Centers for Disease Control and Prevention

Vaccines & Immunizations

Pfizer-BioNTech COVID-19 Vaccine

General Information:
Vaccine: Pfizer-BioNTech COVID-19 Vaccine
Diluent: 0.9% sodium chloride (normal saline, preservative-free)

Vaccine MUST be mixed with diluent before administration.
Multidose vial: Up to 6 doses per vial
Dosage: 0.3 mL

Age Indications:
16 years of age and older

Schedule:
2-dose series separated by 21 days)
A series started with COVID-19 vaccine (Pfizer) should be completed with this product.

Administer:
Intramuscular (IM) injection in the deltoid muscle

EUA

Interim Clinical Considerations

Pfizer BioNTech Covid-19 Vaccine FAQs

ACIP Recommendations

Get the Pfizer-BioNTech COVID-19 Vaccine Training Module for Healthcare Professionals

Administration Overview

Before administering vaccine, screen recipients for contraindications and precautions, even if this is the second dose. The recipient's health condition or recommendations regarding contraindications and precautions for vaccination may change from one visit to the next.

To assess recipients correctly and consistently, vaccination providers should use a standardized, comprehensive screening tool.

Contraindications and Precautions

What are the Contraindications and Precautions +

- Contraindications
  - Severe allergic reaction (e.g., anaphylaxis) to a previous dose or component of either mRNA COVID-19 vaccine. See Appendix B: Ingredients included in Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines.

    - Immediate allergic reaction* of any severity to a previous dose or component of an mRNA COVID-19 vaccine (including polyethylene glycol [(PEG])
    - Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)
- Precautions
    - History of an immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines)
    - Moderate to severe acute illness

*For the purpose of this guidance, an immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms, such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis, that occur within 4 hours following exposure to a previous dose of an mRNA COVID-19 vaccine or any of its components.

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 and 8°C (36°F and 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 25^0C (77^0F) 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. Assess recipient status:
    - Screen for contraindications and precautions.
    - Review vaccination history.
2. Follow aseptic technique. Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.*
3. 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.
4. Before mixing, check the expiration dates of the vaccine and diluent. NEVER use expired vaccine or diluent.
5. With the vaccine at room temperature, gently invert the vial 10 times. Do not shake the vial. If the vial is shaken, discard the vaccine. The vaccine is white to off-white in color and may contain opaque particles. Do not use if liquid is discolored.
6. Using a new, sterile alcohol prep pad for each vial, wipe off the stoppers of the diluent and vaccine vials.
7. 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 any remaining diluent.
    - Do NOT use or save the remaining vaccine diluent to mix additional vaccine or for other uses.
    - 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 between 2^0C and 25^0C (36^0F and 77^0F) and administer within 6 hours. Discard any unused vaccine after 6 hours. Do not return to 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

How to Administer the Vaccine +

1. Choose the correct equipment, including the correct needle size. Use a new, sterile needle and syringe for each injection.
2. 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.
3. 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.
4. Bring the dose of vaccine from the designated preparation area immediately to the patient treatment area for administration.
5. 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).
6. Administer the vaccine immediately by intramuscular (IM) injection in the deltoid muscle.
7. Observe recipients after vaccination for an immediate adverse reaction:
    - **30 minutes**: Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause
    - **15 minutes**: All other persons

*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.

Scheduling Doses +

- Persons age 18 years and older should receive **2 doses at least 21 days apart**.
    - Second doses administered up to 4 days before the recommended date (17 or more days after first dose) are considered valid. However, doses administered earlier do not need to be repeated.
    - **Second doses should be administered as close to the recommended interval as possible.**
        - **Do not use the grace period to schedule appointments for the second dose.**
    - There is no maximum interval between the first and second dose.
- Both doses should be Pfizer-BioNTech COVID-19 vaccine.
    - The safety and efficacy of a mixed-product series have not been evaluated. Both doses of the series should be completed with the same product. However, if 2 doses of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended at this time.
- Administer the vaccine series alone. Do not administer mRNA COVID-19 vaccine at the same time as other vaccines, and wait a minimum interval of 14 days before or after administration of any other vaccine.
    - If mRNA COVID-19 vaccines are inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.

COVID-19 Vaccine (Pfizer) Administration Resources

Pfizer COVID-19 Vaccine Standing Orders

Preparation and Administration Summary

Mixing Diluent and Vaccine Poster

Prevaccination Screening Form
English | Español

Vaccine administration training and clinical materials

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. The diluent and ancillary supply kits are packaged separately from the vaccine.
- Unpack the thermal shipping container following the manufacturer's directions .

How to Store the Pfizer-BioNTech COVID-19 Vaccine

Storing in the Thermal Shipping Container +

CDC recommends 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 for regular maintenance.

Use the Controlant temperature monitoring device (TMD), included with the thermal shipping container, to monitor the temperature.

- Press and hold the "Stop Shipment" button on the TMD for 5 seconds.
- This triggers an e-mail report from the manufacturer on the temperature status of the container during transit. The report will be sent to the provider (facility) e-mail address associated with the order.
- 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 thereafter. Follow the 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^{0}C and -60^{0}C (-112^{0}F and -76^{0}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: Minimum/Maximum (Min/Max) Temperature (preferred)
  Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.

- Option 2: Current Temperature
  If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday. Review the continuous DDL temperature data daily.

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 2^0C and 8^0C (36^0F and 46^0F) for up to 120 hours (5 days). After 120 hours (5 days), remove any remaining vials from the refrigerator and discard following manufacturer and jurisdiction 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 and one of the options below:

- Option 1: Minimum/Maximum (Min/Max) Temperature (preferred)
  Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.

- Option 2: Current Temperature
  If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday. Review the continuous DDL temperature data daily.

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

- 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.

Temperature Excursions +

Temperature excursions or inappropriate storage conditions for any vaccine require immediate action. Any temperature reading outside the recommended ranges is considered a temperature excursion. It is important to note that vaccine manufacturer responses to temperature excursion reports are dependent on information given by the provider to the manufacturer. Completing the Vaccine Troubleshooting Record can help provide needed information for manufacturers to determine the viability of the vaccine.

COVID-19 Vaccine (Pfizer) Storage and Handling Resources

Storage and Handling Summary

Delivery Checklist

Pfizer BUD Guidance and Labels

Vaccine Expiration Date Tracking Tool

Refrigerator Storage Temperature Log (Celsius)

Refrigerator Storage Temperature Log (Fahrenheit)

Ultra-Cold Vaccine Storage Temperature Log (Fahrenheit)

Storage and Handling Labels

Ultra-Cold Vaccine Storage Temperature Log (Celsius)

Vaccine Storage Troubleshooting Record for temperature excursions

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 Event Reporting System (VAERS). FDA requires vaccination providers to report vaccine 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 an EUA. Reporting is encouraged for other clinically significant adverse events, even if it is not 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 information for your patients on common side effects, helpful tips, and when to call a doctor after a COVID-19 vaccination.

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