26 July 2018
EMA/CHMP/464222/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ilumetri

tildrakizumab

On 26 July 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ilumetri, intended for the treatment of moderate to severe plaque psoriasis. The applicant for this medicinal product is Almirall S.A.

Ilumetri will be available as a 100-mg solution for injection. The active substance of Ilumetri is tildrakizumab, an interleukin inhibitor (ATC code: L04AC17) that acts as an immunosupressant by inhibiting the action of interleukin 23, thus reducing the release of proinflammatory cytokines.

The benefits with Ilumetri are its ability to reduce the immune response and inflammatory process, and thereby improve the signs and symptoms of patients with moderate to severe plaque psoriasis. The most common side effects are upper respiratory tract infections, gastroenteritis, nausea, diarrhea, headache, injection site pain and back pain.

The full indication is: "Ilumetri is indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy". It is proposed that Ilumetri be prescribed by physicians experienced in the 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 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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