

# Dosing Schedules for Children 6 Months Through 11 Years of Age

## Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula)



For children 6 months through 4 years of age, see page 2.  
For children 5 through 11 years of age, see page 3.  
For children 6 months through 11 years of age with  
certain kinds of immunocompromise, see page 4.

### EMERGENCY USE AUTHORIZATION

Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula)\* has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 6 months through 11 years of age. 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.

\*Hereafter referred to as Pfizer-BioNTech COVID-19 Vaccine.

## Selected Safety Information

- A person should **NOT** get Pfizer-BioNTech COVID-19 Vaccine if they had a severe allergic reaction after a previous dose of any Pfizer-BioNTech COVID-19 vaccine or to any ingredients in these vaccines.
- There is a remote chance that the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, the vaccination provider may ask you to stay at the place where you received the vaccine for monitoring after vaccination. **If your child experiences a severe allergic reaction, call 9-1-1, or go to the nearest hospital.** Signs of a severe allergic reaction can include:
  - difficulty breathing, swelling of the face and throat, a fast heartbeat, a bad rash all over the body, or dizziness and weakness

Please see Selected Safety Information throughout and click for [Pfizer-BioNTech COVID-19 Vaccine Healthcare Providers and Recipient and Caregiver EUA Fact Sheets](#).

# Dosing Schedule for Children 6 Months Through 4 Years of Age Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula)

**Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) is FDA-authorized under Emergency Use Authorization (EUA) 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.**

## How do I know my child's vaccination schedule?

The dosing regimen and schedule with Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) is based on the number of a child's previous doses with Pfizer-BioNTech COVID-19 Vaccine (Original monovalent) and Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5). These vaccines are no longer authorized for use in the United States.

## Dosing Schedule by Pfizer-BioNTech COVID-19 Vaccination Status

| Number of previous doses of Pfizer-BioNTech COVID-19 vaccine(s)<br>(Bivalent or Original monovalent) <sup>a</sup> | Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) Schedule <sup>b</sup><br>For 6 months through 4 Years of Age   |
|---|---|
| 0 <sup>c</sup>  | <b>3 Doses<sup>d</sup>:</b><br><b>Dose 1:</b> Week 0<br><b>Dose 2:</b> 3 weeks after Dose 1<br><b>Dose 3:</b> ≥8 weeks after Dose 2   |
| 1   | <b>2 Doses<sup>d</sup>:</b><br><b>Dose 1:</b> 3 weeks after receipt of the previous dose of Pfizer-BioNTech COVID-19 vaccine (Bivalent or Original monovalent) <sup>a</sup><br><b>Dose 2:</b> ≥8 weeks after Dose 1 |
| 2 to 4  | <b>Single Dose:</b><br><b>Dose 1:</b> ≥8 weeks after receipt of the previous dose of Pfizer-BioNTech COVID-19 vaccine (Bivalent or Original monovalent) <sup>a</sup>  |

<sup>a</sup>Previous doses of Pfizer-BioNTech COVID-19 vaccine(s) refers to doses with Pfizer-BioNTech COVID-19 Vaccine (Original monovalent) and Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5). These vaccines are 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 4 for dosing information.

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

<sup>d</sup>For individuals turning from 4 to 5 years of age during the vaccination series, all doses of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) should follow the vaccination schedule for 6 mos. through 4 years of age.

**For children aged 6 months through 4 years with certain kinds of immunocompromise, please see page 4.**

## Selected Safety Information (cont'd)

- Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received mRNA COVID-19 vaccines. Myocarditis and pericarditis following Pfizer-BioNTech COVID-19 vaccines have occurred most commonly in adolescent males 12 through 17 years of age. In most of these individuals, symptoms began within a few days following vaccination. The chance of having this occur is very low. **Seek medical attention right away if your child has any of the following symptoms after receiving the vaccine, particularly during the 2 weeks after receiving a dose of the vaccine:**
  - Chest pain
  - Shortness of breath or difficulty breathing
  - Feelings of having a fast-beating, fluttering, or pounding heart

Please see Selected Safety Information throughout and click for Pfizer-BioNTech COVID-19 Vaccine [Healthcare Providers and Recipient and Caregiver](#) EUA Fact Sheets.



# Dosing Schedule for Children 5 Through 11 Years of Age Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula)

## How do I know my child's vaccination schedule?

For children 5 to 11 years of age, dosing schedule is not based on previous vaccination status.

### Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) Schedule<sup>e</sup>

**Children who are unvaccinated** can receive a single dose of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula).

**Children who are previously vaccinated** can receive a single dose of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) administered at least 2 months after the last previous dose of any monovalent COVID-19 vaccine or bivalent COVID-19 vaccine.<sup>f</sup>

<sup>e</sup>For individuals with certain kinds of immunocompromise, see page 4 for dosing information.

<sup>f</sup>COVID-19 vaccine refers to the monovalent COVID-19 vaccines that encode the spike protein of the original SARS-CoV-2 and the bivalent COVID-19 vaccines encoding the spike protein of the original SARS-CoV-2 and of the Omicron variant lineages BA.4 and BA.5 that are no longer authorized for use in the United States.

