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IN BRIEF

Suspension of Johnson & Johnson COVID-19 Vaccine Lifted

On April 23, 2021, on advice from the Advisory Committee on Immunization Practices (ACIP), the FDA and CDC recommended that use of the Johnson & Johnson adenovirus-based COVID-19 vaccine resume despite its association with development of thrombosis with thrombocytopenia syndrome (TTS). Administration of the vaccine had been paused on April 13 because of 6 reports of TTS, but after completing a data review that identified a further 9 cases associated with the formulation, the agencies concluded that the benefits of the vaccine outweighed its risks. About 7.98 million doses of the single-dose vaccine had been administered in the US at the time of the review.¹⁻⁴

All 15 cases of TTS associated with the Johnson & Johnson vaccine occurred in women, 13 of whom were 18-49 years old. Symptom onset occurred 6-15 days after vaccine administration (median 8 days). Cerebral venous sinus thromboses were present in 12 of the women. Platelet factor 4 heparin-induced thrombocytopenia enzyme-linked immunosorbent assay (PF4 HIT ELISA) testing was positive in all 11 women with available results. Three of the women who developed TTS died.⁴

The fact sheet for the Johnson & Johnson vaccine now includes a warning about the risk of TTS, but use of the formulation has not been restricted based on age or sex.⁵ No cases of TTS have been associated with the >200 million Pfizer and Moderna mRNA-based COVID-19 vaccine doses administered in the US.⁴

The American Society of Hematology recommends that patients who present with thrombosis or thrombocytopenia 4-30 days after administration of the Johnson & Johnson vaccine be evaluated promptly for TTS. Patients with confirmed or suspected TTS should not be treated with heparin; intravenous immune globulin and non-heparin anticoagulants should be used instead.⁶ ■

1. In brief: Johnson & Johnson COVID-19 vaccine suspended. *Med Lett Drugs Ther* 2021 May 3 (epub).
2. FDA News Release. FDA and CDC lift recommended pause on Johnson & Johnson (Janssen) COVID-19 vaccine use following thorough safety review. April 23, 2021. Available at: <https://bit.ly/3aHuO3C>. Accessed April 28, 2021.
3. CDC. CDC recommends use of Johnson & Johnson's Janssen COVID-19 vaccine resume. April 25, 2021. Available at: <https://bit.ly/3xqch5M>. Accessed April 28, 2021.
4. T Shimabukuro. Thrombosis with thrombocytopenia syndrome (TTS) following Janssen COVID-19 vaccine. ACIP presentation slides: April 23, 2021 meeting. Available at: <https://bit.ly/3ez3m9r>. Accessed April 28, 2021.
5. FDA. Fact sheet for healthcare providers administering vaccine (vaccination providers). Emergency Use Authorization (EUA) of the Janssen COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19). April 23, 2021. Available at: <https://bit.ly/3e6KEaD>. Accessed April 28, 2021.
6. American Society of Hematology. Thrombosis with thrombocytopenia syndrome (also termed vaccine-induced thrombotic thrombocytopenia). April 25, 2021. Available at: <https://bit.ly/2R7fqXl>. Accessed April 28, 2021.

Online Tables: COVID-19 Treatments and Vaccines

Please check our website for the latest information on COVID-19, including our continuously updated tables: Treatments Considered for COVID-19 and COVID-19 Vaccine Comparison Chart. Available at: www.medicalletter.org/drugs-for-covid-19.

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