



## COVID-19









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

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#### What you need to know:

- The use of Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 Vaccine is paused for now. This is because the safety systems that make sure vaccines are safe received a small number of reports of people who got this vaccine experiencing a rare and severe type of blood clot with low platelets.
- Seek medical care right away if you develop any of the symptoms below.
- If you have any questions at all, call your doctor, nurse, or clinic.

# J&J/Janssen Vaccine Pause Questions and Answers

#### What if I got the J&J/Janssen COVID-19 Vaccine?

- If you got this vaccine **more than three weeks ago**, your risk of developing a blood clot with low platelets is very low.
- If you got this vaccine **within the last three weeks**, your risk of developing a blood clot with low platelets is also very low. However, you should be on the lookout for possible symptoms of a blood clot with low platelets:
  - severe headache
  - backache
  - blurred vision
  - fainting
  - seizures
  - severe pain in your abdomen or stomach
  - severe pain in your chest
  - leg swelling
  - shortness of breath
  - tiny red spots on the skin (petechiae)
  - new or easy bruising or bleeding

#### Should I cancel my vaccination appointment?

If you have an appointment **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.

#### 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 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 at this time while this safety signal and its possible implications are investigated. The pause will give scientists a chance to review the data and decide if recommendations on this specific vaccine need to change. CDC and FDA will share more information on this situation as soon as possible.

#### What do we know?

Scientists and doctors look constantly and carefully at all reported vaccine side effects.

From their monitoring, they saw a small number of reports of people who got the J&J/Janssen COVID-19 Vaccine developing a rare and severe type of blood clot. This type of blood clot is found in the blood vessels that drain blood from the brain and is combined with low platelets. Platelets help blood clot and stop bleeding.

All of these reports were in women between the ages of 18 and 48, and the problems were found up to 2 weeks after vaccination.

There had been more than 7.5 million doses of the J&J/Janssen COVID-19 Vaccine administered as of the time of the pause in the United States.

#### What are we still learning?

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.

#### Why did CDC and FDA recommend a pause?

CDC and FDA recommended this pause to give the agencies time to communicate with and prepare the healthcare system to recognize and treat patients appropriately, as well as gather more information about this situation. Communication with healthcare providers is also re-emphasizing 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 reports, and assess their potential significance.

Report any adverse events after vaccination to v-safe and the Vaccine Adverse Event Reporting System 🖸 .

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

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.

We know the safety systems in place are working. 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.

Learn more about how vaccine safety systems work.

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

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

No. As of April 13, 2021, no reports of blood clots with low platelets have been reported among the more than 180 million doses of the Pfizer-BioNTech or Moderna vaccines administered so far.



### For Healthcare Workers

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

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).

Learn more about storage and labeling of the J&J/Janssen COVID-19 vaccine during this pause.

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