



COVID-19

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

Updated Apr. 1, 2022

General Information

Manufacturer: Pfizer, Inc., and BioNTech

Type of Vaccine: mRNA

Number of Shots: 2 doses in the primary series, given 3–8 weeks apart.

How Given: Shot in the muscle of the upper arm

People ages 5 years and older who are moderately or severely immunocompromised should get a third dose at least 4 weeks after their second dose.

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

Booster Shot: People ages 12 years and older who received a Pfizer-BioNTech primary series should get a booster. Some people can also choose to receive a second booster.

Name: BNT162b2

Brand name: COMIRNATY

[Staying up to date](#) means getting all recommended COVID-19 vaccines, including a [booster shot](#) when eligible.

People who are moderately or severely immunocompromised have specific COVID-19 vaccine recommendations, which include an [additional third dose](#) to complete their primary series, as well as a [booster shot](#) for those eligible.

Who Should Get Vaccinated

The Pfizer-BioNTech vaccine is recommended for people ages 5 years and older.

Who Should NOT Get Vaccinated

- If you have had a [severe allergic reaction](#) or have a diagnosed allergy 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.

Pfizer-BioNTech has updated the formulation of the Pfizer-BioNTech COVID-19 vaccine. The updated formulation has the same active ingredients as the previous formulation but uses different stabilizers (ingredients that help keep the vaccine molecules stable while the vaccine is manufactured, frozen, shipped, and stored). These changes allow for easier shipping and longer storage of vaccines at refrigerator temperatures. This will help improve access to vaccines for people who need them and will decrease waste.

The previous formulation for people ages 12 years and older is no longer being distributed, and once the doses of that formulation have been used, only the updated formulation will be available. Both formulations can be used interchangeably without any safety or effectiveness concerns. Check with your healthcare provider about which formulation they carry if you are concerned about any of the ingredients.

Ingredients in the original Pfizer–BioNTech COVID–19 vaccine for people ages 12 years and older

The original 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) | <ul style="list-style-type: none">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) | <ul style="list-style-type: none">2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide1,2-distearoyl-sn-glycero-3-phosphocholineCholesterol (plant derived)((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) | Work together to help the mRNA enter cells. |

| | | |
|-----------------|---|--|
| Salts and sugar | <ul style="list-style-type: none"> • 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 children’s Pfizer–BioNTech COVID–19 vaccine and the updated formulation for people ages 12 years and older

The Pfizer-BioNTech COVID-19 vaccine for people ages 5 through 11 years old and the updated formulation of the Pfizer-BioNTech COVID-19 vaccine for people ages 12 years and older contain the following ingredients. While the ingredients are the same for all ages, people ages 12 years and older receive a higher dosage than children ages 5 through 11 years old.

| Type of Ingredient | Ingredient | Purpose |
|-----------------------------------|--|---|
| Messenger ribonucleic acid (mRNA) | <ul style="list-style-type: none"> • 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) | <ul style="list-style-type: none"> • 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 | <ul style="list-style-type: none"> • 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

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 or approved 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


- COVID-19 vaccines have undergone—and will continue to undergo—the most intensive safety monitoring in U.S. history. Evidence from the hundreds of millions of COVID-19 vaccines already administered in the United States, and the billions of vaccines administered globally, demonstrates that they are [safe](#) and [effective](#).
- [Side effects](#) that happen within 7 days of getting vaccinated are common but are mostly mild to mostly moderate. Some people have side effects that affect their ability to do daily activities.
- Side effects throughout the body (such as fever, chills, tiredness, and headache) are more common after the second dose of the vaccine.
- There is a rare risk of [myocarditis and pericarditis](#) associated with mRNA COVID-19 vaccination, mostly among males ages 12 through 39 years. The rare risk may be further reduced with a longer interval between the first and second dose. Learn more about [the timing for your second dose](#).

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

How Well the Vaccine Works

- Vaccines reduce the risk of COVID-19, including the risk of severe illness and death among people who are fully vaccinated.

- COVID-19 vaccines are effective, but studies have shown vaccine protection declines over time—especially with the Omicron variant. Learn more about getting a [booster](#) shot to enhance or restore protection against COVID-19.
- All FDA-approved or authorized COVID-19 vaccines provide substantial protection against COVID-19 hospitalization and death.
- CDC will continue to provide updates as we learn more.

Learn about demographic information for people ages [16 years and older](#)  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 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](#)