Pfizer-BioNTech COVID-19 Vaccine (Gray Cap) Age 12 and Over

General Pfizer-BioNTech Vaccine Information

Vaccine: Pfizer-BioNTech COVID-19 Vaccine (gray cap)

DO **NOT** DILUTE THIS FORMULATION.

Discard vial when there is not enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose.

Dosing Information

Do NOT Dilute this formulation before administration.

Multidose vial: Up to 6 doses per vial

Dosage: 0.3 mL

Age Indications

12 years of age and older

Schedule

Primary Series:

2-dose series separated by 21 days*

A series started with Pfizer-BioNTech COVID-19 Vaccine should be completed with this product

Additional Primary Dose:

Moderately and severely immunocompromised people: Administer an additional primary dose at least 28 days after the initial 2-dose primary series.

Booster Dose:

Administer a booster dose at least 6 months after the last dose of a COVID-19 mRNA vaccine primary series (i.e., the 2nd dose or additional primary series dose for moderately or severely immunocompromised people).

- Should be given to people 18 years of age and older (use of heterologous – mix and match – booster doses is allowed; however, mRNA COVID-19 vaccines are preferred)
- May be given to people 16 and 17 years of age based on their individual benefits and risks

Administration

Intramuscular (IM) injection in the deltoid muscle.

Emergency Use Authorization (EUA)

Emergency Use Instructions (EUI)

Interim Clinical Considerations

Pfizer BioNTech COVID-19 Vaccine by Age and Cap Color

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 the recipient is scheduled to receive 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

- History of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- Known diagnosed allergy to a component of the vaccine

Precautions

- History of an immediate allergic reaction[†] to any non-COVID-19 vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies)
  - This includes non-COVID-19 vaccines or injectable therapies with multiple components, and the component(s) that elicited the reaction is unknown.
- History of an immediate (within 4 hours after vaccination) non-severe, allergic reaction to a previous dose of the COVID-19 vaccine

- Contraindication to one type of COVID-19 vaccines (mRNA) is a precaution to other types of COVID-19 vaccines (Janssen) ±
- Moderate to severe acute illness

†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 vaccine or medication.

± Consider consultation with an allergist-immunologist to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVID vax Project. Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

- People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy) have a precaution to Janssen COVID-19 vaccination. People who have previously received an mRNA COVID-19 vaccine dose should wait at least 28 days to receive Janssen COVID-19 vaccine.
- People with a contraindication to Janssen COVID-19 vaccine (including due to a known polysorbate allergy) have a precaution to mRNA COVID-19 vaccination.

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.
  - Unpunctured vials may be stored in the refrigerator for up to 10 weeks
  - Unpunctured vials may be stored between 8°C and 25°C (46°F and 77°F) for a total of 12 hours prior to first puncture.
- Room temperature: Up to 25°C (77°F)
  - Unpunctured vials may be held at room temperature for up to 2 hours (including thaw time).
- Amount of time needed to thaw vaccine varies based on temperature and number of vials.
- Do NOT refreeze thawed vaccine.
- Use CDC's beyond-use date labels for this vaccine to track storage time at refrigerated and frozen temperatures.

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. **Check the vial label to ensure it is the correct formulation based on the age of the recipient. The vial for persons 12 years of age and older that does NOT require diluent has a gray cap and gray boarder on the label.** Allow vaccine to come to room temperature. Vials can be held at room temperature for up to 12 hours before first puncture of the vial stopper
3. Check the:
   - Expiration date on the
   - Any beyond use dates or times
   - NEVER use expired vaccine. NEVER use vaccine after the beyond-use dates or times.
4. With the vaccine at room temperature, gently invert the vial 10 times. Do **NOT** shake the vial. If the vial is shaken, contact the manufacturer. The vaccine is white to off-white in color with no visible particles. Do not use if liquid is discolored or if particles are observed after inverting.

*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.

How to Administer the Vaccine

1. Assess recipient status:
    - Screen for contraindications and precautions.
    - Review vaccination history.
    - Review medical considerations.
2. Choose the correct equipment, including the correct needle size. Use a new sterile needle and syringe for each injection.
3. Clean the stopper on the multidose vial of vaccine with a new, sterile alcohol prep pad. Withdraw 0.3 mL of vaccine into the syringe.
4. Remove any significant air bubbles with the needle still in the vial to avoid loss of vaccine. Ensure the prepared syringe is not cold to the touch.
5. Not the date and time the vaccine was first punctured on the vial. Keep punctured vials of vaccine between 2^{0}C and 25^{0}C (36^{0}F and 77^{0}F) for up to 12 hours. Discard any unused vaccine after 12 hours. Do not return to ultra-cold freezer storage.
6. Bring the dose of vaccine from the designated preparation area immediately to the patient treatment area for administration. **The vial for persons 12 years of age and older has a gray cap and gray border on the label.** Do NOT administer vaccine with an orange cap or has an orange boarded label on the vial.
7. Ensure staff has the correct PPE before administering vaccines and implement policies for the use of face coverings for vaccine recipients (if tolerated).
8. Administer the vaccine immediately by intramuscular (IM) injection in the deltoid muscle.
9. Observe recipients after vaccination for an immediate adverse reaction:
    - 30 minutes: Persons with a history of
        - A contraindication to another type of COVID-19 vaccine product
        - Immediate (within 4 hours of exposure) non-severe allergic reaction to a non-COVID-10 vaccine or injectable therapies
        - Immediate allergic reaction of any severity to a non-COVID-19 vaccine or injectable therapies
        - 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 12 years and older should receive **2 doses at least 21 days apart**.
    - **Second doses should be administered as close to the recommended interval as possible.**
        - Doses inadvertently given before the 4-day grace period (i.e., less than 17 days apart) should be repeated.
    - Both doses should be Pfizer-BioNTech COVID-19 Vaccine.
        - Every effort should be made to determine which vaccine product was received as the first dose.
        - In exceptional situations, if the vaccine product given as the first dose cannot be determined or is no longer available, any mRNA COVID-19 vaccine product may be administered at least 28 days after the first dose.
    - Moderately to severely immunocompromised people: Administer an additional dose at least 28 days after the initial 2-dose primary series.

