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 12 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.


Current as of June 25, 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.
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/clinical-considerations/managing-anaphylaxis.html).

Reports of adverse events following use of the Pfizer-BioNTech COVID-19 Vaccine under EUA suggest increased risks of myocarditis and pericarditis, particularly following the second dose. The decision to administer the Pfizer-BioNTech COVID-19 Vaccine to an individual with a history of myocarditis or pericarditis should take into account the individual’s clinical circumstances.

Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.

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 (82.8%), headache (59.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.8%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%).

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 (8.2%), injection site redness (8.8%), lymphadenopathy (0.8%), and nausea (0.4%).

Following administration of the Pfizer-BioNTech COVID-19 Vaccine, the following have been reported outside of clinical trials:

- Severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions, diarrhea, vomiting, and pain in extremity (arm)
- myocarditis and pericarditis

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 breastfeeding 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.

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.

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 cartons. 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.

SAFETY AND HANDLING RESOURCES

Pfizer-BioNTech COVID-19 Vaccine Shipping and Handling Guidelines Brochures (25-pack carton and 195-pack carton versions)

These brochures contain guidelines on dry ice handling, safety data sheet information, and instructions for returning the temperature-monitoring device and thermal shipping container.

The 195-pack carton brochure also includes information for proper dry ice replenishment when using the thermal shipping container for temporary storage of 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.

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.
GENERAL SAFETY GUIDANCE FOR DRY ICE

**CAUTION**

DO NOT TOUCH—AVOID EYE CONTACT

Use waterproof insulated gloves when removing or adding dry ice to prevent cold burns and frostbite. Avoid contact with face and eyes. Wear safety glasses with side shields or safety goggles.

DO NOT EAT

Dry ice is harmful if eaten or swallowed. If ingested, seek immediate medical care.

DO NOT STORE IN CONFINED SPACES

Dry ice changes to a gas very rapidly at room temperature, displacing oxygen. Only use dry ice in open or well-ventilated areas.

DO NOT PLACE IN AIRTIGHT CONTAINERS

Airtight containers may explode as dry ice rapidly expands to a gas when exposed to temperatures above -109°F (-78°C).

FACTS ABOUT DRY ICE

Dry ice is the frozen form of carbon dioxide. When heated, most frozen solids melt to a liquid form, but dry ice transforms directly into a gas (sublimation). Dry ice sublimes at temperatures at or above -109°F (-78°C).

The main hazards of dry ice include asphyxiation and burns. Use of dry ice in confined spaces (small rooms or walk-in coolers) and/or poorly ventilated areas can result in depletion of oxygen, causing asphyxiation. Exposed skin should be protected from contact with dry ice.

To ensure appropriate controls are in place, review the Dry Ice Safety Data Sheet BEFORE accessing the contents from the thermal shipping container and consult with your Occupational Health Department.

VENTILATION

At room temperature (including most cold storage temperatures), dry ice becomes carbon dioxide gas, which may cause difficulty breathing or suffocation. If dry ice has been in a closed area, trailer, or container, open doors and allow adequate ventilation before entering.

If you feel short of breath or develop a headache, these may be signs that you have inhaled too much carbon dioxide. Leave the area immediately. Carbon dioxide is heavier than air and accumulates in low, poorly ventilated spaces.

Operational practices for accessing a closed area where dry ice is present should be reviewed and agreed upon with your Occupational Health and Safety officer.

BURN TREATMENT

Dry ice may cause cold burns to the skin. Use waterproof insulated gloves when handling dry ice. Seek medical care as directed by the Dry Ice Safety Data Sheet.

DISPOSAL

Once dry ice is no longer needed, open the container and leave it at room temperature in a well-ventilated area. It will readily sublime from a solid to a gas. DO NOT leave dry ice in an unsecured area. DO NOT place in drain or flush in toilet. DO NOT dispose in trash. DO NOT place in a closed area, such as an airtight container or walk-in cooler.

Visit [https://safetydatasheets.pfizer.com/](https://safetydatasheets.pfizer.com/) and type “Dry Ice” in the Enter Product Name field, to obtain the Dry Ice Safety Data Sheet.
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)