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First oral medicine targeting interleukin-23 receptor recommended for plaque psoriasis

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Icotyde shown to clear psoriasis skin lesions in many patients with moderate to-severe plaque psoriasis

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EMA has recommended granting a [marketing authorisation](#) in the European Union for Icotyde (icotrokinra) for the treatment of moderate-to-severe plaque psoriasis in adults and in adolescents from 12 years of age weighing at least 40 kg.

Plaque psoriasis is a common chronic inflammatory skin disease affecting around 1% to 4% of adults and up to 1% of children worldwide. The condition can have a significant impact on people's quality of life, causing both physical and psychological discomfort.

Although a range of treatments is available, there remains a need for effective, safe and convenient treatments for this condition. Many patients do not achieve adequate control of their symptoms, and the effects of treatment can wane over time. Some patients also experience significant side effects.

The [active substance](#) in Icotyde, icotrokinra, works by blocking

the receptor for interleukin-23, a protein that plays a role in the inflammation seen in plaque psoriasis. By blocking the action of interleukin-23, icotrokinra reduces inflammation and symptoms associated with the disease.

While authorised injectable medicines targeting interleukin-23 are available in the EU, Icotyde will be the first authorised oral medicine targeting the interleukin-23 pathway.

In reaching its opinion on Icotyde, EMA considered data from four phase 3 trials involving 2,500 patients with moderate-to-severe plaque psoriasis.

In three of these studies, after 16 weeks, between 50% and 57% of patients who took Icotyde achieved PASI 90 (a 90% or more drop in symptom scores as measured by the Psoriasis Area and Severity Index), compared with between 1% and 4% of patients who took placebo (a dummy treatment). In addition, between 65% and 71% of patients who took Icotyde achieved an IGA score of 0 or 1, meaning their skin was clear or almost clear of psoriasis lesions, compared with 8% to 11% of those who took placebo.

A fourth study involved patients with psoriasis affecting difficult-to-treat areas such as the scalp, genital region, hands and feet.

Icotyde also has a favourable safety profile. The most common side effects reported were fungal infections, which occur in 1.1% of patients.

The opinion adopted by the [CHMP](#) is an intermediary step on Icotyde's path to patient access. The opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide [marketing authorisation](#). Once a [marketing authorisation](#) has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role or use of this medicine in the context of the national health system of that country.

Note: The applicant for Icotyde is Janssen-Cilag International N.V.

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