



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 January 2013
EMA/CHMP/6036/2013
Committee for medicinal products for human use (CHMP)

Summary of opinion¹ (initial authorisation)

Tolucombi

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 Tolucombi 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 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 substances of Tolucombi are telmisartan, a non-peptide angiotensin II receptor (type AT₁) antagonist, and hydrochlorothiazide, a thiazides diuretic.

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

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

The approved indication is:

Treatment of essential hypertension.

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

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

Tolucombi fixed dose combination (80 mg telmisartan/25 mg hydrochlorothiazide) is indicated in adults whose blood pressure is not adequately controlled on Tolucombi 80 mg/12.5 mg (80 mg

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.



telmisartan/12.5 mg hydrochlorothiazide) or adults who have been previously stabilised on telmisartan and hydrochlorothiazide given separately.

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 Tolucombi and therefore recommends the granting of the marketing authorisation.