COVID-19 Vaccine FAQ for Patients



What is an EUA?

An Emergency Use Authorization is allowed in instances where a public health threat is identified, and there are no approved or adequate existing products. The U.S. Food and Drug Administration (FDA) carefully reviews all safety data from clinical trials and authorizes emergency vaccine use only when the expected benefits outweigh potential risks.

Source: FDA. (2021). Emergency Use Authorization for Vaccine Explained. Retrieved from <u>www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained</u>

Am I better off getting COVID-19 instead of getting the vaccine?

Studies show COVID-19 vaccines are safe and very effective. COVID-19 can have serious, lifethreatening complications, and there is no way to predict how COVID-19 will affect a person. It is unknown whether getting COVID-19 protects you from getting the virus again or how long natural immunity lasts. Additionally, when you become infected with the virus, you risk transmitting it to the people around you.

Source: CDC. (2021). Answering Patients' Questions. Retrieved from <u>www.cdc.gov/vaccines/covid-19/hcp/answering-</u> <u>questions.html</u>

Can I stop wearing a mask or social distancing after I get the vaccine?

While the vaccine greatly reduces your risk of contracting COVID-19, you will still need to practice precautions such as wearing a mask, social distancing, and other hygiene measures until public health experts say otherwise.

Source: CDC. (2021). Answering Patients' Questions. Retrieved from <u>www.cdc.gov/vaccines/covid-19/hcp/answering-</u> <u>questions.html</u>

Could the vaccine cause long-term side effects or other problems that we do not know about yet?

The FDA and CDC are continuing the monitor the safety of the vaccine to identify any possible longterm side effects. The CDC's committee charged with evaluating vaccine safety data will take action to address any safety issues that are identified. When you receive the vaccine, you will be provided with resources to report any bad reaction to the vaccine.

Source: CDC. (2021). Answering Patients' Questions. Retrieved from <u>www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html</u>

What is the Vaccine Adverse Event Reporting System? What is the V-safe Monitoring System?

The Vaccine Adverse Event Reporting System (VAERS) is a national monitoring system that tracks people's physical reactions after getting the shot. Healthcare workers and vaccine manufacturers are required to report adverse events that occur after vaccination in VAERS. V-safe is a new smartphone-based health monitoring system for people who receive the COVID-19 vaccine. V-safe uses text messaging and web surveys to provide check-ins with COVID-19 vaccine recipients. They will call to follow-up with anyone who reports a significant bad reaction. A VAERS report will be taken during follow-up if appropriate.

Source: CDC. (2021). Ensuring the Safety of COVID-19 Vaccines in the United States. Retrieved from <u>www.cdc.gov/</u> <u>coronavirus/2019-ncov/vaccines/safety.html</u>

How is the Johnson and Johnson (Janssen) COVID-19 vaccine different from the other two COVID-19 vaccines?

The Johnson and Johnson (Janssen) COVID-19 vaccine differs from other COVID-19 vaccines, because it uses an adenovirus instead of mRNA to stimulate the body's natural immune response. You might be familiar with adenoviruses if you've had the common cold. Adenovirus vaccines use a modified version of a different virus as a vector to deliver instructions for making the spike protein found on the surface of the COVID-19 virus. The genetic material delivered by the adenovirus does not enter the cell nucleus and does not integrate into a person's DNA. Viral vectors, such as adenoviruses, have been used in vaccines since the 1970s against a number of infectious diseases including influenza, Zika Virus, and Ebola.

Source: CDC. (2021). Understanding and Explaining Viral Vector COVID-19 Vaccines.. Retrieved from <u>www.cdc.gov/</u><u>vaccines/covid-19/hcp/viral-vector-vaccine-basics.html</u>

Will the vaccine make you sick?

The vaccine cannot give someone COVID-19, because it does not contain the COVID-19 virus. Side effects can occur with any vaccine. They are a sign that the immune system is working to build up protection against a virus. Symptoms from the vaccine typically resolve within a week, but you should talk to your doctor about if your symptoms do not go away.

Source: CDC. (2021). Answering Patients' Questions. Retrieved from <u>www.cdc.gov/vaccines/covid-19/hcp/answering-</u> <u>questions.html</u>

Is the Johnson and Johnson (Janssen) COVID-19 vaccine safe?

