16 December 2010
EMA/CHMP/605159/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Leflunomide Teva

leflunomide

On 16 December 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Leflunomide Teva 10 mg and 20 mg film-coated tablets intended for the treatment of adult patients with active rheumatoid arthritis. The applicant for this medicinal product is Teva Pharma B.V. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Leflunomide Teva is leflunomide, a selective immunosuppressive agent (ATC code: L04AA13). Leflunomide is a disease-modifying anti-rheumatic agent with antiproliferative properties.

Leflunomide Teva is a generic of Arava, which has been authorised in the EU since 2 September 1999. Studies have demonstrated the satisfactory quality of Leflunomide Teva, and its bioequivalence with the reference product Arava. A question and answer document on generic medicines can be found here.

A pharmacovigilance plan for Leflunomide Teva will be implemented as part of the marketing authorisation.

The approved indication is:

“Leflunomide is indicated for the treatment of adult patients with active rheumatoid arthritis as a "disease-modifying antirheumatic drug" (DMARD). Recent or concurrent treatment with hepatotoxic or haematotoxic DMARDs (e.g. methotrexate) may result in an increased risk of serious adverse reactions; therefore, the initiation of leflunomide treatment has to be carefully considered regarding these benefit/risk aspects. Moreover, switching from leflunomide to another DMARD without following the washout procedure (see section 4.4) may also increase the risk of serious adverse reactions even for a long time after the switching.”

[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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The treatment with Leflunomide Teva should be initiated and supervised by specialists experienced in the 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 will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Leflunomide Teva and therefore recommends the granting of the marketing authorisation.