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

Updated June 10, 2022

Recommended for People 5 Years and Older

Primary Series: 2 doses of Pfizer-BioNTech in the primary series, given 3–8 weeks apart. People who are moderately or severely immunocompromised (have a weakened immune system) should get a 3rd dose at least 4 weeks after their 2nd dose in the primary series.

Boosters: People who received a Pfizer-BioNTech primary series should get a booster. Only some people can get a 2nd booster dose. Use CDC's COVID-19 booster tool to learn if and when you can get boosters to stay up to date with your COVID-19 vaccines.

Learn about the recommended timing between Pfizer-BioNTech COVID-19 vaccines and boosters for:

Ages 18 and Older | Ages 12–17 | Ages 5–11 | Immunocompromised

General Information

Manufacturer: Pfizer, Inc., and BioNTech

Name: BNT162b2

Type of Vaccine: mRNA

Brand name: COMIRNATY

How Given: Shot in the muscle of the upper arm

Does NOT Contain: Eggs, preservatives, latex, metals
View full list of ingredients

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.

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. 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.
- Severe allergic reactions to vaccines are rare but can happen.
- 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.

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)	• 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 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)	• 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)	Work together to help the mRNA enter cells.

	• ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	
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.

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.

Resources

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]

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