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GET A VACCINE

Recommendation to Pause Use of Johnson & Johnson's Janssen COVID-19 Vaccine

Updated Apr. 16, 2021

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html#print

On April 13, 2021, CDC and FDA recommended a pause in the use of Johnson & Johnson's Janssen COVID-19 Vaccine. Of the nearly 7 million doses administered so far in the United States, a small number of reports of a rare and severe type of blood clot have been reported in people after receiving the J&J/Janssen COVID-19 Vaccine. All reports occurred among women between the ages of 18 and 48, and symptoms occurred six to 13 days after vaccination. As of April 13, 2021, of the more than 180 million doses administered so far of the Pfizer-BioNTech or Moderna vaccines, no reports matching those associated with the J&J/Janssen vaccine have been received.

J&J/Janssen COVID-19 Vaccine Update, April 13, 2021

The use of this vaccine is 'paused' for now. This is because the safety systems that make sure vaccines are safe received a small number of reports of a rare and severe type of blood clot happening in people who got this vaccine.

We do not know enough yet to say if the vaccine is related to or caused this health issue. To be extra careful, CDC and FDA recommend that the vaccine not be given until we learn more.

If you got this vaccine, seek medical care urgently if you develop any of the following symptoms:

- severe headache,
- backache,
- new neurologic symptoms,
- severe abdominal pain,
- shortness of breath,
- leg swelling,
- tiny red spots on the skin (petechiae), or
- new or easy bruising

Learn More About the J&J/Janssen Vaccine Pause

What does a "pause" mean?

On April 13, 2021, CDC and the US Food and Drug Administration (FDA) recommended a pause in the use of Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 Vaccine. Although the J&J/Janssen vaccine is still authorized for use, CDC and FDA recommend this vaccine not be given to anyone until we know more. This gives scientists a chance to review the data and decide if recommendations on who should get the vaccine need to change. CDC and FDA will share more information as soon as possible with healthcare providers, people who got the vaccine, and the public.

What do I need to know about the possible safety issue?

Here is what we know now: scientists and doctors always look carefully at all reported side effects.

From their review, they saw a small number of cases of a rare and severe type of blood clot in people who got the J&J/Janssen COVID-19 Vaccine. All reported cases were in women between the ages of 18 and 48, and the problems were found up to two weeks after vaccination.

What if I got this vaccine?

- If you got this vaccine **more than three weeks ago**, your risk of developing a blood clot is very low.
- If you got this vaccine **within the last three weeks**, your risk of developing a blood clot is also very low. However, you should be on the lookout for possible symptoms of a blood clot:
 - Severe headache
 - Blurred vision
 - Fainting
 - Seizures
 - Pain in your abdomen (chest or stomach)
 - Leg pain or swelling
 - Shortness of breath

Get **medical care right away** if you have any of these symptoms and got the J&J/Janssen COVID-19 Vaccine within the last few weeks. If you have any questions at all, call your doctor, nurse, or clinic.

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

No. As of April 13, 2021, no cases of this blood clot issue have been reported among the more than 180 million people who received the Pfizer-BioNTech or Moderna vaccines.

Are COVID-19 vaccines safe?

Yes. COVID-19 vaccine safety is a top priority for the federal government, and all reports of health problems following COVID-19 vaccination are taken very seriously and investigated as needed. We know the safety systems in place are working. 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.

Should I cancel my vaccination appointment?

If you are scheduled to get the J&J/Janssen COVID-19 Vaccine, work with your vaccine provider to reschedule your appointment to get another type of COVID-19 vaccine.

CDC and FDA Recommended to Pause use of the J&J/Janssen COVID-19 Vaccine

CDC and FDA recommended this pause to communicate with and prepare the healthcare system to recognize and treat patients appropriately. Communication with healthcare providers will also emphasize the importance of reporting and how to report severe events in people who have received this vaccine. This pause also will allow CDC's independent advisory committee, the Advisory Committee on Immunization Practices, to meet, review these cases, and assess their potential significance.

Safety Is a Top Priority

COVID-19 vaccine safety is a top priority for the federal government, and all reports of health problems following COVID-19 vaccination are taken very seriously. This potential safety issue was caught early, and this pause reflects the federal government's commitment to transparency as CDC and FDA review these data. COVID-19 vaccines have undergone and will continue to undergo the most intensive safety monitoring in U.S. history.

What to Do If You Received the J&J/Janssen COVID-19 Vaccine

If you received the vaccine **more than three weeks ago**, the risk of developing a blood clot is likely very low at this time.

If you received the vaccine **within the last three weeks**, your risk of developing a blood clot is also very low and that risk will decrease over time.

Contact your healthcare provider and seek medical treatment urgently if you develop any of the following symptoms:

- severe headache,
- backache,
- new neurologic symptoms,

- severe abdominal pain,
- shortness of breath,
- leg swelling,
- tiny red spots on the skin (petechiae), or
- new or easy bruising

If you are **scheduled to get the J&J/Janssen COVID-19 Vaccine**, please work with your vaccine provider to reschedule your appointment to receive another authorized and recommended COVID-19 vaccine. There are two other COVID-19 vaccines authorized and recommended for use in the United States: Pfizer-BioNTech and Moderna.

If you experience any adverse events after vaccination, report them to v-safe and the Vaccine Adverse Event Reporting System 🖸 .

For Healthcare Providers

Healthcare providers are recommended to **pause the use** of the J&J/Janssen COVID-19 Vaccine. **Maintain acute clinical awareness of symptoms** that might represent serious thrombotic events or thrombocytopenia in patients who have recently received the J&J/Janssen COVID-19 Vaccine, including:

- severe headache,
- backache,
- new neurologic symptoms,
- severe abdominal pain,
- shortness of breath,
- leg swelling,
- petechiae, or
- new or easy bruising.

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 handle a patient that presents with thrombosis or thrombocytopenia.

Report adverse events to the Vaccine Adverse Event Reporting System 🗹 .

For Vaccine Providers

Please work with individuals who were scheduled to receive the J&J/Janssen COVID-19 Vaccine in the days ahead to reschedule their appointments to receive another authorized and recommended COVID-19 vaccine (i.e., Pfizer-BioNTech, Moderna).



For Healthcare Workers

Clinical Resources: Toolkits and resources for handling, storing and administering the vaccine.

This page will be updated as more information becomes available.

Last Updated Apr. 16, 2021 Content source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases