Important Drug Safety Notice

TO ALL PARTICIPATING PHARMACIES

Circular Letter MC25-017-CG
August 25, 2025

FDA announced that the Center for Biologics Evaluation and Research (CBER) has suspended the biologics license for Valneva Austria GmbH's Ixchiq (Chikungunya Vaccine, Live). This vaccine was initially approved by FDA under the accelerated approval pathway in November of 2023 for the prevention of disease caused by the chikungunya virus (CHIKV) in individuals 18 years of age and older who are at increased risk of exposure to CHIKV. CBER's decision is based on serious safety concerns related to the vaccine, which appears to be causing chikungunya-like illness in vaccine recipients.

RECOMMENDATIONS

1. The suspension of the license is effective immediately and requires Valneva to stop shipping and selling of IXCHIQ® in the United States. The manufacturer has not provided information regarding recalling any available inventory of the vaccine at this moment.

2. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

3. Expect patients to visit your pharmacy asking for information on this safety issue and prepare your pharmacy staff on how to handle the situation.

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U.S. FOOD & DRUG ADMINISTRATION

FDA Update on the Safety of Ixchiq (Chikungunya Vaccine, Live). FDA Suspends Biologics License: FDA Safety Communication

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AUDIENCE: Patient, Health Care Professional, Pharmacy, Cardiology, Neurology, Internal Medicine, Family Practice, Travel Clinics

UPDATE: *On August 22, 2025, the US FDA's Center for Biologics Evaluation and Research (CBER) has suspended the biologics license for Valneva Austria GmbH's Ixchiq (Chikungunya Vaccine, Live). This vaccine was initially approved by FDA under the accelerated approval pathway in November of 2023 for the prevention of disease caused by the chikungunya virus (CHIKV) in individuals 18 years of age and older who are at increased risk of exposure to CHIKV. CBER's decision is based on serious safety concerns related to the vaccine, which appears to be causing chikungunya-like illness in vaccine recipients. There has been one death from encephalitis directly attributable to the vaccine (CSF PCR was + for the vaccine strain of the virus) and over 20 reported serious adverse events that were consistent with chikungunya-like illness. Reported serious adverse events have included 21 hospitalizations and 3 deaths. Furthermore, the clinical benefit of the vaccine has not yet been verified in confirmatory clinical studies. CBER's benefit-risk analysis broadly shows the vaccine does not have benefits outweighing risks, under most plausible scenarios. For these reasons, CBER believes this vaccine is not safe and that continued administration to the public would pose a danger to health.*

On August 6, 2025, FDA lifted a pause in the use of Ixchiq in individuals 60 years of age and older and approved required updated labeling for Ixchiq, including revising the indication, and adding limitations of use and enhanced warnings and precautions to reflect serious postmarketing adverse reactions including hospitalizations and encephalitis in a person who died, with risk noted for individuals 65 years and older with chronic medical conditions.

On May 9, 2025, FDA issued a safety communication informing the public that the Food and Drug Administration (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

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reports of serious adverse events, including neurologic and cardiac events, in individuals who have received the vaccine.

The November 9, 2023, approval of Ixchiq included a warning in the Prescribing Information informing that the vaccine may cause severe or prolonged chikungunya-like adverse reactions. Ixchiq contains a live, weakened version of the chikungunya virus and may cause symptoms in the vaccine recipient similar to those experienced by people who have chikungunya.

BACKGROUND: Ixchiq contains a live, weakened version of the chikungunya virus and may cause symptoms similar to those of chikungunya disease. Some of the postmarketing reports include adverse events that are consistent with severe complications of chikungunya disease, resulting in hospitalization; one person died from encephalitis.

Continuous monitoring and assessment of the safety of all vaccines remains an FDA priority. Suspected adverse events may be reported to the Vaccine Adverse Event Reporting System (VAERS), which is co-managed by FDA and CDC.

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