

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 September 22, 2021. For the most up-to-date information, visit www.cvdvaccine.com.

Refer to the FDA-authorized Fact Sheet for Vaccination Providers including Full Emergency Use Authorization Prescribing Information for complete instructions on storage and handling, preparation and administration.

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 12 years of age and older. Pfizer-BioNTech COVID-19 Vaccine is authorized for use to provide:

- a two-dose primary series in individuals 12 years of age and older;
- a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and
- a single booster dose in individuals: 65 years of age and older - 18 through 64 years of age at high risk of severe COVID-19 - 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech that is indicated for active immunization to prevent COVID-19 in individuals 16 years of age and older. It is approved for use as a 2-dose primary series for the prevention of COVID-19 in individuals 16 years of age and older. It is also authorized for emergency use to provide:

- a two-dose primary series in individuals 12 through 15 years; a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and
- a single booster dose in individuals: 65 years of age and older - 18 through 64 years of age at high risk of severe COVID-19 - 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.

Please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information available at www.cvdvaccine.com.



Watch the Storage and Handling video

STORE

1. Upon delivery, inspect the thermal shipping container to confirm all vial trays were received. Do not stack or place anything on top of the thermal shipping container.
2. Do not open the vial trays or remove vials until you are ready for thawing or use.
3. Closed-lid vial trays containing 195 vials removed from frozen storage between -90°C to -60°C (-130°F to -76°F) until the expiry date printed on the label. If not stored between -90°C to -60°C (-130°F to -76°F), vials may be stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks. Vials must be kept frozen and protected from light until ready to use. Vials stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks may be returned one time to the recommended storage condition of -90°C to -60°C (-130°F to -76°F). Total cumulative time the vials are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and should not exceed 2 weeks.
4. When you are ready to thaw or use the vaccine
 - Thawed Vials Before Dilution:
 - Thawed Under Refrigeration: Thaw and then store undiluted vials in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 1 month. A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time.
 - Thawed at Room Temperature: For immediate use, thaw undiluted vials at room temperature [up to 25°C (77°F)] for 30 minutes. Thawed vials can be handled in room light conditions. Vials must reach room temperature before dilution.
 - Undiluted vials may be stored at room temperature for no more than 2 hours.
 - Transportation of Thawed Vials : Available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours.
 - Vials After Dilution: After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Any vaccine remaining in vials must be discarded after 6 hours.
 - Do not refreeze.
5. Once an individual vial is removed from a vial tray at room temperature, it should not be returned to frozen storage and should be thawed for use.
6. Immediately store in an ultra-low-temperature freezer. Keep vials protected from light until ready to use. If an ultra-low-temperature freezer is not available, the thermal shipping container may be used to temporarily store the Pfizer-BioNTech COVID-19 Vaccine. If using the thermal shipping container as temporary storage, it must be opened, inspected, and replenished with dry ice within 24 hours of receipt. Confirm the dry ice level. Fill any low areas of the side compartments and the dry ice pod on top with dry ice pellets.
7. It is recommended that the thermal shipping container not be opened for more than 3 minutes at a time and not more than twice a day. The thermal shipping container may be used as temporary storage for up to 30 days from delivery with regular re-icing.
 - Dry ice can be hazardous. Take necessary precautions by reviewing the Dry Ice Safety Data Sheet and consult with your Occupational Health Department. Ensure there is proper ventilation and wear proper safety glasses with side shields or safety goggles and waterproof insulated gloves when handling dry ice
 - Refer to re-icing guidelines in the Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Reference Guide and Video at www.cvdvaccine.com for more information about storage and handling of dry ice

TALLY DOSES AND THAW

1. Plan ahead. Tally the number of doses needed for the immunization session using a system that works for your staff.
2. Remove the number of multiple dose vials you will need from the freezer or thermal shipping container. One vial contains 6 doses of 0.3 mL after dilution.
3. The Pfizer-BioNTech COVID-19 Vaccine should be administered using low dead-volume syringes and/or needles. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.
4. Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by:
 - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]
 - A single tray of vials may take up to 3 hours to thaw; fewer vials will thaw more quickly
 - Thawed vials can be stored in the refrigerator for up to 1 month at 2°C to 8°C
 - Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes, for immediate use

EQUILIBRATE AND DILUTE MULTIPLE DOSE VIAL

Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours. Do not refreeze thawed vials.

