26 March 2026
EMADOC-1700519818-3002663
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Mekinist

trametinib

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 Mekinist. The marketing authorisation holder for this medicinal product is Novartis Europharm Limited.

The CHMP adopted an extension an existing indication as follows:[2]

Melanoma

Trametinib as monotherapy or in combination with dabrafenib is indicated for the treatment of adult**s 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).

Trametinib monotherapy has not demonstrated clinical activity in patients who have progressed on a prior BRAF inhibitor therapy (see section 5.1).

Adjuvant treatment of melanoma

Trametinib in combination with dabrafenib is indicated for the adjuvant treatment of adult**s 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 Mekinist will be as follows:

Melanoma

Trametinib as monotherapy or in combination with dabrafenib 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).

[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

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Trametinib monotherapy has not demonstrated clinical activity in patients who have progressed on a prior BRAF inhibitor therapy (see section 5.1).

Adjuvant treatment of melanoma

Trametinib in combination with dabrafenib 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)

Trametinib in combination with dabrafenib 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 Mekinist 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.