PLEASE READ

IMPORTANT MEDICINE SAFETY INFORMATION

APPROVED BY THE HPRA

An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

14 July 2026

IXCHIQ®▼ (Chikungunya vaccine (live)): Use restricted to individuals at high risk of acquiring chikungunya infection

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

- **IXCHIQ® should only be given to individuals with a high risk of acquiring Chikungunya infection.**
- **This restriction of indication follows a routine EMA review of available safety data which evaluated the impact of serious adverse events reported with the vaccine (including aseptic meningitis), on the benefit-risk balance of IXCHIQ®. Some of these events resulted in hospitalisation and death.**
- **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.**

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.

The restriction of indication for IXCHIQ® follows an EMA review of available safety data as part of a regular 6-monthly periodic safety update report (PSUR) for IXCHIQ®. The review also took into account findings from other recent reviews of the vaccine, including a review of a case of aseptic meningitis in a healthy young adult.

Known serious side effects linked to the vaccine particularly involved individuals aged 65 years and older and individuals with multiple underlying chronic medical conditions (e.g., cardiovascular disease, diabetes mellitus, chronic kidney disease, chronic obstructive pulmonary disease, neurodegenerative

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disease), but also young adults with no relevant comorbidities. In these individuals, serious or prolonged chikungunya-like adverse reactions have been observed, sometimes leading to deterioration of general condition including malaise and decreased appetite, exacerbation of pre-existing diseases, brain disorders like encephalopathy and encephalitis, aseptic meningitis or confusional state.

These serious adverse reactions sometimes resulted in hospitalisation and, in a few cases, in death. Healthcare professionals are therefore reminded that the vaccine should only be given after careful consideration of the potential benefits and risks. It is contraindicated in immunodeficient or immunosuppressed individuals due to disease or medical therapy and should not be co-administered with other vaccines.

The product information of IXCHIQ® will be updated accordingly.

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 medinfo@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
Date: 2026.07.16 18:18:53 +02'00'

Zsuzsanna Unger

Director Pharmacovigilance & QPPV
Valneva Austria GmbH