



## COVID-19

# CDC Recommends Use of Johnson & Johnson's Janssen COVID-19 Vaccine Resume

Updated July 13, 2021

### What You Need to Know

- CDC and the U.S. Food and Drug Administration (FDA) recommend use of Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 Vaccine resume in the United States, after a temporary pause.
- Reports of adverse events following the use of J&J/Janssen vaccine suggest an increased risk of a rare adverse event called thrombosis with thrombocytopenia syndrome (TTS). Nearly all reports of this serious condition, which involves blood clots with low platelets, have been in adult women younger than 50 years old.
- A review of all available data at this time shows that the J&J/Janssen COVID-19 Vaccine's known and potential benefits outweigh its known and potential risks.
- However, women younger than 50 years old especially should be aware of the rare but increased risk of this adverse event and that there are other COVID-19 vaccine options available for which this risk has not been seen.
- CDC and FDA will continue to monitor the safety of all COVID-19 vaccines.
- Seek medical care right away if you develop [any of the symptoms below after receiving](#) the J&J/Janssen COVID-19 Vaccine.
- If you have any questions or concerns, call your doctor, nurse, or clinic.

## J&J/Janssen Vaccine Questions and Answers

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## What if I got or want to get the J&J/Janssen COVID-19 Vaccine?

- 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). However, after reviewing all available safety data, CDC and FDA recommend use of this vaccine resume in the United States given that the known and potential benefits outweigh the known and potential risks.
- This adverse event is rare, occurring 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.
- For three weeks after receiving the vaccine , you should be on the lookout for possible symptoms of a blood clot with low platelets. These include:
  - Severe or persistent headaches or blurred vision
  - Shortness of breath
  - Chest pain
  - Leg swelling
  - Persistent abdominal pain
  - Easy bruising or tiny blood spots under the skin beyond the injection site

Seek medical care right away if you develop one or more of these symptoms.

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## Does CDC recommend vaccination with the J&J/Janssen COVID-19 Vaccine resume?

Yes. The [Advisory Committee on Immunization Practices](#) (ACIP) and CDC recommend vaccination with the J&J/Janssen COVID-19 Vaccine resume among people 18 years and older. However, women younger than 50 years old especially should be aware of the rare but increased risk of thrombosis with thrombocytopenia syndrome (TTS). TTS is a serious condition that involves blood clots with low platelets. There are other COVID-19 vaccine options available for which this risk has not been seen.

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## What do we know about the J&J/Janssen COVID-19 Vaccine and possible health problems?

Since use of COVID-19 vaccines began in the United States, scientists and doctors have constantly and carefully reviewed all reports of vaccine side effects and adverse events. As of April 23, 2021, more than 8 million doses of the J&J/Janssen COVID-19 Vaccine had been given in the United States. As of April 23, 2021, experts reviewing safety reports for this vaccine found 15 reports of women who got the J&J/Janssen COVID-19 Vaccine and later developed thrombosis with thrombocytopenia syndrome (TTS). TTS is a serious condition that involves blood clots with low platelets.

These reports suggest an increased risk of TTS one to two weeks after vaccination with the J&J/Janssen COVID-19 Vaccine. As of April 23, 2021, the reports reviewed all occurred in women between 18 and 59 years old, with a median of 37 years. These reports represent a reporting rate of 7 such events per 1 million vaccinations among women 18 through 49 years old and a rate of 0.9 per 1 million vaccinations among women 50 years and older. For all women, this is a rare adverse event. For women 50 years and older and men of all ages, the adverse event is even more rare. Reports show that symptoms of this adverse event started between 6 and 15 days after vaccination.

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## Why did the pause end?



CDC and FDA have recommended that use of J&J/Janssen COVID-19 Vaccine resume in the United States, effective April 23, 2021. A review of all available data at this time shows that the J&J/Janssen COVID-19 Vaccine's known and potential benefits outweigh its known and potential risks for those recommended to receive it. However, women younger than 50 years old especially should be aware of the rare risk of blood clots with low platelets after vaccination, and that other COVID-19 vaccines are available where this risk has not been seen.

The pause allowed CDC to communicate with healthcare providers and re-emphasize the importance of reporting severe events in people who have received this vaccine, as well as how to report such events. The pause also gave experts time to carefully review all available data and conduct a risk-benefit analysis around the use of this vaccine.

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## What do I need to know about possible safety issues with all COVID-19 vaccines?



COVID-19 [vaccine safety](#) is a top priority for the federal government, and reports of health problems following COVID-19 vaccination are taken very seriously.

Detecting these rare adverse events tells us that the systems in place to monitor the safety of these vaccines are working. The thrombosis with thrombocytopenia syndrome (TTS) reports were detected early, and the pause reflected the federal government's commitment to transparency and safety as CDC and FDA gathered and reviewed additional data. COVID-19 vaccines have undergone and will continue to undergo the most intensive safety monitoring in U.S. history.

Learn more about [how vaccine safety systems work](#).

If you experience any adverse events after vaccination, report them to [v-safe](#) and the [Vaccine Adverse Event Reporting System](#)  (VAERS).

