22 February 2024
EMA/CHMP/28290/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Apremilast Accord

apremilast

On 22 February 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Apremilast Accord, intended for the treatment of psoriatic arthritis, psoriasis and Behcet's disease. The applicant for this medicinal product is Accord Healthcare S.L.U.

Apremilast Accord will be available as 10 mg, 20 mg and 30 mg film-coated tablets. The active substance of Apremilast Accord is apremilast, a selective immunosuppressant (ATC code: L04AA32). Apremilast inhibits the action of phosphodiesterase 4, thereby increasing intracellular cAMP levels. This down-regulates the inflammatory response by modulating the expression of inflammatory cytokines implicated in psoriatic arthritis and psoriasis.

Apremilast Accord is a generic of Otezla, which has been authorised in the EU since 15 January 2015. Studies have demonstrated the satisfactory quality of Apremilast Accord and its bioequivalence to the reference product Otezla. A question and answer document on generic medicines can be found here.

The full indication is:

Psoriatic arthritis

Apremilast Accord, alone or in combination with Disease Modifying Antirheumatic Drugs (DMARDs), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy (see section 5.1).

Psoriasis

Apremilast Accord is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to

[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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

other systemic therapy including cyclosporine, methotrexate or psoralen and ultraviolet-A light (PUVA).

Behçet's disease

Apremilast Accord is indicated for the treatment of adult patients with oral ulcers associated with Behçet's disease (BD) who are candidates for systemic therapy.

Apremilast Accord should be prescribed by physicians experienced in the diagnosis and treatment of psoriasis, psoriatic arthritis or Behçet's disease.

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.