1. Before dilution invert vaccine vial gently 10 times.
 - Do not shake.
 - Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles
 - Do not use if liquid is discolored or if other particles are observed
2. Dilute the vaccine.
 - Obtain sterile 0.9% Sodium Chloride Injection, USP. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent
 - Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle)
 - Cleanse the vaccine vial stopper with a single-use antiseptic swab. Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial. Do not add more than 1.8 mL of diluent. A 3 mL syringe is recommended, although a 5 mL syringe is also acceptable
 - You may feel some pressure in the vial as you add the diluent. Ensure vial pressure is equalized by withdrawing 1.8 mL of air into the empty diluent syringe before removing the needle from the vial. Make sure to discard any saline remaining in the diluent vial
3. Gently invert the diluted vial 10 times to mix. Do not shake.
 - After dilution, the vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter
4. Record the date and time of dilution in the appropriate place on the Pfizer-BioNTech COVID-19 Vaccine vial label. The thawed or diluted vaccine can be handled in room light conditions and must be kept at temperatures between 2°C to 25°C (35°F to 77°F). Avoid exposure to direct sunlight and ultraviolet light. Use within 6 hours from the time of dilution. If not used within 6 hours, it should be discarded.

Undiluted vials cannot be at room temperature for more than 2 hours.

PREPARE AND ADMINISTER MULTIPLE DOSE VIAL

Reminder: Pfizer-BioNTech COVID-19 Vaccine comes in a multiple dose vial that contains 6 doses after dilution

To prepare individual 0.3 mL doses from the diluted multiple dose vial:

1. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine preferentially using low dead-volume syringes and/or needles.

Adjustments to remove air bubbles should be done with the needle still in the vial to avoid loss of vaccine.

Verify the final dosing volume of 0.3 mL and confirm there are no particulates and that no discoloration is observed.

It is recommended to use the same needle to withdraw and administer the dose whenever possible. If a second needle is required for administration, pull back on the syringe plunger until a small amount of air enters the syringe prior to removing the first needle to avoid loss of dosing solution during the needle change.

2. After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain six doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume
- Do not pool excess vaccine from multiple vials

3. Prepared syringes should be administered immediately. Administer the Pfizer-BioNTech COVID-19 Vaccine intramuscularly.

4. Ensure the vaccine recipient understands that a 2nd dose must be received 3 weeks after the 1st dose to complete the series.

Important Safety Information

- Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine

- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine

Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (<https://www.cdc.gov/vaccines/covid-19/>)

- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine
- The Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients

- In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%)

- Severe allergic reactions have been reported following the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials. Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine

- In a clinical study, adverse reactions in adolescents 12 through 15 years of age included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%).

- Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy

- Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion

- There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series

- Vaccination providers must report Adverse Events in accordance with the Fact Sheet to the following website: www.pfizersafetyreporting.com or at the following Email: EGY.AEReporting@pfizer.com or <https://docs.google.com/forms/d/e/1FAIpQLSf2x24f0gPYvpH1DP3vtPs8WX2e6mFgddw6Mw5RrzqSztjVA/viewform>. The reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report

- Vaccination providers should review the Fact Sheet for Information to Provide to Vaccine Recipients/Caregivers and Mandatory Requirements for Pfizer-BioNTech COVID-19 Vaccine Administration Under Emergency Use Authorization

- Please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information available at www.cvdvaccine-us.com



Watch the Preparation and Administration video

SAFELY DISPOSE AND SHIP BACK MATERIALS

1. Discard vaccine vials that:
 - Have been fully discharged and used to administer vaccinations
 - Are more than 6 hours from time of dilutionDiscard vaccine vials in a sharps container as medical waste to ensure they are permanently destroyed. Discard vial trays as medical waste so they cannot be reused.
2. For information about returning the thermal shipping container, refer to the Shipping and Handling Guidelines included in your shipment or available at www.cvdvaccine.com/product-storage-and-dry-ice.



Watch the Returning the Shipping Container video



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BIONTECH



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FIND ADDITIONAL RESOURCES
about the Pfizer-BioNTech COVID-19 Vaccine at

www.cvdvaccine.com