30 May 2024
EMA/CHMP/40091/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ixchiq

chikungunya vaccine (live)

On 30 May 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ixchiq, intended for the prevention of chikungunya disease in adults 18 years and older. The applicant for this medicinal product is Valneva Austria GmbH.

Ixchiq was reviewed under EMA's accelerated assessment programme.

Ixchiq will be available as powder and solvent for solution for injection. Ixchiq is a live attenuated chikungunya vaccine (ATC code: not yet assigned). It contains the live attenuated chikungunya virus (CHIKV) Δ5nsP3 strain of the ECSA/IOL genotype. The exact mechanism by which it protects against CHIKV infection and/or disease has not been determined. Ixchiq elicits neutralising antibodies against CHIKV.

The benefits of Ixchiq is to trigger the production of neutralising antibodies at 28 days and up to 6 months post-vaccination. This effect is expected to confer protection against chikungunya disease The most common side effects with Ixchiq are headache, nausea, myalgia, arthralgia, fatigue, fever, vaccination site reactions (tenderness, pain, erythema, induration, swelling), white blood cell count decrease and liver function test increase.

The full indication is:

> IXCHIQ is indicated for active immunisation for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 18 years and older. The use of this vaccine should be in accordance with official recommendations.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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