



## COVID-19

# Johnson & Johnson's Janssen COVID-19 Vaccine Overview and Safety

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#### General Information

**Name:** JNJ-78436735

Manufacturer: Janssen Pharmaceuticals Companies of

Johnson & Johnson

Type of Vaccine: Viral Vector

**Number of Shots:** 1 shot may be given in some situations.

Booster Shot: Everyone ages 18 years and older should get a booster dose of either Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) at least 2 months after receiving the Johnson & Johnson's Janssen (J&J/Janssen) vaccine in most situations.

How Given: Shot in the muscle of the upper arm.

**Does NOT Contain:** Eggs, preservatives, latex or metals. (See full list of ingredients below).

People who received one dose of J&J/Janssen who want an additional dose or a booster are encouraged to get a Pfizer-BioNTech vaccine.

#### When to Consider J&J/Janssen COVID-19 Vaccine

In most situations, Pfizer-BioNTech or Moderna COVID-19 vaccines are preferred over the J&J/Janssen COVID-19 vaccine for primary and booster vaccination due to the risk of serious adverse events. Vaccine recipients must be informed of the risks and benefits of J&J/Janssen COVID-19 vaccination. The J&J/Janssen COVID-19 vaccine may be considered in some situations, including for persons who:

- Had a severe reaction after an mRNA vaccine dose or who have a severe allergy to an ingredient of Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines).
- Would otherwise remain unvaccinated for COVID-19 due to limited access to Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines).
- Wants to get the J&J/Janssen COVID-19 vaccine despite the safety concerns.

Learn more about the considerations for J&J/Janssen COVID-19 vaccine.

#### Who Should Not Get J&J/Janssen COVID-19 vaccine

If you have had a severe allergic reaction (anaphylaxis) or an immediate allergic reaction, even if it was not severe, to

any ingredient in the J&J/Janssen COVID-19 vaccine (such as polysorbate), you should not get the J&J/Janssen COVID-19 vaccine.

- A severe allergic reaction is one that needs to be treated with epinephrine or EpiPen or requiring additional medical care. Learn about common side effects of COVID-19 vaccines and when to call a doctor.
- An immediate allergic reaction means a reaction within 4 hours of exposure, including symptoms such as hives, swelling, or wheezing (respiratory distress).

If you developed thrombosis with thrombocytopenia syndrome after your initial J&J/Janssen vaccine, you should get the Pfizer-BioNTech or Moderna (mRNA COVID-19 vaccines) for your booster dose.

# Johnson & Johnson (J&J)/Janssen COVID-19 Vaccine Ingredients

The J&J/Janssen COVID-19 vaccine contains a piece of a modified virus that is not the virus that causes COVID-19. This modified virus is called the vector virus. The vector virus cannot reproduce itself, so it cannot cause COVID-19. This vector virus gives instructions to cells in the body to create an immune response. This response helps protect you from getting sick with COVID-19 in the future. After the body produces an immune response, it gets rid of all of the vaccine ingredients just as it would discard any information that cells no longer need. This process is a part of normal body functioning.

All COVID-19 vaccines are manufactured with as few ingredients as possible and with only the necessary amounts of each ingredient. Nearly all of the ingredients in COVID-19 vaccines are also the ingredients in many foods – fats, sugars, and salts. Each ingredient in the vaccine serves a specific purpose as seen in the table below.

# Full list of ingredients

The J&J/Janssen COVID-19 vaccine contains the following ingredients:

Type of Ingredient	Ingredient	Purpose
A harmless version of a virus unrelated to the COVID-19 virus	<ul> <li>Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein</li> </ul>	Provides instructions the body uses to build a harmless piece of a protein from the virus that causes COVID-19. This protein causes an immune response that helps protect the body from getting sick with COVID-19 in the future.
Sugars, salts, acid, and acid stabilizer	<ul> <li>Polysorbate-80</li> <li>2-hydroxypropyl-β-cyclodextrin</li> <li>Trisodium citrate dihydrate</li> <li>Sodium chloride (basic table salt)</li> <li>Citric acid monohydrate (closely related to lemon juice)</li> <li>Ethanol (a type of alcohol)</li> </ul>	Work together to help keep the vaccine molecules stable while the vaccine is manufactured, shipped, and stored until it is ready to be given to a vaccine recipient.

