19 May 2022
EMA/CHMP/260143/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Olumiant

baricitinib

On 19 May 2022, 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.[2] The marketing authorisation holder for this medicinal product is Eli Lilly Nederland B.V.

The CHMP adopted a new indication for alopecia areata. The full indications for Olumiant will therefore be as follows:[3]

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. 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 patients who are candidates for systemic therapy.

Alopecia areata

Baricitinib is indicated for the treatment of severe alopecia areata in adult patients (see section 5.1).

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

[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] This recommendation is without prejudice to the final conclusions of the ongoing referral procedure under Article 20 of Regulation (EC) No 726/2004 resulting from pharmacovigilance data.
[3] New text in **bold**

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the marketing authorisation has been granted by the European Commission.