



Pharmacovigilance Drug Safety Alert

FDA Updates Emergency Use Authorization (EUA) for Janssen COVID-19 Vaccine: Addresses risks of Thrombosis with Thrombocytopenia Syndrome (TTS)

On December 14, 2021, the FDA updated various sections of the Janssen COVID-19 vaccine Authorized [Fact Sheet for Healthcare Providers](#) Administering Vaccine (including Full EUA Prescribing Information) and the Authorized [Fact Sheet for Recipients and Caregivers](#) to address concerns of thrombosis with thrombocytopenia syndrome (TTS).

Cases of TTS following administration of the Janssen COVID-19 Vaccine have been reported to the Vaccine Adverse Events Reporting System (VAERS) and provide evidence for an increased risk of TTS with onset of symptoms approximately one to two weeks after administration of the Janssen COVID-19 Vaccine. Cases have been reported in males and females, in a wide age range of individuals 18 years and older, with the highest reporting rate (approximately 1 case per 100,000 doses administered) in females ages 30-49 years; overall, approximately 15% of TTS cases have been fatal.

Thrombosis with Thrombocytopenia Syndrome (TTS) is identified in VAERS as either:

- a thrombosis in an unusual location for a thrombus (i.e., cerebral vein, visceral artery or vein, extremity artery, central artery or vein) and new-onset thrombocytopenia (i.e., platelet count <150,000/ μ L) occurring any time after vaccination; or
- new-onset thrombocytopenia (i.e., platelet count <150,000/ μ L), thrombosis in an extremity vein or pulmonary artery in the absence of thrombosis at an unusual location, and a positive anti-PF4 antibody ELISA test or functional HIT (heparin- induced thrombocytopenia) platelet test occurring any time after vaccination.

Recommendations

1. Do not administer the Janssen COVID-19 Vaccine to individuals with a history of thrombosis with thrombocytopenia following the Janssen COVID-19 Vaccine or any other adenovirus-vectored COVID-19 vaccines (e.g. AstraZeneca's COVID-19 vaccine which is not authorized or approved in the United States)
2. Continue to report all potentially significant or unusual Adverse Vaccine Events (AVE) following administration of a COVID or other vaccine to the VAERS program as described the [Indian Health Manual](#).
 - Instructions for reporting can be found on the [IHS Pharmacovigilance website](#)
 - Please ensure that you **document "IHS" in field #26 of the form.**

References:

1. U.S. Food and Drug Administration. [Janssen COVID-19 Vaccine](#). Published Dec 14, 2021.
2. U.S. Food and Drug Administration. [Letter Granting EUA Amendment](#). Janssen COVID-19 Vaccine. Updated Dec 14, 2021.