Medicines & Healthcare products Regulatory Agency

DRUG SAFETY UPDATE (DSU)

IXCHIQ Chikungunya vaccine: temporary suspension in people aged 65 years or older

Specialisms: Infection prevention, Infectious disease, Immunology and vaccination

Summary

The Commission on Human Medicines (CHM) has temporarily restricted use of the IXCHIQ Chikungunya vaccine in people aged 65 years and over following very rare fatal reactions reported globally. This is a precautionary measure while the MHRA conducts a safety review. The IXCHIQ vaccine will be available on the UK market from 18 June 2025.

Advice for Healthcare Professionals:

- Chikungunya vaccine (IXCHIQ) is a vaccine to protect against life-threatening Chikungunya virus infection; strict adherence to contraindications and precautions is essential to reduce the risk of very rare but potentially fatal adverse reactions
- following a review of the benefits and risks of the vaccine, CHM has made a recommendation to restrict use of this vaccine in individuals aged 65 years and older, while data is reviewed from global cases
- do not use this vaccine in people aged over 65 years for the period of the suspension
- the product information for the vaccine will not change during this suspension, but a letter for healthcare professionals will be circulated from the company in addition to this Drug Safety Update, to advise of the restrictions on those aged 65 and above
- IXCHIQ vaccine is already contraindicated in all individuals with immunodeficiency or immunosuppression as a result of disease or medical therapy, this includes IgA deficiency
- patients who have received the vaccine should be advised to seek emergency medical attention if they develop signs or symptoms associated with viraemia, including arthralgia, or neurological symptoms including encephalopathy
- all patients who have received the vaccine should receive the manufacturer's patient information leaflet as part of the travel consultation
- further communications will be circulated to inform of the outcome of the review

- report suspected adverse reactions associated with the IXCHIQ vaccine on a Yellow Card

Advice for Healthcare Professionals to Provide to Patients:

- the Chikungunya vaccine is given to those who plan to travel abroad to certain regions, where the Chikungunya virus is present. Chikungunya virus is a potentially life-threatening viral infection
- a live attenuated Chikungunya vaccine, IXCHIQ, is coming to the UK market on 18 June 2025, it has not been available on the UK market before this time
- the IXCHIQ vaccine should not be used for people aged 65 years and over until MHRA has completed a full safety review. This is because there have been rare reports of serious side effects in this age group globally
- during your vaccine consultation you will be assessed by a healthcare professional for vaccine suitability, you will not be given this vaccine if you are aged over 65 years old, or if you are immunosuppressed or immunodeficient. Alternative vaccines are available for these groups
- if you have received a Chikungunya vaccine, you should seek urgent medical attention if you start to experience joint pain, fever, stiff neck or confusion

Trigger for detailed review and recommendations

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 the safety review.

The MHRA is working with the manufacturer of the IXCHIQ vaccine, Valneva. This vaccine was approved by the MHRA in February 2025. There will be no impact on operational issues as this vaccine has only become available in the UK as of 18 June and therefore there is no immediate safety concern.

The decision to restrict the licence until further review is based on global data which has highlighted 23 cases of serious adverse reactions, including two cases reporting a fatal outcome. Given that studies on IXCHIQ mainly involved people below 65 years of age and the vast majority of serious cases concerned people 65 years of age and above, the CHM is temporarily recommending restricting the use of vaccine in individuals aged 65

years and above. There are no changes in the recommendations for vaccination with IXCHIQ for people of 18 to 64 years of age.

The vaccine is currently contraindicated in individuals with immunodeficiency or immunosuppression as a result of disease or medical therapy.

About the IXCHIQ Chikungunya Vaccine

Chikungunya virus is a potentially life-threatening viral infection and protective measures against the disease are essential for anyone travelling to an area where there is a risk of infection.

Chikungunya virus is found in the subtropical regions of the Americas, Africa, Southeast Asia, India, and the Pacific Region, and is spread to humans by the bite of an infected mosquito (Aedes aegypti and Aedes albopictus). It cannot be passed from human to human.

For most people, the balance between the benefits and possible side effects of the IXCHIQ vaccine remains overwhelmingly favourable. However, because the IXCHIQ vaccine contains a live, weakened strain of the Chikunguya virus, strict adherence to contraindications and precautions is essential to reduce the risk of serious side effects in those who may have a weaker immune system.

Serious side effects that resemble Chikunguya infection are very rare but can be fatal, these include rare neurological symptoms including encephalopathy. These risks are more likely to occur in certain groups, particularly people with a weakened immune system.

At vaccination, all vaccinees should receive the manufacturer's patient information leaflet for IXCHIQ vaccine, which advises them on symptoms to be vigilant for following vaccination.

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

For further information see the National Travel Health Network and Centre website.

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