Centers for Disease Control and Prevention

COVID-19

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

Updated Oct. 29, 2021

NOTICE: FDA authorized the use of the Pfizer-BioNTech COVID-19 Vaccine for children ages 5 through 11 years. The Advisory Committee on Immunization Practices is meeting on Tuesday, November 2 to discuss a recommendation for this age group. Watch online here.

General Information

Name: JNJ-78436735

Manufacturer: Janssen Pharmaceuticals Companies of Johnson & Johnson

Type of Vaccine: Viral Vector

Number of Shots: 1 shot

Booster Shot: At least 2 months after receiving your vaccine. You can get any of the COVID-19 vaccines authorized in the United States for your booster shot. People who developed thrombosis with thrombocytopenia syndrome after their initial Janssen vaccine should not receive a Janssen booster dose.

How Given: Shot in the muscle of the upper arm

Does NOT Contain: Eggs, preservatives, latex, metals
See Full List of Ingredients Below

Who Should Get Vaccinated

- The J&J/Janssen COVID-19 Vaccine is recommended for people 18 years and older.
- Learn more about how CDC is making COVID-19 vaccine recommendations.

Who Should NOT Get Vaccinated

- **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 with 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 aren't able to get the J&J/Janssen COVID-19 Vaccine, you may still be able to get a different type of COVID-19

vaccine. Get more information for people with allergies.

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

All COVID-19 vaccine ingredients are safe. Nearly all of the ingredients in COVID-19 vaccines are also the ingredients in many foods – fats, sugars, and salts. The J&J/Janssen COVID-19 vaccine also 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 is harmless. 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 discards 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 very small amounts of each ingredient. 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	• Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein	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	• Polysorbate-80 • 2-hydroxypropyl-β-cyclodextrin • Trisodium citrate dihydrate • Sodium chloride (basic table salt) • Citric acid monohydrate (closely related to lemon juice) • Ethanol (a type of alcohol)	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 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
>
> **You should get a COVID-19 vaccination as soon as possible.** Do not wait for a specific brand. All currently authorized and recommended COVID-19 vaccines are safe and effective, and CDC does not recommend one vaccine over another.
>
> CDC does not recommend mixing products for an initial 2-dose vaccine series or additional doses. Mixing and matching COVID-19 vaccines is allowed for booster shots.

Safety Data Summary

- In clinical trials, side effects were common within 7 days of getting vaccinated and were mostly mild. Some people had side effects that affected their ability to do daily activities.
- Side effects were more common in people 18–59 years old compared to people 60 years and older.
- 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 7 per 1 million vaccinated women between 18 and 49 years old.
  - For women 50 years and older and men of all ages, this adverse event is even more rare.
- Find the latest updates on J&J/Janssen COVID-19 Vaccine and blood clots with low platelets.

- CDC will continue to provide updates as we learn more about the safety of the J&J/Janssen COVID-19 Vaccine in real-world conditions.

> 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 (efficacy) 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. No one who got COVID-19 at least 4 weeks after receiving the J&J/Janssen COVID-19 Vaccine had to be hospitalized.
- CDC will continue to provide updates as we learn more about how well the J&J/Janssen COVID-19 Vaccine works in real-world conditions.

Clinical Trial Demographic Information

Clinical trials for the J&J/Janssen COVID-19 Vaccine included people from the following racial, ethnic, age, and sex categories:

Race:

- 62% White
- 17% Black or African American
- 8% American Indian or Alaska Native
- 5% multiple races
- 4% Asian
- 0.3% Native Hawaiian or Other Pacific Islander

Ethnicity:

- 45% Hispanic or Latino
- 52% not Hispanic or Latino
- 3% unknown

Sex:

- 56% male
- 45% female
- <0.1% undifferentiated or unknown sex

Age breakdown:

- 67% 18–59 years
- 34% 60 years and older
  - 20% 65 years and older
  - 4% 75 years and older

Forty (40.8%) of people who participated in the clinical trials had at least one condition that put them at risk of severe illness from COVID-19. The most frequent underlying medical conditions among participants were obesity (28.7%), high blood pressure (10.2%), type 2 diabetes (7.3%), and HIV infection (2.7%).

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

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