26 February 2026
EMADOC-1700519818-2937601
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Olumiant
baricitinib

On 26 February 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 Olumiant. The marketing authorisation holder for this medicinal product is Eli Lilly Nederland B.V.

The CHMP adopted a change to an existing indication as follows:[2]

Alopecia areata

Baricitinib is indicated for the treatment of severe alopecia areata in adult **and adolescent** patients **12 years of age and older** (see section 5.1).

For information, the full indications for Olumiant will now be:

Rheumatoid arthritis

Baricitinib is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more diseasemodifying antirheumatic drugs (DMARDs). Baricitinib may be used as monotherapy or in combination with methotrexate (see sections 4.4, 4.5 and 5.1 for available data on different combinations).

Atopic dermatitis

Baricitinib is indicated for the treatment of moderate to severe atopic dermatitis in adult and paediatric patients 2 years of age and older who are candidates for systemic therapy.

Alopecia areata

Baricitinib is indicated for the treatment of severe alopecia areata in adult and adolescent patients 12 years of age and older (see section 5.1).

Juvenile idiopathic arthritis

Baricitinib is indicated for the treatment of active juvenile idiopathic arthritis in patients 2 years

[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

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
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of age and older who have had an inadequate response or intolerance to one or more prior conventional synthetic or biologic DMARDs:

- Polyarticular juvenile idiopathic arthritis (polyarticular rheumatoid factor positive [RF+] or negative [RF-], extended oligoarticular),
- Enthesitis related arthritis, and
- Juvenile psoriatic arthritis.

Baricitinib may be used as monotherapy or in combination with methotrexate.

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.