

## VACCINE INFORMATION STATEMENT

# The Pfizer/BioNTech COVID-19 Vaccines: What You Need to Know

Mayo Clinic created this Vaccine Information Statement for use temporarily until the official Centers for Disease Control and Prevention (CDC) versions are available.

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### Why get vaccinated against COVID-19?

COVID-19 vaccines can prevent the COVID-19 infection.

The COVID-19 infection (also called coronavirus disease 2019) is caused by the SARS-CoV-2 virus. Symptoms can range from no symptoms at all to severe acute respiratory syndrome. Most common symptoms include fever, cough, loss of smell or taste and fatigue.

Symptoms usually appear 2 to 14 days after infection. Early symptoms may include a loss of taste or smell. Other symptoms include shortness of breath or difficulty breathing, muscle aches, chills, sore throat, runny nose, headache and chest pain. Some people have experienced rash, nausea, vomiting or diarrhea.

Some people have only mild symptoms or no symptoms at all. Children are less likely to have symptoms and more likely to have a mild form of the illness.

Some people develop lung or organ infections severe enough to result in hospitalization and death. The risk of severe disease increases for people who are over 50 years old, are obese or who have other medical conditions.

SARS-CoV-2 spreads by respiratory droplets or small particles when an infected person coughs, sneezes, sings, talks or breathes, especially when in close contact with other people.

Some people have reported they have gotten the virus more than once. This is called reinfection. But this is not thought to be common.

The virus is more contagious than the flu (influenza). This means it spreads more easily from person to person. It is also more likely to result in hospitalization, critical care and death.

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### The Pfizer/BioNTech COVID-19 original monovalent vaccine

The Pfizer/BioNTech COVID-19 original monovalent vaccine provides protection against COVID-19 infection. It is one of several vaccines developed to protect against the original variants of COVID-19 infection.

The Pfizer/BioNTech COVID-19 vaccine is recommended for everyone 6 months and older.

For those 6 months through 4 years old, the primary vaccine series is given in 3 doses. The first and second doses are the original monovalent vaccine. The second dose is given 3 to 8 weeks after the first dose. The third dose is an updated bivalent vaccine which protects against additional variants of the COVID-19 virus. This dose is given at least 8 weeks after the second dose to complete the primary series.

For those 5 years and older, the primary vaccine series with the original monovalent vaccine is given in 2 doses. The second dose is given 3 to 8 weeks after the first dose.

For those 5 years and older who are moderately or severely immunocompromised, the CDC and Mayo Clinic recommend getting a third dose of the original monovalent vaccine at least 4 weeks after the second dose to complete the primary vaccine series.

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### The Pfizer/BioNTech COVID-19 bivalent booster vaccine

The CDC and Mayo Clinic recommend an mRNA COVID-19 bivalent booster vaccine for everyone 6 months and older. This booster dose should be given 2 months after the last dose of the primary vaccine series or the most recent booster dose.

A child age 6 months to 4 years who received a Pfizer/BioNTech bivalent vaccine as the third dose in their primary series cannot receive a bivalent booster dose until age 5 years or older.

The CDC and Mayo Clinic recommend that you do not get a different vaccine brand for your primary vaccine series. For those 5 years and older with a weakened immune system who receive the additional primary series dose, Mayo Clinic recommends that you also receive the same vaccine brand as your primary series.

For everyone 5 years and older it is safe and acceptable to get any of the authorized brands of bivalent mRNA COVID-19 vaccines as the booster.

For those 6 months through 4 years old who are completing their primary Pfizer series with the bivalent vaccine, the vaccine must be the Pfizer vaccine. This is not a booster.

Ask your health care provider if you have questions.

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### Talk with your health care provider

Tell your vaccine provider if you:

- Have had an allergic reaction after a previous dose of the Pfizer/BioNTech vaccine or have any severe, life-threatening allergy (anaphylaxis) to components in the vaccine, any other vaccine or any injectable therapy.
- Are experiencing signs or symptoms of COVID-19 infection.
- Are acutely ill or contagious with the COVID-19 infection.
- Have a condition that causes your immune system to be weakened or compromised. It is safe to get the vaccine, but this may decrease your body's response to the vaccine.
- Are taking a blood-thinning medication or have a bleeding disorder.
- Are pregnant or breastfeeding.

