EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 March 2014
EMA/133999/2014
Human Medicines Development and Evaluation

Public statement on Onduarp

Withdrawal of the marketing authorisation in the European Union

On 24 November 2011, the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Onduarp, which 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.

Onduarp had been approved for : Treatment of essential hypertension in adults:

Add on therapy
Twynsta 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 Twynsta containing the same component doses.

The marketing authorisation holder (MAH) responsible for Onduarp was Boehringer Ingelheim International GmbH.

On 17 February 2014, the European Commission issued a decision to withdraw the marketing authorisation for Onduarp, following its receipt of a letter dated 20 December 2013 notifying the Commission of the MAH's decision to voluntarily withdraw the marketing authorisation for this product for commercial reasons.

Onduarp was not marketed in any European country.

Pursuant to this decision, the European public assessment report for Onduarp will be updated to reflect that the marketing authorisation is no longer valid.

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