

Intended for U.S. Healthcare Professionals

# Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) Presentation and Dosing Guide Individuals 6 Months Through 11 Years of Age

## Emergency Use Authorization (EUA)

Emergency uses of COVID-19 vaccines from BioNTech and Pfizer, including Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula), have not been approved or licensed by FDA, but have been authorized by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in individuals 6 months of age and older. Emergency uses are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical products under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner. Please see EUA Fact Sheets at [www.cvdvaccine-us.com](http://www.cvdvaccine-us.com).

## Selected Safety Information

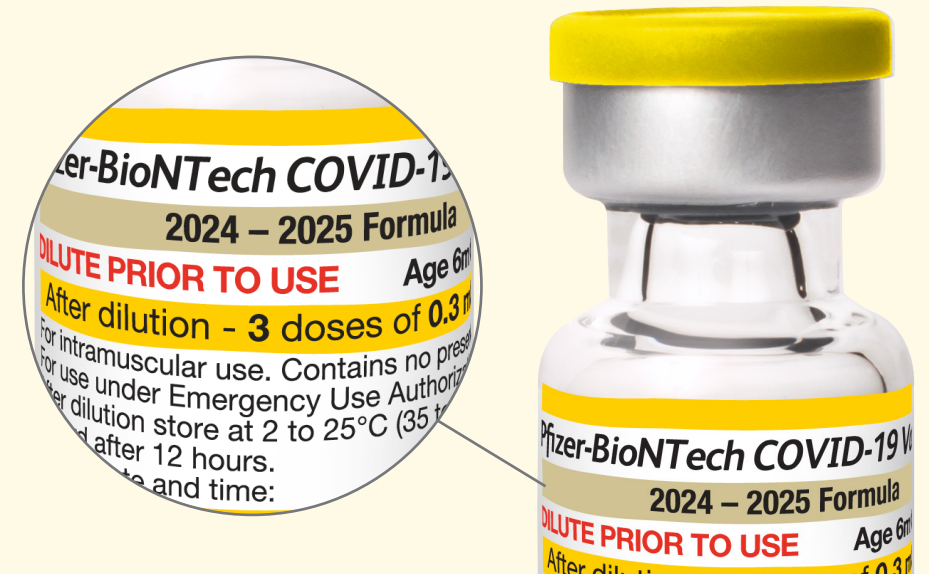
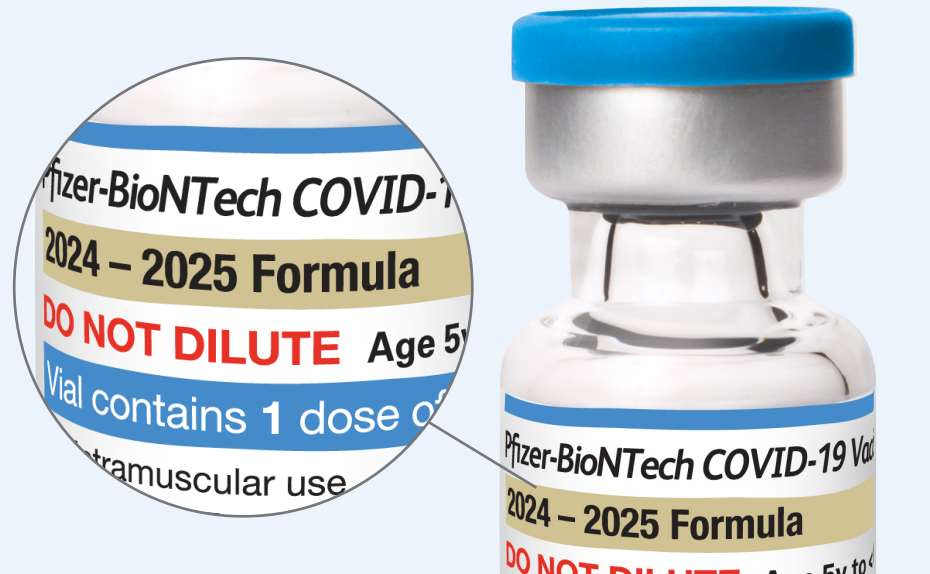
Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine or to individuals who had a severe allergic reaction (e.g., anaphylaxis) following a previous dose of a Pfizer-BioNTech COVID-19 vaccine.



