# COVID-19

## Johnson & Johnson COVID-19 Vaccine Update : Answers to Frequently Asked Questions

**Q:** *What is the status of the Johnson & Johnson COVID-19 vaccine?*

A: The U.S. Food and Drug Administration (FDA) paused distribution and administration of the Johnson & Johnson COVID-19 vaccine on April 13, 2021, following reports of six rare cerebral (brain) blood clots. On April 22, the Centers for Disease Control and Prevention (CDC) and the FDA recommended that use resume. After reviewing all available data during the pause, public health authorities determined that the vaccine's known and potential benefits outweigh it's known and potential risks.

**Q:** *Have vaccine administration guidelines changed in response to the six cases and subsequent investigation?*

A: Guidelines for providers who administer the vaccine have been revised to include a warning about the risk of thrombosis with thrombocytopenia syndrome, which is a rare adverse event. Authorities said women under 50 years old should be aware of the rare but increased risk of this adverse event and advised there are other COVID-19 vaccine options available which do not appear to pose this risk.

**Q:** *What do we know about the six reported cases?*

A: The six reported cases involved women between the ages of 18 and 48. These cases have also been associated with low platelets, which are cell fragments in blood that form clots and stop or prevent bleeding. Scientists hypothesize that it could be an "undesirable immune response" that is generating antibodies against platelets and triggering the blood clots.

**Q:** *What are the signs and symptoms experienced by the six affected women?*

A: The cerebral blood clots appear to have developed one-to-three weeks after vaccine administration. Symptoms of blood clots include leg pain and swelling, shortness of breath, and/or abdominal pain. Symptoms of cerebral venous sinus thrombosis, the type of brain blood clot that has been associated with Johnson & Johnson vaccine administration, include headache, blurred vision, fainting or loss of consciousness, loss of control over movement in one part of the body, and/or seizures.

**Q:** *Should medical care be obtained as soon as symptoms develop?*

A: Yes, anyone who develops these symptoms one-to-three weeks after vaccination with the Johnson & Johnson COVID-19 vaccine should be taken to the nearest hospital to obtain immediate emergency medical care. A call to 911 should be considered.

**Q:** *Are there any conditions that put certain people at higher risk for cerebral venous sinus thrombosis?*

A: Anyone on blood thinners (heparin or coumadin) should discuss their condition with their primary care doctor. If the vaccine affects platelets, the person may be at higher risk for bleeding. Anyone who notices bleeding with minor trauma, such as gums bleeding while brushing or flossing teeth, or increased bruising within one-to-three weeks of receiving the vaccine may want to follow up with their personal physician or seek emergency attention because this could be a sign of platelet dysfunction.

*Q: I have had the Johnson & Johnson vaccine. How worried should I be?*

A: Current evidence indicates there is low cause for concern given that the estimated incidence of cerebral blood clots is less than 1-in-1 million vaccine doses. Blood clots have also been strongly associated with severe COVID-19 infection, and this should not be a reason to forego receiving a vaccine. Over 150 million doses of the Pfizer and Moderna COVID-19 vaccines have been administered in the U.S. They have been shown to be safe and effective. Administration of the Astra-Zeneca vaccine was halted in Europe for similar concerns and was later cleared from any potential associations. The U.S. announced April 26 that it will donate millions of AstaZeneca vaccine doses to other countries following federal safety reviews. It has not been authorized by the FDA for emergency use in the U.S., but it is widely distributed in Europe and other parts of the world.