EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2010
EMA/CHMP/372629/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Telmisartan Actavis

telmisartan

On 24 June 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 Telmisartan Actavis, 20 mg, 40 mg and 80 mg, tablets intended for the treatment of essential hypertension and reduction of cardiovascular morbidity. The applicant for this medicinal product is Actavis Group PTC ehf.

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 Telmisartan Actavis is telmisartan, an angiotensin II receptor antagonist (C09CA07) displaces angiotensin II with very high affinity from its binding site at the AT1 receptor subtype, which is responsible for the known actions of angiotensin II.

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

A pharmacovigilance plan for Telmisartan Actavis will be implemented as part of the marketing authorisation.

The approved indication is: “treatment of essential hypertension in adults and reduction of cardiovascular morbidity in patients with: i) manifest atherothrombotic cardiovascular disease (history of coronary heart disease, stroke, or peripheral arterial disease) or ii) type 2 diabetes mellitus with documented target organ damage, was favourable and therefore recommended the granting of the marketing authorisation”. It is proposed that Telmisartan Actavis is prescribed by physicians experienced in the treatment of hypertension.

[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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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 Telmisartan Actavis and therefore recommends the granting of the marketing authorisation.