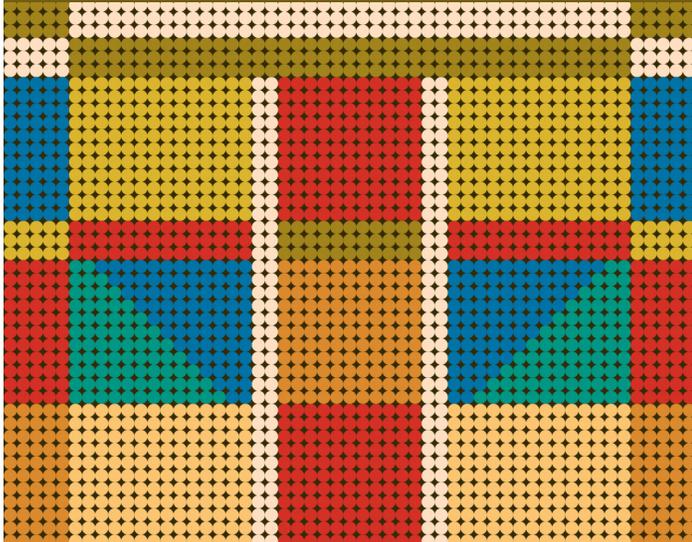


# Information about Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 Vaccine



This fact sheet contains information about Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 vaccine that is intended to help you make the most informed decision possible about getting the vaccine to better protect yourself, your loved ones, and tribal communities, both urban and rural.

The J&J/Janssen COVID-19 vaccine received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) on February 27, 2021 to protect people 18 years and older from COVID-19. The Centers for Disease Control and Prevention (CDC) currently recommends COVID-19 vaccination for everyone ages 12 and up.

## Who is the J&J/Janssen COVID-19 vaccine for?

The J&J/Janssen COVID-19 vaccine has been authorized for those 18 years or older. It is the only COVID-19 vaccine that only requires one dose to be effective. However, you should talk with your provider to discuss the risks and benefits before getting the vaccine if you:

- have any allergies, especially to other vaccines.
- have a bleeding disorder or are on a blood thinner.
- are immunocompromised or are taking medication that affects your immune system.
- have a fever.
- are pregnant or plan to become pregnant.
- are breastfeeding.
- have received another COVID-19 vaccine.<sup>1</sup>

**You should not get the vaccine if you have** had a severe allergic reaction to any of the vaccine ingredients. A list of ingredients can be found on the official Janssen fact sheet.<sup>1</sup>

## Is the J&J/Janssen COVID-19 vaccine safe?

The COVID-19 vaccines have been thoroughly tested and are safe and effective. During clinical trials, over 39,000 people participated in testing this vaccine, including a small number of Native people (1%). According to CDC, over 15 million people have received the J&J/Janssen COVID-19 vaccine as of October 26, 2021.<sup>2</sup>

## What should I know about the temporary pause of the J&J/Janssen vaccine?

A rare risk of blood clots for women younger than 50 has been reported after receiving the J&J/Janssen vaccine. The FDA and CDC put a temporary pause on the administration of the J&J/Janssen vaccine so that experts could review all safety data regarding the event of blood clots. After reviewing the available data, the FDA and CDC determined that the benefits of receiving the J&J/Janssen vaccine outweigh the potential risks and recommended the continued use of the vaccine.

