

### What You Need to Know about the Janssen COVID-19 Vaccine

#### How does the Janssen COVID-19 vaccine work?

All COVID-19 vaccines cause the immune system to respond against the virus that causes COVID-19. The Janssen vaccine is a **viral vector vaccine**.

Viral vector vaccines use a modified version of a virus (a **vector**) to deliver important instructions to our cells. The vector used in the Janssen vaccine is not the virus that causes COVID-19, but a different, harmless virus.

- The vector enters a cell in our body and delivers a gene that instructs our cells to produce a spike protein. The spike protein is a harmless piece of the virus that causes COVID-19. It is only found on the surface of the virus that causes COVID-19.
- The spike protein triggers our immune system to begin producing antibodies and activates other immune cells to fight off what it thinks is an infection.

The FDA approved 2 other vaccines against COVID-19. Pfizer and Moderna vaccines are mRNA vaccines. All 3 vaccines effectively prevent serious illness and death from COVID-19 and have similar potential side effects. To learn more visit: <u>https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines</u>

#### How safe is the viral vector?

The viral vector is not capable of causing illness in humans because it has been genetically modified. It cannot multiply in humans and cannot cause disease.

The viral vector does not affect or interact with our DNA in any way. The genetic material delivered by the viral vector does not integrate into a person's DNA.

#### How many shots am I going to need?

1 dose (shot) in the muscle of the upper arm is needed.

#### Who should get vaccinated?

The Janssen vaccine is recommended for people aged 18 years and older.

#### Who should not get vaccinated?

If you have had a severe or an immediate allergic reaction to any ingredient in the Janssen COVID-19 vaccine (such as polysorbate), you should not get it. To see a list of ingredients visit: <u>https://www.fda.gov/media/146305/download</u>.

- A **severe allergic reaction (anaphylaxis)** is when a person needs to be treated with epinephrine or EpiPen<sup>©</sup> or if they must go to the hospital.
- An **immediate allergic reaction** means a reaction within 4 hours of exposure, including symptoms such as hives, swelling, or wheezing (respiratory distress).

#### How effective is the vaccine?

In clinical trials, the vaccine was 85% effective in preventing moderate to severe/critical COVID-19, 28 days or more after vaccination. Additionally, the vaccine was 100% effective in preventing hospitalization and death caused by COVID-19 infection.

#### How do we know if COVID-19 vaccines are safe?

COVID-19 vaccines were tested in large clinical trials that included tens of thousands of people. This is done to make sure they meet safety standards and see how the vaccines offer protection to people of different ages, races, and ethnicities, as well as those with different medical conditions. No significant safety concerns were identified in the clinical trials. At least 8 weeks of safety What You Need to Know About the Janssen COVID-19 Vaccine data were gathered in the trials. It is unusual for side effects to appear more than 8 weeks after vaccination.

**Important note:** The development of these vaccines has been accelerated while maintaining all safety standards. Rather than eliminating steps from traditional vaccine development timelines, steps were happening at the same time, such as scaling up manufacturing while safety and efficacy data are collected.

#### What are the side effects of the vaccine?

In the vaccine clinical trials, most people did not have serious problems after being vaccinated. The symptoms usually went away on their own within a week. General side effects such as fever, headache, and muscle aches are signs that your immune system is doing exactly what it is supposed to do. It is working to build up protection against disease. If you do not experience any side effects, be assured that the vaccine is just as effective.

On initial review by the CDC about 7 in 1 million people who received the Janssen vaccine developed blood clots with low levels of platelets (blood cells that help your body stop bleeding). This rare event affected mostly females between the ages of 18-49. After a carefuel review of the data, the CDC and FDA concluded that the known and potential benefits of the Janssen vaccine outweigh the risks.

The symptoms of this side effect began about 1-2 weeks after vaccination. **If you develop any of these signs and symptoms seek medical attention right away**:

- Shortness of breath
- Chest pain
- Leg swelling
- Persistent abdominal pain
- Severe or persistent headaches or blurred vision

• Easy bruising or tiny blood spots under the skin beyond the site of the injection (anywhere on the body).

# Is the vaccine safe for pregnant women and people who have conditions or take medications that can weaken the immune system?

The early clinical trials did not test the vaccines in these populations. Based on the current data, the benefit of receiving the COVID-19 vaccine is greater than the risks of getting COVID-19. **Talk to your health care provider about the potential risks and benefits of the vaccine in your specific situation.** 

# I already had COVID-19 and recovered. Do I still need to get vaccinated?

Yes, you should be vaccinated regardless of whether you already had COVID-19. That's because experts do not yet know how long you are protected from getting sick again after recovering from COVID-19. If you were treated for COVID-19 with monoclonal antibodies or convalescent plasma, you should wait 90 days before getting a COVID-19 vaccine. Talk to your health care provider if you are unsure what treatments you received or if you have more questions about getting a COVID-19 vaccine.

# Do I need to wear a mask and avoid close contact with others if I have received the vaccine?

You are considered fully vaccinated 2 weeks after the second dose in a 2-dose series like the Pfizer or Moderna vaccine or 2 weeks after the single-dose vaccine like the Janssen vaccine. People who have been fully vaccinated can start to do some things that they had stopped doing because of the pandemic. While experts learn more about the protection that COVID-19 vaccines provide under real-life conditions, the CDC will update its guidelines frequently. Please visit: <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-</u> <u>vaccinated.html</u> to see the most current guidelines about what fully-vaccinated people can do.

#### Where can I learn more about the COVID-19 Vaccines?

For current and accurate information about the COVID-19 vaccines visit:

- Michigan Medicine: COVID-19 Vaccine Information and Update: <u>https://www.uofmhealth.org/coronavirus/vaccine-info-update</u>
- CDC: COVID-19 Vaccines: <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines</u>
- FDA. Janssen Covid-19 Vaccine Frequently-Asked-Questions <u>https://tinyurl.com/4fzvrkrw</u>

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Adapted from:

CDC: COVID-19 Vaccines. Access at: <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines</u> Approved by: COVID19 Vaccine Patient Education/Communication Workgroup

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