

Johnson & Johnson's Janssen COVID-19 Vaccine Information The Newest Vaccine Approved in the US

A 3rd COVID-19 Vaccine is Approved & Why Immunity to COVID Matters:

It would appear that the US, like so many other countries, is in a true race against time & circumstance to get enough people vaccinated to prevent continuing COVID-19 transmissions. In short, it's vaccinations vs. COVID-19 Variants, although, more properly, SARS-CoV-2 Variants. Enough people have to be fully vaccinated so that transmission, and therefore replication of the virus, goes way down. Each time the virus replicates, it stands a chance of mutating within its viral genetic sequence. Sometimes, the mutation is in our favor and the virus can no longer transmit, replicate, or make people sick. Other times, it becomes more transmissible, causing an increased number of cases or severe illnesses, more deaths, escapes (avoids) the body's protection from current vaccination or previous infection with COVID, or from other treatments (e.g., monoclonal antibody cocktails), and/or go undetected by the current tests for COVID.

First, some clarity about the name of this vaccine. It's routinely referred to as the J&J vaccine but COVID needs to be added to that since J&J makes more than just this one vaccine. However, in other references to this vaccine, especially outside the US, it is often referred to as the Janssen vaccine. Johnson & Johnson is the parent company and a name that is very familiar to those in the US. The pharmaceutical companies of J&J are under the Janssen name. For ease, we will refer to the vaccine as J&J, but that is not meant to ignore the Janssen name since the name on the vial of the "J&J vaccine" is Janssen.

The J&J COVID-19 Vaccine is Different than the Previous Two EUA-Approved Vaccines:

This new COVID-19 J&J (Janssen) vaccine is different from the two previously approved mRNA vaccines. The J&J COVID vaccine is a viral vector vaccine and there are some benefits to this vaccine. There are different types of vaccines which achieve immunity from a pathogen in variety of ways but, ultimately, they all trigger the body to recognize the pathogen, in this case the COVID virus, without actually having to be exposed to the COVID virus. All types of vaccines are designed to leave behind, in the body, enough defensive white blood cells. These include T lymphocytes, for memory of the virus and B lymphocytes, ready to react & fight should the virus attempt to infect the body. We'll explore the way viral vector vaccines work, and the J&J COVID viral vector vaccine specifically, but first a little more about the benefits of the J&J vaccine.

1. The J&J vaccine is a single injection, so its protection (immunity) against COVID is in place just two weeks after the first (only) shot. That shortens the time to be considered fully vaccinated to 2 weeks rather than the 5 or 6 weeks for Pfizer or Moderna, respectively.
2. Research on viral vectors has been in place for decades, complete with hundreds of published studies. Viral vectors have been studied for use as a cancer treatment, in

gene therapy, and a variety of other uses. More to the point, using viral vectors in vaccines have been studied in the lab, as well as in clinical trials, for vaccines against several diseases including HIV, Zika, and RSV (respiratory syncytial virus). There are two Ebola vaccines, developed using viral vector technology, that have been used with success in recent outbreaks of Ebola for the past few years. They are currently deployed for use in Ebola outbreaks in Guinea and the DRC.

3. There is no COVID-19 material that is used in viral vector vaccines. That is not to suggest that the COVID-19 material that is found in the mRNA vaccines is capable of causing COVID illness in anyone receiving the vaccine. They can't. The small piece of protein that is used by the cells to make copies of the harmless protein and then the genetic material (mRNA) is discarded by the cell.

Short Summary on Viral Vector Vaccines & J&J COVID Vaccine Specifically:

In general, viral vector vaccine developers choose another harmless virus to be the vector (aka the transporter). Different viruses have been used as vectors including influenza, measles, and adenovirus (which causes the common cold). **Remember, it is only a small fragment of the vector virus, and not capable of causing an illness of the vector or of the disease for which the vaccine is being developed.** A gene, specific to the disease to be protected against, is added to the viral vector, that is then carried into the cell inside the body, and then uses the cell's processes to make a harmless piece of that virus.

The J&J vaccine uses the adenovirus as the vector (the harmless transport virus), introduces a gene to the vector that contains code (instructions) of what the receiving cell is to do. Then the vector is used to transport the gene first into the human body and then into a human cell. Once inside the cell, the cell's normal processes use the gene to produce the COVID-19 spike protein (just a harmless small piece of the vector virus). The cell then places the spike protein onto its own surface. At this point, the body's immune system recognizes the spike protein as a foreign protein (an antigen and not supposed to be there). This triggers an immune response of white blood cells, with B-cells producing antibodies specific to the SARS-CoV-2 virus, which causes COVID, and T cells activating to fight the perceived infection. The T cells develop memory of the spike protein, so when the body is re-exposed to the same or similar SARS-CoV-2 virus, T cells are activated quickly to fight the infection while the B cells begin to produce antibodies to block the virus. What is still being researched, is how long those T cells last (persist), and whether different COVID variants (mutations within the SARS-CoV-2 virus genetic material) will trigger this learned immune response (the T cell memory) enough to prevent COVID infection.

