Pfizer-BioNTech COVID-19 Vaccine, BIVALENT (Original and Omicron BA.4/BA.5)

[GRAY cap with GRAY Label Border]

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

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals who meet certain criteria.

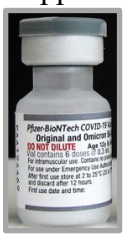
The FDA Pfizer-BioNTech COVID-19 Vaccines website has the most up-to-date information. (https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccines)

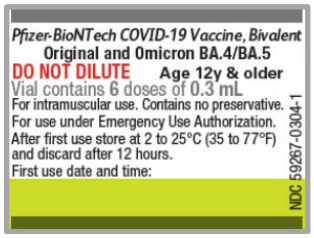
1. VACCINE FORMULATION AND DESCRIPTION

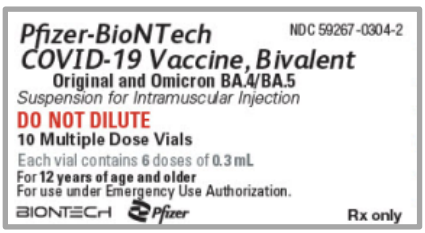
Pfizer-BioNTech Bivalent COVID-19 Vaccine with **gray cap** and **gray label border** is supplied as a frozen suspension for intramuscular injection in single dose and multiple dose vials. The vaccine must be thawed prior to preparation and administration. **DO NOT DILUTE PRIOR TO USE**.

Each 0.3 mL of the Pfizer-BioNTech Bivalent COVID-19 Vaccine, supplied in single dose and multiple dose vials with **gray caps** and **gray label borders,** is formulated to contain 15 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 Wuhan-Hu-1 strain (Original) and 15 mcg of modRNA encoding the S glycoprotein of SARS-CoV-2 Omicron variant lineages BA.4 and BA.5 (Omicron BA.4/BA.5). The S-proteins of the SARS-CoV-2 Omicron variant lineages BA.4 and BA.5 are identical. **Each 0.3 mL dose contains 30 mcg modRNA**. Each 0.3 mL dose of the Pfizer-BioNTech Bivalent COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg ((4-hydroxybutyl) azanediyl) bis(hexane-6,1diyl)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 Bivalent COVID-19 Vaccine does not contain preservative, and the vial stoppers are not made with natural rubber latex.







NDC 59267-0304-1: Multiple dose vial; contains six doses of 0.3 mL
NDC 59267-0304-2: Carton of 10 multiple dose vials

Reference: *Fact Sheet for Healthcare Providers Administering Vaccine: Emergency Use Authorization of Pfizer BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5, Revised 18 April 2023 (https://www.fda.gov/media/167211/download)*

2. STORAGE AND HANDLING

Pfizer-BioNTech Bivalent COVID-19 Vaccine with **gray caps** and **gray 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.

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 -90ºC to -60ºC (-130ºF to -76ºF) 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 [2ºC to 8ºC (35ºF to 46ºF)], thawed and stored for up to 10 weeks. A carton of 10 single dose vials may take up to 2 hours to thaw at this temperature. A carton of 10 multiple dose vials may take up to 6 hours to thaw at this temperature.

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

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

Pfizer-BioNTech Bivalent COVID-19 Vaccine may be stored at room temperature [up to 25ºC (77ºF)] for a total of 12 hours prior to the first puncture.

After first puncture, multiple dose vials should be held between 2ºC to 25°C (35°F to 77°F). Multiple dose vials should be discarded 12 hours after first puncture.

2.2.2. Prepared Syringe Storage

Prepared syringes of the Pfizer-BioNTech Bivalent COVID-19 vaccine should be stored between 2° to 25°C (36° to 77°F) and used within 12 hours after the 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, 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.

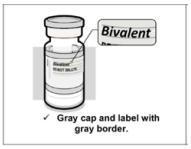
4. VACCINE DOSE PREPARATION AND DISPENSING

4.1. SUPPLIES NEEDED

- Pfizer-BioNTech BIVALENT COVID-19 Vaccine vial with **gray cap** and **gray label border** **(thaw each vial before use)**
- 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)

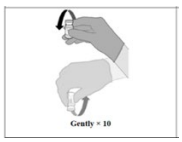
4.2. PREPARATION AND DISPENSING INSTRUCTIONS

1. Receive a Protocol-Specific COVID-19 Vaccination Prescription Form or electronic order.
2. Place all supplies necessary for preparation into the biosafety cabinet.
3. Verify that the vial of Pfizer-BioNTech BIVALENT COVID-19 Vaccine has a **gray cap** and **gray label border** and the label states ***"Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5)"*** and ***"Age 12 y and older"***.



4. Thaw Pfizer-BioNTech BIVALENT COVID-19 Vaccine vial before use either by:
    a. Allowing vial to thaw in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)].
        i. A carton of 10 single dose vials may take up to 2 hours to thaw.
        ii. A carton of 10 multiple dose vials may take up to 6 hours to thaw.
    b. Allowing vial to sit at room temperature [up to 25ºC (77ºF)] for 30 minutes.
    c. Do not refreeze after thawing.

5. Before preparing the dose, mix by inverting the 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.
c. 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. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw the protocol-specified dose of Pfizer-BioNTech Bivalent COVID-19 Vaccine using the provided syringes and needles. **DO NOT DILUTE PRIOR TO PREPARATION**.
    a. If using a multiple dose vial, 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 through 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.

12. Store the prepared syringes between 2°C to 25°C (35°F to 77°F).

13. Document any unused syringes on the COVID-19 Vaccine Accountability Record (Form G) and discard them 12 hours after the first vial puncture, according to your institution's destruction policy.