Pfizer-BioNTech COVID-19 Vaccine Overview and Safety

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NOTICE: HHS announced a plan to begin offering COVID-19 vaccine booster shots this fall. CDC's independent advisory committee, the Advisory Committee on Immunization Practices, will continue to meet and discuss data on the evolution of the pandemic and the use of COVID-19 vaccines. ACIP will make further recommendations on the use of boosters for the public after a thorough review of the evidence.

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

Manufacturer: Pfizer, Inc., and BioNTech

Type of Vaccine: mRNA

Number of Shots: 2 shots, 21 days apart
Some immunocompromised people should get 3 shots

How Given: Shot in the muscle of the upper arm

Does NOT Contain: Eggs, preservatives, latex, metals
Full List of Ingredients

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 an mRNA COVID-19 vaccine (such as polyethylene glycol), you should not get either of the mRNA COVID-19 vaccines.
- If you had a severe or immediate allergic reaction **after getting the first dose of an mRNA COVID-19 vaccine**, you should not get a second dose of either of the mRNA COVID-19 vaccines.
- 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 an mRNA COVID-19 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 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 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 Year Olds

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 14–23, 2020

Safety and Reactogenicity Data

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