26 March 2026
EMADOC-1700519818-2971643
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (post authorisation)**

# Tafinlar

## dabrafenib

On 26 March 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 Tafinlar. The marketing authorisation holder for this medicinal product is Novartis Europharm Limited.

The CHMP adopted a new indication as follows:

> Differentiated thyroid cancer (DTC)
>
> Dabrafenib in combination with trametinib is indicated for the treatment of adult patients with locally advanced or metastatic differentiated thyroid cancer with a BRAF V600E mutation, refractory to or not eligible for radioactive iodine (RAI) who have progressed during or after prior systemic therapy (for biomarker-based patient selection, see section 4.2).

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

> Melanoma
>
> 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).
>
> Adjuvant treatment of melanoma
>
> Dabrafenib in combination with trametinib is indicated for the adjuvant treatment of adult patients with Stage III melanoma with a BRAF V600 mutation, following complete resection.
>
> Non-small cell lung cancer (NSCLC)
>
> Dabrafenib in combination with trametinib is indicated for the treatment of adult patients with advanced non-small cell lung cancer with a BRAF V600 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

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**Differentiated thyroid cancer (DTC)**

**Dabrafenib in combination with trametinib is indicated for the treatment of adult patients with locally advanced or metastatic differentiated thyroid cancer with a BRAF V600E mutation, refractory to or not eligible for radioactive iodine (RAI) who have progressed during or after prior systemic therapy (for biomarker-based patient selection, see section 4.2).**

For information, the CHMP also adopted an extension to an existing indication on 26 March 2026 to extend the use of Tafinlar to adolescents from 12 years of age with melanoma. Information on this change is provided in a dedicated summary of opinion available from 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.