

# Pfizer-BioNTech COVID-19 Vaccine, MONOVALENT

[ **MAROON cap** with **MAROON Label Border** ]

For 6 Months through 4 Years of Age

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

The U.S. Food and Drug Administration (FDA) has 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.

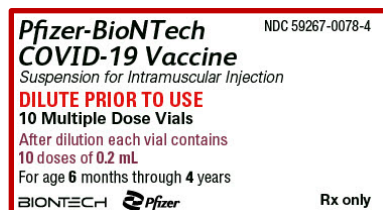
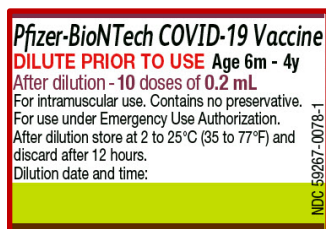
(<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccines>)

### 1. VACCINE FORMULATION AND DESCRIPTION

Pfizer-BioNTech COVID-19 Vaccine with **maroon cap** and **maroon label border** is supplied as a frozen suspension for intramuscular injection in multiple dose vials containing 0.4 mL per vial. **The vaccine must be thawed and diluted with 0.9% Sodium Chloride Injection, USP prior to preparation and administration.**

Each **0.2 mL** dose of the Pfizer-BioNTech COVID-19 Vaccine supplied in multiple dose vials with **maroon caps** and **maroon label borders** contains **3 mcg of modRNA** encoding the viral spike (S) glycoprotein of the SARS-CoV-2 Wuhan-Hu-1 strain (Original). Each 0.2 mL dose also includes the following ingredients: lipids (0.04 mg ((4hydroxybutyl) azanediyl) bis(hexane-6,1-diyl) bis(2-hexyldecanoate), 0.005 mg 2[(polyethylene glycol)-2000] N, N-ditetradecylacetamide, 0.01 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.02 mg cholesterol), 3.2 mg sucrose, 0.006 mg tromethamine, and 0.04 mg tromethamine hydrochloride. The diluent (sterile 0.9% Sodium Chloride Injection, USP) contributes 1.52 mg sodium chloride per dose.

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



NDC 59267-0078-1: Multiple dose vial; contains 10 doses of 0.2 mL (**after dilution**)

NDC 59267-0078-4: 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 (Maroon Cap and Maroon Label Borders)*, Revised: 14 March 2023  
(<https://www.fda.gov/media/159312/download>)

## **2. STORAGE AND HANDLING**

Pfizer-BioNTech COVID-19 Vaccine vials with **maroon caps** and **maroon label borders** 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 December 8, 2022, this formulation is not used in DAIT studies)*

### **2.1. Vaccine 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 2 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 (**maroon caps** and **maroon label 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 dilution.

**After dilution**, the vial should be held between 2°C to 25°C (35°F to 77°F). Vials should be discarded 12 hours after dilution. Disregard instructions on vial and carton labels which state that a vial should be discarded 6 hours after dilution.

#### **2.2.2. Prepared Syringe Storage**

Prepared syringes of the Pfizer-BioNTech COVID-19 Vaccine (**maroon cap** and **maroon label border**) should be stored between 2° to 25°C (35° to 77°F) and administered within 12 hours after dilution. Discard vial and prepared syringes 12 hours after dilution. 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 diluted 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 December 8, 2022, this formulation is not used in DAIT studies)*

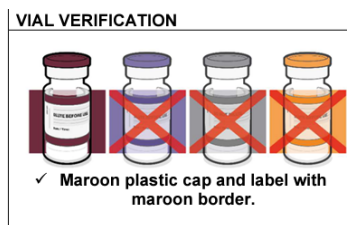
### **4. VACCINE DOSE PREPARATION AND DISPENSING**

#### **4.1. SUPPLIES NEEDED**

- Pfizer-BioNTech COVID-19 Vaccine vial with **maroon cap** and **maroon label border**
- Diluent: sterile, preservative-free 0.9% Sodium Chloride for Injection, USP (provided by DAIT)
- 3 mL syringe and 21G x 1.5” needle for mixing
- 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 **maroon cap** and **maroon label border**.

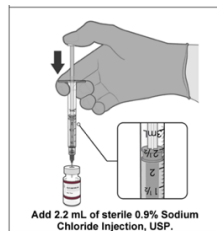


4. Thaw Pfizer-BioNTech COVID-19 Vaccine vial before use either by:
  - a. Allowing the vial to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of 10 vials may take up to 2 hours to thaw in the refrigerator.
  - b. Allowing the vial to sit at room temperature [up to 25°C (77°F)] for 30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

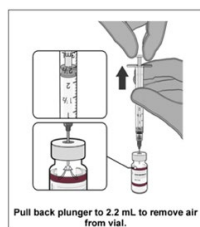
5. Before dilution, mix by inverting vaccine vial gently 10 times. **Do not shake.**



- a. Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain opaque amorphous particles.
  - b. Do not use if liquid is discolored or if other particles are observed. Complete an Investigational Product Complaint Form M and submit to DAIT.
6. Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent.
- a. Using aseptic technique, withdraw **2.2 mL** of diluent into a transfer syringe (21-gauge or narrower needle). Cleanse the vaccine vial stopper with a single-use antiseptic swab. Add **2.2 mL** of sterile 0.9% Sodium Chloride Injection, USP into the vaccine vial



7. Equalize vial pressure before removing the needle from the vial by withdrawing 2.2 mL air into the empty diluent syringe.



8. Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. **Do not shake.** Inspect the vaccine in the vial. The vaccine will be a white to off-white suspension. Do not use if vaccine is discolored or contains particulate matter.



9. Record the date and time of dilution on the vial label. Store the diluted vial between 2° to 25°C (35° to 77°F). Discard any unused vaccine 12 hours after dilution.
10. 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.
  - a. The administration needle size will depend on the participant's weight and size
11. Cap the syringe with an administration needle or syringe cap, according to your institution's procedure, and keep sterile.
12. 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
13. Repeat Steps 10 through 12 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
14. If the protocol and your institution allow providing public doses of vaccine, follow steps 10 and 11 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
15. 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.
16. Store the prepared syringes between 2°C to 25°C (35°F to 77°F).
17. Document any unused syringes on the COVID-19 Vaccine Accountability Record (Form G) and discard them and discard them 12 hours after dilution, according to your institution's destruction policy.