

THE PFIZER-BIONTECH COVID-19 VACCINE RESOURCE GUIDE

Your guide to utilizing the Pfizer-BioNTech COVID-19 Vaccine resources

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.

Current as of April 15, 2021. For the most up-to-date information, visit www.cvdvaccine-us.com.



ABOUT THIS RESOURCE GUIDE

This guide contains resources designed to assist you and your vaccination site in handling and administering the Pfizer-BioNTech COVID-19 Vaccine.

Learn about each resource and how it can help ensure the vaccine is handled and administered correctly, according to the dosing schedule. These resources are also available at **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

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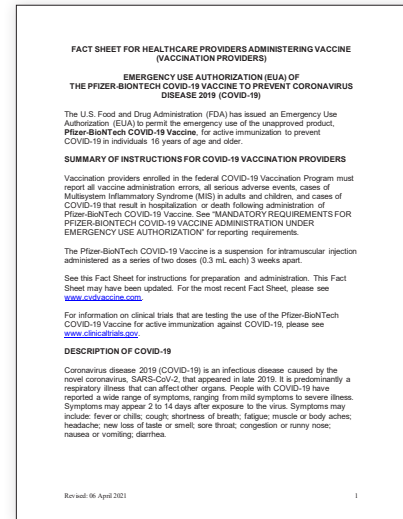
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EMERGENCY USE AUTHORIZATION (EUA) FACT SHEETS

Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)

This fact sheet for vaccination providers details important prescribing information regarding the Pfizer-BioNTech COVID-19 Vaccine, including information on Emergency Use Authorization (EUA), a summary of instructions for COVID-19 vaccination providers, and information on product description, storage, handling, preparation, administration, and mandatory reporting requirements.

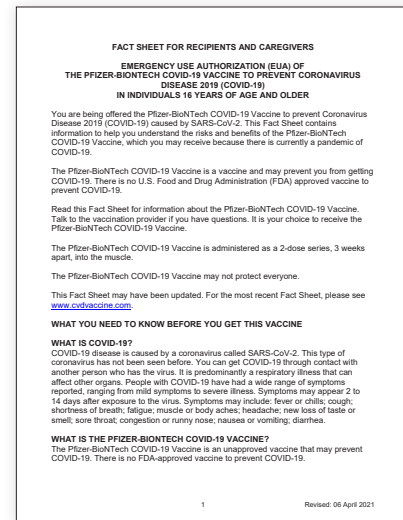
You and your staff should familiarize yourselves with the contents of this fact sheet, including the Full EUA Prescribing Information.



Prior to an individual receiving the vaccine, you must provide the vaccine recipient or their caregiver a copy of the Fact Sheet for Recipients and Caregivers. Alternatively you may direct the individual or their caregiver to www.cvdvaccine-us.com to obtain a copy of the Fact Sheet.

Fact Sheet for Recipients and Caregivers

The fact sheet for recipients and caregivers provides information about the indication and side effects of the Pfizer-BioNTech COVID-19 Vaccine, what recipients and caregivers should tell the healthcare provider prior to receiving the vaccine, and it defines emergency use authorization.

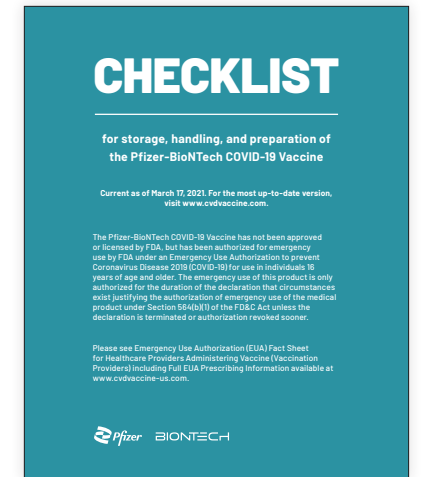


PREPARE TO RECEIVE THE VACCINE

Checklist for Storage, Handling, and Preparation

This is a list of materials your clinic will need for storage, handling, and preparation of the Pfizer-BioNTech COVID-19 Vaccine, as well as guidance for receiving the thermal shipping container.

You and your staff should review this checklist before you receive the shipments.



Pfizer-BioNTech COVID-19 Vaccine Video (A Guide to Product Handling and Administration at Your Vaccination Center)

Chapter 1: Storage and Handling

This video serves as a guide on how to receive, store, and handle the vaccine vial trays. It explains how to open the thermal shipping container in which the vaccine arrives, how the vaccine should be stored, and safety and procedural information about using dry ice.



Chapter 2: Preparation and Administration

This video gives step-by-step directions on how to prepare the vaccine for administration, how to administer the vaccine to patients, and how to discard the vaccine vials.



Vaccination providers should refer to the Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) for detailed instructions.

Chapter 3: Returning the Thermal Shipping Container

This video provides instructions for returning the thermal shipping container, the timing of return, discarding medical waste, and the return shipping label information.



