COMMUNICATION

COM-2025-028

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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:

05/09/2025

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:

The FDA and CDC recommend pause in use of Ixchiq® (chikungunya vaccine, live) in individuals 60 years of age and older while postmarketing safety reports are investigated

FDA and CDC Recommend Pause in Use of Ixchiq® (Chikungunya Vaccine, Live)

It is for this reason that we are notifying you that on 05/09/2025, the U.S. Food and Drug Administration (FDA) published a safety communication for the following product(s): Ixchiq® (Chikungunya Vaccine, Live).

Reason for Communication:

The FDA and the Centers for Disease Control and Prevention (CDC) are recommending a pause in the use of Ixchiq® (Chikungunya Vaccine, Live) in individuals 60 years of age and older, while these Agencies investigate postmarketing reports of serious adverse events, such as neurologic and cardiac events, in individuals who have received the vaccine. As of May 7, 2025, 17 serious adverse events, including two that resulted in death, have been reported in individuals 62 through 89 years of age who received Ixchiq® during postmarketing use globally. Six of these reports have been from the United States (U.S.). Most of the serious adverse events that have been reported to the Vaccine Adverse Event Reporting System (VAERS) have been in individuals with underlying chronic medical conditions. It is important to note that adverse events reported to VAERS may not be causally related to vaccination. Approximately 80,000 doses of Ixchiq® have been distributed globally. The FDA will conduct an updated benefit-risk assessment for the use of Ixchiq® in individuals 60 years of age and older. The FDA and CDC will update the public when the Agencies finalize their evaluation of this safety issue.

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-2025-028 May 2025

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REFERENCES

1. U.S. Food and Drug Administration. (2025). *FDA and CDC Recommend Pause in Use of Ixchiq (Chikungunya Vaccine, Live) in Individuals 60 Years of Age and Older While Postmarketing Safety Reports are Investigated*: https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-and-cdc-recommend-pause-use-ixchiq-chikungunya-vaccine-live-individuals-60-years-age-and-older#:~:text=The%20Food%20and%20Drug%20Administration%20(FDA)%20and,investigate%20postmarketing%20reports%20of%20serious%20adverse%20events%2C

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