## Ingredients that are NOT used in COVID-19 vaccines

The above table lists ALL ingredients in the J&J/Janssen COVID-19 vaccine. There are NO ingredients in this vaccine beyond what is listed in that table. The J&J/Janssen COVID-19 vaccine has:

• No preservatives like thimerosal or mercury or any other preservatives.

- No antibiotics like sulfonamide or any other antibiotics.
- No medicines or therapeutics like ivermectin or any other medications.
- No tissues like aborted fetal cells, gelatin, or any materials from any animal.
- **No food proteins** like eggs or egg products, gluten, peanuts, tree nuts, nut products, or any nut byproducts (COVID-19 vaccines are not manufactured in facilities that produce food products).
- **No metals** like iron, nickel, cobalt, titanium, rare earth alloys, or any manufactured products like microelectronics, electrodes, carbon nanotubes or other nanostructures, or nanowire semiconductors.
- No latex. The vial stoppers used to hold the vaccine also do not contain latex.

### Possible Side Effects

In the arm where you got the shot:

- Pain
- Redness
- Swelling

Throughout the rest of your body:

- Tiredness
- Headache
- Muscle pain
- Chills
- Fever
- Nausea

These side effects may happen within a day or two of getting the vaccine. They are normal signs that your body is building protection and should go away within a few days.

# **Fainting After Vaccination**

Fainting (syncope) and other events that may be related to anxiety like rapid breathing, low blood pressure, numbness, or tingling can happen after getting any vaccine. Although uncommon, these events are not unexpected, and they are generally not serious.

According to information from the Vaccine Adverse Event Reporting System (VAERS) , there were 653 reports of fainting events (fainting and near-fainting) among nearly 8 million doses of J&J/Janssen COVID-19 vaccine administered in the United States in March and April 2021. This translates to a rate of about 8 fainting events for every 100,000 doses of the J&J/Janssen COVID-19 vaccine given. These events occurred during the recommended 15-minute wait after vaccination. It's not clear at this time whether these events were associated with the vaccine or with anxiety, possibly related to preexisting concerns some people who chose to get the one-dose J&J/Janssen COVID-19 vaccine may have about needles or shots.

By comparison, the rate of fainting after flu vaccination in 2019–2020 was 0.05 per 100,000 doses.

Learn more about possible side effects after getting a COVID-19 vaccine.

#### Other Authorized and Recommended COVID-19 Vaccines in the United States

- Pfizer-BioNTech
- Moderna

# Safety Data Summary

In most situations, Pfizer-BioNTech or Moderna COVID-19 vaccines are preferred over the J&J/Janssen COVID-19 vaccine for primary and booster vaccination due to the risk of serious adverse events.

- There is a plausible causal relationship between J&J/Janssen COVID-19 vaccine and a rare and serious adverse event—blood clots with low platelets (thrombosis with thrombocytopenia syndrome, or TTS).
  - It occurs at a rate of about 3.83 cases per million Janssen doses and has resulted in deaths.
  - Read about the latest updates on J&J/Janssen COVID-19 vaccine.

Learn more about vaccine safety monitoring after a vaccine is authorized or approved for use.

### How Well the Vaccine Works

- The J&J/Janssen COVID-19 vaccine was 66.3% effective in clinical trials at preventing laboratory-confirmed COVID-19 infection in people who received the vaccine and had no evidence of being previously infected. People had the most protection 2 weeks after getting vaccinated.
- In the clinical trials, the vaccine had high efficacy at preventing hospitalization and death in people who did get sick.

# Clinical Trial Demographic Information

Learn more about demographic information for people who participated in the trials [PDF – 62 pages] 🗹 .

#### **Related Pages**

- > Possible Side Effects
- Safety of COVID-19 Vaccines
- > Benefits of Getting Vaccinated
- > How Vaccines Work
- > Viral Vector Vaccines



#### For Healthcare Workers

Johnson & Johnson's Janssen COVID-19 Vaccine: General information, schedule, and administration overview.

#### More Information

Johnson & Johnson's Janssen COVID-19 Vaccine Fact Sheet for Recipients and Caregivers [242 KB, 7 pages]

Safety and Reactogenicity Data