



## COVID-19

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

Updated June 1, 2021

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Johnson & Johnson's Janssen COVID-19 Vaccine: The Centers for Disease Control and Prevention (CDC) and the US Food and Drug Administration (FDA) recommend that use of Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 Vaccine resume in the United States, effective April 23, 2021. However, women younger than 50 years old should especially be aware of the rare risk of blood clots with low platelets after vaccination. There are other COVID-19 vaccines available for which this risk has not been seen. If you received a J&J/Janssen COVID-19 Vaccine, here is what you need to know. Read the CDC/FDA statement.

## **General Information**

**Name:** JNJ-78436735

Manufacturer: Janssen Pharmaceuticals

Companies of Johnson & Johnson

Type of Vaccine: Viral Vector

Number of Shots: 1 shot

How Given: Shot in the muscle of the

upper arm

Does NOT Contain: Eggs, preservatives,

latex

Full List of Ingredients [242 KB, 7 pages]

#### Who Should Get Vaccinated

- The J&J/Janssen COVID-19 Vaccine is recommended for people aged 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.

## 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 have been 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 the first COVID-19 vaccine that is available to you.** 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.

## Safety Data Summary

- In clinical trials, side effects were common within 7 days of getting vaccinated but were mostly mild to moderate.
- 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 illness in people who had no evidence of prior infection. People had the most protection 2 weeks after getting vaccinated.
- 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.
- Early evidence suggests that the J&J/Janssen COVID-19 Vaccine might provide protection against asymptomatic infection, which is when a person is infected by the virus that causes COVID-19 but does not get sick.
- 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</li>

#### Age breakdown:

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

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



#### For Healthcare Workers

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

## **Related Pages**

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

### More Information

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

Safety and Reactogenicity Data

Last Updated June 1, 2021 Content source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases