26 February 2026
EMADOC-1829012207-42285
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Xolremdi

mavorixafor

On 26 February 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation under exceptional circumstances[2] for the medicinal product Xolremdi[3], intended for the treatment of WHIM syndrome (warts, hypogammaglobulinaemia, infections and myelokathexis) in adults and adolescents from 12 years of age.

The applicant for this medicinal product is X4 Pharmaceuticals (Austria) GmbH.

Xolremdi will be available as 100 mg hard capsules. The active substance of Xolremdi is mavorixafor, an immunostimulant (ATC code: L03AX24). In patients with WHIM syndrome, gain-of-function mutations in the *CXCR4* receptor gene lead to increased responsiveness to CXCL12 and retention of leukocytes in the bone marrow. Mavorixafor is a CXC chemokine receptor 4 (CXCR4) antagonist that binds to the CXCR4 receptor, preventing its interaction with CXCL12. By inhibiting this interaction, mavorixafor increases mobilisation of neutrophils, lymphocytes and monocytes from the bone marrow into the peripheral circulation.

The benefit of Xolremdi is an increased number of circulating mature neutrophils and lymphocytes, as observed in a randomised, double-blind, placebo-controlled study in 31 patients with WHIM syndrome. Some improvements were observed in reducing infections, but an effect on warts could not be shown. A preventive effect of Xolremdi on malignancies for patients with WHIM syndrome could not be derived.

The most common side effects with Xolremdi are gastrointestinal effects (nausea, diarrhoea, vomiting, dyspepsia and abdominal pain), rash and headache.

The full indication is:

> Xolremdi is indicated in patients 12 years of age and older for the treatment of WHIM syndrome

[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
[2] In exceptional circumstances, an authorisation may be granted subject to certain specific obligations, to be reviewed annually. This happens when the applicant can show that they are unable to provide comprehensive data on the efficacy and safety of the medicinal product, due to the rarity of the condition it is intended for, limited scientific knowledge in the area concerned, or ethical considerations involved in the collection of such data.
[3] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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(warts, hypogammaglobulinemia, infections and myelokathexis) to increase the number of circulating mature neutrophils and lymphocytes.

Treatment with Xolremdi should only be initiated by specialist physicians with experience in the diagnosis or management of immune deficiencies.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.