06 September 2012
EMA/328034/2012
Human Medicines Development and Evaluation

Public statement

Riprazo HCT (aliskiren/hydrochlorothiazide)

Withdrawal of the marketing authorisation in the European Union

On 13 April 2011 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Riprazo HCT (aliskiren/hydrochlorothiazide). Riprazo HCT was approved for the treatment of essential hypertension.

The marketing authorisation holder (MAH) responsible for Riprazo HCT was Novartis Europharm Ltd.

The European Commission was notified by letter dated 26 July 2012 of the MAH's decision to voluntarily withdraw the marketing authorisation for Riprazo HCT for commercial reasons.

On 30 August 2012 the European Commission issued a decision to withdraw the marketing authorisation for Riprazo HCT. Pursuant to this decision the European Public Assessment Report for Rprazo HCT will be updated to reflect the fact that the marketing authorisation is no longer valid.

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