COVID-19 mRNA Vaccine
COMIRNATY® OMICRON XBB.1.5
(Presentation: 30 mcg/0.3 mL)

Supplier: Pfizer
Gray Vial Cap
Gray Label Border

INDICATIONS:

- Individuals 12 years of age and older. See COVID-19 Vaccine Eligibility.

The vaccine is not approved for use in those less than 12 years of age.

DOSES AND SCHEDULE:[A, B]

- Individuals 12 years of age and older: 1 dose given as 0.3 mL (30 mcg) **IM** at least 6 months[C] after last dose of COVID-19 vaccine, regardless of previous COVID-19 vaccination history.

- Individuals 12 years 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 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 [D]
2 doses	1 dose	8 weeks after last dose [E]
1 dose	2 doses	8 weeks after last dose *and* between doses [E]
0 doses	3 doses	8 weeks between doses [E]

ADMINISTRATION:

- No dilution required. **Do not dilute this presentation of the vaccine.**
- Low dead-volume syringes and/or needles should be used if available to extract the maximum number of doses.
- Prior to use and after thawing, gently invert the vial 10 times to mix; **do not shake**. Prior to mixing, the thawed vaccine may contain white to off-white opaque amorphous particles.
- After mixing the vaccine should appear as a white to off-white suspension with no visible particles. Do not use if liquid is discolored or if particles are observed after mixing.

[A] Moderna COVID-19 XBB.1.5 mRNA vaccine is the preferred product for 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] A 3 month minimum interval may be considered for operational considerations or other exceptional circumstances.
[D] An 8 week minimum interval may be considered. For optimal response, the recommended interval should be observed.
[E] A 28 day minimum interval may be considered. For optimal response, the recommended interval should be observed.

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ADMINISTRATION (continued):
Storage and Handling:[A]

- Frozen vials prior to use:
  - The vaccine must be stored at ultra-low temperatures of -90°C to -60°C up to the end of its expiry date and kept in the original packaging, until ready to use.
  - **Do not store vaccine at -25°C to -15°C.**
  - The vaccine can be stored for up to 30 days in a validated thermal container with dry ice; requires re-icing with 20-23 kg of new dry ice every 5 days if opened twice daily.
- Product should be thawed/held prior to use, in one of the following ways:
  - From the freezer to the refrigerator:
    - A carton of 10 vials may take up to 6 hours to thaw in the refrigerator (+2°C to +8°C).
    - The vaccine may be stored at +2°C to +8°C for up to 10 weeks.
  - From the freezer to room temperature:
    - Vials can be thawed at room temperature (up to +25°C) for 30 minutes. The vaccine can be stored at room temperature (up to +25°C) for up to 12 hours prior to first vial puncture.
  - Do not refreeze thawed vials.
  - The vaccine must be kept between +2°C to +25°C and **used within 12 hours** after first vial puncture. Avoid exposure to direct sunlight and ultraviolet light. Thawed vials can be handled in room light conditions.
  - The vaccine can be pre-loaded into a syringe for up to 12 hours.
  - Ensure that the vial of vaccine/pre-loaded syringe is clearly labelled with the date and time of first vial puncture.

[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 Pfizer-BioNTech COVID-19 mRNA Vaccine (including dry ice procedures).

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ADMINISTRATION (continued):

Summary of Vial Thawing and Storage:

<table>
<tr><td rowspan="2">Store at ultra-low temperatures upon receiving the vaccines in:

Ultra-low temperature freezer
(-90°C to -60°C)

Or

Thermal shipping container
(-90°C to -60°C)</td><td>Regular Use</td><td>Step 1
Thaw in refrigerator (+2°C to +8°C):
• 6 hours for cartons of 10 vials (less time is needed for a fewer number of vials).
• Store in refrigerator for up to 10 weeks.</td><td>Step 2
At room temperature (up to +25°C):
• Store at room temperature (up to +25°C) for no more than 12 hours prior to first vial puncture.</td><td>Step 3
Post puncture:
• Store at +2°C to +25°C and use within 12 hours (from the time of first vial puncture).
• Any unused vaccine must be discarded after 12 hours.</td></tr>
<tr><td>Immediate Use</td><td>Step 1
Thaw to room temperature (up to +25°C) for 30 minutes
• Store at room temperature for no more than 12 hours prior to first vial puncture.</td><td colspan="2">Step 2
Post puncture:
• Store at +2°C to +25°C and use within 12 hours (from the time of first vial puncture).
• Any unused vaccine must be discarded after 12 hours.</td></tr>
</table>

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.[A]

PRODUCT COMPONENTS:

Potential allergens: 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide.
Other components: ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate); 1,2-distearoyl-sn-glycero-3-phosphocholine; cholesterol; sucrose; tromethamine; tromethamine hydrochloride.

[A] Alternatively, such individuals may be offered Novavax COVID-19 vaccine if they are age-eligible.

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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.[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.

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.

[A] Alternatively, such individuals may be offered Novavax COVID-19 vaccine if they are age-eligible.

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SPECIAL CONSIDERATIONS (continued):

- 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.
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. COMIRNATY® Omicron 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