

## COVID-19 mRNA Vaccine COMIRNATY® Bivalent (Original/Omicron BA.4/BA.5) Supplier: Pfizer (Presentation: 30 mcg/0.3 mL) Gray Vial Cap

### INDICATIONS: <sup>A, B</sup>

- Booster dose for 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 or for doses in a primary series.

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### DOSES AND SCHEDULE:

- Booster dose: 1 dose given as 0.3 mL (30 mcg) **IM**, at least 6 months after completion of the primary series or a previous booster dose. <sup>C</sup> See [BOOSTER DOSES](#).

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### 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.

### Storage and Handling: <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.
  - **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.

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

<sup>B</sup> A Moderna Bivalent vaccine is the preferred product for those who are moderately to severely immunosuppressed; however, if unavailable, or upon client request, the Pfizer Bivalent vaccine can be given.

<sup>C</sup> The booster dose can be provided at a minimum interval of at least 5 months from completion of the primary series or a previous booster dose. The exception to this is the Janssen vaccine for which the minimum interval is 8 weeks between the single dose of Janssen vaccine and the booster dose.

<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.
- 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.

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>• 6 hours for cartons 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 (up to +25°C) for no more than 12 hours prior to first vial puncture.</li> </ul>	<b>Step 3</b> <b>Post puncture:</b> <ul style="list-style-type: none"> <li>• Store at +2°C to +25°C and use within 12 hours (from the time of first vial puncture).</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 no more than 12 hours prior to first vial puncture.</li> </ul>	<b>Step 2</b> <b>Post puncture:</b> <ul style="list-style-type: none"> <li>• Store at +2°C to +25°C and use within 12 hours (from the time of first vial puncture).</li> <li>• Any unused vaccine must be discarded after 12 hours.</li> </ul>	

**BOOSTER DOSES:**

No further booster doses following a bivalent COVID-19 mRNA booster dose are recommended at this time, with the exception of the individuals for whom a spring 2023 bivalent booster dose may be recommended. See [COVID-19 Vaccine Eligibility](#), Spring 2023 Eligibility Criteria.

**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.<sup>A</sup>

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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; sodium chloride; 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 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.<sup>A</sup>
- 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 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

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<sup>A</sup> Alternatively, such individuals may be offered Novavax COVID-19 vaccine if they are age-eligible. Janssen COVID-19 vaccine should only be considered when all other authorized COVID-19 vaccines are contraindicated or have been refused, due to the reduced effectiveness and the possible adverse effects specifically associated with viral vector vaccines (e.g., Thrombosis with Thrombocytopenia Syndrome [TTS]).

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### PRECAUTIONS (continued):

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 SARS-CoV-2 infection.
- Recipients should practice public health measures for prevention of SARS-CoV-2 infection and transmission regardless of vaccination with COVID-19 vaccine.

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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 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. 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. Rates of myocarditis and pericarditis following Pfizer-BioNTech Bivalent COVID-19 mRNA vaccination are unknown at this time, but expected to be very low.

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**REFERENCES:**

1. [COMIRNATY® Original & Omicron BA.4/BA.5 vaccine product monograph](#)
2. [National Advisory Committee on Immunization: Guidance on an additional COVID-19 booster dose in the spring of 2023 for individuals at high risk of severe illness due to COVID-19](#)