COMMUNICATION

COM-2025-041

1 JULY 2025

URGENT PLEASE REVIEW

Safety Notification

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate you with the latest up-to-date drug safety information.

U.S. Food & Drug Administration Publication Date:

06/25/2025

Drug Indication:

For active immunization to prevent coronavirus disease 2019 (COVID-19).

Safety Topic:

FDA approves required updated warning in labeling of mRNA COVID-19 vaccines regarding myocarditis and pericarditis following vaccination.

FDA Approves Required Updated Warning in Labeling of mRNA COVID-19 Vaccines

It is for this reason that we are notifying you that on 06/25/2025 the U.S. Food and Drug Administration (FDA) published a safety communication for the following product(s): Comirnaty (COVID-19 Vaccine, mRNA) and Spikevax (COVID-19 Vaccine, mRNA).

Reason for Communication:

The FDA has required and approved updates to the Prescribing Information for Comirnaty (COVID-19 Vaccine, mRNA) manufactured by Pfizer Inc. and Spikevax (COVID-19 Vaccine, mRNA) manufactured by ModernaTX, Inc. to include new safety information about the risks of myocarditis and pericarditis following administration of mRNA COVID-19 vaccines. Specifically, the FDA has required each manufacturer to update the warning about the risks of myocarditis and pericarditis to include information about the estimated unadjusted incidence of myocarditis and/or pericarditis following administration of the 2023-2024 Formula of mRNA COVID-19 vaccines and the results of a study that collected information on cardiac magnetic resonance imaging (cardiac MRI) in people who developed myocarditis after receiving an mRNA COVID-19 vaccine. The FDA also required each manufacturer to describe the new safety information in the Adverse Reactions section of the Prescribing Information and the Information for Recipients and Caregivers.

Remember you can report adverse events related to vaccines at Vaccine Adverse Event Reporting System (VAERS) by any of the following ways:

Complete and submit the report online.

Report using a writable PDF form and then uploading to the website. If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366. If you need additional help submitting a report, you may call the VAERS toll-free information line at 1-800-822-7967 or send an email to info@vaers.org.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252- ext. 219. Our pharmacists will help you.

In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

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REFERENCES:

1. U.S. Food and Drug Administration. (2025). *FDA Approves Required Updated Warning in Labeling of mRNA COVID-19 Vaccines Regarding Myocarditis and Pericarditis Following Vaccination* https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-approves-required-updated-warning-labeling-mrna-covid-19-vaccines-regarding-myocarditis-and

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