



**The Pocket Guide to**

# **PREPARATION & ADMINISTRATION**

**of the Pfizer-BioNTech COVID-19 Vaccine**

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

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 to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 16 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

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](http://www.cvdvaccine-us.com).



Current as of April 15, 2021. For the most up-to-date information, visit [www.cvdvaccine-us.com](http://www.cvdvaccine-us.com).

# Important Safety Information

- Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (eg, 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/clinical-considerations/managing-anaphylaxis.html>)

- 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, including anaphylaxis, and other hypersensitivity reactions, diarrhea, vomiting, and pain in extremity (arm) have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine 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

- 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 VAERS online at <https://vaers.hhs.gov/reportevent.html>. For further assistance with reporting to VAERS call 1-800-822-7967. 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*
- Before administration of Pfizer-BioNTech COVID-19 Vaccine, 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](http://www.cvdvaccine-us.com)

# Diluting

## the Pfizer-BioNTech COVID-19 Vaccine

### Before Dilution

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1. When vial is at room temperature, **gently invert** vaccine vial 10 times. **Do not shake.** Inspect the liquid in the vial.

- The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles. Do not use if discolored or other particles are present

### Dilution

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2. Using aseptic technique, withdraw 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP into a 3-mL syringe with a 21-gauge or narrower needle. A 5-mL syringe is also acceptable.

**Do not use bacteriostatic saline or other diluents.**



3. Cleanse the vaccine vial stopper with a single-use antiseptic swab. Add diluent to the vaccine vial. Do not add more than 1.8 mL of diluent to the vaccine vial.

- Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe
- Discard any saline remaining in the diluent vial

**Multiple dose vials must be diluted within 2 hours of being placed in room temperature conditions.**

## After Dilution

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**The vial now contains six 0.3 mL doses of vaccine.**



**4. Gently invert** the diluted vial 10 times to mix. **Do not shake.** Inspect the liquid in the vial.

- The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter



**5.** Record the date and time of dilution on the vaccine vial label.

- Diluted vaccine:
  - Can be handled in room light conditions. Avoid exposure to direct sunlight and ultraviolet light
  - Must be kept at temperatures between 2°C to 25°C (35°F to 77°F)
  - Should be discarded if not used within 6 hours from the time of dilution

# Preparing & Administering

## the Pfizer-BioNTech COVID-19 Vaccine



**1.** Using aseptic technique, cleanse the vaccine vial stopper with a single-use antiseptic swab and withdraw 0.3 mL of the diluted vaccine.\*

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

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**Low dead-volume syringes and/or needles are preferred. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.**

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**2.** Verify the final dosing volume of 0.3 mL and confirm there are no particulates or discoloration in the vaccine.

### **Irrespective of the type of syringe and needle used:**

- 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

\*Use the same needle to withdraw and administer the dose whenever possible. If a second needle is required, pull back the syringe plunger until a small amount of air enters the syringe prior to removing the first needle to avoid loss of vaccine during the needle change.

**After dilution, multiple dose vials contain 6 doses of vaccine.**



**3. Immediately administer the prepared vaccine.**

The vaccine is administered intramuscularly.

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**Discard any unused vaccine 6 hours after dilution.**

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**4.** Ensure the vaccine recipient understands that a second dose must be received 3 weeks after the first dose to complete the series.

## **Select Important Safety Information**

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  - 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/clinical-considerations/managing-anaphylaxis.html>)

**Please see full Important Safety Information on inside front cover.**

## Downloadable Materials for Your Practice, Clinic, or Hospital

Additional resources to support the proper storage, handling, preparation, and administration of the Pfizer-BioNTech COVID-19 Vaccine can be found at [www.cvdvaccine-us.com](http://www.cvdvaccine-us.com).

View Resources



[www.cvdvaccine-us.com](http://www.cvdvaccine-us.com)



Manufactured by  
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Manufactured for  
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Emergency Use Authorization Holder

The Pfizer-BioNTech COVID-19 Vaccine, which is based on BioNTech proprietary mRNA technology, was developed by both BioNTech and Pfizer.

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