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## Has this issue been seen with the other COVID-19 vaccines?



No. As of April 23, 2021, thrombosis with thrombocytopenia syndrome (TTS)—blood clots with low platelets—has not been linked to the Pfizer-BioNTech or Moderna COVID-19 vaccines after more than 210 million doses administered.

## If I'm currently using hormonal birth control (hormonal contraception), should I use a different type of birth control method or consider a different vaccine? ▼


People using hormonal birth control can receive any FDA-authorized COVID-19 vaccine. There are no recommendations to stop taking hormonal birth control (birth control pills, implant, patch, ring, or shot) before or after receiving the J&J/Janssen COVID-19 Vaccine. Although the risk of blood clots is increased with some hormonal birth control methods (for example, certain types of birth control pills, patch, and ring), based on the available data, experts believe that these factors do not make people more likely to develop thrombosis with thrombocytopenia syndrome (TTS) after receiving the J&J/Janssen COVID-19 Vaccine. As noted above, TTS is a rare condition that involves blood clots with low platelets. All women younger than 50 years old (regardless of their birth control use) should be aware of the rare but increased risk for TTS following vaccination with the J&J/Janssen COVID-19 vaccine. Other COVID-19 vaccines (Pfizer-BioNTech, Moderna) are available where this risk has not been seen. If you are concerned about your current method of birth control, please talk with your healthcare provider.

## If I'm pregnant or recently pregnant, should I get a different COVID-19 vaccine? ▼

Pregnant or recently pregnant people can receive any FDA-authorized COVID-19 vaccine. Based on available data, experts believe that being pregnant or recently pregnant does not make someone more likely to develop thrombosis with thrombocytopenia syndrome (TTS) after receiving the J&J/Janssen COVID-19 Vaccine. As noted above, TTS is a rare condition that involves blood clots with low platelets. All women younger than 50 years old—regardless of whether they are pregnant or recently pregnant—should be aware of the rare but increased risk for TTS. Other COVID-19 vaccines (Pfizer-BioNTech, Moderna) are available where this risk has not been seen. CDC continues to collect information from people vaccinated during all trimesters of pregnancy about their health and the health of their babies up to three months old to understand the benefits and risks of COVID-19 vaccination during pregnancy.



### For Healthcare Workers

Review the revised [Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Provider\)](#)[external icon](#) , which has been revised to include a warning about the risk of thrombosis with thrombocytopenia syndrome (TTS) that has occurred in a small number of people who have received the Janssen COVID-19 Vaccine.

Read the official CDC health alert, [Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson COVID-19 Vaccine](#), which includes details about how to assess and care for a patient that presents with thrombosis or thrombocytopenia.



### For Vaccine Providers

You may resume use of the Janssen COVID-19 Vaccine.

Review the [Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\)](#), [\[PDF\]](#) which has been revised to include a warning about the risk of thrombosis with thrombocytopenia syndrome (TTS) that has occurred in a small number of people who have received the Janssen COVID-19 Vaccine.

## Related Research

[MMWR: Safety Monitoring of the Janssen \(Johnson & Johnson\) COVID-19 Vaccine — United States, March–April 2021](#)

[MMWR: Anxiety-Related Adverse Event Clusters After Janssen COVID-19 Vaccination — Five U.S. Mass Vaccination Sites, April 2021](#)

## Printouts

# Talking to Patients about Safety of the Janssen COVID-19 Vaccine

Effective April 23, 2021, CDC and FDA recommend use of the Janssen COVID-19 Vaccine (Johnson & Johnson) resume in the United States. **The available data show that the vaccine's known and potential benefits outweigh its known and potential risks.** You can offer the Janssen COVID-19 Vaccine to people 18 years and older who want to get vaccinated against COVID-19.

As a clinician, your answers to patient questions matter. Your strong recommendation can help them make an informed decision and feel

### If your patient has questions about the safety of the Janssen COVID-19 Vaccine:

- ➔ Discuss the possibility of a **rare but increased risk** of blood clots with low platelets seen after receipt of the Janssen COVID-19 Vaccine.
- ➔ To date, most of these reports have been in adult women younger than 50 years old, but there have been reports in men and older women.



FACTSHEET

Talking to Patients about J&J/Janssen COVID-19 Vaccine

Effective April 23, 2021, CDC and FDA recommend that use of the Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 Vaccine resume in the United States.

Download PDF: [English](#) [158 KB, 1 page] | [Español](#) [105 KB, 1 página]

## What do I need to know about Johnson & Johnson's Janssen COVID-19 Vaccine (J&J/Janssen) now?

There is a risk of a rare but serious condition involving blood clots and low platelets in people after receiving the J&J/Janssen COVID-19 Vaccine. **This risk is very low.**

**This problem is rare and happened in about 7 per 1 million vaccinated women between 18 and 49 years old.**

For women 50 years and older and men of any age, this problem is even more rare.

This problem has not been linked to the other two COVID-19 vaccines (Pfizer-BioNTech and Moderna).



PRINTOUT

Last Updated July 13, 2021

What do I need to know about Johnson & Johnson's Janssen COVID-19 Vaccine (J&J/Janssen) now?

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