

COVID-19 mRNA Vaccine COMIRNATY® (Pediatric presentation: 10 mcg/0.2 mL)

Supplier: Pfizer

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.

DOSES AND SCHEDULE:

- Primary series for individuals 5-11 years of age^A: 2 doses given as 0.2 mL (10 mcg) **IM**, 8 weeks apart.^{B, C, D}

ADMINISTRATION:

- This product is differentiated from the adult/adolescent product by an orange vial cap and an orange border around the vial label.
- 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.^E 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.
- The withdrawal of 10 doses from a single vial is dependant, in part, on the type of syringes and needles used to withdraw doses from the vials; low dead-volume syringes and/or needles should be used if available, as standard syringes and needles may not facilitate the extraction of a 10th dose from a single vial. Additional strategies for extraction of 10 doses:
 - Allow contents to settle for 20 seconds after final inversion.
 - Go slow: withdrawing the diluted vaccine too quickly may result in fizzing.
 - Adjustments to remove air bubbles and dose calibration should be done with the needle still in the vial to avoid loss of vaccine.
 - When drawing the 10th dose, place the needle tip just inside the rubber stopper; slightly tilt vial and ensure the needle bevel is facing down and close to the vial neck.
 - Use the same needle to withdraw and administer.

^A The minimum age for vaccine receipt is based on age at presentation (i.e., the vaccine may be offered to individuals on or after their 5th birthday).

^B Children less than 12 years of age who commence a series with the 10 mcg formulation and have turned 12 years of age by the time the second dose is due may receive the 30 mcg formulation that is authorized for individuals aged 12 years and older to complete their primary series. If the second dose is given as the 10 mcg formulation, this dose should be considered valid and the series complete.

^C While the Health Canada authorized schedule for this product is 21 days between dose 1 and 2, the preferred interval in BC is 8 weeks. This interval may be shortened in outbreak communities at the direction of the Medical Health Officer and for individuals who meet approved criteria for an expedited dose 2. If administration of the second dose is delayed beyond 8 weeks, the series does not need to be restarted.

^D The minimum interval between doses is 19 days. NOTE: there is no '4-day grace period' allowance to the minimum interval. For optimal response, immunizers should observe the recommended 8-week interval as much as possible, however, doses given earlier than recommended may still be considered valid and need not be repeated if minimum intervals are observed.

^E It is not required that the vaccine reach room temperature prior to dilution, however the vaccine must be fully thawed.

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ADMINISTRATION (continued):

- If there is enough vaccine left in the vial for a complete 0.2 mL dose after 10 doses have been removed from the vial, another dose(s) can be drawn and administered.
- Following withdrawal of all available 0.2 mL doses, the residual vaccine from up to three vials may be withdrawn into the same syringe to constitute a full dose provided the vials are from the same manufacturer and the same lot number. See [addendum](#) for more information.

Storage and Handling / Dilution Requirements: ^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 ^B 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.
 - 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. ^C
- **This multi-dose product contains no preservative.**
- The vaccine must be kept between +2°C to +25°C and **used within 12 hours** ^D 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.

^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 \(including dry ice procedures\)](#).

^B 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 6 months from the date of manufacture.

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

^D Vial labels and cartons may state that a vial should be discarded 6 hours after dilution; however the information in the [Product Monograph](#) stating 12-hour stability supersedes the number of hours printed on vial labels and cartons.

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Summary of Vial Thawing and Storage:

