25 June 2026
EMADOC-1700519818-3086715
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Opzelura

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On 25 June 2026, 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 Opzelura. The marketing authorisation holder for this medicinal product is Incyte Biosciences Distribution B.V.

The CHMP adopted a new indication as follows:[2]

Vitiligo

Opzelura is indicated for the treatment of non-segmental vitiligo with facial involvement in adults and adolescents from 12 years of age.

Atopic dermatitis

Opzelura is indicated for the treatment of moderate atopic dermatitis in adult patients for whom topical corticosteroids and topical calcineurin inhibitors are inadequate or inappropriate.

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

[1] Summary 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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