Centers for Disease Control and Prevention

COVID-19

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

Updated Nov. 15, 2021

What You Need to Know

- On April 23, 2021 CDC and the U.S. Food and Drug Administration (FDA) recommended use of Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 vaccine resume in the United States after a temporary pause.
- Reports after the use of J&J/Janssen COVID-19 vaccine suggested an increased risk of a rare adverse event called thrombosis with thrombocytopenia syndrome (TTS). Most 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 available data showed 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 they should know about other available COVID-19 vaccine options for which this risk has not been seen.
- CDC and FDA continue to monitor the safety of all COVID-19 vaccines.
- **Seek medical care right away** if you develop any of the symptoms of TTS after receiving a COVID-19 vaccine.
- If you have any questions or concerns, call your doctor, nurse, or clinic.

J&J/Janssen Vaccine Questions and Answers

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

- Effective April 23, 2021, CDC and FDA recommended that use of the J&J/Janssen COVID-19 vaccine resume in the United States. However, women younger than 50 years old especially should be made aware of a rare risk of blood clots with low platelets after vaccination, called thrombosis with thrombocytopenia syndrome (TTS), and they should know about other available COVID-19 vaccine options for which this risk has not been seen.
- TTS is a rare adverse event. For women ages 50 years and older and men of all ages, this adverse event is even more rare.
- You should be on the lookout for possible symptoms of a blood clot with low platelets for several weeks after vaccination. These symptoms include the following:
  - 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.

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

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

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 been monitoring reports of vaccine side effects and adverse events. Results from monitoring the J&J/Janssen COVID-19 vaccine indicate that the most frequently reported side effects are headache, fever, chills, injection site pain, and fatigue. These side effects usually start within a day or two of getting the vaccine. Side effects might affect the ability to do daily activities, but they usually go away in a few days.

Some people have reported fainting events (fainting and near-fainting) after J&J/Janssen vaccination. These events happened during the recommended 15-minute wait after vaccination. It's not clear at this time whether these events were associated with the vaccine itself or with anxiety about vaccination. Concerns about needles or shots may have led some people to choose the one-dose J&J/Janssen COVID-19 vaccine.

Reports also suggest an increased risk of TTS after vaccination with the J&J/Janssen COVID-19 vaccine. The Vaccine Adverse Event Reporting System (VAERS) reports show that symptoms of TTS started between 3 and 15 days after vaccination. TTS is a rare adverse event. For women ages 50 years and older and men of all ages, this adverse event is even more rare. View the latest update of total confirmed TTS cases following J&J/Janssen COVID-19 vaccine.

CDC and FDA are monitoring reports of Guillain-Barré Syndrome (GBS) in people who have received the J&J/Janssen COVID-19 vaccine. GBS is a rare disorder where the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis. Most people fully recover from GBS, but some have permanent nerve damage. Preliminary reports of GBS have been identified in VAERS (see Selected Adverse Events page for latest counts). These cases have largely been reported about 2 weeks after vaccination and mostly in men, many 50 years and older. CDC will continue to monitor and evaluate reports of GBS happening after COVID-19 vaccination and will share more information as it becomes available.

Why did the pause end?

CDC and FDA recommended that use of J&J/Janssen COVID-19 vaccine resume in the United States, effective April 23, 2021. A review of available data showed 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 they should know that there are other COVID-19 vaccine options available where this risk has not been seen.

The pause allowed CDC to provide data and information to healthcare providers about important considerations in the evaluation of patients who might have TTS. The pause also gave an opportunity to re-emphasize the importance of reporting clinically 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.

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 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 more 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 an adverse event after vaccination, report it to the Vaccine Adverse Event Reporting System (VAERS).

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

As of November 5, 2021, two confirmed cases of TTS following mRNA COVID-19 vaccination (Moderna) have been reported to VAERS after more than 411 million doses of mRNA COVID-19 vaccines were administered in the United States. Based on available data, there is not an increased risk for TTS after mRNA COVID-19 vaccination.

If I got the J&J/Janssen COVID-19 vaccine, should I get a booster dose?

CDC recommends that people ages 18 years and older receive a booster shot at least 2 months after receiving their J&J/Janssen COVID-19 vaccine. **However, people who developed TTS after their initial J&J/Janssen COVID-19 vaccine should not receive a J&J/Janssen COVID-19 booster dose**.

CDC's recommendations allow for mixing and matching COVID-19 vaccine products for booster shots. This means if you got a J&J/Janssen vaccine for your first shot, you can get a Pfizer-BioNTech or Moderna COVID-19 vaccine for your booster. You may choose which COVID-19 vaccine you receive as a booster shot. You may wish to discuss with your healthcare provider the product that is most appropriate for you.

So far, reactions reported after getting a booster shot have been similar to those of the primary series. Fever, headache, fatigue and pain at the injection site have been the most commonly reported side effects, and overall, most side effects have been mild to moderate.

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, some 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 TTS after receiving the J&J/Janssen COVID-19 vaccine.

TTS is a rare condition that involves blood clots together with low platelet levels. All women younger than 50 years old (regardless of their birth control use) should be aware of the rare but increased risk for TTS after vaccination with the J&J/Janssen COVID-19 vaccine. Other COVID-19 vaccine options are available for which 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 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

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 are available for which 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 3 months old to better understand the benefits and risks of COVID-19 vaccination during pregnancy.

For Healthcare Workers

Review the Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers), which has been revised to include a warning about the risk of TTS that has occurred in a small number of people who have received the J&J/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 J&J/Janssen COVID-19 vaccine.

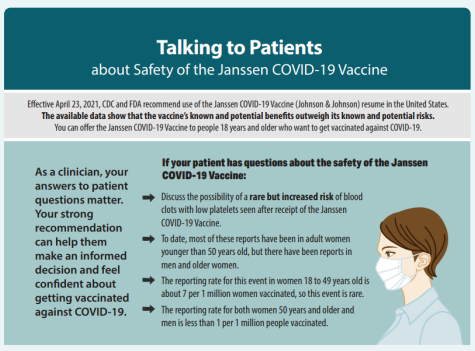
Review the Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers), which has been revised to include a warning about the risk of TTS that has occurred in a small number of people who have received the J&J/Janssen COVID-19 vaccine.

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



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.

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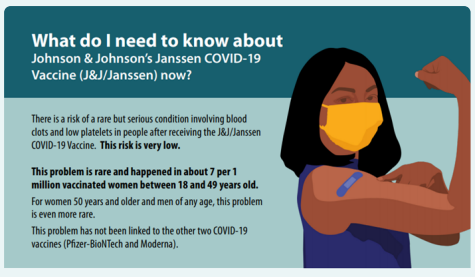

PRINTOUT

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

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