COVID-19 mRNA Vaccine
SPIKEVAX®
Omicron KP.2
(Presentation: 0.1 mg/mL)

Supplier: Moderna
Royal Blue Vial Cap
Coral Blue 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 months of age.

DOSES AND SCHEDULE: [A]

- Individuals 6 months to 4 years of age (inclusive):[B]
  - Previously vaccinated with 2 or more doses:[C] 1 dose given as 0.25 mL (25 mcg) **IM** at least 3 months [D] after last dose of COVID-19 vaccine.
  - Previously vaccinated with 1 dose: 1 dose given as 0.25 mL (25 mcg) **IM** at least 8 weeks [E] after last dose of COVID-19 vaccine.
  - NOT previously vaccinated: 2 doses given as 0.25 mL (25 mcg) **IM**, 8 weeks apart. [E, F]
- Individuals 5-11 years of age (inclusive):[C] 1 dose given as 0.25 mL (25 mcg) **IM** at least 3 months [D] after last dose of COVID-19 vaccine.
- Individuals 12 years of age and older:[C] 1 dose given as 0.5 mL (50 mcg) **IM** at least 3 months [D] after last dose of COVID-19 vaccine.
- Individuals 6 months to 4 years of age (inclusive) who are moderately to severely immunosuppressed: Individuals in this age group who are moderately to severely immunosuppressed (see COVID-19 Vaccine Eligibility) should receive at least 3 doses [G] of COVID-19 vaccine with at least 1 of these doses being the COVID-19 KP.2 vaccine per age-appropriate dosing recommendations. Refer to intervals in table below.

Recommendations for Moderately to Severely Immunosuppressed Clients: 6 mo – 4 y		
COVID-19 Vaccination History	**Number of Dose(s) of COVID-19 KP.2 Vaccine**	**Recommended Interval Between Doses**
3 or more doses [C]	1 dose	≥ 3 months after last dose [D]
2 doses	1 dose	8 weeks after last dose [E]
1 dose	2 doses	8 weeks after last dose and 8 weeks between doses [E]
0 doses	3 doses	8 weeks between doses [E]

[A] Previously vaccinated includes any product type or formulation of World Health Organization Emergency Use Authorization Qualified COVID-19 Vaccine, unless otherwise specified.
[B] These individuals should receive at least 2 doses of COVID-19 vaccine. If any dose in the series was a Pfizer vaccine, these individuals should receive a total of at least 3 doses of COVID-19 vaccine at a recommended interval of 8 weeks between doses.
[C] No prior receipt of COVID-19 KP.2 vaccine.
[D] An interval of at least 3 months can be used due to the unknown seasonality of SARS-CoV-2 and the expected duration of protection from vaccine.
[E] A 28 day minimum interval may be considered. For optimal response, the recommended interval should be observed.
[F] Children turning from 4 years to 5 years of age during the vaccination series should receive both doses.
[G] If any dose in the series was a Pfizer COVID-19 vaccine, these individuals should have a total of at least 4 doses of COVID-19 vaccine with at least one of these doses being the COVID-19 KP.2 formulation. When a 4-dose series is indicated, the recommended interval is 8 weeks between doses.

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DOSES AND SCHEDULE (continued):

Individuals 5 years of age and older who are moderately to severely immunosuppressed:
Individuals in this age group who are moderately to severely immunosuppressed (see COVID-19 Vaccine Eligibility) should receive a total of at least 2 doses of COVID-19 vaccine per age-appropriate dosing recommendations above, with at least one of these doses being the COVID-19 KP.2 formulation. Refer to intervals in table below. Those who self-declare a recommendation by their health care provider are eligible to receive a 3-dose series, at a recommended interval of 8 weeks between doses.[A] New recipients of HSCT or CART should receive a 3-dose series, at a recommended interval of 8 weeks between doses.

