

## VACCINE INFORMATION STATEMENT

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

Mayo Clinic created this Vaccine Information Statement for use temporarily until the official CDC versions are available.

**1**

### **Why get vaccinated against COVID-19?**

**This COVID-19 vaccine** can prevent 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 none 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, 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 (within 6 feet) with other people.

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

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

**2**

### **The Pfizer/BioNTech COVID-19 vaccine**

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

In a randomized, controlled trial involving over 40,000 volunteers, the vaccine prevented COVID-19 in 95% of people vaccinated. The 95% prevention rate was about the same no matter the age, sex, ethnicity or race of the people who received it.

The Pfizer/BioNTech COVID-19 vaccine is recommended for everyone 5 years of age and older. The vaccine is given in two doses. The second dose is given at least 21 days after the first.

If you or your child are moderately or severely immunocompromised, it is recommended to get a third dose at least 4 weeks after the second dose.

**3**

### **The Pfizer/BioNTech COVID-19 vaccine for ages 5 to 11**

The Pfizer/BioNTech COVID-19 vaccine dose given to children 5 to 11 years old is one-third the dose given to adults and children 12 years and older.

## 4

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

A booster dose of Pfizer/BioNTech vaccine is available to all people 12 years and older. The booster is the same dosage given in the initial vaccine series.

Get the first booster dose 5 months after you received the second dose of your initial vaccine series.

Adults 50 years and older can choose a second booster dose of Pfizer/BioNTech vaccine at least 4 months after the first booster dose.

If you are moderately or severely immunocompromised, get the first booster dose 3 months after you received the third dose of your initial vaccine series.

The second booster dose of Pfizer/BioNTech vaccine is also available to people ages 12 years and older who are moderately or severely immunocompromised. The second booster dose is given at least 4 months after the first booster dose.

Health care providers recommend you get the same brand mRNA vaccine for your booster doses. However, it is safe and acceptable to get any of the authorized mRNA COVID-19 vaccine boosters.

**Do not get a different vaccine brand for your booster dose unless you are 18 years and older.**

Ask your health care provider if you have questions.

## 5

### 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.

## 6

### Risks of a vaccine reaction

- **Pain.** Most people had pain where the shot was given. This happened with both doses. 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 second dose of Pfizer/BioNTech vaccine even if you had one of these reactions after the first 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.

**7**

## **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.*

**8**

## **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)

## 9

### 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 second COVID-19 vaccine dose. Sign up for V-SAFE at <https://vsafe.cdc.gov> when you get your first dose of COVID-19 vaccine.