

Primary Care Job Aid: 5 to 11 Pfizer-BioNTech (Comirnaty) COVID-19 Vaccine

Purpose: This job aid will provide instruction on how to store, prepare, reconstitute, and administer the **Pfizer-BioNTech (Comirnaty) COVID-19 vaccine for ages 5 to 11** in primary care settings.

For any concern about vaccine suitability or stability, please contact pharmacists@halton.ca.

Vaccine Storage Requirements



Storage Condition	Time
Refrigerator (+2°C to +8°C)	Up to 10 weeks*
Room Temperature (up to +25°C)	No more than 24 hours prior to dilution (pre-puncture) And No more than 24 hours after dilution (post-puncture)

*Note: The date written on the vaccine vial is the date of manufacturer, not the expiry date. Regardless of storage condition, the vaccine should not be used after 6 months from the date of manufacture printed on the vial and cartons.

- **Vaccine vials will be delivered to primary care settings in a thawed state.** Do not refreeze thawed vials.
- Vials will be packaged in foam and must remain in the foam to protect from light during storage.
- The vaccine should be stored in a designated area in the vaccine fridge (i.e. shelf or tray).
- During storage, minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light. Thawed vaccine vials can be handled in room light conditions.

Vaccine vials must be individually labelled to decrease the risk of vaccine administration errors, and vaccine wastage. Thawed Unopened Vials (Prior to Dilution)

- Can be **stored in refrigeration** (+2°C to +8°C) for **up to 10 weeks**.
- Can be **stored at room temperature** (up to 25°C) for **no more than 24 hours**.

Labelling Note: the Date and Time that the vaccine must be used by will be indicated on the vaccine vial label. Discard any vaccine that is not used before the 'use by date & time'.

Thawed Vials (After Dilution):

- Must be stored between +2°C to +25°C and **must be used within 24 hours** from the time of reconstitution.

*Labelling Note: the date and time that the vaccine is reconstituted must be marked on the vial label. **Discard any vaccine that is not used within 24 hours.***

Sample Vaccine Vial Label:

Information on the **Right Side** of the label will be **completed by Halton Region Public Health**.

Date & Time of Reconstitution: (must use within 12 hours)	(5-11) Pfizer COVID-19 Vaccine
2021-12-05 @ 1030	Use by Date & Time: 2022-05-18 @ 0830
LOT #: EL1404	

Information on the **Left Side** of the label must be **completed by primary care** when vaccine is used.

Step 1: VACCINE PREPARATION



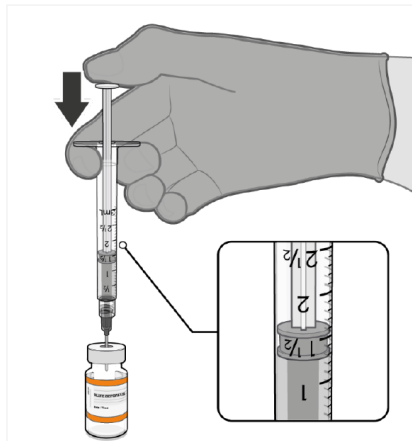
✓ Orange plastic cap and label with orange border.



Gently × 10

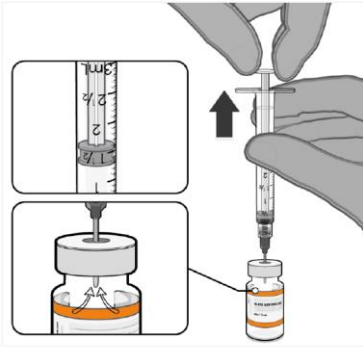
- The vial must reach room temperature **before dilution and must be diluted within 24 hours** of exposure to room temperature (up to 25°C).
- Remove vaccine vial from refrigeration and document the time placed at room temperature on the vial label. Only remove vials from refrigeration as they are needed.
- **Vials must sit at room temperature for 15 minutes prior to dilution.**
- Check 'use by date and time' on the vaccine vial label.
- Verify that the vial has an orange plastic cap and a label with an orange border that states "Age 5y to <12y."
- Invert vaccine vial gentle **10 times**. DO NOT SHAKE.
- Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles. Do not use if the liquid is discoloured or if other particles are observed.

Step 2: RECONSTITUTION



Add 1.3 mL of sterile 0.9% sodium chloride injection, USP.

- Check diluent expiry date. Only use 0.9% Sodium Chloride Injection, USP as the diluent.
Note: diluent will be sent with the vaccine.
 - Using aseptic technique, withdraw 1.3 mL of 0.9% NaCl into a transfer syringe with 21-gauge or narrower needle.
 - Using aseptic technique add 1.3 mL of 0.9% NaCl diluent into the vaccine vial.
Note: there will be remaining volume in the diluent vial. Do not reuse diluent vials, discard after single use.
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- Equalize vial pressure before removing the needle from the vial by withdrawing 1.3 mL of air into the empty syringe. (Note: trace amounts of vaccine will be visible in syringe).



