#### **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 versions are available.

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# 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 develop lung or organ infections severe enough to result in hospitalization and death. The risk of severe disease increases with age over 50 years, obesity, and the presence of 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 each other.

Some people have reported they have gotten the virus twice, 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 people 16 years of age and older. The vaccine is given in two doses as a series. The second dose is given 21 days after the first.

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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.
- Had COVID-19 infection in the last 90 days.
- Have a condition that causes your immune system to be weakened or compromised.
  This may decrease the response to the vaccine.
- Are taking an anticoagulant medication or you have a bleeding disorder.
- Are pregnant or breastfeeding.

In some situations, health care providers recommend delaying a person receiving the vaccine until a later time.

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. 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.

For all people, these symptoms got better without medical care, and usually within 24 to 36 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.

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# What if there is a serious problem?

An allergic reaction could occur after you leave the clinic. If you have signs of a severe allergic reaction, such as hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness, call 9-1-1 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 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

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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/other mobile device. Mayo Clinic asks all COVID-19 vaccine recipients to take part. It uses text messaging and web surveys to provide personalized health checkins 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.