

## Vaccines & Immunizations

# Pfizer–BioNTech COVID–19 Vaccine



**General Information:**

Diluent: 0.9% sodium chloride  
(normal saline, preservative-free)

**Mix before using**

Multi-dose vial: 5 doses per vial  
Dosage: 0.3 mL

**Age Indications:**

16 years of age and older

**Schedule:**

2 doses series separated by 21 days

Both doses must be COVID-19 vaccine (Pfizer)

**Administer:**

Intramuscular (IM) injection in the deltoid muscle



EUA



Interim Clinical Considerations



Pfizer BioNTech Covid-19 Vaccine FAQs



ACIP Recommendations



Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites

### Administration Overview

How to Thaw, Prepare, and Administer the Pfizer-BioNTech Vaccine

## How to thaw the vaccine

- Vaccine may be thawed in the refrigerator or at room temperature.
- Refrigerator: Between 2°C to 8°C (36°F to 46°F).
  - 25 to 195 vials may take 2 to 3 hours to thaw in the refrigerator.
  - Fewer number of vials will take less time.
- Room temperature (up to 25°C [77°F]) between 30 minutes and 2 hours.
- Vials at room temperature must be mixed within 2 hours or returned to the refrigerator.
- Do NOT refreeze thawed vaccine.

## How to prepare the vaccine

1. Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.\*
2. Remove vaccine from the freezer or refrigerator. Allow vaccine to come to room temperature. Vials can be held at room temperature for up to 2 hours before mixing. After 2 hours return unmixed vials to the refrigerator.
3. Before mixing, check the expiration dates of the vaccine and diluent. NEVER use expired vaccine or diluent.
4. With the vaccine at room temperature, gently invert vial 10 times. Do not shake the vial. If the vial is shaken, discard the vaccine. The vaccine is a white to off-white in color and may contain opaque particles. Do not use if liquid is discolored.
5. Using a new, sterile alcohol prep pad for each vial, wipe off the stoppers of the diluent and vaccine vials.
6. Using a 21-gauge (or narrower) needle, **withdraw 1.8 mL** of 0.9% sodium chloride (normal saline, preservative-free) into a mixing syringe. After use, discard diluent vial and remaining diluent.
7. Do NOT use bacteriostatic normal saline or other diluents to mix the vaccine.
8. Inject 1.8 mL 0.9% sodium chloride (normal saline, preservative-free) diluent into the vaccine vial.
9. Using the mixing syringe, remove 1.8 mL of air from the vaccine vial to equalize the pressure in the vaccine vial.
10. Gently invert the vial containing vaccine and diluent 10 times. The vaccine will be off-white in color. Do not use if discolored or contains particulate matter. Do not shake. If the vial is shaken, discard the vaccine.
11. Note the date and time the vaccine was mixed on the vial.
12. Keep mixed vaccine at room temperature (2°C to 25°C [36°F to 77°F]) and administer within 6 hours. Discard any unused vaccine after 6 hours. Do not return to refrigerator or freezer storage.

\*Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between patients.

1. Ensure staff has the correct PPE before administering vaccines and implement policies for the use of face coverings for people older than 2 years of age (if tolerated).
2. Choose the correct equipment, including the correct needle size. Use a new, sterile needle and syringe for each injection.
3. Cleanse the stopper on the vial of mixed vaccine with a new, sterile alcohol prep pad. Withdraw 0.3 mL of mixed vaccine into the syringe. Ensure the prepared syringe is not cold to the touch.
4. Remove any air bubbles with the needle still in the vial to avoid loss of vaccine. Use the same needle\* to withdraw and administer the vaccine, unless contaminated or damaged.
5. Administer the vaccine immediately by intramuscular (IM) injection in the deltoid muscle.

\*Changing needles between drawing vaccine from a vial and injecting it into a recipient is not necessary unless the needle has been damaged or contaminated.

## COVID-19 Vaccine (Pfizer) Administration Resources

[Pfizer Covid-19 Vaccine Standing Orders](#) 

[Preparation and Administration Summary](#) 

[Mixing Diluent and Vaccine Poster](#) 

[Pre-Vaccination Screening Form](#) 



### Document the Vaccination


COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system for the jurisdiction (i.e., immunization information system) as soon as practicable and no later than 72 hours after administration.

## Storage and Handling Overview



**Store vaccine in an ultra-cold freezer, thermal shipping container, or refrigerator.**

See guidance below for each storage unit.

- Vaccine will arrive at a temperature between -80°C and 60°C (-112°F to -76°F) in a thermal shipping container with dry ice. A signature will be required when the vaccine is delivered.
- The diluent and ancillary supply kits will arrive separately from the vaccine.
- Unpack the thermal shipping container following the [manufacturer's direction](#) .

