



COVID-19

Pfizer-BioNTech COVID-19 Vaccine Overview and Safety (also known as COMIRNATY)

Updated Sept. 20, 2021

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NOTICE: FDA authorized the use of Pfizer-BioNTech's COVID-19 Vaccine to be administered as boosters at least six months after completion of the primary Pfizer-BioNTech series in [certain populations](#). The [Advisory Committee on Immunization Practices](#) is meeting on Thursday, September 23, from noon to 3pm ET to discuss a recommendation on booster shots.

Cases of myocarditis and pericarditis in adolescents and young adults have been reported more often after getting the second dose than after the first dose of one of the two mRNA COVID-19 vaccines, Pfizer-BioNTech or Moderna. **These reports are rare and the known and potential benefits of COVID-19 vaccination outweigh the known and potential risks, including the [possible risk of myocarditis or pericarditis](#).**

General Information

Name: BNT162b2

How Given: Shot in the muscle of the upper arm

Manufacturer: Pfizer, Inc., and BioNTech

Does NOT Contain: Eggs, preservatives, latex, metals
[Full List of Ingredients](#)

Type of Vaccine: [mRNA](#)

Brand name: COMIRNATY

Number of Shots: 2 shots, 21 days apart

[Some immunocompromised people](#) should get 3 shots

Pfizer-BioNTech (COMIRNATY) Name Change

Pfizer-BioNTech (COMIRNATY) received U.S. Food and Drug Administration (FDA) approval on August 23, 2021, for individuals 16 years of age and older. Once vaccines are approved by the FDA, companies can market the vaccines under brand names. COMIRNATY is the brand name for the Pfizer-BioNTech COVID-19 Vaccine. Now that the FDA-authorized Pfizer-BioNTech COVID-19 vaccine has been approved by the FDA for individuals 16 years of age and older, it will be marketed as COMIRNATY. The use of the name Pfizer-BioNTech will still be used for individuals 12-15 years old since this age group has not been approved. There has **been no change** in the formulation of the vaccine since the name change.

Learn more about [Booster Shots](#).

Who Should Get Vaccinated

- The Pfizer-BioNTech vaccine is recommended for people 12 years and older.
- Learn more about how the Centers for Disease Control and Prevention (CDC) is making COVID-19 [vaccine recommendations](#).

Who Should NOT Get Vaccinated

- **If you have had a severe allergic reaction (anaphylaxis) or an immediate allergic reaction**, even if it was not severe, to any ingredient in the Pfizer-BioNTech COVID-19 vaccine (such as polyethylene glycol), you should not get this vaccine.
- If you had a severe or immediate allergic reaction **after getting the first dose of a Pfizer-BioNTech COVID-19 vaccine**, you should not get a second dose of either of this vaccine.
- A severe allergic reaction is one that needs to be treated with epinephrine or EpiPen or with medical care. Learn about [common side effects of COVID-19 vaccines](#) and when to call a doctor.
- An immediate allergic reaction means a reaction within 4 hours of exposure, including symptoms such as hives, swelling, or wheezing (respiratory distress).

If you aren't able to get this vaccine, you may still be able to get a different type of COVID-19 vaccine. Get more [information for people with allergies](#).

Possible Side Effects

In the arm where you got the shot:

- Pain
- Redness
- Swelling

Throughout the rest of your body:

- Tiredness
- Headache
- Muscle pain
- Chills
- Fever
- Nausea

These side effects happen within a day or two of getting the vaccine. They are normal signs that your body is building protection and should go away within a few days.

Learn more about [possible side effects after getting a COVID-19 vaccine](#).

Other authorized and recommended COVID-19 vaccines in the United States

- [Moderna](#)
- [Johnson & Johnson's Janssen](#)

You should get a COVID-19 vaccination as soon as possible. Do not wait for a specific brand. All currently authorized and recommended COVID-19 vaccines are [safe](#) and [effective](#), and CDC does not recommend one vaccine over another.

