

April 15, 2021

COM-2021-020

Dear provider of pharmaceutical services,

The third vaccine for preventing coronavirus disease COVID-19, on February 27 of the current year, received the U.S. Food and Drug Administration emergency use authorization (EUA). Until the beginning of April, more than 6 million vaccines manufactured by Johnson & Johnson (Janssen) were administered in the U.S. and its territories.

On April 13, 2021, CDC and FDA recommended a pause in the use of Johnson & Johnson's Janssen COVID-19 vaccine due to six reported U.S. cases of a rare and severe type of blood clot in individuals after receiving the preventive drug. This adverse event occurred among women between 18 y/o and 48 y/o, and symptoms occurred 6 to 13 days after vaccination.

Among the more than 180 million people who received the Pfizer-BioNTech or Moderna vaccines, no similar adverse events have been reported.

Recommendations for healthcare professionals:

- Stop using the Johnson & Johnson's Janssen COVID-19 vaccine until FDA recommends continuing the vaccination process with this drug.
- Educate patients about the importance of getting vaccinated against COVID-19 disease. There still other vaccines authorized by FDA in the market.
- Advise patients to talk with their healthcare provider if they develop a severe headache, abdominal pain, leg pain, or shortness of breath within three weeks after vaccination.
- Report adverse events to the Vaccine Adverse Event Reporting System (VAERS) at https://vaers.hhs.gov/reportevent.html.

Additional information can be found at the <u>FDA Alerts Portal</u> and <u>Centers for Disease and Control Prevention (CDC)</u> website.

Remember that medical literature is dynamic and is continuously changing as new scientific knowledge is developed. We exhort the frequent revision of treatment guidelines to assure that your recommendations are consistent with the most updated information.





PharmPix is committed to the health and wellness of our members. It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

References:

- CDC. (2021). Joint CDC and FDA Statement on Johnson & Johnson COVID-19 Vaccine. Retrieved on April 14, 2021 from: https://www.cdc.gov/media/releases/2021/s0413-JJ-vaccine.html
- FDA alerts. (2021). Janssen COVID-19 Vaccine Frequently Asked Questions (Updated April 14, 2021). Retrieved on April 14, 2021 from: <a href="https://www.drugs.com/fda/janssen-covid-19-vaccine-frequently-asked-questions-updated-april-14-2021-14440.html?utm_source=ddc&utm_medium=email&utm_campaign=Daily+Mednews+++April+15++2021&utm_content=Janssen+COVID+19+Vaccine+Frequently+Asked+Questions++Updated+April+14++2021+&hash2=6d381464e0496954c05e5a46e234225d

