21 May 2026
EMADOC-1700519818-3101293
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Erbitux

cetuximab

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 Erbitux. The marketing authorisation holder for this medicinal product is Merck Europe B.V.

The CHMP adopted a new indication as follows:[2]

> Erbitux is indicated for the treatment of patients with epidermal growth factor receptor (EGFR)-expressing, RAS wild-type metastatic colorectal cancer
>
> - in combination with irinotecan-based chemotherapy,
> - in first-line in combination with FOLFOX,
> - as a single agent in patients who have failed oxaliplatin- and irinotecan-based therapy and who are intolerant to irinotecan.
>
> For details, see section 5.1.
>
> **Erbitux is indicated for the treatment of adult patients with BRAF V600E mutant metastatic colorectal cancer in combination with encorafenib in patients who have received prior systemic therapy.**
>
> **For details, see section 5.1; for biomarker-based patient selection, see section 4.2.**
>
> Erbitux is indicated for the treatment of patients with squamous cell cancer of the head and neck
>
> - in combination with radiation therapy for locally advanced disease,
> - in combination with platinum-based chemotherapy for recurrent and/or metastatic disease.

For information, on 21 May 2026 the CHMP adopted another new indication to extend the use of Erbitux in combination with encorafenib and FOLFOX for the first line treatment of adults with BRAF V600E mutant metastatic colorectal cancer. Further information is available in a dedicated summary of opinion

[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, removed text as strikethrough

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
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

available on the EMA website.

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.