

## COVID-19 mRNA Vaccine COMIRNATY® OMICRON XBB.1.5

(6 months – 4 years of age presentation: 3 mcg/0.2 mL)

**Supplier: Pfizer**  
**Maroon Vial Cap**  
**Maroon Label Border**

### INDICATIONS:

- Individuals 6 months to 4 years of age (inclusive). See [COVID-19 Vaccine Eligibility](#).

The vaccine is not approved for use in those less than 6 months of age.

### DOSES AND SCHEDULE: <sup>A, B</sup>

- Individuals 6 months to 4 years of age:<sup>C</sup>
  - Previously vaccinated with 2 or more doses: 1 dose given as 0.2 mL (3 mcg) **IM** at least 6 months <sup>D</sup> after last dose of COVID-19 vaccine. If only two doses of Pfizer COVID-19 vaccine were given previously, the recommended interval to the COVID-19 XBB.1.5 vaccine is 8 weeks <sup>E</sup> after the last dose.
  - Previously vaccinated with 1 dose: 2 doses given as 0.2 mL (3 mcg) **IM**, 8 weeks <sup>E</sup> after last dose of COVID-19 vaccine and an interval of 8 weeks <sup>E</sup> between doses.
  - NOT previously vaccinated: 3 doses given as 0.2 mL (3 mcg) **IM**, 8 weeks <sup>E</sup> between doses.
- Individuals 6 months to 4 years of age 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 4 doses <sup>F</sup> of Pfizer 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 Pfizer COVID-19 XBB.1.5 Vaccine	Recommended Interval Between Doses
3 or more doses	1 dose	6 months after last dose <sup>G</sup>
2 doses	2 doses	8 weeks after last dose <i>and</i> between doses <sup>E</sup>
1 dose	3 doses	8 weeks after last dose <i>and</i> between doses <sup>E</sup>
0 doses	4 doses	8 weeks between doses <sup>E</sup>

<sup>A</sup> 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.

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

<sup>C</sup> For mixed series, 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.

<sup>D</sup> A 3 month minimum interval may be considered for operational considerations or other exceptional circumstances.

<sup>E</sup> A 28 day minimum interval may be considered. For optimal response, the recommended interval should be observed.

<sup>F</sup> For mixed series, if any dose in the series is a Pfizer COVID-19 vaccine (3 mcg dose), 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.

<sup>G</sup> An 8 week minimum interval may be considered. For optimal response, the recommended interval should be observed.

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### ADMINISTRATION:

- **This product requires dilution.**
- Prior to dilution and after thawing, gently invert the vial 10 times to mix; **do not shake**.
- Allow the vaccine to come to room temperature (up to +25°C) prior to dilution.<sup>A</sup> Dilute the vaccine with 2.2 mL of the sodium chloride (0.9%) provided for this purpose, using a needle 21-gauge or narrower. Discard remaining diluent.
- Gently invert the vial containing the diluted product 10 times to mix; **do not shake**.
- After dilution, the vaccine will be an off-white suspension. Inspect vials to confirm there are no particulates and no discolouration. If any is observed do not administer the vaccine.
- Low dead-volume syringes and/or needles should be used if available to extract the maximum number of doses.

### Storage and Handling / Dilution Requirements:<sup>B</sup>

- 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.
- Vials prior to dilution:
  - The frozen vial contains 0.4 mL and needs to be thawed before mixing with the diluent. A carton of 10 vials can be thawed in the refrigerator for 2 hours or at room temperature (up to +25°C) for 30 minutes.
  - The vaccine may be stored at +2°C to +8°C for up to 10 weeks.
  - The vaccine may be at room temperature (up to +25°C) for up to 24 hours, with no more than 12 hours from the time of dilution (first puncture).
  - While at room temperature avoid exposure to direct sunlight and ultraviolet light. Thawed vials can be handled in room light conditions.
  - Do not refreeze thawed vials.
- Vials after dilution:
  - Once thawed and the vial has come to room temperature (up to +25°C) add 2.2 mL of sodium chloride diluent and discard any remaining diluent.<sup>A</sup>
  - **This multi-dose product contains no preservative.**  
The vaccine must be kept between +2°C to +25°C and **used within 12 hours** from the time of dilution, ensuring that the total cumulative time at room temperature (> +8°C to +25°C), pre- and post-dilution, does not exceed 24 hours. Avoid exposure to direct sunlight and ultraviolet light. After dilution, the vaccine vials can be handled in room light conditions.

<sup>A</sup> It is not required that the vaccine reach room temperature prior to dilution, however the vaccine must be fully thawed.

<sup>B</sup> 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):

- The vaccine can be pre-loaded into a syringe for up to 12 hours. Ensure that the diluted vial of vaccine/pre-loaded syringe is clearly labelled with the date and time of dilution.

### Summary of Vial Thawing and Storage:

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)	Regular Use	Step 1	Step 2	Step 3
		<b>Thaw in refrigerator (+2°C to +8°C):</b> <ul style="list-style-type: none"> <li>• 2 hours for a carton of 10 vials (less time is needed for a fewer number of vials).</li> <li>• Store in refrigerator for up to 10 weeks.</li> </ul>	<b>At room temperature (up to +25°C):</b> <ul style="list-style-type: none"> <li>• Store at room temperature for up to 24 hours, with no more than 12 hours from the time of dilution.</li> </ul>	<b>Post dilution:</b> <ul style="list-style-type: none"> <li>• Store at +2°C to +25°C and use within 12 hours (from the time of dilution), ensuring that the total cumulative time at room temperature (&gt; +8°C to +25°C), pre- and post-dilution, does not exceed 24 hours.</li> <li>• Any unused vaccine must be discarded after 12 hours.</li> </ul>
	Immediate Use	Step 1	Step 2	
		<b>Thaw to room temperature (up to +25°C) for 30 minutes</b> <ul style="list-style-type: none"> <li>• Store at room temperature for up to 24 hours with no more than 12 hours from the time of dilution.</li> </ul>	<b>Post dilution:</b> <ul style="list-style-type: none"> <li>• Store at +2°C to +25°C and use within 12 hours (from the time of dilution), ensuring that the total cumulative time at room temperature (&gt; +8°C to +25°C), pre- and post-dilution, does not exceed 24 hours.</li> <li>• Any unused vaccine must be discarded after 12 hours.</li> </ul>	

### 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.

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### 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.

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### 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; sodium chloride; cholesterol; sucrose; tromethamine, tromethamine hydrochloride.

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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) 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 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

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### PRECAUTIONS (continued):

medical professional for heart issues. For more information refer to the [NACI](#) summary.

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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.

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### ADVERSE EVENTS:

**Local:** pain, swelling, redness.

**Systemic:** fatigue, headache, myalgia, chills, arthralgia, fever, nausea and vomiting. Infants and toddlers may experience irritability, sleepiness and decreased appetite.

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 2<sup>nd</sup> 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.

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### 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](#)