15 March 2017
EMEA/H/C/002073

Public statement

Rasilamlo

Withdrawal of the marketing authorisation in the European Union

On 25 June 2015, the European Commission withdrew the marketing authorisation for Rasilamlo (aliskiren / amlodipine) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Novartis Europharm Ltd, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Rasilamlo was granted marketing authorisation in the EU on 14 April 2011 for treatment of essential hypertension in adult patients whose blood pressure is not adequately controlled with aliskiren or amlodipine used alone. The product had not been marketed in the EU since 2014.

The European Public Assessment Report (EPAR) for Rasilamlo will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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