PLEASE READ

IMPORTANT MEDICINE SAFETY INFORMATION

APPROVED BY THE HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

19 September 2025

Ixchiq®▼ (Chikungunya vaccine (live-attenuated)): lifting of temporary contraindication in adults 65 years and older; warning on severe adverse reactions, including encephalitis

Dear Healthcare Professional,

Valneva in agreement with the European Medicines Agency and the Health Products Regulatory Authority (HPRA) would like to inform you of the following:

Summary

- **The temporary contraindication in adults aged 65 and older has been lifted. Irrespective of age, Ixchiq should be administered only when there is a significant risk of chikungunya infection and following a thorough individual benefit-risk assessment.**
- **Serious adverse reactions including, but not limited, to chikungunya-like adverse reactions have been observed, particularly in individuals aged 65 years and older and in those with comorbidities. These reactions resulted in deterioration of general health, exacerbation of chronic medical conditions and cardiac and neurological events, leading to hospitalisation and, in a few cases, death.**
- **Cases of encephalitis, including one with fatal outcome, have been reported following vaccination with Ixchiq. Vaccinees should be advised to seek immediate medical attention if they experience symptoms suggestive of encephalitis.**
- **Healthcare professionals are reminded that:**
    - **Ixchiq is contraindicated in immunodeficient and immunosuppressed individuals due to disease or medical therapy, independent of age (e.g., from malignancies, chemotherapy, immunosuppressive therapy, congenital immunodeficiency, or HIV infection with severe immunosuppression).**
    - **Ixchiq is not recommended to be co-administered with other vaccines.**

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Background on the safety concern

Ixchiq has been authorised in the European Union (EU) since 28 June 2024 for the active immunisation for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 18 years of age and older, which was later extended to adolescents 12 years and older. Ixchiq contains live-attenuated CHIKV of the Δ5nsP3 strain. In May 2025, following reports of serious adverse events after vaccination, the use of Ixchiq was temporarily contraindicated in individuals aged 65 years and above, pending the outcome of an EU-wide review undertaken by the European Medicines Agency (EMA).

As of 13 May 2025, 36,000 doses of Ixchiq have been estimated to be administered across France (including La Réunion), the United States, other EU countries, and Canada. Among these, it is estimated that 37% were administered to individuals aged 65 years and older, those at highest risk for severe outcomes from CHIKV infection.

As of 25 May 2025, 28 cases of serious adverse events following vaccination with Ixchiq have been reported worldwide, including 18 from France, including La Réunion, eight from the United States, and one each from Austria and Canada. A total of 22 serious cases involved vaccinated individuals aged 65 years and older, three of which resulted in death.

An evaluation of post-marketing data has confirmed the occurrence of serious adverse events, which mainly involved vaccinees aged 65 years and older and vaccinees with multiple underlying chronic medical conditions. In these individuals, serious adverse events, including but not limited to chikungunya-like adverse reactions have been observed, leading to exacerbation of pre-existing conditions and/or a deterioration of general health. Reactions included in particular encephalitis, encephalopathy, confusional state, malaise, and decreased appetite, and sometimes resulted in hospitalisation and, in a few cases, in death. Vaccinees should be advised to seek immediate medical attention if they experience any symptoms suggestive of such adverse reactions.

While most serious adverse events occurred in older people, Ixchiq is effective at triggering the production of antibodies against the chikungunya virus, which may be of particular benefit for older people at increased risk of severe chikungunya disease. As a consequence, the temporary contraindication for use of Ixchiq in adults aged 65 and older has been lifted.

Overall, for people of all ages, the vaccine should only be given when there is a significant risk of chikungunya infection and after a careful consideration of the benefits and risks.

The product information of Ixchiq is being updated accordingly.

Healthcare professionals are reminded that Ixchiq is contraindicated in individuals who are immunosuppressed because of disease or medical treatment. This includes malignancies, chemotherapy, immunosuppressive therapy, congenital immunodeficiency, or HIV infection with severe immunosuppression.

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Healthcare professionals are also reminded that Ixchiq is not recommended to be co-administered with other vaccines.

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via HPRA

Pharmacovigilance, website: www.hpra.ie.

Reports of suspected adverse reactions can also be made to the company, contact details below. Please include the batch details, if available.

Company contact point

If you have any questions, please get in touch with the contact persons listed in the packaging documents. You can also contact our medical information service at infoixchiq@valneva.com or +43 1 20620 1444 if you have any questions about the information in this letter or about the safe and effective use of IXCHIQ®.

Sincerely,

valneva

Digitally signed by Zsuzsanna UNGER
Reason: I have reviewed this document
Date: 2025.09.19 12:13:06 +02'00'

Zsuzsanna Unger

Director Pharmacovigilance & QPPV
Valneva Austria GmbH