18 September 2025
EMA/314083/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Remsima

infliximab

On 18 September 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Remsima. The marketing authorisation holder for this medicinal product is Celltrion Healthcare Hungary Kft.

The CHMP adopted a new pharmaceutical form and a new strength, concentrate for solution for infusion 40 mg/mL (in two vial presentations, 100 mg in 2.5 mL and 350 mg in 8.75 mL). The new formulation is associated with the following new contraindication:

> Patients with hereditary fructose intolerance (HFI). Prior to initiating treatment, HFI should be excluded on age-appropriate clinical grounds (see section 4.4).

For the full list of contraindications for each pharmaceutical form, please refer to the summary of products characteristics (SmPC).

Detailed recommendations for the use of this product will be described in the updated SmPC, which will be published on the EMA website in all official European Union languages after a decision on this change to 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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