Pause lifted on Johnson & Johnson’s COVID-19 Vaccine

The vaccine is once again recommended for persons 18 years of age and older in the U.S. after a temporary pause.

The benefit of protecting against COVID-19 outweighs the rare risk of blood clots with low platelets after vaccination with the Johnson & Johnson vaccine.

Why was the vaccine paused?

- In April 2021, the CDC and the Food and Drug Administration (FDA) vaccine safety monitoring system received 15 reports of blood clots (thrombosis) combined with low blood platelet counts (thrombocytopenia) about one to two weeks following Johnson & Johnson (Janssen) COVID-19 vaccine. This condition is now being referred to as thrombosis with thrombocytopenia syndrome or TTS.

- The reports signaled CDC and FDA to recommend a pause in vaccination with Johnson & Johnson (Janssen) COVID-19 vaccine. This allowed time to 1) educate health care providers about the condition and treatment, 2) gather additional data about TTS, 3) look for any additional cases.

- If you have any questions or concerns, call your doctor, nurse, or clinic.

Why was the pause lifted?

- A review of all available data at this time shows that the Johnson & Johnson COVID-19 vaccine’s benefits outweigh its risks.

- The pause gave medical experts time to carefully review all available data and compare the risks and benefits around the use of this vaccine. The vaccine experts at the Advisory Council on Immunization Practices (ACIP) recommended resuming the Johnson & Johnson vaccine because it helps protect more people from sickness, hospitalization, and death.

- To learn more about the evidence behind the ACIP, CDC, and FDA recommendation to resume the use of the Johnson & Johnson COVID-19 vaccine see the slides or video recording of the ACIP meeting on the topic at: www.cdc.gov/vaccines/acip/meetings/index.html

Should I get the Johnson & Johnson (Janssen) COVID-19 Vaccine?

- The Centers for Disease Control and Prevention (CDC) and Wisconsin Department of Health Services (DHS) recommend vaccination with the Johnson & Johnson COVID-19 Vaccine among people 18 years and older.
- Data show the benefits of vaccination outweigh the risks.
- Because even healthy, young adults can get seriously sick or die from COVID-19, the small risk of this condition is still very small compared to the benefits of protecting yourself from the virus.
- This vaccine only requires you to get one shot in order to be fully protected from COVID-19.
- There are also other COVID-19 vaccine options, such as Pfizer and Moderna, that require two doses of the vaccine.
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, with a rate of less than 1 in 1 million vaccinations.

As of April 23, 2021, 15 women reported developing TTS out of nearly 8 million doses of Johnson & Johnson vaccine administered in the U.S.

For reference, health experts expect roughly 0.7-1.6 in 1 million people to experience clots with low platelets, regardless of vaccination.

However, women under 50 years should be aware of this rare but possible risk of TTS.

The signs of TTS after getting the Johnson & Johnson COVID-19 vaccine may appear within three weeks after vaccination and include:

- Severe headache (especially when it appears 6 or more days after vaccination)
- Backache
- New neurologic symptoms
- Severe abdominal pain
- Leg pain or swelling
- Tiny red spots on the skin
- New or easy bruising
- Shortness of breath

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

Will vaccine safety monitoring continue?

Yes, experts will continue to investigate this rare side effect to make sure it remains an uncommon side effect and to make sure there are no other risk factors that have not been identified. 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. COVID-19 vaccines have undergone and will continue to undergo the most intensive safety monitoring in U.S. history.

What are some of the key take-away messages?

- The available data show that the vaccine's known and potential benefits outweigh its known and potential risks.
- As of April 23, 2021, 15 people — of the 8 million who have gotten the Johnson & Johnson vaccine to date — have reported serious blood clotting side effects.
- These events are extremely rare.
- The risk of getting a serious blood clot from the Johnson & Johnson (Janssen) COVID-19 vaccine is less than of getting a blood clot from smoking or for those hospitalized with COVID-19.
- Safety monitoring is working and the government is prioritizing the safety of Americans. The safety monitoring system for vaccines identified the issue quickly, and this was shared with the public transparently, showing a commitment to safety.
- If you experience any adverse events after vaccination, report them to v-safe and the Vaccine Adverse Event Reporting System (VAERS).


Why do some people develop TTS?

- It is still unclear what causes TTS to develop after getting vaccinated.
- There did not appear to be a pattern of risk factors (such as oral contraceptive use or obesity) in those who developed TTS.
- To date, TTS has not been linked to the Pfizer or Moderna COVID-19 vaccines.