21 April 2017
EMA/CHMP/244798/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Skilarence

dimethyl fumarate

On the 21 April 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Skilarence, intended for the treatment of psoriasis. The applicant for this medicinal product is Almirall S.A.

Skilarence will be available as 30-mg and 120-mg gastro-resistant tablets. The active substance of Skilarence is dimethyl fumarate. The benefits in psoriasis are believed to be mediated mainly by the anti-inflammatory and immunomodulating effects of dimethyl fumarate and its metabolite monomethyl fumarate. These effects are thought to be mainly mediated by an interaction with intracellular reduced glutathione, which helps to regulate the altered transcriptional activity of the nuclear factor kappa-light-chain-enhancer of activated B-cells (NF-κB).

The benefits with Skilarence are its ability to improve the signs and symptoms of psoriasis. The most common side effects are gastrointestinal events, flushing and lymphopenia.

The full indication is: "Skilarence is indicated for the treatment of moderate to severe plaque psoriasis in adults in need of systemic medicinal therapy". It is proposed that Skilarence be prescribed by physicians experienced in the treatment of psoriasis.

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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