

Pfizer-BioNTech COVID-19 Vaccine, MONOVALENT

[GRAY cap with GRAY Label Border]

Primary Series for 12 Years of Age and Older

Formulation, Storage, Preparation, Dispensing and Administration Instructions for Use

The U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals who meet certain criteria.

The FDA Pfizer-BioNTech COVID-19 Vaccines website has the most up-to-date information.

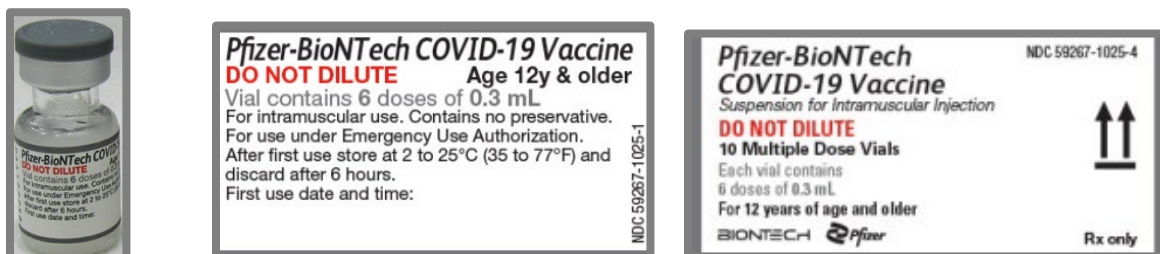
(<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccines>)

1. VACCINE FORMULATION AND DESCRIPTION

Pfizer-BioNTech COVID-19 Vaccine with **gray cap and gray label border** is supplied as a frozen suspension for intramuscular injection in multiple dose vials containing 2.25 mL per vial. The vaccine must be thawed prior to preparation and administration. **DO NOT DILUTE PRIOR TO USE.**

Each **0.3 mL** dose of the Pfizer-BioNTech COVID-19 Vaccine supplied in multiple dose vials with **gray caps and gray label borders** contains **30 mcg of modRNA** encoding the viral spike (S) glycoprotein of the SARS-CoV-2 Wuhan-Hu-1 strain. Each 0.3 mL dose also includes the following ingredients: lipids (0.43 mg ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.19 mg cholesterol), 0.06 mg tromethamine, 0.4 mg tromethamine hydrochloride, and 31 mg sucrose.

The Pfizer-BioNTech COVID-19 Vaccine does not contain preservative, and the vial stoppers are not made with natural rubber latex.



NDC 59267-1025-1: Multiple dose vial; contains 6 doses of 0.3 mL

NDC 59267-1025-4: Carton containing 10 multiple dose vials

Reference: *Fact Sheet For Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (Gray Cap and Gray Label Borders)*, Revised: 8 December 2022
(<https://www.fda.gov/media/153715/download>)

2. STORAGE AND HANDLING

Pfizer-BioNTech COVID-19 Vaccine vials with **gray cap** and **gray label border** will be shipped to sites frozen at ultra-cold conditions in thermal containers with dry ice. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Refer to the protocol-specific pharmacy manual for quantities of initial and subsequent shipments sent to your site. (*As of August 31, 2022, this formulation is no longer used in DAIT studies*)

2.1. Vial Storage Prior to Use

2.1.1. Freezer: Once the shipment is received, remove the vial cartons from the shipping container and store vaccine in an ultra-low temperature freezer at -90°C to -60°C (-130°F to -76°F) for up to 18 months from the date of manufacture.

DO NOT store vials at -25°C to -15°C (-13°F to 5°F).

2.1.2. Refrigerator: Frozen vials may be transferred to the refrigerator [2°C to 8°C (35°F to 46°F)], thawed and stored for up to 10 weeks. A carton of 10 multiple dose vials may take up to 6 hours to thaw in the refrigerator. The 10-week refrigerated expiry date should be recorded on the carton at the time of transfer. Once vials are thawed, they should not be refrozen.

Regardless of storage condition, the vaccine should not be used after 18 months from the date of manufacture printed on the vial and cartons.

2.2. Vaccine Storage During Use

2.2.1. Vaccine Vial Storage During Use

If not previously thawed at 2°C to 8°C (35°F to 46°F), allow vials to thaw at room temperature [up to 25°C (77°F)] for 30 minutes.

Pfizer-BioNTech COVID-19 Vaccine multiple dose vials with gray caps and labels with gray borders may be stored at room temperature [8°C to 25°C (46°F to 77°F)] for a total of 12 hours prior to the first puncture. After first puncture, the vial should be held between 2°C to 25°C (35°F to 77°F). Vials should be discarded 12 hours after first puncture. Disregard instructions on vial and carton labels which state that a vial should be discarded 6 hours after the first puncture.

