16 December 2010
EMA/646092/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Ifirmacombi

irbesartan / hydrochlorothiazide

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 Ifirmacombi 150/12.5 mg, 300/12.5 mg and 300/25 mg film coated tablets intended for essential hypertension. This fixed dose combination is indicated in adult patients whose blood pressure is not adequately controlled on irbesartan or hydrochlorothiazide alone. 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 Ifirmacombi are irbesartan/hydrochlorothiazide, an angiotensin-II antagonist and diuretic, (ATC code C09DA04). Irbesartan blocks all actions of angiotensin-II mediated by the AT1 receptor and hydrochlorothiazide is a thiazide diuretic.

Ifirmacombi is a generic of CoAprovel, which has been authorised in the EU since 15 October 1998. Studies have demonstrated the satisfactory quality of Ifirmacombi, and its bioequivalence with the reference product CoAprovel. A question and answer document on generic medicines can be found here.

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

The approved indication is: “Treatment of essential hypertension. This fixed dose combination is indicated in adult patients whose blood pressure is not adequately controlled on irbesartan or hydrochlorothiazide”.

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.

[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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7<sector fax>
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

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