COVID-19 mRNA Vaccine
SPIKEVAX™
(6 months – 5 years of age presentation: 0.1 mg/mL)

SUPPLIER: Moderna
Royal Blue Vial Cap

INDICATIONS:
• Children 6 months to 5 years of age (inclusive). See COVID-19 Vaccine Eligibility.

The vaccine is approved for use in those 6 months of age to 5 years of age only.

DOSES AND SCHEDULE:
• Primary series for children 6 months – 5 years of age (inclusive): 2 doses given as 0.25 mL (25 mcg) IM, 8 weeks apart. A, B, C, D

For children 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.

ADMINISTRATION:
• No reconstitution required.
• Low dead-volume syringes and/or needles should be used if available to extract the maximum number of doses.
• Do not puncture the vial more than 10 times.

Storage and Handling: E
• 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.

A When a child starts a series at 4 years of age and turns 5 prior to completing their primary series, the Moderna vaccine (25 mcg) is recommended to complete the series. However, if pediatric Pfizer-BioNTech vaccine (10 mcg) is given, the dose should be considered valid and the series complete.

B While the Health Canada authorized schedule for this product is 28 days between dose 1 and 2, the recommended interval is 8 weeks and is associated with optimal vaccine effectiveness. 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. If administration of the second dose is delayed beyond 8 weeks, the series does not need to be restarted.

C The minimum interval between doses is 28 days. NOTE: there is no ‘4-day grace period’ allowance to the minimum interval. For optimal response, immunizers should observe the recommended 8-week interval 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.

D Children should receive the age-appropriate vaccine formulation based on their age on the day of vaccination. If a child moves from a younger age group to an older age group during the primary series, they should receive the vaccine dosage for the older age group for all subsequent doses.

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):
- 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.\(^A\)
  - 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 for children 6 months to 4 years of age at this time. A booster dose of a bivalent COVID-19 mRNA vaccine is recommended for individuals 5 years of age and older at least 6 months after the primary series has been completed.\(^B\) See COVID-19 Vaccine Eligibility for booster dose recommendations.

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.

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,\(^A\) 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.
- NACI is currently only recommending one booster dose after the primary series for children 5-11 years of age. However, at the provider's discretion, a bivalent booster dose (as per recommended interval) could be offered to children considered at high risk of severe COVID-19 who have previously received a booster dose with the monovalent Pfizer-BioNTech COVID-19 mRNA vaccine. For other children 5-11 years of age, the bivalent vaccine is not recommended if a monovalent booster has already been received, but may be provided upon parent/guardian request.
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PRECAUTIONS (continued):

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) should
delay COVID-19 vaccination until they have recovered from illness and for 90 days after the
date of diagnosis of MIS-C.

• 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, if an age-eligible product is available,
because of the lower rate of myocarditis/pericarditis compared to the Moderna vaccine in
older age groups. 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. Initiation or completion of a COVID-19 primary series
may be deferred in those who have tested positive for COVID-19 (by PCR or rapid antigen
test) until 8 weeks 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.
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ADVERSE EVENTS:
Local: pain, swelling, redness, axillary (or groin) 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. Infants and toddlers may experience irritability (crying), sleepiness and loss of appetite.

Rare cases of facial paralysis/Bell’s palsy have been reported in the adult population using the age appropriate product.

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. Rates of myocarditis and pericarditis following COVID-19 mRNA vaccination are unknown in the under 5 year age group at this time, but expected to be very rare and lower than in the over 5 year age group. 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.

REFERENCES:
1. Moderna vaccine product monograph
2. National Advisory Committee on Immunization: Recommendations on the use of Moderna Spikevax COVID-19 vaccine in children 6 months to 5 years of age