For eligible individuals 6 months through 11 years of age

## Identifying vials of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula)

Verify the vials (including labels) prior to preparation for administration to help avoid vaccine administration errors

	Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) Multiple Dose Vial <b>DILUTE BEFORE USE</b>	Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) Single Dose Vial <b>DO NOT DILUTE</b>
<b>Variant Composition<sup>1</sup></b>	After dilution, each 0.3 mL dose is formulated to contain 3 mcg of modRNA encoding Omicron variant lineage KP.2	Each 0.3 mL dose is formulated to contain 10 mcg of modRNA encoding Omicron variant lineage KP.2
<b>Age Group<sup>1</sup></b>	6 months through 4 years <sup>a</sup>	5 through 11 years <sup>a</sup>
<b>Cap Color &amp; Label<sup>1</sup></b> <i>Cap colors and labels with matching borders</i>  <b>Verify vial label states “2024-2025 Formula”</b>	<p>Yellow</p> 	<p>Blue</p> 
<b>NDC Codes<sup>1</sup></b>	<p><b>Multiple Dose Vial:</b> 59267-4426-01</p> <p><b>Carton of 10 Multiple Dose Vials:</b> 59267-4426-02</p>	<p><b>Single Dose Vial:</b> 59267-4438-01</p> <p><b>Carton of 10 Single Dose Vials:</b> 59267-4438-02</p>
<b>CPT® Codes<sup>2</sup></b>	91318	91319
<b>CVX Codes<sup>2</sup></b>	308	310

### Important Reminder

Previous COVID-19 vaccines are no longer available for use in the United States.<sup>1</sup>

FDA and CDC guidance is to check inventory and dispose of previous COVID-19 vaccines according to state and local regulations.

Identify the vial cap color for respective presentation and confirm vial label states “2024-2025 Formula.”

Please see following page for dosage and storage information for individuals 6 months through 11 years of age.

<sup>a</sup>For individuals turning from 4 to 5 years of age during the vaccination series who have received 1 or 2 doses of Pfizer-BioNTech COVID-19 vaccine, administer a single dose of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) supplied in vials with blue caps and labels with blue borders, on or after the date the individual turns 5 years of age.<sup>1</sup>

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## Selected Safety Information

### Management of Acute Allergic Reactions

Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of Pfizer-BioNTech COVID-19 Vaccine.

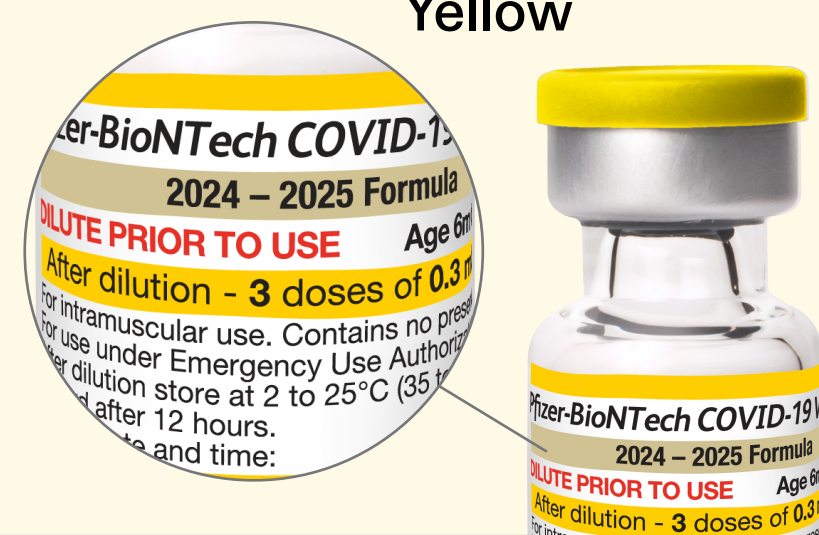
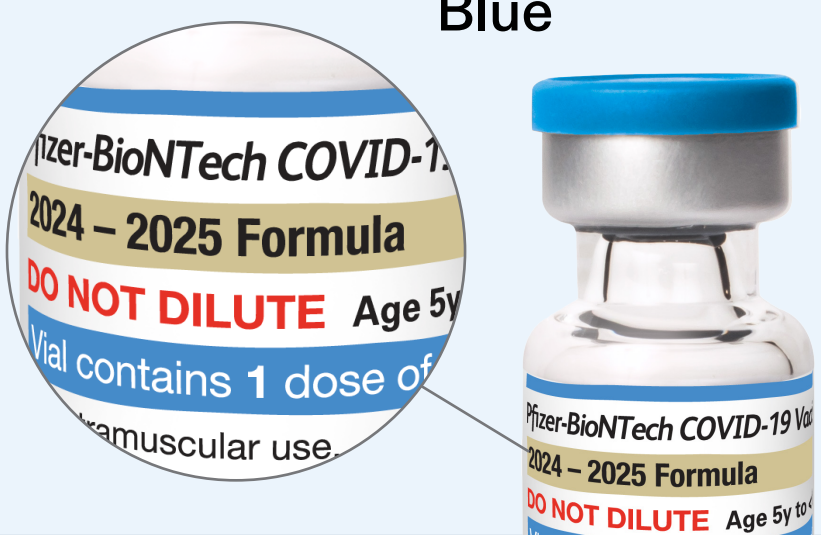
Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention (CDC) guidelines (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>).

