22 September 2011
EMA/CHMP/690726/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

ONDUARP

Telmisartan / amlodipine

On 22 September 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending the granting of a marketing authorisation for the medicinal product ONDUARP 40 mg/5 mg, 40 mg/10 mg, 80 mg/5 mg and 80 mg/10 mg tablets intended for the treatment of essential hypertension in adults. The applicant for this medicinal product is Boehringer Ingelheim International GmbH. 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 ONDUARP are amlodipine (as besilate) and telmisartan, anti hypertensive agents; ATC Code: C09DB04.

ONDUARP combines two antihypertensive compounds with complementary mechanisms to control blood pressure in patients with essential hypertension: an angiotensin II receptor antagonist, telmisartan, and a dihydropyridinic calcium channel blocker, amlodipine.

The benefits with ONDUARP are its ability to have an additive antihypertensive effect, reducing blood pressure to a greater degree than either component alone. The most common side effects are dizziness and peripheral oedema.

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

The approved indication is:

Treatment of essential hypertension in adults:

Add on therapy
ONDUARP is indicated in adults whose blood pressure is not adequately controlled on amlodipine.

Replacement therapy
Adult patients receiving telmisartan and amlodipine from separate tablets can instead receive tablets of ONDUARP containing the same component doses.

[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 ONDUARP and therefore recommends the granting of the marketing authorisation.