23 July 2026
EMADOC-1829012207-57557
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Icotyde

icotrokinra

On 23 July 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Icotyde, intended for the treatment of plaque psoriasis in adults and adolescents.

The applicant for this medicinal product is Janssen-Cilag International N.V.

Icotyde will be available as 200 mg film-coated tablets. The active substance of Icotyde is icotrokinra, an immunosuppressant and interleukin inhibitor (ATC code: L04AC28). Icotrokinra is a synthetic peptide that binds selectively to the IL-23 receptor (IL-23R) with high affinity and competitively antagonises the binding of IL-23.

The benefits of Icotyde are its ability to inhibit the IL-23/IL-23R-dependent release of proinflammatory cytokines leading to a decrease in disease severity and skin involvement, as shown in four phase 3 randomised, multi-centre, double-blind, placebo and/or active comparator-controlled studies involving nearly 2,500 adults and adolescents. The most common side effects are fungal infections.

The full indication is:

> ICOTYDE is indicated for the treatment of moderate to severe plaque psoriasis in adults, and adolescents 12 years of age and older and weighing at least 40 kg, who are candidates for systemic therapy.

Icotyde should be initiated under the guidance and supervision of a physician experienced in the diagnosis and treatment of plaque psoriasis.

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.

[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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