17 January 2013
EMA/CHMP/774027/2012
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Actelsar HCT

Telmisartan/hydrochlorothiazide

On 17 January 2013 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Actelsar HCT, 40mg/12.5 mg, 80mg/12.5 mg and 80mg/25 mg tablets intended for treatment of essential hypertension. The applicant for this medicinal product is Actavis Group hf. 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 substances of Actelsar HCT are telmisartan, a non-peptide angiotensin II receptor (type AT_1) antagonist, and hydrochlorothiazide, a thiazides diuretic.

Actelsar HCT is a generic of MicardisPlus, which has been authorised in the EU since 19 April 2002. Studies have demonstrated the satisfactory quality of Actelsar HCT, and its bioequivalence with the reference product MicardisPlus. A question and answer document on generic medicines can be found here.

A pharmacovigilance plan for Actelsar HCT will be implemented as part of the marketing authorisation.

The approved indication is: Treatment of essential hypertension.

Actelsar HCT fixed dose combination (40 mg telmisartan/12.5 mg hydrochlorothiazide) is indicated in adults whose blood pressure is not adequately controlled on telmisartan alone.

Actelsar HCT fixed dose combination (80 mg telmisartan/12.5 mg hydrochlorothiazide) is indicated in adults whose blood pressure is not adequately controlled on telmisartan alone.

Actelsar HCT fixed dose combination (80 mg telmisartan/25 mg hydrochlorothiazide) is indicated in adults whose blood pressure is not adequately controlled on Actelsar HCT 80 mg/12.5 mg (80 mg telmisartan/12.5 mg hydrochlorothiazide) or adults who have been previously stabilised on telmisartan and hydrochlorothiazide given separately.

[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 Actelsar HCT and therefore recommends the granting of the marketing authorisation.