VACCINE INFORMATION STATEMENT

The Johnson & Johnson Janssen COVID-19 Vaccine: What You Need to Know

**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 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.

This 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.

**The Johnson & Johnson Janssen COVID-19 vaccine**

The 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.

Mayo Clinic is committed to patient safety. The Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) recommended a brief pause to determine the safety of this vaccine.

On April 23, 2021, the U.S. Advisory Committee on Immunization Practices concluded the benefits of this vaccine outweigh risks.

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

If you are moderately or severely immunocompromised, it is recommended to get an additional mRNA dose at least 4 weeks after the first dose.

Mayo Clinic and the CDC prefer the Pfizer and Moderna vaccines over the Johnson & Johnson Janssen vaccine. This is due to vaccine effectiveness and safety.

**The Johnson & Johnson Janssen COVID-19 vaccine booster**

All people who received the Janssen vaccine should get a booster.
Healthy people ages 18 through 49 years who received a Janssen COVID-19 vaccine as the single primary series dose should get a first booster dose at least 2 months afterward. Moderna or Pfizer/BioNTech mRNA vaccines are preferred for the first booster dose.

Healthy people ages 18 through 49 years who received Janssen COVID-19 vaccines for both their primary series dose and first booster dose may receive a second booster dose using an mRNA vaccine. Get this second booster at least 4 months after the first booster dose for a total of 3 doses.

Healthy people ages 50 years and older who received a Janssen COVID-19 vaccine as the single primary series dose should get a first booster dose at least 2 months afterward. Moderna or Pfizer/BioNTech mRNA vaccines are preferred for the first booster dose. A second booster dose using an mRNA vaccine is recommended at least 4 months after the first booster dose for a total of 3 doses.

If you are moderately or severely immunocompromised, get the first booster dose 2 months after your additional mRNA dose. Get a second mRNA booster dose at least 4 months after the first booster dose for a total of 4 doses.

Tell your vaccine provider if you:

- Have had an allergic reaction after a previous dose of an adenovirus vector vaccine or have a 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.

Risk of 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 had 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 had nausea after receiving the vaccine.

- Fever. About 1 in 11 adults had a fever after receiving the vaccine.

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

Some people 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:

- **Blood clotting.** In a few rare cases, people have experienced blood clots after this vaccine. The clots occurred about 1 to 2 weeks after the vaccine. In these few cases, most were women between the ages of 18 and 49. Get medical care right away if you have any of the following symptoms in the first 3 weeks:
  - Severe or persistent headaches.
  - Blurred vision.
  - Shortness of breath.
  - Chest pain.
  - Leg swelling.
  - Persistent abdominal pain.
  - Easy bruising.
  - Tiny blood spots under the skin beyond the site of your injection.

- **Guillain-Barré syndrome.** In a few rare cases, people have developed Guillain-Barré syndrome after receiving this vaccine. This is a nerve disorder in which the body’s immune system damages nerve cells. This can cause muscle weakness and sometimes paralysis. In most cases, symptoms began within 42 days after getting the vaccine. Seek medical care right away if you have any of the following symptoms after receiving this vaccine:
  - Weakness or tingling, especially in the legs or arms, that gets worse and spreads to other parts of the body.
  - Difficulty walking.
  - Difficulty with facial movements, including speaking, chewing or swallowing.
  - Double vision or inability to move your eyes.
  - Loss of control of bladder or bowel function.

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### 6 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 may 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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### 7 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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### 8 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/](https://vsafe.cdc.gov/) when you get your dose of COVID-19 vaccine.