VALNEVA UK LTD
Centaur House
Ancells Business Park
Ancells Road
Fleet Hampshire
GU51 2UJ, *United Kingdom*

17th June 2025

Dear Healthcare Professional,

IXCHIQ®▼ powder and solvent for solution for injection Chikungunya vaccine (live) temporarily paused in people aged 65 and over as precautionary measure

Prescribing information and adverse event reporting information can be found below

MHRA Marketing Authorisation number PLGB 41385/0007

Please read important MHRA Drug Safety update on IXCHIQ here

Valneva UK in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

Summary

- **As of 02 May 2025, 17 serious adverse events have been reported worldwide in people aged between 62 to 89 years following vaccination with IXCHIQ.**
- **As a temporary measure, while a thorough assessment of all available data is performed, IXCHIQ must not be used in adults aged 65 years and above. IXCHIQ can continue to be used in people aged 18-64 years, in accordance with official recommendations.**
- **Healthcare professionals are also reminded that IXCHIQ, Chikungunya vaccine (live), is contraindicated in immunodeficient or immunosuppressed individuals due to disease or medical therapy, independent of age.**

Background on the safety concern

IXCHIQ has been authorised in the UK since 5th February 2025 for the active immunisation for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 18 years and older. IXCHIQ contains live-attenuated CHIKV of the Δ5nsP3 strain.

As of the most recent estimated data, a total of approximately 37,900 doses of IXCHIQ have been administered across La Réunion, mainland France (including overseas departments), the United States, the European Union (EU), and Canada. Among these, it is estimated that 43 percent (16,236 doses) were administered to individuals aged 65 years and older, those at highest risk for severe outcomes from CHIKV infection.

As of 02 May 2025, 19 cases of serious adverse events (SAEs) following vaccination with IXCHIQ have been reported worldwide, thereof 12 from France including La Reunion and 6 from the United States and 1 from Austria. Many of the patients affected also had other illnesses and the exact cause of these

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adverse events and their relationship with the vaccine have not yet been determined. So far, 17 serious cases involved vaccinated individuals aged between 62 and 89 years, two of which resulted in death.

Following global reports of serious adverse events in older people, the government's independent expert advisory body, the Commission on Human Medicines (CHM), has temporarily restricted use of a chikungunya vaccine called IXCHIQ in people aged 65 and over until a further safety review has been concluded. This is a precautionary measure while the MHRA conducts a safety review. IXCHIQ can continue to be used in people aged 18-64 years, in accordance with official recommendations.

In addition, healthcare professionals are reminded that IXCHIQ is contraindicated in patients who are immunodeficient or immunosuppressed because of disease or medical treatment. These include patients with congenital immunodeficiency, haematological cancers and solid tumours, patients with HIV infection who are severely immunocompromised and patients receiving chemotherapy or long-term immunosuppressive therapy.

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store and include the vaccine brand and batch/Lot number if available.
Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

IXCHIQ ▼ is subject to additional monitoring. This will allow quick identification of new safety information.
Please report ANY suspected adverse drug reactions (ADRs) to drugs and vaccines identified by the black triangle▼ to the MHRA through the Yellow Card Scheme.

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Legal category: POM. **Packaging Quantities:** 1 vial of powder, 1 pre-filled syringe of solvent without needles. **Marketing authorisation holder:** Valneva Austria GmbH. Campus Vienna Biocenter 3, A-1030 Vienna, Austria. **Marketing authorisation numbers: PLGB 43185/0007**

For full prescribing information and details of other side effects please refer to the Summary of Product Characteristics which can be found at https://products.mhra.gov.uk or https://www.medicines.org.uk/emc

Full prescribing information is available on request from: Medical Information, VALNEVA AUSTRIA GMBH, Campus Vienna Biocenter 3, 1030 Vienna, Vienna, Austria, FB-Nr: FN 389960 x / HG Wien.
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Email: **infoIXCHIQ@valneva.com**

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View Prescribing Information for IXCHIQ®

Adverse events should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
Adverse events should also be reported to the Valneva UK Ltd Medical Information department on Tel: 01506 446608 or via email: safety@valneva.com