

COVID-19 Vaccine Information Brief

May 9, 2022

Changes to the document from the previous version are highlighted in yellow.

IMPORTANT/NEW COVID-19 Vaccine Information

- **FDA Limits Use of Janssen COVID-19 Vaccine to Certain Individuals**

FDA Limits Use of Janssen COVID-19 Vaccine to Certain Individuals

The U.S. Food and Drug Administration has limited the authorized use of the Janssen COVID-19 Vaccine to *individuals 18 years of age and older for whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine.*

Key Points

- After conducting an updated analysis, evaluation and investigation of reported cases, the FDA has determined that the risk of thrombosis with thrombocytopenia syndrome (TTS), a syndrome of rare and potentially life-threatening blood clots in combination with low levels of blood platelets with onset of symptoms approximately one to two weeks following administration of the Janssen COVID-19 Vaccine, warrants limiting the authorized use of the vaccine.
- The FDA has determined the known and potential benefits of the vaccine for the prevention of COVID-19 outweigh the known and potential risks for individuals 18 years of age and older for whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and for individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine.
- The [Fact Sheet for Healthcare Providers Administering Vaccine](#) now reflects the revision of the authorized use of the Janssen COVID-19 Vaccine and includes a warning statement at the beginning of the fact sheet for prominence which summarizes information on the risk for TTS. Additionally, information on the revision to the authorized use of the vaccine and updated information on the risk of blood clots with low levels of blood platelets has been added to the [Fact Sheet for Recipients and Caregivers](#).

Current Status

- The FDA and CDC have continuously monitored for and investigated all suspected cases of TTS reported to VAERS. In an updated analysis of TTS cases following administration of the Janssen COVID-19 Vaccine reported to VAERS through March 18, 2022, the FDA and CDC have identified 60 confirmed cases, including nine fatal cases. The FDA has determined the reporting rate of TTS is 3.23 per million doses of vaccine administered and the reporting rate of TTS deaths is 0.48 per million doses of vaccine administered.
- In making the determination to limit the authorized use of the Janssen COVID-19 Vaccine, the agency considered the reporting rates of TTS and TTS deaths following administration of the Janssen COVID-19 Vaccine are not appreciably lower than previously reported. Furthermore, the factors that put an individual at risk for TTS following administration of Janssen COVID-19 Vaccine remain unknown. The FDA also considered individuals with TTS may rapidly deteriorate, despite prompt diagnosis and treatment, TTS can lead to long-term and debilitating health consequences and that TTS has a high death rate. The agency also considered the availability of alternative authorized and approved COVID-19 vaccines which provide protection from COVID-19 and have not been shown to present a risk for TTS.

Examples of those who *may* receive Janssen COVID-19 Vaccine

Examples of individuals who may still receive the Janssen COVID-19 Vaccine include:

- Individuals who experienced an anaphylactic reaction after receipt of an mRNA COVID-19 vaccine
- Individuals who have personal concerns with receiving mRNA vaccines and would otherwise not receive a COVID-19 vaccine and individuals who would remain unvaccinated for COVID-19 due to limited access to mRNA COVID-19 vaccines.

Resources

- [Janssen COVID-19 Vaccine](#)
 - [Fact Sheet for Healthcare Providers Administering Vaccine](#)
 - [Fact Sheet for Recipients and Caregivers](#)
 - [COVID-19 Vaccines](#)
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