

VACCINE INFORMATION STATEMENT

The Johnson & Johnson Janssen 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 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 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 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 six feet) with another person.

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 Johnson & Johnson Janssen COVID-19 vaccine

The Johnson & Johnson Janssen COVID-19 vaccine provides protection against the COVID-19 infection. It is one of several vaccines developed to protect against the COVID-19 infection.

In a randomized, controlled trial with results from about 40,000 volunteers, the vaccine was 66% effective in preventing moderate-to-severe disease, 85% effective in preventing severe disease, and 100% effective in preventing COVID-19-related hospitalization and death. For severe disease, the prevention rate was about the same no matter the age, health, race, ethnicity, or virus variant of the people who received it.

The Johnson & Johnson Janssen COVID-19 vaccine is recommended for adults 18 years of age and older. The vaccine is given as one dose.

3 Talk with your health care provider

Tell your vaccine provider if you:

- Have had an allergic reaction after a previous dose of an adenovirus vector vaccine or have any severe, life-threatening allergy (anaphylaxis) to components in the vaccine, any other vaccine, or any injectable therapy. While you may get the vaccine, if you have a history of anaphylaxis you will need to stay for 30 minutes after the injection so you can be observed.
- Are experiencing signs or symptoms that suggest you may have the COVID-19 infection.
- Are acutely ill or contagious with the COVID-19 infection.
- Had a COVID-19 infection in the last 90 days.
- 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 blood-thinning medication or you 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.

4 Risks of a vaccine reaction

- **Pain.** About 1 in 2 adults had pain where the shot was given.
- **Redness or swelling.** A few people had redness or swelling where the shot was given.
- **Headache.** About 1 in 3 adults experienced a headache after receiving the vaccine.
- **Muscle pain.** About 1 in 3 adults had muscle pain after receiving the vaccine.
- **Nausea.** About 1 in 7 adults experienced nausea after receiving the vaccine.
- **Fever.** About 1 in 11 adults experienced a fever after receiving the vaccine.

Most side effects were mild or moderate. Fever occurred within 2 days of injection and lasted no more than a day or two. About 1 in 3 had local reactions where the shot was given lasting more than a week. Headache, muscle pain, and fever occurred more commonly in younger adults.

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 your vaccine appointment. **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. It uses text messaging and web surveys to provide personalized health check-ins after your COVID-19 vaccination. V-SAFE allows you to report any side effects after COVID-19 vaccination to the CDC soon after they occur. You can enroll in V-SAFE on your phone or other mobile device. Mayo Clinic asks all COVID-19 vaccine recipients to take part. Sign up for V-SAFE at <https://vsafe.cdc.gov/> when you get your dose of COVID-19 vaccine.