19 September 2024
EMA/CHMP/416713/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Otezla

apremilast

On 19 September 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Otezla. The marketing authorisation holder for this medicinal product is Amgen Europe B.V.

The CHMP adopted a new indication as follows:

Paediatric psoriasis

Otezla is indicated for the treatment of moderate to severe plaque psoriasis in children and adolescents from the age of 6 years and weighing at least 20 kg who are candidates for systemic therapy.

For information, the full indications for Otezla will be as follows:[2]

Psoriatic arthritis

Otezla, 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

Otezla is indicated for the treatment of moderate to severe chronic plaque psoriasis (PSOR) in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or psoralen and ultraviolet-A light (PUVA).

Paediatric psoriasis

Otezla is indicated for the treatment of moderate to severe plaque psoriasis in children and adolescents from the age of 6 years and weighing at least 20 kg who are

[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
[2] New text in bold

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candidates for systemic therapy.

Behçet's disease

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

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR) and made available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.