

**THE S.T.E.P.S. to Pfizer-BioNTech COVID-19 Vaccination**

Your guide to proper storage, handling, and administration for the Pfizer-BioNTech COVID-19 Vaccine

Current as of February 1, 2021. For the most up-to-date information, visit www.cvdvaccine-us.com.

Refer to the Pfizer-BioNTech COVID-19 Vaccine providers for full information. Use this informercial to provide information to patients or caregivers for your clinic, hospital setting, or vaccine distribution site.

The Pfizer-BioNTech COVID-19 Vaccine has been approved by the FDA for use under an Emergency Use Authorization (EUA) by the FDA under the terms of Section 563a of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FDA has authorized emergency use of this product under limited circumstances. As of the date of this instruction, circumstances exist justifying the authorization of emergency use of the vaccine product under Section 563a of the FD&C Act for use in individuals 16 years of age and older who have been hospitalized with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection.


**S TORE**

- 1. Before opening, ensure the thermal shipping container to contain all containers were involved. Do not stretch or play around on the top of the thermal shipping container.
- 2. Do not open the vials trays or remove vials until you are ready for thawing or use.
- 3. Please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information at www.cvdvaccine-us.com. The Pfizer-BioNTech COVID-19 Vaccine has not been approved or licensed by FDA, but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) by the FDA under the terms of Section 563a of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FDA has authorized emergency use of this product under limited circumstances. As of the date of this instruction, circumstances exist justifying the authorization of emergency use of the vaccine product under Section 563a of the FD&C Act for use in individuals 16 years of age and older who have been hospitalized with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection.
- 4. To prepare individual 0.3 mL doses from the diluted multiple dose vial:

**T ALL DOSES AND THAW**

- 2. Do not open the vial trays or remove vials until you are ready for thawing or use.
- 4. Allow vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)] and store them protected from light until ready to use.

**Q UILIDATE AND DISPOSE MULTIPLE VIAL**

Refer to the Pfizer-BioNTech COVID-19 Vaccine containers in a multiple dose that contains 6 doses after dilution to be administered using low dead-volume syringes and/or needles.

- 1. Once the liquid has exerted a single-use antiseptic swab, and withdraw 0.3 mL of the Pfi zer-BioNTech COVID-19 Vaccine using low dead-volume syringes and/or needles.
- 2. Adjustments to remove air bubbles should be done with the needle still in the vial to avoid loss of vaccine.
- 3. A 3 mL syringe is recommended, although a 5 mL syringe is also acceptable. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfi zer-BioNTech COVID-19 Vaccine using low dead-volume syringes and/or needles.
- 4. The remaining liquid in the vial after dilution should be administered using low dead-volume syringes and/or needles.

**R EPAIRE AND ADMINISTER MULTIPLE VIAL**

Refer to the Pfizer-BioNTech COVID-19 Vaccine containers in a multiple dose that contains 6 doses after dilution.

- 1. Before dilution, wash vials in a gentle 10 times. Do not pool excess vaccine from multiple vials
- 2. The diluent supplied for the Pfi zer-BioNTech COVID-19 Vaccine is 0.9% Sodium Chloride Injection, USP. The active ingredient is a Suspension of mRNA-1273, which is a Complexing Agent.

**A FTER USE**

- 1. Invert vaccine vial gently 10 times. Invert vaccine vial gently 10 times. Invert vaccine vial gently 10 times. Invert vaccine vial gently 10 times. Invert vaccine vial gently 10 times.
- 2. The Pfi zer-BioNTech COVID-19 Vaccine is not recommended for use in individuals 16 years of age and older who have been hospitalized with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection.

**N OTICE**

- 1. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.
- 2. The Pfi zer-BioNTech COVID-19 Vaccine is only recommended for use in individuals 16 years of age and older who have been hospitalized with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection.
- 3. Access the liquid in the vial after dilution. The liquid is a white to off-white suspension and may contain white to off-white amorphous particles. Inspect the liquid in the vial for appearance and clarity.
- 4. The remaining liquid in the vial after dilution should be administered using low dead-volume syringes and/or needles.
- 5. Do not open the vial trays or remove vials until you are ready for thawing or use.

**I MPORTANT SAFETY INFORMATION**

- 1. After dilution, vials of Pfi zer-BioNTech COVID-19 Vaccine contain six doses of 0.3 mL each. Vials of low dead-volume syringes and/or needles can be used to extract six doses from a single vial. Standard syringes and needles are used, they may not be sufficient volume to extract as much as the single vial. Due to the type of length and needle.
- 2. The amount of vaccine remaining in the dilution cannot be made up of any volume of 0.2 mL. Do not pool excess vaccine from multiple vials.

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**A SAFELY DISPOSE AND SHIP BACK MATERIALS**

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