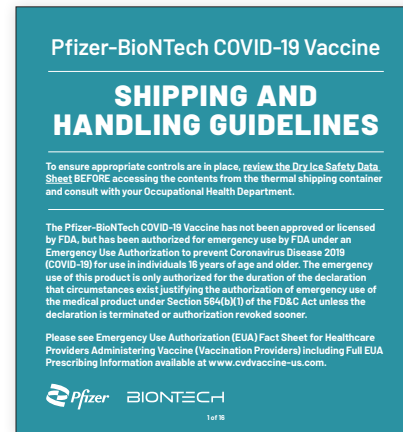
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SAFETY AND HANDLING RESOURCES

Pfizer-BioNTech COVID-19 Vaccine Shipping and Handling Guidelines Brochure

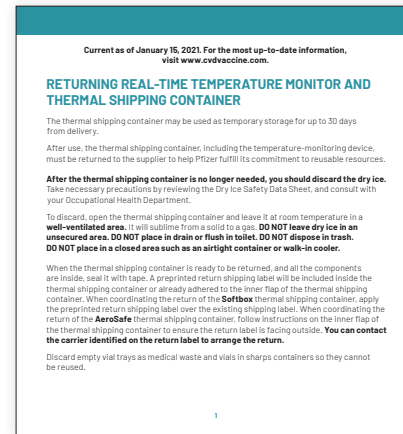
This brochure contains guidelines on dry ice handling, dry ice replenishment, safety data sheet information, and instructions for the return of the temperature-monitoring device and thermal shipping container.

Use the information in this brochure to help ensure safe handling and timely replenishment of the dry ice in the thermal shipping containers for the Pfizer-BioNTech COVID-19 Vaccine.



Returning Temperature-Monitoring Device and Thermal Shipping Container

This provides instructions for how to return the Temperature-Monitoring Device and Thermal Shipping Container.



Ultra-Low-Temperature (ULT) Freezer Vendor List

This is a list of vendors who offer ULT freezers.



SAFETY AND HANDLING RESOURCES (cont'd)

Dry Ice Safety Data Sheet

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risks. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Product Safety Data Sheet

This safety data sheet for the Pfizer-BioNTech COVID-19 Vaccine is to help occupational health and safety specialists assure workplace safety and comply with applicable laws.

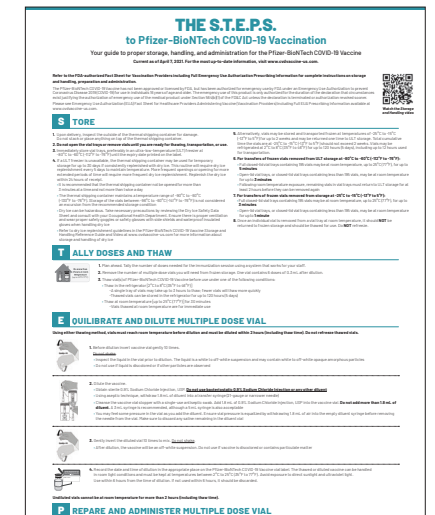
You can access these Safety Data Sheets at www.pfizer.com/products/safety-data-sheets.

DOSING AND ADMINISTRATION RESOURCES

A 'How to Administer the Vaccine' Poster for Vaccination Providers

This poster provides step-by-step instructions for you and your immunization staff in preparation, administration, and storage of the Pfizer-BioNTech COVID-19 Vaccine.

Refer to chapter 2 of the Pfizer-BioNTech COVID-19 Vaccine Video for step-by-step directions on how to prepare the vaccine for administration, how to administer the vaccine to patients, and how to discard the vaccine vials.



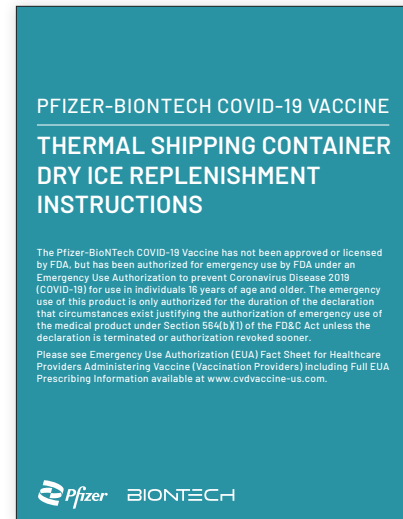
Please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information available at www.cvdvaccine-us.com.

DRY ICE RESOURCES

(See Safety and Handling Resources for Dry Ice Safety Data Sheet)

Dry Ice Replenishment Requirements Sheet

This contains information and instructions on dry ice replenishment and pellet size.



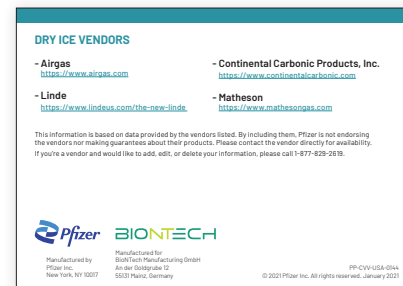
Safe Handling Guidelines for Dry Ice

This contains information about dry ice, general safety guidance, and handling and disposal procedures.



Dry Ice Vendor List

This contains a list of dry ice vendors.



CONNECT WITH US

For general questions about the Pfizer-BioNTech COVID-19 Vaccine:

www.cvdvaccine-us.com



1-877-VAX-C019

(1-877-829-2619)



BIONTECH

Manufactured by
Pfizer Inc.
New York, NY 10017

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany
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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