DO NOT DILUTE PRIOR TO USE.

2.2.2. Prepared Syringe Storage

Prepared syringes of the Pfizer-BioNTech COVID-19 Vaccine (**gray cap** and **gray label borders**) should be stored between 2°C to 25°C (35°F to 77°F) and administered within 12 hours after first puncture. Discard punctured vial and prepared syringes after 12 hours. Do not refreeze prepared syringes.

2.3. Transportation of Vials

If local redistribution is needed, undiluted vials may be transported at -90°C to -60°C (-130°F to -76°F) or at 2°C to 8°C (35°F to 46°F), when using shipping containers which have been qualified to maintain temperature and under routine transport conditions with shaking and vibration minimized. **Transporting punctured vials is not allowed.**

Approvals are needed from DAIT/ NIAID for any local transportations greater than 10 minutes.

3. DOSAGE, SCHEDULE, AND ADMINISTRATION

Refer to each DAIT protocol for the protocol-specific dose, dosing frequency and administration schedule. *(As of August 31, 2022, this formulation is no longer used in DAIT studies)*

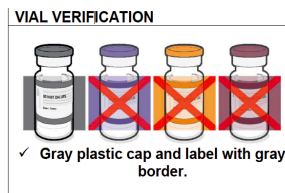
4. VACCINE DOSE PREPARATION AND DISPENSING

4.1. SUPPLIES NEEDED

- Pfizer-BioNTech COVID-19 Vaccine vial with **gray cap** and **gray label border**
- 1 mL syringes (provided by DAIT)
- 23 – 25 gauge 1” or 1.5” needles (provided by DAIT)
- Sterile alcohol pads
- Pre-printed protocol-specific participant syringe dispensing labels
- Pre-printed syringe labels for public vaccination (if applicable)

4.2. PREPARATION AND DISPENSING INSTRUCTIONS

1. Receive a Protocol-Specific COVID-19 Vaccination Prescription Form or electronic order.
2. Remove the required number of Pfizer-BioNTech COVID-19 Vaccine vials from storage.
3. Verify that the vial of Pfizer-BioNTech COVID-19 Vaccine has a **gray cap** and **gray label border**.



4. Thaw Pfizer-BioNTech COVID-19 Vaccine vial before use either by:
 - a. Allowing the vial to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of 10 vials may take up to 6 hours in the refrigerator.
 - b. Allowing the vial to sit at room temperature [up to 25°C (77°F)] for 30 minutes.
 - c. After thawing do not refreeze.
5. Before use, mix by inverting vaccine vial gently 10 times. **Do not shake.**



- a. Inspect the vial contents before mixing; the thawed vaccine may contain white to off-white opaque amorphous particles.
 - b. Inspect the liquid in the vial after mixing; The vaccine should appear as a white to off-white suspension with no visible particles. Do not use if liquid is discolored or if other particles are observed.
6. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw the protocol-specified dose of Pfizer-BioNTech COVID-19 Vaccine using the provided syringes and needles. **DO NOT DILUTE PRIOR TO PREPARATION.**



- a. Record the date and time of first vial puncture on the vial label
 - b. The administration needle size will depend on the participant's weight and size
7. Cap the syringe with an administration needle or syringe cap, according to your institution's procedure, and keep sterile.
8. Label each prepared syringe with the provided pre-printed protocol-specific participant labels.
- a. Complete the syringe label with the following information: Participant ID, Participant Initials, Dose, Vaccine Preparation Date and Time, Expiration Date and Time, Pharmacist Initials
9. Repeat Steps 5 through 8 for study participants.
- a. Document preparation/dispensing information on the COVID-19 Vaccine Accountability Record (Form G) and the Participant-Specific Accountability, Preparation, And Treatment Assignment Record
10. If the protocol and your institution allow providing public doses of vaccine, follow steps 5 and 7 and label the prepared syringe with non-protocol-specific pre-printed labels for public vaccination
- a. Refer to the most recent Emergency Use Authorization instructions for the age-appropriate dose.
 - b. Document preparation/dispensing information on the Patient / Recipient-Specific Accountability and Preparation, and Administration Record (if applicable) and follow the instructions on the form to fill in the required information
11. If the amount of vaccine remaining in the vial cannot provide a full dose, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.
12. Store the prepared syringes between 2°C to 25°C (35°F to 77°F).
13. Document any unused syringes and discard them 12 hours after the first vial puncture, according to your institution's destruction policy.