



PAEDIATRIC Pfizer/BioNTech mRNA-CV 10µg Vaccine Preparation

Preparation and administration of this vaccine should only be carried out by fully authorised, provisionally authorised or pharmacist vaccinators (not COVID-19 Vaccinators Working Under Supervision) that have completed IMAC's Pfizer Paediatric vaccine training.

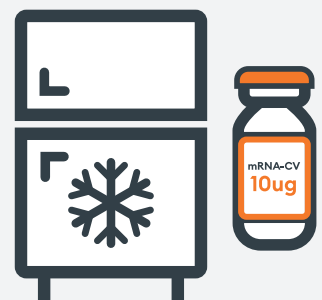
All usual infection prevention and stock management processes for preparing multidose vials should be followed.

Each multi-dose vial contains 10 doses of 0.2mL AFTER DILUTION

1. STORAGE

- Vaccine will be delivered to site thawed. Do not refreeze.
- Store vials in manufacturer's carton to ensure vials are not separated from their USE BY date (which is only printed the carton) and to protect from light. Keep in a clearly labelled section of fridge, separated from other vaccines.
- When stock arrives check USE BY date on box and highlight for quick reference.
- Store unopened, undiluted vials at **+2°C to +8°C for up to 10 weeks**, which is the USE BY date printed on carton label.
- Pfizer Paediatric mRNA-CV vaccine comes as a concentrate and will **REQUIRE DILUTION**.

Store at +2°C to +8°C for up to 10 weeks



2. PREPARE WORK AREA

Vaccine should be prepared in dedicated space away from any other vaccines and distractions. Two appropriately trained staff need to work together, documenting second checks on dilution record.

Have appropriate supplies to hand:

- 1mL LDS syringe with 25G non-LDS needle (16mm and 25mm needles to be available), 3mL syringe
- Syringe labels (available from logistics)
- Dilution record (available from IMAC)
- Alcohol swabs, indelible pen, wipeable vaccine container, hand sanitiser, Paediatric Pfizer vaccine preparation directions, sharps bin

Clear workspace, clean/sanitise surfaces, and equipment.

Perform hand hygiene.

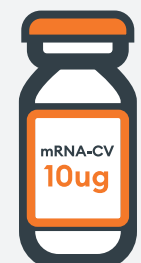


3. SELECT VACCINE FROM THE FRIDGE

- **Confirm correct vaccine selected: vials should have a plastic orange cap on top of vial. Label will have orange border and orange writing "mRNA-CV 10ug".**
- Check vaccine is in date by confirming USE BY printed on carton.
- Add information to dilution record.
- **Second person checks correct vaccine selected and initials dilution record.**

Orange cap

10ug



4. PRIOR TO DILUTION

- Bring vial to room temperature (up to 2 hours). It should not feel cold to touch.
- Ensure orange cap is intact.
- **Invert the vial gently 10 times. DO NOT SHAKE.**
- Inspect the vial. Prior to dilution, the thawed suspension may contain white to off-white opaque amorphous particles.

