

## COVID-19 mRNA Vaccine COMIRNATY® Bivalent (Original/Omicron BA.4/BA.5) Supplier: Pfizer (5-11 years of age presentation: 10 mcg/0.2 mL) **Orange Vial Cap**

### INDICATIONS:

- Individuals 5-11 years of age (inclusive). See [COVID-19 Vaccine Eligibility](#).

The vaccine is approved for use in those 5-11 years of age only.

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### DOSES AND SCHEDULE:

- Booster dose for individuals 5-11 years of age <sup>A</sup>: 1 dose given as 0.2 mL (10 mcg) **IM**, at least 6 months after completion of the primary series. <sup>B</sup>

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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>C</sup> Dilute the vaccine with 1.3 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 discoloration. 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>D</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 <sup>E</sup> and kept in the original packaging, until ready to use.
  - 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 1.3 mL and needs to be thawed before mixing with the diluent. A carton of 10 vials can be thawed in the refrigerator for 4 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.

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<sup>A</sup> The minimum age for vaccine receipt is based on age at presentation.

<sup>B</sup> A minimum interval of at least 5 months between completion of the primary series and the booster dose.

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

<sup>D</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 \(including dry ice procedures\)](#).

<sup>E</sup> The date printed on the vial and carton is the date of manufacture. When stored at -90°C to -60°C, the vaccine may be used for up to 18 months from the date of manufacture.

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### ADMINISTRATION (continued):

- Do not refreeze thawed vials.
- Vials after dilution:
  - Once thawed and the vial has come to room temperature (up to +25°C) add 1.3 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.
  - 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

<b>Store at ultra-low temperatures upon receiving the vaccines in:</b>  Ultra-low temperature freezer (-90°C to -60°C)  <b>Or</b>  Thermal shipping container (-90°C to -60°C)	<b>Regular Use</b>	<b>Step 1</b> <b>Thaw in refrigerator (+2°C to +8°C):</b> <ul style="list-style-type: none"> <li>● 4 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>Step 2</b> <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>Step 3</b> <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>
	<b>Immediate Use</b>	<b>Step 1</b> <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>Step 2</b> <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>	

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

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### BOOSTER DOSES:

No further booster doses are recommended at this time, including individuals 5-11 years of age who have received a monovalent COVID-19 mRNA vaccine for their booster dose.<sup>A</sup>

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

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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 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, 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.

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<sup>A</sup> 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):

- 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 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 mRNA vaccines and are no longer being followed by a 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 confirmed SARS-CoV-2 infection.
- Individuals who have had at least 2 doses of mRNA vaccine and have had a COVID-19 infection are well protected against serious disease and hospitalization; however, for those who wish to receive an additional dose, an interval of 6 months is recommended between vaccine or infection whichever was more recent.
- Recipients should practice public health measures for prevention of SARS-CoV-2 infection and transmission regardless of vaccination with COVID-19 vaccine, at this time.

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### 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.

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

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**ADVERSE EVENTS (continued):**

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. 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.

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**REFERENCES:**

1. [Pfizer vaccine product monograph](#)
2. [National Advisory Committee on Immunization: Updated recommendations on the use of COVID-19 vaccine booster doses in children 5 to 11 years of age and concurrent vaccine administration.](#)