**From:** dph.immunizations@ct.gov <noreply@everbridge.net>
**Sent:** Thursday, May 15, 2025 9:29 AM
**Subject:** Chikungunya Vaccine Update: Recommended Pause of Use in Adults 60 Years of Age and Older

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Summary

The FDA and the CDC are recommending a pause in the use of Ixchiq (Chikungunya Vaccine, Live) in individuals 60 years of age and older while the agencies investigate post-marketing reports of serious adverse events, including 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 post-marketing use globally. Six of these reports have been from the United States. 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. Adverse events reported to VAERS may not be causally related to vaccination. Approximately 80,000 doses of Ixchiq have been distributed globally.

Some of the post-marketing reports include adverse events that are consistent with severe complications of chikungunya disease, resulting in hospitalization; one person died from encephalitis. The FDA-approved Prescribing Information includes a warning to inform that the vaccine may cause severe or prolonged chikungunya-like adverse reactions.

In addition, although not commonly reported during the clinical studies, severe chikungunya-like adverse reactions that prevented daily activity and/or required medical intervention occurred in 1.6% of Ixchiq recipients and none of the placebo recipients. Two recipients with severe chikungunya-like adverse reactions were hospitalized. In addition, some recipients had prolonged chikungunya-like adverse reactions that lasted for at least 30 days.

FDA will conduct an updated benefit-risk assessment for the use of Ixchiq in individuals 60 years of age and older. In addition, FDA and CDC will continue the evaluation of post-marketing safety reports for Ixchiq. While the safety of Ixchiq for use in individuals 60 years of age and older is being further assessed, FDA and CDC are recommending a pause in use of the vaccine in this age group. FDA and CDC will update the public when the agencies complete their evaluation of this safety issue.

**BACKGROUND:** On November 9, 2023, 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. Ixchiq contains a live, weakened version of the chikungunya virus and may cause symptoms similar to those of chikungunya disease.

Health care professionals and patients are encouraged to report adverse events to the Vaccine Adverse Event Reporting System (VAERS).

Thank you for your continued support and cooperation.

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