18 March 2010
EMA/CHMP/143991/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Tolura

telmisartan

On 18 March 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 Tolura, 20 mg, 40 mg, 80 mg, tablets intended for the treatment of hypertension. The applicant for this medicinal product is Krka, d.d., Novo mesto. 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 Tolura is telmisartan, an Angiotensin II-antagonist medicinal product *(ATC Code*: C09CA07) that displaces angiotensin II from its binding site at the AT_1 receptor, which is responsible for the known actions of angiotensin II.

Tolura is a generic of Micardis, which has been authorised in the EU since 16 December 1998. Studies have demonstrated the satisfactory quality of Tolura, and its bioequivalence with Micardis. A question-and-answer document on generic medicines can be found here.

The approved indication is: “Treatment of essential hypertension in adults”.

A pharmacovigilance plan for Tolura, as for all medicinal products, will be implemented as part of the marketing authorisation.

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 Tolura and therefore recommends the granting of the marketing authorisation.

[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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