23 July 2015
EMA/CHMP/444359/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Tafinlar

dabrafenib

On 23 July 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Tafinlar. The marketing authorisation holder for this medicinal product is Novartis Europharm Ltd.

The CHMP adopted an extension to the existing indication as follows[2]:
"Dabrafenib **as monotherapy or in combination with trametinib** is indicated for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation (see **sections 4.4 and** 5.1.)."

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[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
[2] New text in bold, removed text as strikethrough

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