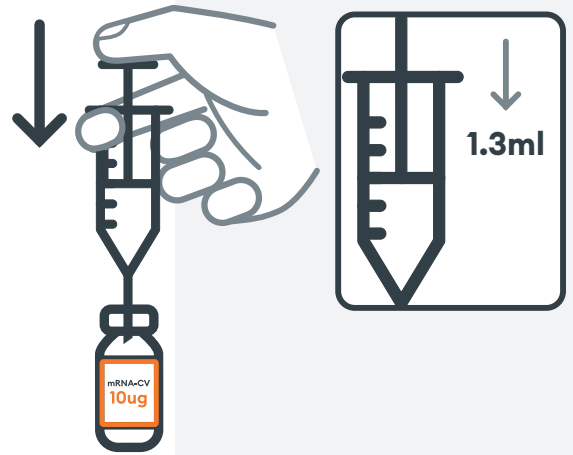
Gently x 10



CONTINUED OVERLEAF ►

5. DILUTING THE VACCINE

- Remove orange cap from top of vial.
- Cleanse stopper with alcohol swab and allow to dry.
- Use supplied diluent (0.9% sodium chloride). Record expiry date and batch number on dilution record.
- Using 3mL syringe with 25mm 25G non-LDS needle **withdraw 1.3mL saline. Second person to check this volume.**
- **Slowly add 1.3mL diluent into vial.**
- Prior to removing needle, **equalize vial by withdrawing 1.3mL air.**
- Discard needle and syringe into sharps bin.
- **Gently invert vial 10 times. DO NOT SHAKE.**
- Inspect the diluted vaccine. It should be a white to off-white suspension with no particulates visible. Do not use if particulates visible.



6. LABELLING VACCINE

DILUTED VACCINE STORED IN SYRINGE HAS 6 HOUR EXPIRY

- If all 10 doses are to be withdrawn from the vial at once, then label each individual syringe with **USE BY (date/time) of 6 hours from time of dilution.**

DILUTED VACCINE STORED IN VIAL HAS 12 HOUR EXPIRY

- If withdrawing doses as needed from vial, write the **USE BY (date/time) on the vial which is 12 hours from time of dilution. You also need to label each syringe with USE BY date and time, (6 hours from draw up OR expiry time from vial, whichever is soonest).**

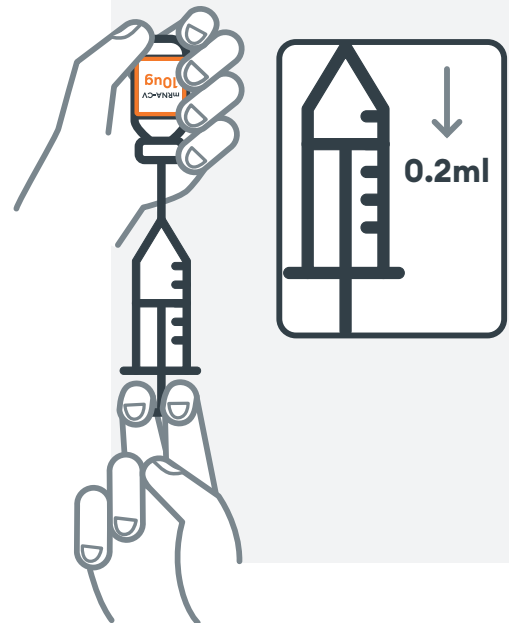
Diluted vaccine is more stable when stored in vial due to microbiological risk of storing vaccine in syringe.

- **Diluted vials and prepared syringes can be stored at 2°C to 30°C.** If refrigerated, allow the diluted suspension to come to room temperature before administration.
- **Vials and syringes need to be stored in a clearly defined area, separated from other vaccines.**
- All syringes must have labels attached to the needle guards. Labels available from logistics.



7. PREPARING EACH DOSE

- Cleanse stopper with alcohol swab and allow to dry.
- Each dose is drawn up using the needles they will be administered with. Prepare 1mL syringe and needle (either 16mm or 25mm needle depending on size of child) using standard infection control techniques.
- Withdraw **0.2mL** vaccine from diluted vial.
- Carefully replace the needle guard and place into clean tray.
- **Label each syringe with USE BY of 6 hours from time dose was drawn up or USE BY of 12 hours from vial dilution, whichever occurs first.**
- **Obtain a second check for each dose.**
- If drawing up doses from a partially used diluted vial: double check it is the correct vaccine, check date and time of dilution have been written on the vial and is within limits.
- Use dilution template to record all steps in the preparation process and keep for three years.



DOCUMENTATION: A separate Dilution Record document will contain vial number, time removed from fridge, sub batch and expiry date of vaccine (from box), batch and expiry date of saline, time drawn up, expiry time of doses drawn, number of doses drawn, initials of person preparing, initials of person checking. A vaccine allocation record document may be used to record vial number, vaccinators name and time syringes were given to vaccinator.