Centers for Disease Control and Prevention
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COVID-19

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

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Updates as of April 25, 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

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.

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.

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.

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.

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).

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.

For Healthcare Workers

Review the revised Janssen COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providersexternal 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), 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.

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 Factsheet

Getting Your Vaccine

Johnson & Johnson's Janssen COVID-19 Vaccine (J&J/Janssen) Print Resources

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

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