- For more information, please see Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States
- Administer a booster dose at least 6 months after the last dose of a COVID-19 mRNA vaccine primary series (i.e., the 2nd dose or additional primary series dose for moderately or severely immunocompromised people).
  - Should be given to people 18 years of age and older (use of heterologous – mix and match – booster doses is allowed; however, mRNA COVID-19 vaccines are preferred)
  - May be given to people 16 and 17 years of age based on their individual benefits and risks
- COVID-19 vaccines and other vaccines may be coadministered with other vaccines, including simultaneous administration.

COVID-19 Vaccine (Pfizer) Administration Resources

› Pfizer COVID-19 Vaccine (Gray Cap) Standing Orders (12 years of age and older) (updated 12/21/21)

› Preparation and Administration Summary (Gray Cap)

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 or refrigerator.
DO NOT STORE VACCINE IN FREEZER.
See guidance below for each storage unit.

- Vaccine will arrive at a temperature between -90°C and -60°C (-130°F to -76°F) in a thermal shipping container with dry ice. The vial for people 12 years of age and older that does not require diluent has a gray cap and gray border on the label.
- An ancillary supply kit will arrive separately from the vaccine.
- Follow the manufacturer's guidance for unpacking the vaccine .
- Remove the temperature monitoring device from the shipping container and return using the included prelabeled foldable return box.
- Dispose of the single-use thermal shipping container. Do NOT use the thermal shipping container for storage.*

*Thermal shipping containers delivered to Alaska, Hawaii, and the US-affiliated Pacific Islands may be used as temporary storage. Refer to the manufacturer for more detailed guidance on using the thermal shipping container for storage: https://www.cvdvaccine-us.com/product-storage-and-dry-ice

How to Store the Pfizer-BioNTech COVID-19 Vaccine

Storing in the Thermal Shipping Container

Do NOT store the 12 years of age and older formulation (gray cap) in the thermal shipping container.

Storing in an Ultra-Cold Freezer

Before mixing, the vaccine may be stored in an ultra-cold freezer between -90^{0}C and -60^{0}C (-130^{0}F and -76^{0}F).

Store vaccine vials upright in the tray or box.

- Protect from light.
- Vaccine may be stored until the expiration date. Vaccine expires 9 months after the manufacture date.
- The manufacture date is printed on the vial (gray cap)
- Count out 9 months, using the month printed on the vial as month 1.
- The vaccine expires on the last day of the 9th month
- Expired vaccine should NEVER be administered. To prevent this, use CDC's COVID-19 Vaccine Expiration Date Tracking Tool
- As the expiration date approaches, contact the manufacturer to determine if it has been extended. Do not discard vaccine without ensuring the expiration date has passed.

Storing in the Freezer

Do NOT store the 12 years of age and older formulation (gray cap) in the freezer.

Storing in the Refrigerator

Before first puncture of the vial stopper, the vaccine may be stored in the refrigerator between 2^{0}C and 8^{0}C (36^{0}F and 46^{0}F) for up to 10 weeks. After ten weeks, contact the manufacturer for guidance. If directed to discard any remaining vials, follow manufacturer's and jurisdiction's guidance on proper disposal.

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

Store vaccine in the tray or box and protect from light.

Do NOT refreeze thawed vaccine.

Monitoring Temperature

Ultra-cold freezer or refrigerator: Storage unit temperatures must be monitored regularly, checked, and recorded at the beginning of the workday to determine if any temperature excursions have occurred since the last temperature check. For accurate temperature monitoring, use a digital data logger (DDL) with a detachable probe that best reflects vaccine temperatures.

- Ultra-cold temperatures: Use a probe designed specifically to measure ultra-cold temperatures.
- Refrigerated storage: Use a probe buffered with glycol, glass beads, sand, or Teflon®.

Check and record the temperature daily using CDC's temperature log. Use one of the options below:

- **Option 1 (preferred): Minimum/Maximum (Min/Max) Temperatures** Most DDLs display min/max 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.

temperature at the start and end of the workday. Review the continuous DDL temperature data daily.

For CDC temperature logs, see Storage and Handling Resources below.

Storing Diluent

The 12 years of age and older formulation (gray cap) does NOT require 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. 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 (Gray Cap)
- Pfizer (Gray Cap) BUD Guidance and Labels
- Storage and Handling Labels (Gray Cap)
- Vaccine Expiration Date Tracking Tool
- Refrigerator Storage Temperature Log (Celsius)
- Refrigerator Storage Temperature Log (Fahrenheit)
- Ultra-Cold Vaccine Storage Temperature Log (Fahrenheit)
- 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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