14 September 2023
EMA/CHMP/343776/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Olumiant

baricitinib

On 14 September 2023, 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 an extension to an existing indication to include the treatment of paediatric patients from 2 years of age and older with moderate to severe atopic dermatitis. For information, the full indications for Olumiant will be as follows[2]:

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 disease modifying anti rheumatic drugs. Olumiant may be used as monotherapy or in combination with methotrexate.

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

Alopecia Areata
Baricitinib is indicated for the treatment of severe alopecia areata in adult patients.

Juvenile Idiopathic Arthritis
Baricitinib is indicated for the treatment of active juvenile idiopathic arthritis in patients 2 years of age and older who have had an inadequate response or intolerance to one or more prior conventional synthetic or biologic disease-modifying antirheumatic drugs (DMARDs):

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

[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

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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- 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 in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.