



Instructions for multi-dose vial Pfizer/BioNTech vaccine: preparation and administration

1. STORAGE

Pfizer vaccine vials will thaw during distribution to clinics. **DO NOT REFREEZE.**

Store undiluted vials at +2°C to +8°C for up to 31 days. This includes distribution time.

For dilution, vials can be stored at room temperature (but less than +30°C) for an additional two hours at most.

Pfizer vaccine comes as a concentrate and MUST be diluted.

Avoid exposure of vaccine to direct sunlight, or UV light at all times.

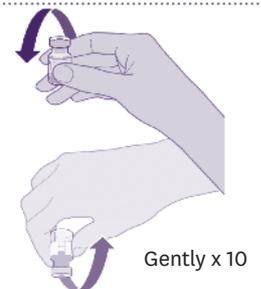
After dilution, store vials between +2°C and +30°C and use within six hours. **You must monitor room temperature.**

Vaccine preparation should always take place in a well-lit, dust free area, away from distractions.

Two appropriately trained staff need to work together, independently checking each other's work.

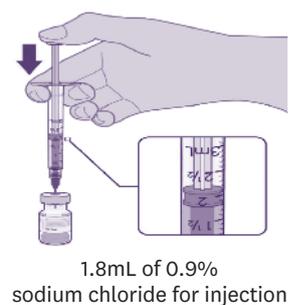
2. PRIOR TO DILUTION

1. The vaccine should be brought to room temperature. It should not feel cold to touch.
2. Check the expiry date & time printed on the box.
3. Check the vial stopper is intact.
4. Invert the vaccine vial gently 10 times. **DO NOT SHAKE.**
5. Inspect the vial. The thawed suspension may contain white to off-white opaque amorphous particles. Do not use if discoloured, save the vial and report as an incident.



3. DILUTING THE VACCINE

1. Remove purple plastic cap guard on top of vaccine vial carefully using an aseptic technique.
2. Cleanse vaccine vial stopper with a single-use antiseptic/alcohol swab and leave to dry for 30 seconds.
3. Use **supplied diluent** (0.9% sodium chloride for injection). Check expiry date and batch number.
4. Open diluent just before use. Diluent that is opened and not used immediately must be discarded. Only prepare saline syringes as they are needed.
5. Using aseptic technique, withdraw **1.8 mL** of diluent into a syringe (using a 25-gauge orange standard needle). Discard the rest of the saline.
6. Independently check this volume with an appropriately trained colleague.

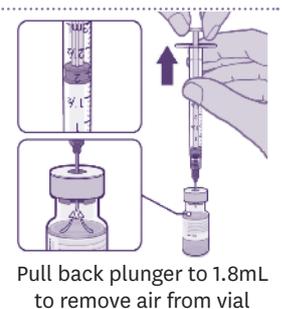


Slowly add 1.8 mL of diluent into the vaccine vial.

4. EQUALIZE

Before withdrawing the needle, equalize vial pressure by keeping the needle above the fluid level and **withdrawing 1.8 mL of air** into the now empty diluent syringe. You may notice a very small amount of liquid in the syringe that had been held inside the needle. This should stay in the syringe.

- Remove the syringe and needle attached to the vaccine vial and discard.
- After dilution, the vial contains 2.25 mL from which 6 or occasionally 7 doses of 0.3 mL can be extracted.



5. AFTER DILUTION

Gently invert vial containing diluted vaccine **10 times** to mix. **DO NOT SHAKE.**

Inspect vaccine in vial. It should be an off-white suspension with no particulates visible.

Do not use if discoloured or contains particulates, save vial and report as incident.

6. LABELLING VACCINE

Label the vaccine doses, one label per dose of vaccine:

- Name of vaccine.
- Diluent name and expiry date.
- Vaccine sub batch number (number on box including the extra 3 digits).
- Expiry date for vaccine sub batch, (this is the expiry date on the box not the vial).
- Time the syringe must be used by (6 hours from time of dilution) .
- Who prepared the vaccine and who checked it.

Vaccine must be used within 6 hours of dilution and can be stored at room temperature.

If returned to the fridge, allow to return to room temperature, ie not cold to touch, before administration.

The 6-hour allowance for use is in addition to the 31 days storage, once defrosted.

7. PREPARATION OF INDIVIDUAL 0.3ML DOSES OF PFIZER/BIONTECH

Each dose is drawn up using the needles that they will be administered with.

All doses must be drawn up from the vial at the same time so you can confirm dilution was correct. See section on Doses.

Cleanse the vial stopper with a single-use antiseptic swab and allow to dry.

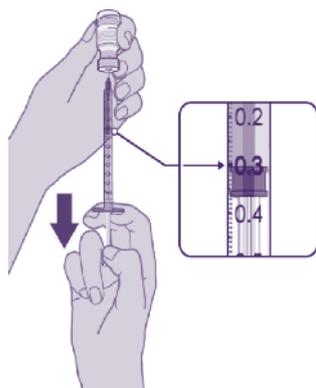
Prepare syringes and needles

Prepare syringes and needles only as required. Always open packets by unpeeling them, do not push needles or syringe out through wrap as this contaminates them. Do not prepare them in advance as this increases risk of contamination.

- Take a 1 ml syringe with either a BD [non LDS] Orange 25mm (1") needle or LDS Orange Needle 25g x 25mm (1") or a 23-25G x 1.5" 38mm length [for someone with a larger arm].
 - Due to a temporary issue with the fit of syringes to needles, we recommend non-LDS needles with vernacare syringes OR LDS needles with non-vernacare syringes (BD or other brand).
- Ensure the syringe and needles fit firmly together. If the connection is not tight, discard the syringe and needle before starting to draw up vaccine.

Drawing up vaccine

- Slowly withdraw slightly more vaccine than the 0.3 mL dose, then slowly return the plunger to the 0.3 mL dose.
- We recommend you always have syringes ready with both lengths of needles to accommodate all sizes of clients.



- This vaccine is now ready for patient administration, do not swap the needle. This needle will be used to administer the vaccine to the patient.
- Carefully replace the needle guard.
- Place syringe onto a firm, cleaned tray.
- Draw up the next dose of vaccine in the same manner. It is not necessary to swab the top of the vial between drawing up each dose of vaccine if drawn up one after the other.
- Pierce the stopper in a different place each time.
- Each dose must contain 0.3 mL of vaccine. It is acceptable to **gently** flick or tap the syringe to remove air bubbles.
- You do not need to protect from normal light, but good practice is to cover from view with something that does not touch the syringes.

If the vial is left for any time, eg while administering the vaccine, then the top will need to be cleansed and time allowed for the alcohol to dry, before the next dose is withdrawn.

Doses

If you are using non LDS needles you should have 5 or 6 doses, with LDS needles you will have 6 or 7 doses. If you have more or less than this, a dilution error is likely to have occurred. Discard all the doses, and report as an incident including the vaccine batch number. If the amount of vaccine remaining in the vial cannot provide a full 0.3 mL dose, discard vial and remaining diluted vaccine. Do not pool excess vaccine from multiple vials.

Discard any unused vaccine six hours after dilution.

Larger patients will need 23-25G x 1.5" 38mm length. Each vaccinator should have at least one longer needle available. Please see the vaccine administration handout for more information.

8. ADMINISTRATION

Visually inspect each dose in each syringe just prior to administration:

- Check volume is 0.3 mL.

If vaccine has leaked out of the needle or hub, then the dose should be discarded.

- Do not use if there is discoloration or particulate matter.
- Administer vaccine intramuscularly into the deltoid.