

Dosing Schedules for Children 6 Months Through 11 Years of Age

Pfizer-BioNTech COVID-19 Vaccine (2024-2025 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](#).



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EMERGENCY USE AUTHORIZATION

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.

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

Important Safety Information and Authorized Use

- Your child 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

Important Safety Information continues on the next page.

Please see **Important Safety Information throughout and click for Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers and EUA Fact Sheet for Recipients and Caregivers.**

Dosing Schedule for Children 6 Months Through 4 Years of Age Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula)

Pfizer-BioNTech COVID-19 Vaccine (2024-2025 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 (2024-2025 Formula) are based on the number of a child's previous doses. 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.

Dosing Schedule by Pfizer-BioNTech COVID-19 Vaccination Status

Number of Previous Doses of Pfizer-BioNTech COVID-19 Vaccine(s) ^a	Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) Dosing Regimen, Dose, and Schedule ^b
0 Not previously vaccinated with any COVID-19 vaccine	3 Doses (0.3 mL each): Dose 1: Week 0 Dose 2: Week 3 (3 weeks after Dose 1) Dose 3: ≥8 weeks after Dose 2
1	2 Doses (0.3 mL each): Dose 1: 3 weeks after receipt of the previous dose of a Pfizer-BioNTech COVID-19 vaccine ^a Dose 2: ≥8 weeks after Dose 1
≥2	Single Dose (0.3 mL): Dose 1: ≥8 weeks after receipt of the last previous dose of a Pfizer-BioNTech COVID-19 vaccine ^a

^aPrevious dose refers to a dose of any prior Pfizer-BioNTech COVID-19 Vaccine that is no longer authorized for use in the United States.

^bFor individuals with certain kinds of immunocompromise, see page 4 for dosing information.

^cFor 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, the healthcare provider will administer a single dose of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) authorized for those 5 through 11 years of age, on or after the date the individual turns 5 years of age.

For children aged 6 months through 4 years with certain kinds of immunocompromise, please see [page 4](#).

Important Safety Information (cont'd)

- 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 Important Safety Information throughout and click for [Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers](#) and [EUA Fact Sheet for Recipients and Caregivers](#).

Dosing Schedule for Children 5 Through 11 Years of Age Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula)

Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) Schedule^d

For children 5 to 11 years of age, the dosing schedule is not based on previous COVID-19 vaccination status.

A single dose (0.3 mL) of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) is administered to children 5 through 11 years of age who have not received a COVID-19 vaccine (2024-2025 Formula).

Children previously vaccinated must wait at least 2 months since their last previous dose of any COVID-19 vaccine.^e

^dFor individuals with certain kinds of immunocompromise, see page 4 for dosing information.

^ePrevious dose refers to a dose of any prior COVID-19 vaccine that is 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](#).

Important 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

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
- Pfizer-BioNTech COVID-19 Vaccine may not protect everyone

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

For Children 6 Months Through 11 Years of Age With Certain Kinds of Immunocompromise

Children with certain kinds of immunocompromise^f should complete at least a 3-dose series of a COVID-19 vaccine based on their age and dosing schedule.^{g,h} At least 1 dose should be with a COVID-19 vaccine (2024-2025 Formula).

Pfizer-BioNTech COVID-19 Vaccine (2024-2025 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 (2024-2025 Formula) based on their age.

If previously vaccinated with 1 or 2 dose(s) of a prior Pfizer-BioNTech COVID-19 Vaccine,ⁱ complete the remaining dose(s) in the 3-dose series with Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) dose(s) based on their age.

If previously vaccinated with 3 or more doses of a prior COVID-19 vaccine,ⁱ receive a single dose of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) based on their age at least 2 months following the last dose.

^fCertain 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.

^g**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 for individuals 5 years through 11 years of age, on or after the date the individual turns 5 years of age.

^h**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.

ⁱPrior COVID-19 vaccines are no longer authorized for use in the United States.

Important notes for immunocompromised individuals turning from 11 to 12 years of age during the vaccination series:

- If your child is immunocompromised and turning from 11 to 12 years of age during the vaccination series for immunocompromised individuals, your child is being offered COMIRNATY (COVID-19 Vaccine, mRNA) 2024-2025 Formula.
 - COMIRNATY is an FDA-approved vaccine for individuals 12 years of age and older that is authorized under EUA to complete the dosing schedule. Under the authorized dosing schedule, these individuals receive the Pfizer-BioNTech COVID-19 Vaccine before they turn 12 years old, and complete the vaccination series with COMIRNATY on or after the date the individual turns 12 years old.
- The dosing schedule is: Dose 1: Week 0; Dose 2: Week 3; Dose 3: ≥4 weeks after Dose 2.
- The information in this Fact Sheet about the Pfizer-BioNTech COVID-19 Vaccine, including information about the benefits, risks, and ingredients of that vaccine, also applies to your child's use of COMIRNATY, except with respect to the dosing schedule and the ages authorized for use.

A healthcare provider may give additional age-based dose(s) of Pfizer-BioNTech COVID-19 Vaccine (2024-2025 Formula) to immunocompromised individuals 6 months through 11 years of age.

- 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.
- Vaccinations may not provide full immunity to COVID-19 in people who are immunocompromised; therefore, your child should continue to maintain physical precautions to help prevent COVID-19. Your child's close contacts should be vaccinated as appropriate.

Important Safety Information (cont'd)

- **Tell your vaccination provider about all of your child's medical conditions, including if your child:**
 - has 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 is on a blood thinner
 - is immunocompromised or is 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 EUA Fact Sheet for Healthcare Providers](#) and [EUA Fact Sheet for Recipients and Caregivers](#).

Important 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
- Febrile seizures (convulsions during a seizure)

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. Please include "Pfizer-BioNTech COVID-19 Vaccine (2024-2025 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 or by calling 1-800-438-1985.

Authorized Use

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Please click here for [Pfizer-BioNTech COVID-19 Vaccine Healthcare Providers Fact Sheet](#) and [Vaccine Recipient and Caregiver EUA Fact Sheet](#).