Please see additional Important Safety Information on page 6.

Please click for Pfizer-BioNTech COVID-19 Vaccine [Vaccination Provider](#) and [Recipient and Caregiver](#) EUA Fact Sheets.

For eligible individuals 6 months through 11 years of age

Verify the vials (including labels) prior to preparation for administration to help avoid vaccine administration errors

	Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) Multiple Dose Vial <sup>1</sup> <b>DILUTE BEFORE USE</b>	Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) Single Dose Vial <sup>1</sup> <b>DO NOT DILUTE</b>
<b>Age Group</b>	6 months through 4 years <sup>a</sup>	5 through 11 years <sup>a</sup>
<b>Cap Color &amp; Label</b> <i>Cap colors and labels with matching borders</i>	<b>Yellow</b> 	<b>Blue</b> 
<b>Dose</b>	3 mcg	10 mcg
<b>Dose Volume</b>	0.3 mL	0.3 mL
<b>Dilution</b>	1.1 mL <sup>b</sup>	DO NOT DILUTE
<b>Doses per Vial</b>	<b>Multiple Dose Vial<sup>c</sup>:</b> 3 doses per vial (after dilution)	<b>Single Dose Vial:</b> 1 dose per vial
<b>Storage Conditions<sup>e</sup></b>		
<b>Ultra-Low-Temperature (ULT) Freezer</b> [-90°C to -60°C (-130°F to -76°F)]	18 months <sup>d</sup>	18 months <sup>d</sup>
<b>Freezer</b> [-25°C to -15°C (-13°F to 5°F)]	<b>DO NOT STORE</b>	<b>DO NOT STORE</b>
<b>Refrigerator</b> [2°C to 8°C (35°F to 46°F)]	10 weeks	10 weeks
<b>Room Temperature</b> [8°C to 25°C (46°F to 77°F)]	12 hours prior to first puncture <sup>f</sup>	12 hours prior to use
<b>After First Puncture</b> [2°C to 25°C (35°F to 77°F)]	Discard 12 hours after dilution <sup>d</sup>	N/A

**Important Reminder**  
Previous COVID-19 vaccines are no longer available for use in the United States.<sup>1</sup>

FDA and CDC guidance is to check inventory and dispose of previous COVID-19 vaccines according to state and local regulations.

Identify the vial cap color for respective presentation and confirm vial label states “2024-2025 Formula.”

**Do not refreeze thawed vials.<sup>1</sup>**

**Refer to product labeling for detailed thawing instructions and information related to product handling.**

<sup>a</sup>For individuals turning from 4 to 5 years of age during the vaccination series who have received 1 or 2 doses of Pfizer-BioNTech COVID-19 vaccine, administer a single dose of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) supplied in vials with blue caps and labels with blue borders, on or after the date the individual turns 5 years of age.<sup>1</sup>

<sup>b</sup>ONLY use sterile 0.9% Sodium Chloride Injection, USP, as the diluent.<sup>1</sup>

<sup>c</sup>If the amount of vaccine 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.<sup>1</sup>

<sup>d</sup>If cartons are received refrigerated at 2°C to 8°C (35°F to 46°F), they should be stored in a refrigerator at 2°C to 8°C (35°F to 46°F). Regardless of storage condition, the vaccine should not be used after the expiration date printed on the vial and cartons.<sup>1</sup>

<sup>e</sup>During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Do not refreeze thawed vials.<sup>1</sup>

<sup>f</sup>After dilution, multiple dose vials should be held between 2°C to 25°C (35°F to 77°F). Multiple dose vials should be discarded 12 hours after dilution.<sup>1</sup>

For eligible individuals 6 months through 11 years of age

**Individuals 6 Months Through 4 Years of Age  
Pfizer-BioNTech COVID-19 Vaccination Status<sup>1</sup>:**



**Multiple Dose Vial**

3 mcg per dose

(Contains 3 doses)

