

**Pfizer BioNTech
COVID-19 Vaccine
Pocket Guide for Providers**



**Indiana
Department
of
Health**

March 2021

SHIPMENT

Where do the materials come from?

3 separately acquired components mixed onsite

	SOURCE	
	McKesson	Pfizer/BioNTech
Vaccine Multidose Vials on dry ice (6 doses/vial)		X
Diluent At room temperature	X	
Ancillary Kit For administration and mixing	X	



Transfer of product from the thermal shipper must be done in less than 5 minutes to prevent premature thawing.

Upon Arrival of Thermal Shipper

All shipments contain a GPS Temperature Monitoring device that is enabled when the shipper is packed. This ensures distribution within required temperatures. Upon ownership transfer, Pfizer Quality processes and controls ensure that the product has arrived under acceptable conditions. Temperature records will be emailed to facilities. Please refer to the number on the back for issues with your shipment.



Disable GPS logger by pressing the Stop button.



Inspect product to ensure all order quantities are present and not damaged.



Remove dry ice pod from shipper using appropriate gloves/PPE.



Remove the box containing the vial trays. If you feel resistance, remove the vial trays individually from the box.



Quickly transfer to cold storage. Re-ice if unable to transfer immediately.



Refer to www.in.gov/isdh/17094.htm for Indiana's guidance on temporary storage.

SHIPMENT

STORAGE & HANDLING

1. Ultra-Low Temperature Freezer

- Store as frozen liquid at -80°C to -60°C for up to 6 months.
- If your Digital Data Logger reads in Fahrenheit, store at -112°F to -76°F for up to 6 months.
- The thermal shipper should be returned within 30 days of receiving the thermal shipper.
- Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition.

2. 2°C to 8°C Refrigerator

- Can be stored at 2°C to 8°C (35°F to 46°F) up to 5 days.
 - Room temperature hold time is no more than 2 hours.
 - Thaw from frozen for 3 hours at 2°C to 8°C (35°F to 46°F) or 30 minutes at room temperature for immediate use.
 - Post dilution in use period is 6 hours.
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Note: After dilution, one vial contains 6 doses of 0.3 mL. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL.

Storage of Frozen Vials

- 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 -80°C to -60°C (-112°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.

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.
- Any hours used for transport at 2°C to 8°C (35°F to 46°F) count against the 120-hour limit for storage at 2°C to 8°C (35°F to 46°F).

STORAGE & HANDLING



VACCINE PREPARATION


Wear gloves when removing vials from ultracold storage. Remove the number of vials needed as quickly as possible and return the tray to frozen storage. Do not expose to room temperature for more than 10 minutes before choosing a thawing option (shown below).

There are **two options** for thawing vials:

Option 1

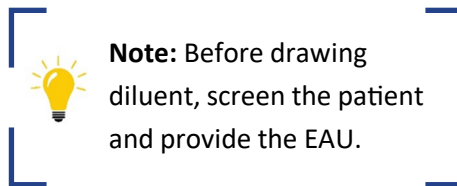
1. Transfer frozen vials immediately to refrigerator, and thaw for 3 hours at 2°C to 8°C (35°F to 46°F).
2. Vials may be stored in refrigerator for up to 5 days or 120 hours before dilution.

Option 2

1. Thaw at room temperature for 30 minutes if using immediately.
 2. Vials may be held at room temperature for no more than 2 hours prior to dilution.
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Please prepare the following supplies needed **per 1 Vial Pfizer BioNTech COVID-19 Vaccine** (six 30mcg doses/vial):

- 1 vial 0.9% sodium chloride (at least 2mL)
- 1 diluent syringe/needle (3mL or 5mL syringe/21G needle recommended)
- 6 dosing syringes/needles (1mL syringe/IM injection needle)
- Alcohol swabs, gloves, appropriate PPE as needed





VACCINE PREPARATION



DILUENT WITHDRAWAL

Please follow the steps below:

1. Once vial is thawed, add 1.8mL of 0.9% sodium chloride to vial using a 21-gauge needle.
 2. Remove 1.8mL of air from vial before removing needle to equalize pressure.
 3. Invert gently 10 times to mix once diluent is added; do not shake vial.
 4. Before drawing first dose, clean vial stopper with single-use antiseptic swab.
 5. Using sterile dosing syringe and IM needle, remove 0.3mL of solution from vial. **This is one dose.**
 6. Repeat steps 4 and 5 for the remaining five doses in vial.
 7. **Once diluted, vaccine must be used within 6 hours and stored between 2°C and 25°C (35°F to 77°F).**
 8. Record the date and time of dilution on vaccine vial label, and discard any unused vaccine 6 hours after dilution.
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Regardless of the volume of the diluent vial, it **must be used only ONCE**. After removing 1.8mL to dilute the vaccine, the diluent vial must be discarded.

DILUENT WITHDRAWAL



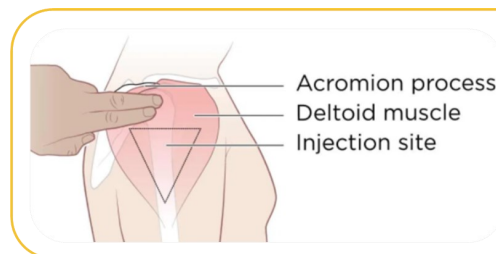
VACCINE ADMINISTRATION

Before Administration

- Visually inspect each dose in the dosing syringe prior to administration. The diluted vaccine will be an off-white suspension with no particulates or discoloration.
- Verify the final dosing volume of 0.3mL.

During Administration

- Administer a single 30 mcg/0.3mL dose at first visit.
- Use an appropriate gauge needle for body type (23-25 gauge).
- Administer intramuscularly in the deltoid muscle.



After Administration

- Discard all used materials in appropriate waste receptacles/ sharps containers.
- The second 30mcg/0.3mL dose should be given 21 days after first dose.
- Provide COVID-19 vaccine record card to patient, noting the date and time for second dose.
- Monitor patient for 15 minutes and report any adverse reaction on VAERS.



The second dose must be Pfizer BioNTech COVID-19 vaccine; it is not interchangeable with other COVID-19 vaccines.

VACCINE ADMINISTRATION

Vaccinator Training:

LMS:INvest at <https://chirp.in.gov/> or www.in.gov/isdh/17094.htm

Vaccinator Questions:

<https://eportal.isdh.in.gov/C19VaxHelpDeskCustomer>

Pfizer-BioNTech Storage and Handling Website:

<https://www.cvdvaccine-us.com/product-storage-and-dry-ice>

Manufacturer Questions:

Contact Pfizer at 800-438-1985

Shipment Issues:

Contact Pfizer Customer Service at 877-829-2619



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