15 December 2016
EMA/CHMP/843822/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Olumiant

baricitinib

On 15 December 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Olumiant, intended for the treatment of rheumatoid arthritis. The applicant for this medicinal product is Eli Lilly Nederland B.V.

Olumiant will be available as 2 mg and 4 mg film-coated tablets. The active substance of Olumiant is baricitinib, a selective and reversible inhibitor of Janus kinase (JAK) 1 and 2 (ATC code: L04AA37). Janus kinases are enzymes that transduce intracellular signals from cell surface receptors for a number of cytokines and growth factors involved in haematopoiesis, inflammation and immune function.

Olumiant reduces the symptoms of rheumatoid arthritis. The most common side effects are increased LDL cholesterol, upper respiratory tract infections and nausea.

The full indication is: “Olumiant 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 (see sections 4.4, 4.5 and 5.1 for available data on different combinations).”

It is proposed that Olumiant be prescribed by physicians experienced in the diagnosis and treatment of rheumatoid arthritis.

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

[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

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