COMMUNICATION

COM-2025-056

15 AUGUST 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:

08/06/2025

Drug Indication:

Prevention of disease caused by chikungunya virus in individuals 18 years of age and older who are at increased risk of exposure to chikungunya virus

Safety Topic:

FDA Removes Recommended Pause in Use and Approves Required Updated Labeling

FDA Removes Recommended Pause in Use of Ixchiq® (Chikungunya Vaccine, Live)

It is for this reason that we are notifying you that on 08/06/2025 the U.S. Food and Drug Administration (FDA) published an updated safety communication for the following product(s): Ixchiq® (Chikungunya Vaccine, Live).

Reason for Communication:

On May 9, 2025, the FDA issued a safety communication informing the public that the FDA and the Centers for Disease Control and Prevention (CDC) jointly recommended a pause in the use of Ixchiq® (Chikungunya Vaccine, Live) in individuals 60 years of age and older while the Agencies undertook an investigation of postmarketing reports of serious adverse events, including neurologic and cardiac events, in individuals who have received the vaccine.

The FDA has completed an updated benefit-risk assessment of Ixchiq, including for use in individuals 18 years of age and older. Based on the available data, and its benefit-risk assessment, the FDA has removed the recommended pause in the use of Ixchiq® in individuals 60 years of age and older and has approved updates to the Prescribing Information and Patient Information.

Background Information:

On November 9, 2023, the FDA approved Ixchiq® for the prevention of disease caused by chikungunya virus in individuals 18 years of age and older who are at increased risk of exposure to chikungunya virus.

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/.

PharmPix Drug Safety Communication Number COM-2025-056 August 2025

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REFERENCES:

1. U.S. Food and Administration (2025). *FDA Update on the Safety of Ixchiq (Chikungunya Vaccine, Live*. https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-update-safety-ixchiq-chikungunya-vaccine-live

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