

Guidance for Comirnaty 10mcg (Pfizer) COVID-19 Vaccine Preparation

1. STORAGE REQUIREMENTS

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.
- Comirnaty 10mcg vaccine comes as a concentrate and will **REQUIRE DILUTION.**

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



2. PREPARE WORK AREA

Vaccine preparation should always take place in a well-lit, dust free, dedicated quiet workspace, away from distractions. The workspace should not have the presence of any other vials of vaccine, including Comirnaty 10mcg.

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 Comirnaty vaccine training. A second appropriately trained staff member must provide documented double checks.

Ensure you have the appropriate equipment and supplies to hand prior to removing vaccine from fridge. This includes:

- 1mL LDS syringe with 25G non-LDS needle (16mm and 25mm needles to be available), 3mL syringe
 - If longer needle needed, use 1mL syringe plus 38mm needle
- single-use alcohol swabs
- indelible pen
- wipeable container for drawn up vaccine
- labels for syringes
- vaccine log sheet
- sharps bin
- hand sanitiser
- *Preparation of Comirnaty 10mcg (quick reference guide)* clearly displayed in preparation workspace

- Clean workstation and vaccine tray with disinfectant wipes.
- Perform hand hygiene before preparing the vaccine and before and after administering it to patient.



3. SELECT VACCINE FROM THE FRIDGE

- **Confirm correct vaccine selected: vials should have an orange plastic cap on top of vial. Label will have an 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.**



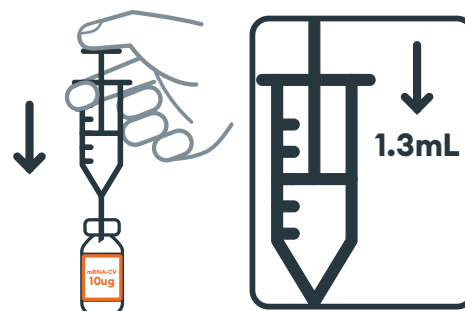
4. PRIOR TO DILUTION

- 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.



5. DILUTING THE VACCINE

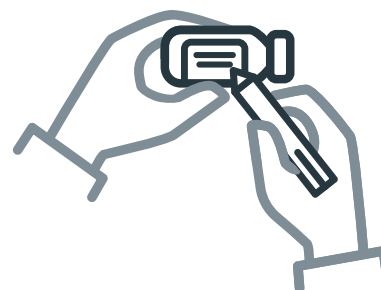
- Remove orange cap from top of vial.
- Cleanse stopper with alcohol swab and allow to dry.
- Use supplied diluent (0.9% sodium chloride). Record expiry date and batch number on dilution record.
- Using 3mL syringe with 25mm 25G non-LDS needle **withdraw 1.3mL saline. Second person to check this volume.**
- **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 THE VACCINE

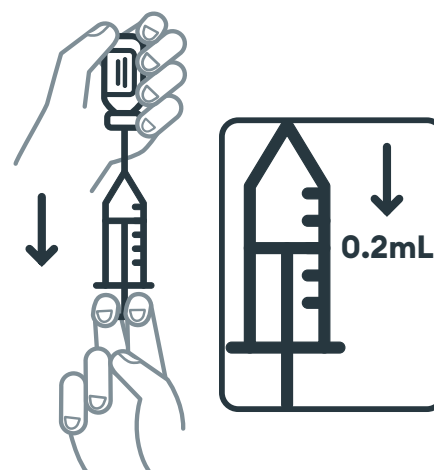
DILUTED VACCINE STORED IN SYRINGE HAS 6 HOUR EXPIRY

- **All 10 doses are to be withdrawn from the vial at once, label each individual syringe with USE BY (date/time) of 6 hours from time of dilution.**
- **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.**
- Drawing up from partially used diluted vials is not recommended.
- Use dilution template to record all steps in the preparation process and keep for three years.



FOR FURTHER GUIDANCE PLEASE CONTACT 0800 IMMUNE (0800 466 863)