25 July 2024
EMA/CHMP/323249/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Braftovi

encorafenib

On 25 July 2024, 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 Braftovi. The marketing authorisation holder for this medicinal product is Pierre Fabre Medicament.

The CHMP adopted a new indication as follows:

Non-small cell lung cancer (NSCLC)

Encorafenib in combination with binimetinib is indicated for the treatment of adult patients with advanced non-small cell lung cancer with a BRAF V600E mutation.

For information, the full indications for Braftovi will be as follows:[2]

Melanoma

Encorafenib in combination with binimetinib 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)~~.

Colorectal cancer (CRC)

Encorafenib in combination with cetuximab, is indicated for the treatment of adult patients with metastatic colorectal cancer ~~(CRC)~~ with a BRAF V600E mutation, who have received prior systemic therapy ~~(see sections 4.4 and 5.1)~~.

Non-small cell lung cancer (NSCLC)

Encorafenib in combination with binimetinib is indicated for the treatment of adult patients with advanced non-small cell lung cancer with a BRAF V600E mutation.

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

[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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(EPAR) and made available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.