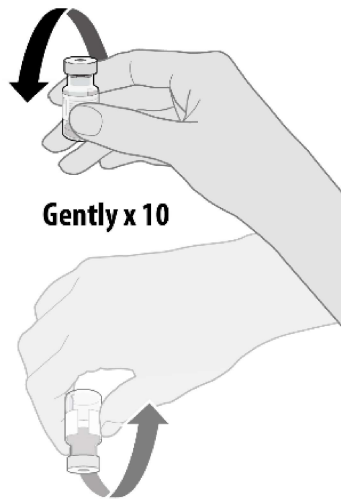


THAWING PRIOR TO DILUTION²

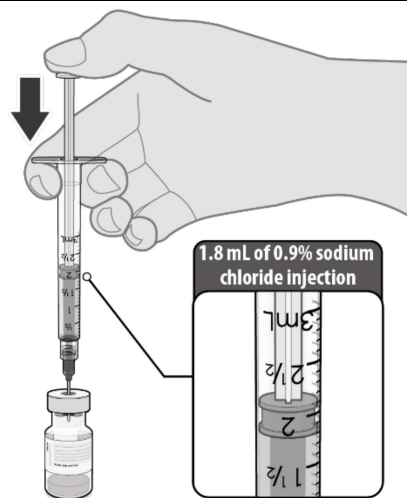


- Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by:
 - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to five days (120 hours).
 - Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes.
- Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.

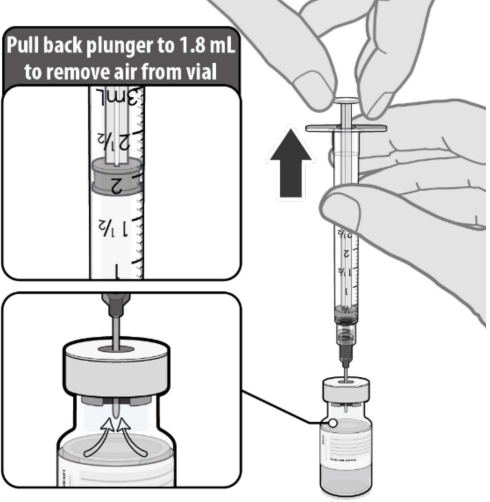
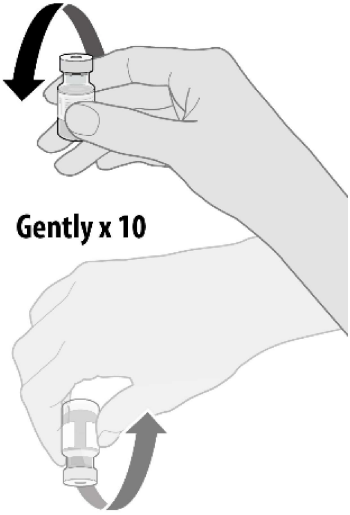
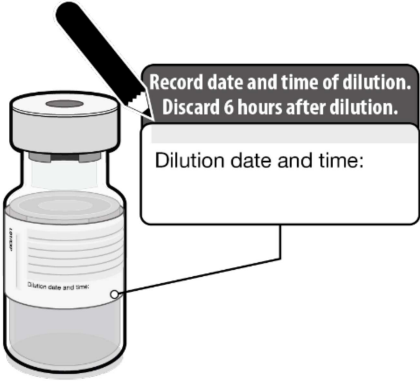


- Before dilution invert vaccine vial gently 10 times.
- Do not shake.
- Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles.
- Do not use if liquid is discolored or if other particles are observed.

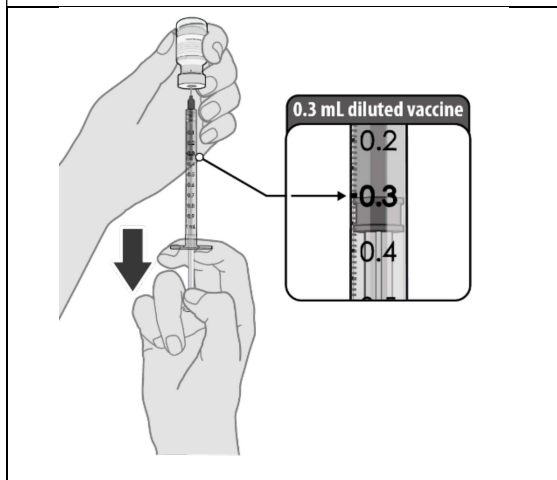
DILUTION²



- Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent.
- Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle).
- Cleanse the vaccine vial stopper with a single-use antiseptic swab.
- Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.

 <ul style="list-style-type: none">• Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.	
 <ul style="list-style-type: none">• Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix.• <u>Do not shake.</u>• Inspect the vaccine in the vial.• The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.	
 <ul style="list-style-type: none">• Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label.• Store between 2°C to 25°C (35°F to 77°F).• Discard any unused vaccine 6 hours after dilution.	

PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE²



- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine.
- Administer immediately.

Storage and Handling--Additional Points

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.²

Do not refreeze thawed vials.²

Thawed Vials Before Dilution

Thawed vials can be handled in room light conditions.²

Vials After Dilution

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Do not refreeze.²

Degradation of RNA in the vaccine has been observed when stored for longer than 6 hours in syringes. Microbiological risk was assessed through a microbiological challenge study which showed that microbiological growth has a greater potential to occur after 6 hours.¹

Dose Preparation

The EUA Prescribing Information states that after thawing and before dilution, invert the vials gently 10 times. Also, after dilution the EUA Prescribing Information states to gently invert the diluted vial 10 times to mix. Do not shake.²

Vials should be mixed before and after dilution by gentle inversion. No studies have been conducted to evaluate shaking of vials during vaccine preparation, but the results of the transportation study support the conclusion that the vaccine can be exposed to some shaking stress. Without additional data, vaccine vials which are aggressively shaken should be discarded.¹

Needle Size During Dose Preparation

Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle). Cleanse the vaccine vial stopper with a single-use antiseptic swab. Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.²

A 21 gauge or narrower needle must be used to add the diluent. Use of a larger needle does not harm the vaccine but may result in leaking from the stopper when doses are withdrawn. Stoppers meet USP<381>, ISO 8871-5, and Ph Eur 3.2.9 requirements for functional testing of the stopper (penetrability, fragmentation, and self-sealing capacity) when punctured up to 10 times with a 21 gauge needle and with an 18 gauge needle, however use of an 18 gauge needle in dose preparation studies led to leaking during dose withdrawal.¹

REFERENCES

1. Pfizer-BioNTech COVID-19 Vaccine. Data on file (28). Pfizer Inc.
2. Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccines including the Full EUA Prescribing Information. Pfizer/BioNTech.