The FDA and CDC's Advisory Committee on Immunization Practices (ACIP) carefully review all safety data from clinical trials before authorizing emergency vaccines and recommend the vaccine for use only when the expected benefits outweigh potential risks. The FDA and CDC will continue to monitor the safety of these vaccines. There is a reporting system in place to identify any possible side effects or adverse events.

Source: CDC. (2021). Answering Patients' Questions. Retrieved from <u>www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html</u>

How is the Johnson and Johnson (Janssen) COVID-19 vaccine administered?

The Johnson and Johnson (Janssen) COVID-19 vaccine is administered intramuscularly with a single injection. After administration, the person receiving the vaccine will be monitored for 15 minutes by clinic staff.

Source: CDC. (2021). Answering Patients' Questions. Retrieved from <u>www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html</u>

Johnson and Johnson (Janssen) COVID-19 Vaccine

What are the ingredients in the Johnson and Johnson (Janssen) COVID-19 vaccine?

The Johnson and Johnson (Janssen) COVID-19 vaccine contains: citric acid monohydrate (0.14 mg), trisodium citrate dihydrate (2.02 mg), ethanol (2.04 mg), 2-hydroxypropyl-β-cyclodextrin (HBCD) (25.50 mg), polysorbate-80 (0.16 mg), sodium chloride (2.19 mg).

Source: Janssen (2021). Fact Sheet for Healthcare Providers. Retrieved from <u>www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf.</u>

What are the potential risks and side effects of the Johnson and Johnson (Janssen) COVID-19 Vaccine?

Side effects that have been reported with the Johnson and Johnson (Janssen) Vaccine include:

- Injection site pain
- Headache
- Fatigue
- Muscle aches
- Nausea

In very rare cases, the Johnson and Johnson (Janssen) COVID-19 vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Johnson and Johnson (Janssen) COVID-19 vaccine. For this reason, your vaccination provider will ask you to stay at the clinic for 15 minutes after you receive the shot for monitoring.

Signs of a severe allergic reaction can include difficulty breathing, swelling of your face and throat, a fast heartbeat, a bad rash all over your body, dizziness, and weakness. These may not be all the possible side effects of the Johnson and Johnson (Janssen) COVID-19 vaccine. Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Johnson and Johnson (Janssen) COVID-19 vaccine.

Source: Janssen (2021). Fact Sheet for Healthcare Providers. Retrieved from <u>www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf.</u>

If I have already had COVID-19, how long do I need to wait to get the COVID-19 Vaccine?

If you previously had a COVID-19 infection, you can receive the COVID-19 vaccine. People with a current COVID-19 infection should wait until they have recovered from the illness and their isolation period is over to get the vaccine. If you received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment, it is recommended that you wait 90 days before vaccination. If you did not receive any of these treatments for a COVID-19 infection, there is no recommended minimum amount of time between infection and vaccination.

Source CDC. (2021). Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States. Retrieved from: www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

Can I get the Johnson and Johnson (Janssen) COVID-19 vaccine if I'm pregnant or breastfeeding?

There are currently no available data on the safety of the Johnson and Johnson (Janssen) COVID-19 vaccines in pregnant individuals. However, studies are ongoing and expected to be available soon. Pregnant people who develop a COVID-19 infection are at increased risk of poor pregnancy outcomes. Pregnant people may choose to be vaccinated. A conversation between the patient and their doctor may help with decisions of whether or not to vaccinate. When making a decision, pregnant people should consider their level of COVID-19 transmission in their community, their own level of exposure to COVID-19, the risks of a COVID-19 infection to the patient and potential risk to the fetus, and the side effects of the vaccine. There are no data on the safety of the Johnson and Johnson (Janssen) COVID-19 vaccine in lactating people. A lactating person may choose to be vaccinated.

Source CDC. (2021). Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States. Retrieved from: <u>cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html</u>

Can I get the vaccine if I have had food or other allergy?

If you have a history of food, pet, insect, venom, environmental, latex, or other allergies not related to vaccines or injectable therapies you can still receive the Johnson and Johnson (Janssen) COVID-19 vaccine. A 30 minute observation period following vaccination is recommended for anyone with a history of a severe allergic reactions.

Source CDC. (2021). Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States. Retrieved from: <u>cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html</u>



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