For children aged 5 through 11 years with certain kinds of immunocompromise, please see page 4.

## Selected Safety Information (cont'd)

Additional symptoms, particularly in children, may include:

- Fainting
- Unusual and persistent irritability
- Unusual and persistent poor feeding
- Unusual and persistent fatigue or lack of energy
- Persistent vomiting
- Persistent pain in the abdomen
- Unusual and persistent cool, pale skin
- Fainting can happen after getting injectable vaccines, including Pfizer-BioNTech COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received the vaccine for monitoring after vaccination
- People with weakened immune systems may have a reduced immune response to Pfizer-BioNTech COVID-19 Vaccine
- The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone

Please see Important Safety Information throughout and click for Pfizer-BioNTech COVID-19 Vaccine [Healthcare Providers and Recipient and Caregiver](#) EUA Fact Sheets.



# For children 6 months through 11 years of age with certain kinds of immunocompromise

Children with certain kinds of immunocompromise<sup>g</sup> should complete at least a 3-dose series of a COVID-19 vaccine based on their age.<sup>h,i</sup> At least 1 dose should be with a COVID-19 vaccine (2023-2024 Formula).

## Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) Dosing for Immunocompromised Children 6 months through 11 Years

**If not previously vaccinated**, complete a 3-dose series of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) based on their age.

**If previously vaccinated with 1 or 2 dose(s)** of Pfizer-BioNTech COVID-19 Vaccine (Original monovalent) and/or Pfizer-BioNTech COVID-19 Vaccine, Bivalent, complete the remaining dose(s) in the 3-dose series with Pfizer-BioNTech COVID-19 Vaccine (2023-2024) dose(s) based on their age.

**If previously vaccinated with 3 or more doses**, can receive a single dose of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) based on their age and at least 2 months following the last previous dose.<sup>j</sup>

<sup>g</sup>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>h</sup>**Dosing schedule for 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, all doses of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) should follow the vaccination schedule for 6 mos. through 4 years of age.

<sup>i</sup>**Dosing schedule for 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. Individuals turning from 11 to 12 years of age during the vaccination series may complete the series with doses of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula).

<sup>j</sup>For immunocompromised individuals 6 months through 4 years of age, the last previous dose refers to the last dose of Pfizer-BioNTech COVID-19 Vaccine (Original monovalent) or Pfizer-BioNTech COVID-19 Vaccine, Bivalent, which are no longer authorized for use in the U.S.

## Additional COVID-19 vaccine doses may be given with healthcare provider guidance.

- An additional dose of Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) based on a child's age may be administered at the discretion of a healthcare provider at least 2 months following the last dose of a COVID-19 vaccine (2023-2024 Formula).
- Immunocompromised individuals 6 months through 11 years of age may receive additional doses of Pfizer-BioNTech COVID-19 Vaccine. For more information, talk to your child's healthcare provider.

## Select Safety Information (cont'd)

- **Tell your vaccination provider about all of your medical conditions, including if you:**
  - have any allergies
  - has had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
  - has a fever
  - has a bleeding disorder or are on a blood thinner
  - is immunocompromised or are on a medicine that affects the immune system
  - is pregnant or is breastfeeding
  - has received another COVID-19 vaccine
  - has ever fainted in association with an injection

Please see **Important Safety Information** throughout and click for Pfizer-BioNTech COVID-19 Vaccine **Healthcare Providers** and **Recipient and Caregiver** EUA Fact Sheets.



## Select Safety Information (cont'd)

- Side effects that have been reported with Pfizer-BioNTech COVID-19 vaccines include:
  - Severe allergic reactions
  - Non-severe allergic reactions such as rash, itching, hives, or swelling of the face
  - Myocarditis (inflammation of the heart muscle)
  - Pericarditis (inflammation of the lining outside the heart)
  - Injection site pain/tenderness
  - Tiredness
  - Headache
  - Muscle pain
  - Arm pain
  - Fainting in association with injection of the vaccine
  - Chills
  - Joint pain
  - Fever
  - Injection site swelling
  - Injection site redness
  - Nausea
  - Feeling unwell
  - Swollen lymph nodes (lymphadenopathy)
  - Decreased appetite
  - Diarrhea
  - Vomiting
  - Dizziness
  - Irritability

These may not be all the possible side effects. Serious and unexpected side effects may occur. Call the vaccination provider or healthcare provider about bothersome side effects or side effects that do not go away.

Report vaccine side effects to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to [www.vaers.hhs.gov/reportevent.html](http://www.vaers.hhs.gov/reportevent.html). Please include "Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) EUA" in the first line of box #18 of the report form.

In addition, individuals can report side effects to Pfizer Inc. at [www.pfizersafetyreporting.com](http://www.pfizersafetyreporting.com) or by calling 1-800-438-1985.

### AUTHORIZED USE

**Pfizer-BioNTech COVID-19 Vaccine** (2023-2024 Formula)\* is FDA authorized under Emergency Use Authorization (EUA) 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 see Important Safety Information throughout and click for Pfizer-BioNTech COVID-19 Vaccine [Healthcare Providers and Recipient and Caregiver](#) EUA Fact Sheets.**