



DRUG SAFETY UPDATE (DSU)

IXCHIQ Chikungunya vaccine: UK marketing authorisation withdrawn following safety review

Specialisms: Infection prevention, Infectious disease, Immunology and vaccination

Summary

Following advice from the Commission on Human Medicines (CHM), the MHRA has concluded that the benefit-risk balance for the IXCHIQ chikungunya vaccine is no longer considered favourable and the UK marketing authorisation has been withdrawn. Healthcare professionals should no longer prescribe or administer the IXCHIQ vaccine and should instead consider alternative measures to reduce the risk of chikungunya infection in individuals travelling to affected areas.

Advice for Healthcare Professionals:

- the UK marketing authorisation for the IXCHIQ vaccine (chikungunya vaccine) has been withdrawn and the product is being removed from the UK market
- do not prescribe, supply or administer the IXCHIQ vaccine, and dispose of any remaining stock in accordance with local policies
- ensure that any materials, systems or communications referring to available UK vaccination options are updated to remove the IXCHIQ vaccine
- advise travellers of alternative measures to prevent chikungunya infection, including other available vaccines for chikungunya, avoidance of mosquito bites and adherence to current health-related travel advice
- patients who have previously received the IXCHIQ vaccine do not need to take any specific action as a result of this regulatory decision. However, they should seek medical advice if they have experienced a suspected adverse reaction following IXCHIQ vaccination
- continue to report suspected adverse reactions associated with the IXCHIQ vaccine on a [Yellow Card](#)

Advice for Healthcare Professionals to Provide to Patients:

- following a review of all available evidence the MHRA has withdrawn the UK marketing authorisation for the IXCHIQ vaccine because the benefits of this vaccine are no longer considered to outweigh its risks
- individuals who have already received the IXCHIQ vaccine do not need another vaccination or any other specific medical treatment because of this decision
- anyone who experiences a suspected side effect following vaccination should seek medical advice and report it on a [Yellow Card](#)

Background

IXCHIQ is a live attenuated vaccine indicated for the prevention of chikungunya virus infection in adults travelling to high-risk areas. Since its authorisation, serious adverse reactions have been reported, including chikungunya-like symptoms and rare neurological events such as encephalitis. These cases have occurred predominantly in older adults and individuals with underlying medical conditions, but were also reported in individuals with no known health conditions. Some cases resulted in hospitalisation or death.

Following review of post-authorisation safety data and consultation with the CHM, the MHRA has withdrawn the marketing authorisation for the IXCHIQ vaccine, as the benefits of receiving this vaccine for UK travellers no longer outweigh the risks. Therefore, healthcare professionals must no longer prescribe, supply or administer the IXCHIQ vaccine and should dispose of any remaining stock in accordance with local policies.

There is no risk to individuals who have previously received IXCHIQ vaccination and did not experience side effects, and no revaccination or other medical intervention is required. Any individuals who have previously received IXCHIQ vaccination and experienced side effects are advised to seek medical advice and report to the Yellow Card scheme.

Individuals travelling from the UK to regions with known chikungunya transmission are advised to consider alternative measures to prevent possible infection, such as vaccination with an alternative vaccine, prevention of mosquito bites through the use of netting or repellent, and adherence to health-related travel advice.

Reporting advice

Healthcare professionals, patients, and caregivers are asked to submit reports using the Yellow Card scheme electronically using:

- the [Yellow Card website](#).
- the Yellow Card app; download from the [Apple App Store](#) or [Google Play Store](#)
- some clinical IT systems for healthcare professionals (EMIS, SystmOne, Vision, MiDatabank, and Ulysses)

When reporting suspected adverse drug reactions, please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, and treatment dates.

Additional information

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