YELLOW cap and label with YELLOW border

**DILUTE PRIOR TO USE**

Number of Previous Doses of Pfizer-BioNTech COVID-19 Vaccine(s) <sup>a</sup>	Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) Dose and Schedule <sup>b</sup>
0 previous doses <sup>c</sup>	<b>3 doses,<sup>d</sup> 0.3 mL each</b> Dose 1: Week 0 Dose 2: Week 3 Dose 3: ≥8 weeks after Dose 2
1 previous dose	<b>2 doses,<sup>d</sup> 0.3 mL each</b> Dose 1: 3 weeks after receipt of the previous dose of Pfizer-BioNTech COVID-19 vaccine <sup>a</sup> Dose 2: ≥8 weeks after Dose 1
≥2 previous doses	<b>Single dose, 0.3 mL</b> ≥8 weeks after receipt of the last previous dose of Pfizer-BioNTech COVID-19 vaccine <sup>a</sup>

<sup>a</sup>Previous dose refers to a dose of any prior Pfizer-BioNTech COVID-19 vaccine that is no longer authorized for use in the United States.

<sup>b</sup>For individuals with certain kinds of immunocompromise previously vaccinated with Pfizer-BioNTech COVID-19 vaccines, see page 5 for further dosing information.<sup>1</sup>

<sup>c</sup>Not previously vaccinated with any COVID-19 vaccine.<sup>1</sup>

<sup>d</sup>For individuals turning from 4 to 5 years of age during the vaccination series who have received 1 or 2 doses of Pfizer-BioNTech COVID-19 vaccine, administer a single dose of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) supplied in vials with blue caps and labels with blue borders, on or after the date the individual turns 5 years of age.<sup>1</sup>

**Individuals 5 Through 11 Years of Age  
Irrespective of COVID-19 Vaccination Status<sup>1</sup>:**



**Single Dose Vial**

10 mcg per dose

BLUE cap and label with BLUE border

**DO NOT DILUTE**

**Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) Dose and Schedule<sup>a</sup>**

**Single Dose, 0.3 mL**

If previously vaccinated, administer the dose ≥2 months after receipt of the last previous dose of COVID-19 vaccine<sup>b</sup>

<sup>a</sup>For individuals with certain kinds of immunocompromise, see page 5 for further dosing information.<sup>1</sup>

<sup>b</sup>Previous dose refers to a dose of any prior COVID-19 vaccine that is no longer authorized for use in the United States.

**Individuals 6 Months Through 11 Years of Age With Certain Kinds of Immunocompromise** See next page for details.

**Selected Safety Information**

**Myocarditis and Pericarditis**

Postmarketing data with authorized or approved mRNA COVID-19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following vaccination. For the Pfizer-BioNTech COVID-19 Vaccine, the observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae.

The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html>).

Please see additional Important Safety Information on page 6.

Please click for Pfizer-BioNTech COVID-19 Vaccine [Vaccination Provider](#) and [Recipient and Caregiver](#) EUA Fact Sheets.

For eligible individuals 6 months through 11 years of age

## Individuals 6 Months Through 11 Years of Age With Certain Kinds of Immunocompromise

Individuals 6 months through 11 years of age with certain kinds of immunocompromise\* should complete at least a 3-dose series with an age-appropriate dose and dosing schedule\*\* of a COVID-19 vaccine. At least 1 dose should be with a COVID-19 vaccine (2024-2025 formula).<sup>1</sup>

- If previously not vaccinated, complete the 3-dose series with age-appropriate doses of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula)
- If previously vaccinated with 1 or 2 dose(s) of a prior Pfizer-BioNTech COVID-19 vaccine,<sup>§</sup> complete the remaining dose(s) in the 3-dose series with age-appropriate doses of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula)
- If previously vaccinated with 3 or more doses of a prior COVID-19 vaccine,<sup>§</sup> administer a single age-appropriate dose of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) at least 2 months following the last previous dose

\*Certain kinds of immunocompromise refers to individuals who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.<sup>1</sup>

<sup>†</sup>Dosing schedule for immunocompromised individuals 6 months through 4 years of age for Pfizer-BioNTech COVID-19 vaccines: Dose 1: Week 0; Dose 2: Week 3; Dose 3: ≥8 weeks after Dose 2. For individuals turning from 4 to 5 years of age during the vaccination series, complete the series with doses of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) supplied in vials with blue caps and labels with blue borders, on or after the date the individual turns 5 years of age.