Pull back plunger to 1.3 mL to remove air from vial.



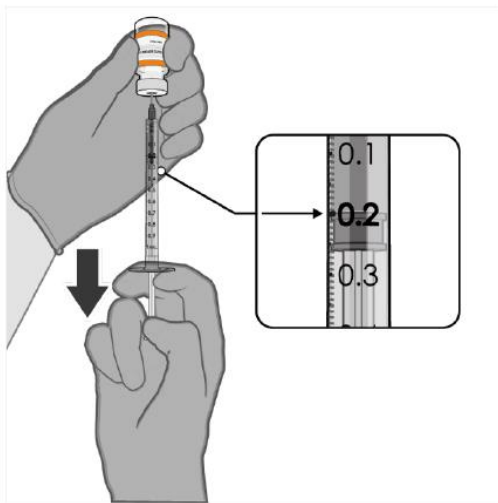
Gently × 10



Use within 12 hours after dilution.


- Gently invert the vial containing the Pfizer-BioNTech COVID-19 vaccine **10 times to mix**. DO NOT SHAKE.
- Inspect the vaccine, vaccine should be an off-white suspension. Do not use if the vaccine if liquid is discoloured or if other particles are observed.
- Record the date and time of reconstitution on the vaccine vial label. Store between (+2°C to 25°C). **Discard any vaccine that is not used within 24 hours.**

Step 3: Prepare Individual Doses of Vaccine



Withdraw 0.2 mL dose of vaccine

- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
 - Carefully withdraw **0.2 mL** of the vaccine into the syringe.
 - Once a dose is withdrawn from the vial it should be administered immediately. Pre-loading syringes is strongly discouraged.
 - Each dose must contain **0.2 mL** of vaccine. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 ml, discard the vial. Do not pool excess vaccine from multiple vials.
 - After dilution, **each vial contains 10 doses**. In order to ensure consistent withdrawal of 10 doses of 0.2 mL, it is important to adhere to minimizing volume loss during dose extraction. Low dead-volume syringes and/or needles can be used to extract 10 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract 10 doses from a single vial.
 - **If more than 10 doses are withdrawn** from the vial, this must be entered in COVax as an **extra dose** (if training and access to inventory section has been provided) or reported to pharmacists@halton.ca.
 - **If less than 10 doses are withdrawn** from the vial, this must be entered in COVax as a **wasted dose** (if training and access to inventory section has been provided) or reported to pharmacists@halton.ca.
- Note:** it is recommended to mark down how many doses were yielded from the vial on the side the vaccine vial i.e. If

	<p>10 doses were yielded, write down the number 10 on the side of the vial. This will help with reconciliation.</p>
<p>Step 5: ADMINISTER VACCINE</p>	<ul style="list-style-type: none"> • Vaccine must be administered within 24 hours of dilution. • Visually inspect each dose in the syringe prior to administration to verify the correct dose and confirm there are no particulates and no discoloration. The diluted vaccine will be an off-white suspension. • Administer intramuscularly, preferably in the deltoid. • Document dose administered in Covax.
<p>Tips to Avoid Wastage</p>	<ul style="list-style-type: none"> • Schedule patients in groups of 10. • Create a backup list of eligible patients and process and contact them in the case of appointment cancellations or no shows. • Avoid opening a vial if all doses cannot be administered within 24 hours* <p>Note: pre-loading syringes is strongly discouraged because it increases risk of contamination, vaccine administration errors, and vaccine wastage.</p> <p>*While it is important to minimize vaccine wastage and every effort should be made to administer all doses of COVID-19 vaccine in a vial, please do not hesitate to puncture a vial for individual vaccinations for patients who may be vaccine-hesitant or unlikely to return for a follow-up appointment.</p>
<p>Secure Disposal of Vaccine Vials and Packaging</p> 	<ul style="list-style-type: none"> • Empty vials should be stored securely and properly disposed of per regulation and guidelines by the Ministry of the Environment and Climate Change. • Before disposing of empty vials, the labels must be destroyed by removing the label, tearing the label, or marking the label. • All packaging associated with the vaccine must be discarded.

Additional Resources:

[Product Monograph – Pfizer-BioNTech COVID-19 Vaccine](#)

[Administration of COVID-19 Vaccine](#) – Ministry of Health

[COVID-19 Vaccine Storage and Handling](#), Ministry of Health

[Registration Guidance Manual for Generators of Liquid Industrial and Hazardous Waste](#)