

COVID-19 mRNA Vaccine SPIKEVAX® XBB.1.5 (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, B}

- Individuals 6 months to 4 years of age (inclusive):^C
 - Previously vaccinated with 2 or more doses: 1 dose given as 0.25 mL (25 mcg) **IM** at least 6 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): 1 dose given as 0.25 mL (25 mcg) **IM** at least 6 months ^D after last dose of COVID-19 vaccine, regardless of previous COVID-19 vaccination history.
- Individuals 12 years of age and older: 1 dose given as 0.5 mL (50 mcg) **IM** at least 6 months ^D after last dose of COVID-19 vaccine, regardless of previous COVID-19 vaccination history.
- Individuals 6 months of age and older who are moderately to severely immunosuppressed: Individuals who are moderately to severely immunosuppressed (see [COVID-19 Vaccine Eligibility](#)) should have a total of at least 3 doses ^G of COVID-19 vaccine with at least one of these doses being the COVID-19 XBB.1.5 formulation per age-appropriate dosing recommendations above. Refer to intervals in table below.

Recommendations for Moderately to Severely Immunosuppressed Clients		
Previous COVID-19 Vaccination History	Number of Dose(s) of COVID-19 XBB.1.5 Vaccine	Recommended Interval Between Doses
3 or more doses	1 dose	6 months after last dose ^H
2 doses	1 dose	8 weeks after last dose ^E
1 dose	2 doses	8 weeks after last dose <i>and</i> between doses ^E
0 doses	3 doses	8 weeks between doses ^E

^A Moderna COVID-19 XBB.1.5 mRNA vaccine is the preferred product for children 6 months to 4 years of age, as well as individuals who are moderately to severely immunosuppressed due to a potentially greater immune response induced by this vaccine in these populations; however, if unavailable, or upon client request, an age-appropriate Pfizer COVID-19 XBB.1.5 vaccine can be given.

^B Previously vaccinated includes any [World Health Organization Emergency Use Authorization Qualified COVID-19 Vaccine](#).

^C If any dose in the series is a Pfizer-BioNTech vaccine (3 mcg dose), a total of at least 3 doses of COVID-19 vaccine with at least one of these doses being the COVID-19 XBB.1.5 formulation is recommended.

^D A 3 month minimum interval may be considered for operational considerations or other exceptional circumstances.

^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 For children 6 months to 4 years of age who are moderately to severely immunosuppressed, if any dose in the series is a Pfizer COVID-19 vaccine (3 mcg), a total of at least 4 doses of COVID-19 vaccine with at least one of these doses being the COVID-19 XBB.1.5 formulation is recommended. See the [Pfizer COVID-19 XBB.1.5 \(6 months – 4 years of age\)](#) product page.

^H An 8 week minimum interval may be considered. For optimal response, the recommended interval should be observed.

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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:^A

- 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.^B
 - Swirl the vial gently after thawing and between each withdrawal. Do not shake.
- Do not refreeze thawed vials.

BOOSTER DOSES:

No further doses are recommended following COVID-19 vaccination with the XBB.1.5 formulation 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.^C

^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:

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).

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.^A
- 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-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 vaccines and are no longer being followed by a medical professional for heart issues. For more information refer to the [NACI](#) summary.

^A 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.
- COVID-19 vaccine 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.

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 (used in primary series but not in subsequent booster doses). Typical onset of symptoms is within the first week after vaccination. This event 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® XBB.1.5 vaccine product monograph](#)
2. [National Advisory Committee on Immunization: Guidance on the use of COVID-19 vaccines in the fall of 2023](#)
3. [National Advisory Committee on Immunization: Addendum to the guidance on the use of COVID-19 vaccines in the fall 2023](#)