Centers for Disease Control and Prevention

COVID-19

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

Updated Jan. 6, 2022

General Information

Manufacturer: Pfizer, Inc., and BioNTech

Type of Vaccine: mRNA

Number of Shots: 2 shots, 21 days apart
Moderately or severely immunocompromised people ages 5 years and older should get an additional primary shot at least 28 days after their second shot.

How Given: Shot in the muscle of the upper arm

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

Booster Shot: Everyone ages 12 years and older is recommended to get a booster shot at least 5 months after completing their Pfizer-BioNTech primary series. Teens 12-17 years old can only get a Pfizer-BioNTech COVID-19 vaccine booster. For adults 18 years and older, a booster dose of either Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) is preferred in most situations.

Name: BNT162b2

Brand name: COMIRNATY

Who Should Get Vaccinated

- The Pfizer-BioNTech vaccine is recommended for people ages 5 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** 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 allergic reaction **after getting a dose of the Pfizer-BioNTech COVID-19 vaccine**, you should not get another dose of an mRNA vaccine.
- A severe allergic reaction can cause a rapid heartbeat, difficulty breathing, swelling of the throat, or a generalized rash or hives. A person with a severe allergic reaction needs to be treated with epinephrine (often given as an EpiPen®) and should seek immediate medical attention.

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.

Pfizer-BioNTech (COMIRNATY) Name Change

Pfizer-BioNTech (COMIRNATY) received U.S. Food and Drug Administration (FDA) approval on August 23, 2021, for individuals ages 16 years 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. After FDA approval, the FDA-authorized Pfizer-BioNTech COVID-19 vaccine for individuals ages 16 years and older was marketed as COMIRNATY. **No change was made to the vaccine's formula** with the name change.

The Pfizer-BioNTech vaccine label remains for individuals ages 5–15 years since the vaccine is authorized but not yet approved for this age group.

Pfizer-BioNTech COVID-19 Vaccine Ingredients

All COVID-19 vaccine ingredients are safe. Nearly all of the ingredients in COVID-19 vaccines are ingredients found in many foods – fats, sugars, and salts. The Pfizer-BioNTech COVID-19 vaccine also contains a harmless piece of messenger RNA (mRNA). The COVID-19 mRNA teaches cells in the body how to create an immune response to the virus that causes COVID-19. This response helps protect you from getting sick with COVID-19 in the future. After the body produces an immune response, it discards all of the vaccine ingredients, just as it would discard any substance that cells no longer need. This process is a part of normal body functioning.

All COVID-19 vaccines are manufactured with as few ingredients as possible and with very small amounts of each ingredient. Each ingredient in the vaccine serves a specific purpose as seen in the table below.

Ingredients in Pfizer-BioNTech COVID-19 vaccine for people ages 12 years and older

The Pfizer-BioNTech COVID-19 vaccine for people ages 12 years and older contains the following ingredients:

Type of Ingredient	Ingredient	Purpose
Messenger ribonucleic acid (mRNA)	• Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Provides instructions the body uses to build a harmless piece of a protein from the virus that causes COVID-19. This protein causes an immune response that helps protect the body from getting sick with COVID-19 in the future.
Lipids (fats)	• 2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide • 1,2-distearoyl-sn-glycero-3-phosphocholine • Cholesterol (plant derived) • ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	Work together to help the mRNA enter cells.
Salts and sugar	• Dibasic sodium phosphate dihydrate • Monobasic potassium phosphate • Potassium chloride (common food salt) • Sodium chloride (basic table salt) • Sucrose (basic table sugar)	Work together to help keep the vaccine molecules stable while the vaccine is manufactured, frozen, shipped, and stored until it is ready to be given to a vaccine recipient.

Ingredients in Pfizer-BioNTech COVID-19 vaccine for people ages 5–11

years

The Pfizer-BioNTech COVID-19 vaccine for people ages 5 through 11 years old contains the following ingredients:

Type of Ingredient	Ingredient	Purpose
Messenger ribonucleic acid (mRNA)	• Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Provides instructions the body uses to build a harmless piece of a protein from the virus that causes COVID-19. This protein causes an immune response that helps protect the body from getting sick with COVID-19 in the future.
Lipids (fats)	• 2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide • 1,2-distearoyl-sn-glycero-3-phosphocholine • Cholesterol (plant derived) • ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	Work together to help the mRNA enter cells.
Sugar and acid stabilizers	• Sucrose (table sugar) • Tromethamine • Tromethamine hydrochloride	Work together to help keep the vaccine molecules stable while the vaccine is manufactured, frozen, shipped, and stored until it is ready to be given to a vaccine recipient.