Recommendations for Moderately to Severely Immunosuppressed Clients: ≥ 5 years		
COVID-19 Vaccination History	**Number of Dose(s) of COVID-19 KP.2 Vaccine**	**Recommended Interval Between Doses**
2 or more doses [B]	1 dose	≥ 3 months after last dose [C]
1 dose	1 dose	8 weeks after last dose [D]
0 doses	2 doses	8 weeks between doses [D]

- Spring 2025 Dose:
  - Individuals 6 months to 11 years of age (inclusive): 1 dose given as 0.25 mL (25 mcg) **IM** at least 3 months [C] after last dose of COVID-19 vaccine. See BOOSTER DOSES.
  - Individuals 12 years of age and older: 1 dose given as 0.5 mL (50 mcg) **IM** at least 3 months [C] after last dose of COVID-19 vaccine. See BOOSTER DOSES.

ADMINISTRATION:

- No reconstitution required.
- If available, low dead-volume syringes and/or needles can be used to extract the maximum number of doses.

Storage and Handling:[E]

- 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 50 days prior to first use, protected from light.
  - After first vial puncture, the vaccine must be used within 24 hours if stored refrigerated (+2°C to +8°C) or 12 hours if stored at room temperature (up to +25°C).

[A] Additional doses above the authorized schedule are intended to improve the immune response in individuals who are moderately to severely immunosuppressed. This may be especially important in individuals who have not had a prior SARS-CoV-2 infection as they do not benefit from hybrid immunity. For such individuals, a total of 3 doses may be provided to enhance protection.
[B] No prior receipt of COVID-19 KP.2 vaccine.
[C] An interval of at least 3 months can be used due to the unknown seasonality of SARS-CoV-2 and the expected duration of protection from vaccine.
[D] A 28 day minimum interval may be considered. For optimal response, the recommended interval should be observed.
[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):

- The vaccine can be pre-loaded into a syringe for up to 24 hours from first vial puncture if stored refrigerated (+2°C to +8°C) or 12 hours if stored at room temperature (up to +25°C).
- 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.[A]
  - Swirl the vial gently after thawing and between each withdrawal. Do not shake.
- Do not refreeze thawed vials.

BOOSTER DOSES:
An additional dose of COVID-19 KP.2 vaccine in Spring 2025 is recommended for select populations at increased risk of severe disease, as outlined on the COVID-19 Vaccine Eligibility page under Spring 2025 Recommendations. For individuals who are not at increased risk of severe disease, an additional dose in Spring 2025 is not recommended, however those who wish to receive an additional dose may receive one.

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:
Potential allergens: 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000-DMG).
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).

[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.

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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 an mRNA vaccine 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 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 COVID-19 vaccine should be offered because of the lower rate of myocarditis/pericarditis following the Pfizer Comirnaty original (30 mcg) vaccine compared to the Moderna Spikevax original (100 mcg) vaccine among individuals 12 years of age and older. Informed consent should include the unknown rates of recurrence of myocarditis and/or pericarditis following receipt of additional doses of the Pfizer 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 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.

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SPECIAL CONSIDERATIONS (continued):

- For previously vaccinated individuals, COVID-19 vaccine may be deferred in those who have tested positive for COVID-19 (by PCR or rapid antigen test) until 3 months from symptom onset or, for asymptomatic cases, from the time of the positive test.
- For individuals who have not yet completed their primary series, COVID-19 vaccine 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. If these individuals are moderately to severely immunosuppressed, a 4-8 week interval may be considered.

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.

Rare cases of myocarditis (inflammation of the heart muscle) and/or pericarditis (inflammation of the lining around the heart) have been reported following vaccination with prior formulations of COVID-19 vaccines. These are more often seen after the 2nd dose received, when spacing between the first and second dose was less than 8 weeks, in males, in those 12-29 years old, and with use of a Moderna 100 mcg dose. The risk of myocarditis and/or pericarditis is now expected to be lower due to the use of a single dose of COVID-19 vaccine in most individuals in this age group starting vaccination and potentially due to a lower dosage of the available Moderna Spikevax vaccine (50 mcg in the current formulation compared to 100 mcg in the original monovalent formulation). Typical onset of symptoms is within the first week after vaccination. An increase in myocarditis and/or pericarditis has not been observed in younger children. Follow-up studies of those who experienced myocarditis continues, but the majority of individuals respond well to conservative therapy such as anti-inflammatory treatment and recover quickly.

REFERENCES:

1. Moderna SPIKEVAX® vaccine product monograph
2. National Advisory Committee on Immunization: Guidance on the use of COVID-19 vaccines for 2025 to summer 2026