

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A 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.
B Alternatively, such individuals may be offered Novavax COVID-19 vaccine if they are age-eligible. Janssen COVID-19 vaccine should only be considered when all other authorized COVID-19 vaccines are contraindicated or refused, due to the reduced effectiveness and the possible adverse effects specifically associated with viral vector vaccines (e.g., Thrombosis with Thrombocytopenia Syndrome [TTS]).
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PRECAUTIONS (continued):
- 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.

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.
- COVID-19 booster doses may be deferred in those who have tested positive for COVID-19 (by PCR or rapid antigen test) until 3-6 months from symptom onset or, for asymptomatic cases, from the time of the positive test. For more information refer to the NACI statement.
- 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.
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ADVERSE EVENTS (continued):
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-eighteenth 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) vaccine product monograph
2. National Advisory Committee on Immunization: Updated guidance on COVID-19 vaccine booster doses in Canada