Ingredients that are NOT used in COVID-19 vaccines

The above table lists ALL ingredients in the Pfizer-BioNTech COVID-19 vaccine. There are NO ingredients in this vaccine beyond what is listed in the table. The Pfizer-BioNTech COVID-19 vaccine has:

- **No preservatives** like thimerosal or mercury or any other preservatives.
- **No antibiotics** like sulfonamide or any other antibiotics.
- **No medicines or therapeutics** like ivermectin or any other medications.
- **No tissues** like aborted fetal cells, gelatin, or any materials from any animal.
- **No food proteins** like eggs or egg products, gluten, peanuts, tree nuts, nut products, or any nut byproducts (COVID-19 vaccines are not manufactured in facilities that produce food products).
- **No metals** like iron, nickel, cobalt, titanium, rare earth alloys, or any manufactured products like microelectronics, electrodes, carbon nanotubes or other nanostructures, or nanowire semiconductors.
- **No latex**. The vial stoppers used to hold the vaccine also do not contain latex.

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

Nausea

These side effects 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 COVID-19 vaccines in the United States

- Moderna (ages 18 years and older)
- Johnson & Johnson's Janssen (ages 18 years and older)

You should get a COVID-19 vaccination as soon as possible. All currently approved or authorized COVID-19 vaccines are safe and effective. However, CDC recommends that people who are starting their vaccine series or getting a booster dose get either Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines). The mRNA vaccines are preferred over Johnson & Johnson's Janssen COVID-19 vaccine in most circumstances.

CDC does not recommend mixing products for a two-dose primary series or an additional primary dose. For a booster dose, adults ages 18 years and older may choose which vaccine product they get. CDC recommends either Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) in most circumstances. Although mRNA vaccines are preferred, the J&J/Janssen COVID-19 vaccine may be considered in some situations.

Safety Data Summary

- Side effects that happen within 7 days of getting vaccinated are common but are mostly mild. Some people have side effects that affect their ability to do daily activities.
- Side effects (such as fever, chills, tiredness, and headache) throughout the body are more common after the second dose of the vaccine.
- Rare 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.
- All FDA-approved or authorized COVID-19 vaccines have undergone and will continue to undergo the most intensive safety monitoring in U.S. history. This monitoring includes using both established and new safety monitoring systems to make sure that COVID-19 vaccines are safe.

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 ages 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 had >90% efficacy in preventing laboratory-confirmed COVID-19 infection in children ages 5–15 years, and the immune response in children ages 5–15 years was at least as strong as the immune response in people ages 16–25 years.
- In clinical trials, the vaccine also had >90% efficacy in 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 ages 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 ages 16 years and older who participated in the trials.

12–15 Years Old

Clinical trials for the Pfizer-BioNTech vaccine in people ages 12–15 years 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

<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 ages 12–15 years who participated in the trials.

5–11 Years Old

Clinical trials for the Pfizer-BioNTech vaccine in people ages 5–11 years included people from the following racial and ethnic, age, and sex categories:

Race

- 79% White
- 6% African American
- 6% Asian
- 8% other race, multiracial, or race not reported
- <1% American Indian or Alaska Native

Ethnicity

- 79% not Hispanic or Latino
- 21% Hispanic or Latino

Sex

- 53% male
- 47% female

Learn more about demographic information for people ages 5–11 years who participated in the trials.

Related Pages

- Possible Side Effects
- Safety of COVID-19 Vaccines
- Benefits of Getting Vaccinated
- How Vaccines Work

For Healthcare Workers

Pfizer-BioNTech COVID-19 Vaccine: General information, schedule, and administration overview.

More Information

Pfizer-BioNTech COVID-19 Vaccine for People 12 Years of Age and Older Fact Sheet for Recipients and Caregivers [PDF – 6 pages]

Pfizer-BioNTech COVID-19 Vaccine for People 5 through 11 Years of Age 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

Last Updated Jan. 6, 2022