This is probably the appropriate place to add that those with immunosuppression, either because of certain diseases/conditions, medications, or extreme age, may not be able to mount a robust immune response, even when fully vaccinated. That is one of the reasons that it is recommended that those in any of these groups, still wear masks, social distance, and avoid large crowds or inside venues, even when fully vaccinated.

It is also worth noting that research continues on how long vaccine immunity may last. There are signs that it may persist for 'a while' but it is too soon to determine or even make a scientific guess at this time. There is also research on developing booster shots that cover the new variants, an increase in genetic sequencing of COVID virus samples to detect new variants as they appear, and to determine their prevalence. Other countries are much further along in virus sequencing, but the CDC has built partnerships with private labs, medical centers/universities, etc., to increase US viral sequencing.

Specifics about the J&J Vaccine:

1. You should read the FDA Janssen (J&J) Fact Sheet for Recipients & Caregivers for all the specifics related to this vaccine: <https://www.fda.gov/media/146305/download>
2. It is a single shot, administered IM, into the deltoid muscle of the upper arm.
3. It is currently recommended for those 18 years and older although trials are beginning for babies > 6 months and children < 18.
4. The vaccine **DOES NOT** contain eggs, preservatives, or latex. It **DOES** contain polysorbate, adenovirus type 26, citric acid, monohydrate, trisodium citrate dihydrate, ethanol, 2-hydroxypropyl -B-cyclodextrin (HBCD), & sodium chloride
5. Tell the vaccination provider if you have, or are, any of the following. You may also discuss them you're your PCP or other health care provider. They don't necessarily keep you from getting the vaccine:
 - a. any allergies (including those components of the vaccine in the 2nd part of #4)
 - b. a fever
 - c. a bleeding disorder or are on a blood thinner
 - d. immunocompromised or on a medication that affects your immune system
 - e. pregnant or plan on becoming so
 - f. breastfeeding
 - g. received another COVID-19 vaccine
6. **Side Effects** typically start within a day or two, but can occur within 7 days receiving the vaccination, are mostly mild to moderate, and should go away in a few days. If you have any questions or concerns, check with your PCP or other health care provider. Side effects are most common in those 18-59 years old.

Note: these symptoms are likely signals that your immune system is mounting an immune response to the vaccine (a good sign). However, a lack side effects doesn't indicate your immune system is not responding appropriately either.

The following **side effects** include the most common (but you may have others too):

In the arm where you got the shot: Pain, Redness, and/or Swelling

More systemic: Fatigue/Tiredness, Headache, Muscle Pain, Chills, Fever, Nausea

7. If any symptoms suggest an **allergic reaction, including those found below** (most occur within 15-30 minutes), **call 911 or seek medical care**, depending on the level of symptoms. **Make sure they know you received a COVID vaccination & when.**

Serious Symptoms Include – (it can be only one symptom but, most often, is more than one):

Feeling of impending doom (like you might die)

Loss of Consciousness, Confusion, Disorientation, Dizziness, Lightheadedness, Weakness

Difficulty Breathing, Shortness of Breath, Stridor, Bronchospasm (Wheezing), Hypoxia

Hypotension (low BP), Tachycardia (fast heart rate)

Swelling of Your Eyes, Lips, Tongue or Throat (also known as **angioedema**)

Diaphoresis (sweating profusely with sweat unexpected; **soaking your clothes**)

Skin may have **Rash, Itching, or Flushing** (turning pink or red). These can occur without it being serious, but **Anaphylaxis** (which is life threatening) has one or more of these in 90% of cases).

Less Serious - Rash or Itchy Skin - can often be managed at home if: 1) the sole symptom(s), 2) there is close monitoring for other symptoms listed above, & 3) someone is with you to help assess and help you, if needed. At any rate, consider checking with your PCP or going to Urgent Care.

In summary and to be clear about the Janssen (J&J) vaccine, per the CDC, (*Understanding and Explaining Viral Vector COVID-19 Vaccines*, last updated Mar.2, 2021 & *Understanding Viral Vector COVID-19 Vaccines*, last updated Mar. 2, 2021), reports the following:

1. "At the end of the process, our bodies have learned how to protect us against future infection with the virus that causes COVID-19. The benefit is that we get this protection from a vaccine, without ever having to risk the serious consequences of getting sick with COVID-19. Any temporary discomfort experienced after getting the vaccine is a natural part of the process and an indication that the vaccine is working."
2. "Viral vectors cannot cause infection with COVID-19 or with the virus used as the vaccine vector."
3. "The genetic material delivered by the viral vector does not integrate into a person's DNA. They do not affect or interact with our DNA in any way."
4. Viral vector vaccines use a modified version of a different virus as a vector to deliver instructions, in the form of genetic material (a gene), to a cell. The vaccine does not cause infection with either COVID-19 or the virus that is used as the vector."

For more definitive & specific information, a list of Resources & Links is available with this document's post.