# COVID-19 mRNA Vaccine
# COMIRNATY®
## Omicron LP.8.1
## (Presentation: 30 mcg/0.3 mL)

**Supplier: Pfizer**
Gray Vial Cap
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**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.

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**DOSES AND SCHEDULE:**

- Individuals 12 years of age and older: 1 dose given as 0.3 mL (30 mcg) **IM** at least 3 months [A] after last dose of COVID-19 vaccine.

- Individuals 12 years of age and older who are moderately to severely immunosuppressed:
  Individuals in this age group who are moderately to severely immunosuppressed (see COVID-19 Vaccine Eligibility) should have a total of at least 2 doses of COVID-19 vaccine per age-appropriate dosing recommendations above, with at least one of these doses being the COVID-19 LP.8.1 formulation. Refer to intervals in table below. Those who self-declare a recommendation by their health care provider are eligible to receive a 3-dose series, at a recommended interval of 8 weeks between doses.[B] New recipients of HSCT or CART should receive a 3-dose series, at a recommended interval of 8 weeks between doses.

| Recommendations for Moderately to Severely Immunosuppressed Clients | | |
|---|---|---|
| **COVID-19 Vaccination History** | **Number of Dose(s) of COVID-19 LP.8.1 Vaccine** | **Recommended Interval Between Doses** |
| 2 or more doses | 1 dose | 3 months after last dose [A] |
| 1 dose | 1 dose | 8 weeks after last dose [C] |
| 0 doses | 2 doses | 8 weeks between doses [C] |

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**ADMINISTRATION:**

- The vaccine is supplied as:
  - multi-dose vials (MDV) containing 6 doses of 0.3 mL that do not require dilution or reconstitution.
  - single dose 0.3 mL prefilled syringes (PFS).

**Storage and Handling:[D]**

**Storage:**

- Multi-dose vials of vaccine may arrive frozen at ultra-low temperatures (-90°C to -60°C) in thermal containers with dry ice or at refrigerated temperatures (+2°C to +8°C).

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[A] An interval of at least 3 months can be used due to the unknown seasonality of SARS-CoV-2 and the expected duration of protection from vaccine.

[B] Additional doses above the authorized schedule are intended to improve the immune response in individuals who are moderately to severely immunosuppressed. This may be especially important in individuals who have not had a prior SARS-CoV-2 infection as they do not benefit from hybrid immunity. For such individuals, a total of 3 doses may be provided to enhance protection.

[C] A 28 day minimum interval may be considered. For optimal response, the recommended interval should be observed.

[D] 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):**

- Frozen vaccine:
  - Vaccine that arrives frozen may be stored in an ultra-low temperature freezer at -90°C to -60°C up to the end of its expiry date.
  - **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.
- Refrigerated vaccine:
  - Vaccine that arrives under refrigerated conditions should be stored refrigerated (+2°C to +8°C). **Do not freeze.**
  - Vaccine may be stored refrigerated for up to 10 weeks from the date of transfer from frozen storage to refrigerated storage conditions. Ensure the vaccine carton has been updated to reflect the new expiry date.

- Pre-filled syringes may be stored refrigerated (+2°C to +8°C) up until the expiry date printed on the carton and syringe labels. **Do not freeze.**

**Thawing:**

- Multi-dose vials of vaccine that have been stored frozen can be thawed in a refrigerator (+2°C to +8°C) or at room temperature (up to +25°C).
  - From the freezer to the refrigerator:
    - A carton of 10 multi-dose vials may take up to 6 hours to thaw in the refrigerator (+2°C to +8°C).
    - Once moved to a refrigerator, the vaccine may be stored at +2°C to +8°C for up to 10 weeks. Ensure the 10-week expiry date is included on the vaccine carton.
  - 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.**

**Use:**

- Prior to use and after thawing, gently invert the vial 10 times to mix. Do not shake.
- Prior to mixing, the thawed vaccine is a white to off-white suspension and 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.
- Multi-dose vials:
  - If available, low dead-volume syringes and/or needles can be used to withdraw each dose from a multi-dose vial. If these are not used, there may not be sufficient volume to extract 6 doses.
  - After first vial puncture, the vaccine must be kept between +2°C to +25°C and used within 12 hours.

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**ADMINISTRATION (continued):**

- Ensure that the vial of vaccine is clearly labelled with the date and time of first vial puncture.

- Pre-filled syringes:
  - Syringes can be stored at temperatures of +8°C to +25°C for up to 12 hours after removal from refrigerated conditions. Discard the pre-filled syringe if not used within this time.
  - Do not shake.

**BOOSTER DOSES:**
No further doses are recommended following COVID-19 vaccination with the LP.8.1 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.

**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.

**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.

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**PRECAUTIONS (continued):**

- 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 COVID-19 vaccine should be offered because of the lower rate of myocarditis/pericarditis following the Pfizer Comirnaty original (30 mcg) vaccine compared to the Moderna Spikevax original (100 mcg) vaccine among individuals 12 years of age and older. Informed consent should include the unknown rates of recurrence of myocarditis and/or pericarditis following receipt of additional doses of the Pfizer 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.

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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.
- For previously vaccinated individuals, COVID-19 vaccine may be deferred in those who have tested positive for COVID-19 (by PCR or rapid antigen test) until 3 months from symptom onset or, for asymptomatic cases, from the time of the positive test.
- For individuals that have not yet completed their primary series, COVID-19 vaccine may be deferred in those who have tested positive for COVID-19 (by PCR or rapid antigen test) until 8 weeks from symptom onset or, for asymptomatic cases, from the time of the positive test. If these individuals are moderately to severely immunosuppressed, a 4-8 week interval may be considered.

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**ADVERSE EVENTS:**
**Local**: pain, swelling, redness.
**Systemic:** fatigue, headache, myalgia, chills, arthralgia, fever, nausea and vomiting.

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**ADVERSE EVENTS (continued):**
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. The risk of myocarditis and/or pericarditis is now expected to be lower due to the use of a single dose of COVID-19 vaccine in most individuals in this age group starting vaccination and potentially due to a lower dosage of the available Moderna Spikevax vaccine (50 mcg in the current formulation compared to 100 mcg in the original monovalent formulation). Typical onset of symptoms is within the first week after vaccination. An increase in myocarditis and/or pericarditis 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.