



26 March 2026

[EMADOC-1700519818-3002663](#)

Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (post authorisation)

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# 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 an extension to an existing indication, as follows:<sup>2</sup>

### Melanoma

Dabrafenib as monotherapy or in combination with trametinib is indicated for the treatment of adults **and adolescents aged 12 years and older**~~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 adults **and adolescents aged 12 years and older**~~patients~~ with Stage III melanoma with a BRAF V600 mutation, following complete resection.

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

### Melanoma

Dabrafenib as monotherapy or in combination with trametinib is indicated for the treatment of adults and adolescents aged 12 years and older with unresectable or metastatic melanoma with a BRAF V600 mutation (see sections 4.4 and 5.1).

### Adjuvant treatment of melanoma

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<sup>1</sup> Summary of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

<sup>2</sup> New text in bold, removed text as strikethrough



Dabrafenib in combination with trametinib is indicated for the adjuvant treatment of adults and adolescents aged 12 years and older 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 adults with advanced non-small cell lung cancer with a BRAF V600 mutation.

For information, the CHMP adopted another new indication on 26 March 2026 for Tafinlar to extend its use to differentiated thyroid cancer (DTC). 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.