## How to Store the Pfizer-BioNTech COVID-19 Vaccine

### Storing in the Thermal Shipping Container

CDC recommends providers consider using the thermal shipping container for temporary storage only. The container requires significant support to store vaccine at proper temperatures, including, trained staff, a regular supply of dry ice and standard operating procedures on regular maintenance.

Use the Controlant Temperature Monitoring Device (TMD), included with the thermal shipping container, to monitor the temperature.

- Up to 4 contacts can be identified to receive e-mails and text alerts on the temperature status of the container.
- Review daily e-mails on the status of the container.
- Save the final e-mail (full summary of status reports).

Replenish dry ice pellets (10 mm to 16 mm) within 24 hours of delivery and every 5 days after. Follow manufacturer's guidance for adding dry ice.

- Dry ice will be sent for the first re-icing.
- Additional dry ice shipments will NOT be provided. Arrange for dry ice to maintain the temperature of the container after the first re-ice.

Removing vaccine vials/doses for use:

- Determine the number of vials needed before opening the thermal shipping container.
- Open the thermal shipping container no more than 2 times per day for up to 3 minutes each time. Use packaging tape to reseal the outer carton after each entry.

Store vaccine vials upright in the tray and protect from light.

## Storing in an Ultra-Cold Freezer

Vaccine may be stored in an ultra-cold freezer between  $-80^{\circ}\text{C}$  and  $-60^{\circ}\text{C}$  ( $-112^{\circ}\text{F}$  and  $-76^{\circ}\text{F}$ ).

Use a digital data logger (DDL) with a probe designed specifically to measure ultra-cold temperatures. Check and record the temperature daily using a temperature log for ultra-cold storage units. Use one of the options below:

- **Option 1:** If the DDL can measure minimum/maximum temperatures (min/max), check and record the min/max temperatures at the start of each
- **Option 2:** If the DDL does not read min/max temperatures, check and record the current temperature at the start and end of each workday.

Vaccine may be stored until the expiration date. The expiration date could be extended as more stability data become available. Store vaccine vials upright in the tray and protect from light.

## Storing in the Refrigerator

Before mixing, the vaccine may be stored in the refrigerator between  $2^{\circ}\text{C}$  and  $8^{\circ}\text{C}$  ( $36^{\circ}\text{F}$  and  $46^{\circ}\text{F}$ ) for up to 120 hours (5 days). After 120 hours (5 days), remove any remaining vials from the refrigerator and discard following the manufacturer's and your jurisdiction's guidance on proper disposal.

Use a DDL with a detachable probe that best reflects vaccine temperatures (e.g., probe buffered with glycol, glass beads, sand, or Teflon®). Check and record the temperature daily using a temperature log for ultra-cold storage units. Use one of the options below:

- **Option 1:** If the DDL can measure minimum/maximum temperatures (min/max), check and record the min/max temperatures at the start of each workday.
- **Option 2:** If the DDL does not read min/max temperatures, check and record the current temperature at the start and end of each workday.

Use beyond use date labels to track how long the vaccine has been in the refrigerator. Monitor the beyond-use-date/time.

- Place vaccine vials removed from frozen storage at the same time together in a resealable plastic bag or similar container.
- Complete the information on the storage label and attach it to the container holding the unmixed vaccine
- Once labeled, store unmixed vaccine vials upright in the refrigerator.

**Thawed vaccine cannot be refrozen.**

## Storing Diluent

0.9% sodium chloride (normal saline, preservative-free) diluent is included in the ancillary supply kits. Follow the manufacturer's guidance for storing the diluent.

# COVID-19 Vaccine (Pfizer) Storage and Handling Resources

[Storage and Handling Summary](#) 

[Pfizer BUD Guidance and Labels](#) 

[Delivery Checklist](#) 

[Storage and Handling Labels](#) 

[Vaccine Expiration Date Tracking Tool](#) 

[Refrigerator Storage Logger \(Celsius\)](#) 

[Refrigerator Storage Logger \(Fahrenheit\)](#) 


[Ultra-Cold Vaccine Storage Logger \(Fahrenheit\)](#) 

[Ultra-Cold Vaccine Storage Logger \(Celsius\)](#) 

[Dry Ice Safety](#) 




## Report Adverse Events

Adverse events that occur in a recipient after COVID-19 vaccination are required to be reported to the Vaccine Adverse Events Reporting System (VAERS). FDA requires vaccination providers report vaccination administration errors, serious adverse events, cases of multisystem inflammatory syndrome, and cases of COVID-19 that result in hospitalization or death after administration of COVID-19 vaccine under EUA. Reporting is encouraged for other clinically significant adverse events, whether it is clear that a vaccine caused the adverse event. Complete and submit reports to [VAERS online](#) .

For further assistance with reporting to VAERS, call 1-800-822-7967.



## What to Expect after a COVID-19 Vaccination

[Print out information](#)  on the common side effects, helpful tips, and when to call a doctor after a COVID-19 vaccination for your patients.

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