<sup>‡</sup>Dosing schedule for immunocompromised individuals 5 through 11 years of age for Pfizer-BioNTech COVID-19 vaccines: Dose 1: Week 0; Dose 2: Week 3; Dose 3: ≥4 weeks after Dose 2. For individuals turning from 11 to 12 years of age during the vaccination series, complete the 3-dose series with 1 or 2 doses, as applicable, of COMIRNATY® (COVID-19 Vaccine, mRNA) (2024-2025 Formula) (hereafter "COMIRNATY") on or after the date the individual turns 12 years of age. If the individual turning 12 years of age receives 2 doses of COMIRNATY to complete the vaccination series or receives a dose of COMIRNATY less than 2 months after receipt of the last previous dose of COVID-19 vaccine to complete the vaccination series, then those uses of COMIRNATY are authorized under EUA. The FDA has authorized under EUA these uses of COMIRNATY, which is an FDA-licensed vaccine indicated for active immunization to prevent COVID-19 in individuals 12 years of age and older. Refer to <https://www.cvdvaccine.com> for additional information about COMIRNATY.

<sup>§</sup>These prior COVID-19 vaccines are no longer authorized for use in the United States.<sup>1</sup>

An age-appropriate additional dose of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) may be administered at least 2 months following the last dose of a COVID-19 vaccine (2024-2025 formula).<sup>||</sup> Age-appropriate additional doses of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances. The timing of the additional doses may be based on the individual's clinical circumstances.<sup>1</sup>

<sup>||</sup>For immunocompromised individuals 6 months through 4 years of age, the last dose of a COVID-19 vaccine (2024-2025 formula) refers to a dose with Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula).<sup>1</sup>

<sup>¶</sup>For immunocompromised individuals 5 through 11 years of age, the last dose of a COVID-19 vaccine (2024-2025 formula) refers to a dose with Moderna COVID-19 Vaccine (2024-2025 Formula) or Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula).<sup>1</sup>

## Selected Safety Information

### Syncope

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

### Altered Immunocompetence

Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished response to Pfizer-BioNTech COVID-19 Vaccine.

Please see additional Important Safety Information on page 6.

Please click for Pfizer-BioNTech COVID-19 Vaccine [Vaccination Provider](#) and [Recipient and Caregiver](#) EUA Fact Sheets.

## IMPORTANT SAFETY INFORMATION

Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine or to individuals who had a severe allergic reaction (e.g., anaphylaxis) following a previous dose of a Pfizer-BioNTech COVID-19 vaccine.

### Management of Acute Allergic Reactions

Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions 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 (CDC) guidelines (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html>).

### Myocarditis and Pericarditis

Postmarketing data with authorized or approved mRNA COVID-19 vaccines demonstrate increased risks of myocarditis and pericarditis, particularly within the first week following vaccination. For the Pfizer-BioNTech COVID-19 Vaccine, the observed risk is highest in males 12 through 17 years of age. Although some cases required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae.

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### Limitation of Vaccine Effectiveness

Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients.

## Adverse Reactions

Solicited adverse reactions included:

- 6 months through 23 months of age: Injection site redness; swelling and tenderness; decreased appetite; drowsiness; fever; irritability.
- 2 through 11 years of age: Injection site pain; redness and swelling; chills; diarrhea; fatigue; fever; headache; new or worsened joint pain; new or worsened muscle pain; vomiting.

Vaccination providers must report all vaccine administration errors, all serious adverse events, cases of myocarditis, cases of pericarditis, cases of Multisystem Inflammatory Syndrome (MIS), and cases of COVID-19 that result in hospitalization or death following administration of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) to the Vaccine Adverse Event Reporting System (VAERS) by submitting online at <https://vaers.hhs.gov/reportevent.html>. Vaccination providers administering COMIRNATY (COVID-19 Vaccine, mRNA) (2024-2025 Formula) under EUA must adhere to the same reporting requirements. For further assistance with reporting to VAERS call 1-800-822-7967. The reports should include the words “Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) EUA” in the description section of the report. To the extent feasible, report adverse events to Pfizer 1-800-438-1985 or provide a copy of the VAERS form to Pfizer <https://www.pfizersafetyreporting.com/>

## AUTHORIZED USE

Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 6 months through 11 years of age.

**Please click for Pfizer-BioNTech COVID-19 Vaccine Vaccination Provider and Recipient and Caregiver EUA Fact Sheets.**

**References:** 1. Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (6 months through 11 years of age); BioNTech Manufacturing GmbH and Pfizer Inc.; August 22, 2024. 2. Fall season respiratory vaccine codes. Centers for Disease Control and Prevention. Updated August 7, 2024. Accessed August 13, 2024. <https://www.cdc.gov/vaccines/programs/iis/fall-season-respiratory-codes.html>



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

Manufactured by  
Pfizer Inc.  
New York, NY 10001

COVID-19 vaccines from BioNTech and Pfizer, which are based on BioNTech proprietary mRNA technology, were developed by both BioNTech and Pfizer.



Find additional resources about  
Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) at:  
[www.cvdvaccine-us.com](http://www.cvdvaccine-us.com)