European Medicines Agency

London, 10 September 2009
Doc. Ref.: EMEA/575961/2009

PUBLIC STATEMENT ON

Tekturna
(aliskiren)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 22 August 2007 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Tekturna (aliskiren). Tekturna is approved for the treatment of essential hypertension.

The marketing authorisation holder (MAH) responsible for Tekturna was Novartis Europharm Ltd. The European Commission was notified by letter dated 17 August 2009 of the MAH's decision to voluntarily withdraw the marketing authorisation for Tekturna for commercial reasons.

Tekturna has not been marketed anywhere in the European Union and there is no intention to market Tekturna in the future. Tekturna was an additional application to Rasilez, intended for co-marketing purposes.

The MAH will maintain the Marketing Authorisations for the four other medicinal products containing aliskiren, i.e. Rasilez, Enviage, Riprazo and Sprimeo.

On 02 September 2009 the European Commission issued a decision to withdraw the marketing authorisation for Tekturna. Pursuant to this decision the European Public Assessment Report for Tekturna will be updated to reflect that the marketing authorisation is no longer valid.

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