While the event of blood clots is extremely rare (around 7 in one million vaccinated women between ages 18-49), it is important to be aware of this risk. If you receive the J&J/Janssen vaccine you should be on the lookout for possible symptoms of a blood clot for three weeks after receiving the vaccine.<sup>3</sup> These symptoms include severe or persistent headaches or blurred vision, shortness of breath, chest pain, leg swelling, constant abdominal pain, or easy bruising/tiny blood spots under the skin beyond the injection site. Seek medical care right away if you develop one or more of these symptoms.<sup>3</sup>

## How does the J&J/Janssen COVID-19 Vaccine work?

The J&J/Janssen vaccine is made from a different, harmless virus that has been modified to deliver instructions to cells. This starts an immune response in our bodies that will produce antibodies to protect against future infection of COVID-19. Scientists began using viral vector technology in the 1970s and viral vector vaccines have been used or studied for other diseases such as Ebola, the flu, and HIV. More information about viral vector vaccines can be found on the CDC website.<sup>4</sup>

## How is the J&J/Janssen COVID-19 vaccine given?

The vaccine is given in a single dose that is injected into the muscle in your upper arm.

## Will I need a COVID-19 booster shot?

Based on available data, scientists have determined that a booster shot will be needed to maintain protection against COVID-19 over time. The vaccines are working well to prevent severe illness and hospitalization as a result of COVID-19, but a booster dose will help give us increased protection from the virus and new variants that may occur. Many other vaccines also require booster shots, including the flu shot, HPV vaccine and Tdap (Tetanus, Diphtheria, Pertussis) vaccine.

Booster shots of the J&J/Janssen COVID-19 vaccine are now available under EUA by the FDA. If you are 18 years of age and older and received the J&J/Janssen vaccine at least two months ago, you are now eligible to receive a booster shot. The FDA also authorized “mix and match” booster shots for eligible individuals. This means you may choose to receive the same vaccine type that you originally received (J&J/Janssen) or one of the other currently available booster shots (Moderna or Pfizer).<sup>5</sup>

## Will the J&J/Janssen COVID-19 vaccine prevent me from getting COVID-19?

Clinical trials show that the J&J/Janssen vaccine has been shown to prevent COVID-19, however it may not protect everyone.<sup>3</sup> It is important to continue to practice safety measures to help stop the spread of COVID-19, even after you are vaccinated. Safety measures differ based on state, county, and city and may include:

- wearing a mask to protect others who either do not have the vaccine or are still waiting for theirs.
- watching your distance.
- washing your hands.
- following local public health recommendations.

## What are the benefits of getting vaccinated?

- We protect ourselves from serious illness and hospitalization.
- We make our families and communities less vulnerable to infection.
- We are significantly less likely to get severe COVID-19 symptoms or fall deathly ill.

## What are the risks of getting vaccinated?

Common side effects that have been reported after receiving the J&J/Janssen vaccine include:

- pain, swelling, or redness at the injection site.
- headache or fatigue.
- muscle pain.
- chills or fever.
- nausea.<sup>1</sup>

These symptoms typically resolve within 24 hours. Call your provider if any side effects do not go away. In addition, you can report any side effects to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to <https://vaers.hhs.gov/reportevent.html>. You can also report side effects to Janssen Biotech, Inc. at 1-800-565-4008.

CDC and FDA are also monitoring reports of Guillain-Barré Syndrome (GBS) in people who have received the J&J/Janssen vaccine. These reports are considered rare, with around 233 preliminary reports made to VAERS and over 15 million doses of the J&J/Janssen vaccine administered. GBS is a rare disorder where the body’s immune system damages nerve cells. Most people fully recover from GBS, but some have permanent nerve damage. Cases have been reported mostly in men, many 50 years and older, and occurred about 2 weeks after vaccination. CDC will continue to monitor these reports and share information as it becomes available.<sup>3</sup>

If you have other concerns or questions, you can visit [www.janssencovid19vaccine.com](http://www.janssencovid19vaccine.com) or call 1-800-565-4008.

## References

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3. CDC. Johnson & Johnson’s Janssen COVID-19 Vaccine Overview and Safety. Centers for Disease Control and Prevention. Updated October 4, 2021. Accessed October 26, 2021. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/janssen.html>
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5. CDC. Who is Eligible for a COVID-19 Vaccine Booster Shot? Centers for Disease Control and Prevention. Updated October 22, 2021. Accessed October 26, 2021. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html>