21 May 2026
EMADOC-1700519818-2963478
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Braftovi
encorafenib

On 21 May 2026, 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:

> Encorafenib in combination with cetuximab and FOLFOX is indicated for the first line treatment of adult patients with metastatic colorectal 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.
>
> Colorectal cancer (CRC)
>
> Encorafenib in combination with cetuximab is indicated for the treatment of adult patients with metastatic colorectal cancer with a BRAF V600E mutation, who have received prior systemic therapy.
>
> **Encorafenib in combination with cetuximab and FOLFOX is indicated for the first line treatment of adult patients with metastatic colorectal cancer with a BRAF V600E mutation.**
>
> 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.

[1] Summary 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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For biomarker-based patient selection, see section 4.2.

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