<p>Store at ultra-low temperatures upon receiving the vaccines in:</p> <p>Ultra-low temperature freezer (-90°C to -60°C)</p> <p>Or</p> <p>Thermal shipping container (-90°C to -60°C)</p>	<p>Regular Use</p>	<p>Step 1</p> <p>Thaw in refrigerator (+2°C to +8°C):</p> <ul style="list-style-type: none"> • 4 hours for a carton of 10 vials (less time is needed for a fewer number of vials). • Store in refrigerator for up to 10 weeks. 	<p>Step 2</p> <p>At room temperature (up to +25°C):</p> <ul style="list-style-type: none"> • Store at room temperature for up to 24 hours, with no more than 12 hours from the time of dilution. 	<p>Step 3</p> <p>Post dilution:</p> <ul style="list-style-type: none"> • 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 (> +8°C to +25°C), pre- and post-dilution, does not exceed 24 hours. • Any unused vaccine must be discarded after 12 hours.
		<p>Step 1</p> <p>Thaw to room temperature (up to +25°C) for 30 minutes</p> <ul style="list-style-type: none"> • Store at room temperature for up to 24 hours with no more than 12 hours from the time of dilution. 	<p>Step 2</p> <p>Post dilution:</p> <ul style="list-style-type: none"> • 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 (> +8°C to +25°C), pre- and post-dilution, does not exceed 24 hours. • Any unused vaccine must be discarded after 12 hours. 	

BOOSTER DOSES:

No booster doses are recommended 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.

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PRODUCT COMPONENTS (continued):

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.

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.
- There is insufficient evidence on the receipt of COVID-19 vaccine following receipt of anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma for treatment or prevention of COVID-19. Therefore, COVID-19 vaccination should be deferred for at least 90 days to avoid potential interference of the antibody therapy with vaccine-induced immune response. Deferral is not required following treatment with tocilizumab or sarilumab.
- 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 those who experienced a physician-diagnosed myocarditis or pericarditis event following a previous dose of a COVID-19 mRNA vaccine with no other cause identified, until further information about the risk of recurrence is available. 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.

SPECIAL CONSIDERATIONS:

- COVID-19 vaccines can be administered concomitantly or at any time before or after the administration of another inactivated or live vaccine.
- A complete series of COVID-19 vaccine may be offered to individuals without contraindications who have recovered from PCR-confirmed 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, at this time.

ADVERSE EVENTS:

Local: pain, swelling, redness.

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ADVERSE EVENTS (continued):

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](#)). These events have been reported in BC at a rate of 1.5 per 100,000 doses of mRNA vaccine administered, and are seen more often after the second dose, and in males under 40 years of age. 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.

REFERENCES:

1. [Pfizer vaccine product monograph](#)
2. [National Advisory Committee on Immunization: Recommendations on the use of the Pfizer-BioNTech COVID-19 Vaccine \(10 mcg\) in children 5 to 11 years of age.](#)

ADDENDUM: Pooling residual vaccine from up to three vials to constitute an extra dose

Following withdrawal of all available 0.2 mL doses, a full 0.2 mL dose may be constituted from the residual vaccine volume from up to three separate vials, provided the vials are from the **same manufacturer** and **same lot number**. In order to minimize the risk of microbial contaminants and maintain product quality, the following processes should be followed:

- Only vials containing *residual* vaccine volume are to be used to prepare a full dose when using multiple vials to constitute a single dose. Residual volume should *not* be combined with contents from a different vial that still contains at least one full dose of the vaccine (to minimize the chance of contaminating the contents of a vial that still contains multiple doses of the vaccine).
- Given this vaccine does not contain preservative and therefore has a short timeline for its use following dilution (i.e., 12 hours), pooling of residual vaccine from two or three vials must occur as soon as possible - it is *not* recommended to save multiple vials with residual volume for use at one time (e.g., the end of the clinic).
- Perform hand hygiene before handling the vaccine. Strictly adhere to aseptic technique while handling the vaccine and minimize the number of vial punctures.
- Firmly and briskly wipe the surface of the rubber stopper with an alcohol swab for initial *and subsequent uses*, being sure to apply friction, and allow it to dry for at least 10 seconds.
- To assist with the withdrawal of residual vaccine from the vial, invert the vial and ensure the end of the needle is below fluid level and situated in the groove of the vial stopper.
- Once the residual vaccine is withdrawn, keep the needle in the vial when expelling air bubble(s) to minimize vaccine wastage.
- Check the syringe to ensure it contains the total 0.2 mL dose prior to administration.
- If not administered immediately, the syringe should be clearly labeled with the date and time of the vial with the shortest timeframe for use.