In some situations, your health care provider may decide to postpone the COVID-19 vaccination to a future visit.

People with minor illnesses, such as a bladder infection, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting this COVID-19 vaccine.

Your health care provider can give you more information and answer any questions.

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### Risks of a vaccine reaction

- **Pain.** Most people had pain where the shot was given. In some, the injection pain was severe enough to prevent them from doing daily activities.
- **Redness or swelling.** A few people had redness or swelling where the shot was given.
- **Fever.** About 1 in 5 people, 18 to 55 years old, got a fever after they received the vaccine. 1 in 3 of the people who had fevers had a temperature ranging from 100.4 to 101.1 degrees Fahrenheit. The rest ranged from 101.3 to 102.0 degrees Fahrenheit. Only 1 in 10 people, 65 to 85 years old, got a fever after the second dose, ranging from 100.4 to 101.1 degrees Fahrenheit.
- **Fatigue.** About 1 in 4 to 3 in 4 people had fatigue after they received the vaccine. This was more common with the second dose and in younger adults. The fatigue was sometimes severe enough to prevent them from doing daily activities.
- **Chills.** About 1 in 3 to 1 in 2 people had chills. For some, this was severe.
- **Headache, muscle pain or joint pain.** This was reported by some.

These reactions are more frequent and more severe after the second dose and in those 65 years and younger. These side effects generally occurred within 2 days after vaccination and got better in 24 to 48 hours.

You should still get the recommended doses of the Pfizer/BioNTech vaccine even if you had one of these reactions after a previous dose.

People sometimes faint after medical procedures, including vaccinations. Tell your provider if you feel dizzy, have vision changes or have ringing in your ears.

As with any medicine, there is a very small chance of a vaccine causing a severe allergic reaction, other serious injury or death.

Other risks include:

- **Myocarditis and pericarditis.** In a few rare cases, people have developed inflammation of the heart muscle, called myocarditis, or inflammation of the lining outside the heart, called pericarditis, after receiving this vaccine. In people who developed these conditions, symptoms began within a few days of the vaccination. These symptoms are more common after the second dose of vaccine. Most of those who developed these conditions were male adolescents and adults 12 through 39 years of age. Males in this age group, and anyone under the age of 65, can choose to increase the time between the first and second mRNA vaccine dose to 8 weeks. This can lower the risk of these two conditions. The increased time between doses is not recommended if you have a weakened immune system or during time periods where there are high rates of local COVID-19 transmission. Waiting longer than 8 weeks will not help more. **Seek medical care right away if you have any of these symptoms:**

- Chest pain.
- Shortness of breath.
- Heart palpitations, a fast-beating heart, feeling like your heart skips a beat, or feeling like your heart is fluttering.

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### **What if there is a serious problem?**

An allergic reaction could occur after you leave your vaccine appointment. **If you have signs of a severe allergic reaction, such as hives, swelling of the face or throat, difficulty breathing, a fast heartbeat, dizziness or weakness, call 911 or have someone drive you to the nearest hospital.**

For other symptoms that concern you, call your health care provider.

Adverse or allergic reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report or you can do it yourself. Visit the VAERS website at [www.vaers.hhs.gov](http://www.vaers.hhs.gov) or call **1-800-822-7967**.

*VAERS is only for reporting reactions and VAERS staff does not give medical advice.*

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### **How can I learn more?**

- Ask your health care provider.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit the CDC at [www.cdc.gov/vaccines](http://www.cdc.gov/vaccines)

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### **How can I help?**

V-SAFE is a voluntary vaccine safety data collection system. You can enroll in V-SAFE on your phone or other device. Mayo Clinic asks all COVID-19 vaccine recipients to take part. It uses text messaging and web surveys to provide personalized health check-ins after COVID-19 vaccination. V-SAFE allows you to report any side effects after COVID-19 vaccination to the CDC soon after they occur.

It also reminds you to get your next recommended COVID-19 vaccine dose. Sign up for V-SAFE at <https://vsafe.cdc.gov> when you get your first dose of COVID-19 vaccine.