COVID-19 vaccines are not interchangeable. If you received a Pfizer-BioNTech or Moderna COVID-19 vaccine, you should get the same product for your second shot.

Safety Data Summary

- In clinical trials, [reactogenicity symptoms](#) (side effects that happen within 7 days of getting vaccinated) were common but were mostly mild. Some people had side effects that affected their ability to do daily activities.
- Side effects (such as fever, chills, tiredness, and headache) throughout the body were more common after the second dose of the vaccine.
- CDC will continue to provide updates as we learn more about the safety of the Pfizer-BioNTech vaccine in [real-world conditions](#).

Learn more about [vaccine safety monitoring](#) after a vaccine is authorized or approved for use.

How Well the Vaccine Works

- Based on [evidence from clinical trials](#) in people 16 years and older, the Pfizer-BioNTech (COMIRNATY) vaccine was 95% effective at preventing laboratory-confirmed infection with the virus that causes COVID-19 in people who received two doses and had no evidence of being previously infected.
- In clinical trials, the Pfizer-BioNTech vaccine was also highly effective at preventing laboratory-confirmed COVID-19 infection in adolescents 12–15 years old, and the immune response in people 12–15 years old was at least as strong as the immune response in people 16–25 years old.
- The vaccine was also highly effective in clinical trials at preventing COVID-19 among people of diverse age, sex, race, and ethnicity categories and among people with underlying medical conditions.
- Evidence shows mRNA COVID-19 vaccines offer similar protection in [real-world conditions](#) as they have in clinical trial settings—reducing the risk of COVID-19, including severe illness by 90% or more, among people who are fully vaccinated.
- CDC will continue to provide updates as we learn more.

Clinical Trial Demographic Information: 16 Years and Older

Clinical trials for the Pfizer-BioNTech (COMIRNATY) vaccine in people 16 years and older included people from the following racial and ethnic, age, and sex categories:

Race

- 82% White
- 10% African American
- 4% Asian
- 3% other races, multiracial, or race not reported
- <1% Native Hawaiian or Other Pacific Islander
- <1% American Indian or Alaska Native

Ethnicity

- 73% not Hispanic or Latino
- 26% Hispanic or Latino
- <1% not reported

Sex

- 51% male
- 49% female

Age

- 58% 16 to 55 years
- 42% 55 years and older
- 21% 65 years and older
- 4% 75 years and older

The most frequent underlying medical conditions among clinical trial participants were obesity (35%), diabetes (8%), and pulmonary disease (8%).

Learn more about demographic information for people [16 years and older](#) who participated in the trials.

Clinical Trial Demographic Information: 12–15 Years Old

Clinical trials for the Pfizer-BioNTech vaccine in people 12–15 years old included people from the following racial and ethnic, age, and sex categories:

Race

- 86% White
- 5% African American
- 6% Asian
- <3% other race, multiracial, or race not reported
- <1% Native Hawaiian or Other Pacific Islander
- <1% American Indian or Alaska Native

Ethnicity

- 88% not Hispanic or Latino
- 12% Hispanic or Latino
- <1% not reported

Sex

- 51% male
- 49% female

Learn more about demographic information for people [12–15 years old](#) who participated in the trials

Related Pages

- › [Possible Side Effects](#)
- › [Safety of COVID-19 Vaccines](#)
- › [Benefits of Getting Vaccinated](#)
- › [How Vaccines Work](#)
- › [mRNA Vaccines](#)



For Healthcare Workers

[Pfizer-BioNTech COVID-19 Vaccine: General information, schedule and administration overview.](#)

More Information

[Pfizer-BioNTech COVID-19 Vaccine Fact Sheet for Recipients and Caregivers \[PDF – 6 pages\]](#)

[MMWR: Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14, 2020](#)

United States, December 14–23, 2020

Safety and Reactogenicity Data

Last Updated Sept. 20, 2021