National Centre for Pharmacoeconomics
NCPE Ireland

NCPE Plain English Summary

Drug name: dabrafenib plus trametinib (pronounced: duh-BRA-feh-nib and truh-MEH-tih-nib) for the adjuvant treatment of adult patients with stage III melanoma with a BRAF V600 mutation, following complete resection.

Brand name: Tafinlar® plus Mekinist®

What is the NCPE?

The National Centre for Pharmacoeconomics (NCPE) is a team of experts who look at the health benefits and costs of medicines. The HSE asks us to advise on whether or not a new medicine is good value for money. We give unbiased advice to help the HSE provide the most effective, safe and cost-effective (value for money) treatments for patients.

How do we make our recommendations?

Our main focus is on the health benefits and cost effectiveness of a medicine. We look at the wider costs and health benefits associated with a new medicine, for example:

- Does the new medicine work better than other treatments available in Ireland?
- Is the new medicine easier to give or easier to take compared with other treatments available in Ireland?
- Does the new medicine reduce the need for patients to be hospitalised?
- Does the new medicine improve the quality of a patient's life over other treatments available in Ireland?
- Will the new medicine save resources elsewhere within the health system?

We review the information from clinical trials along with the cost and value for money data presented by the pharmaceutical company. We ask doctors and other healthcare professionals for advice about any health benefits of the new medicine compared with current treatments. We also ask patient organisations to send us their views on how the new drug may improve patients' day-to-day experience of living with a disease.

What are dabrafenib and trametinib used for?

Dabrafenib (Mekinist®) and trametinib (Tafinlar®) are cancer medicines used together to treat adults whose cancer cells have a specific genetic mutation (change) called 'BRAF V600'. It is used for the treatment of stage III melanoma after surgery. In melanoma cancer with this

mutation, an abnormal form of the protein BRAF is present. This then switches on another protein called MEK which stimulates cell division; this uncontrolled division of cells leads to cancer. This combined treatment acts on both BRAF (dabrafenib (Tafinlar®)) and MEK (trametinib (Mekinist®)) thereby slowing down the growth and spread of the cancer.

What recommendation has the NCPE made to the HSE?

We have recommended that the HSE should consider funding dabrafenib in combination with trametinib if its cost effectiveness (value for money) can be improved. The HSE will consider our recommendation and make the final decision about reimbursement (funding). When making the funding decision, the HSE will also consider the additional criteria outlined in the Health (Pricing and Supply of Medical Goods) Act 2013.

The NCPE has not received a Patient Organisation Submission associated with this submission.

Why did we make this recommendation?

After reviewing the data presented by the pharmaceutical company, we concluded that the medicine may work as well or better than other ways to manage this condition. However, the price of the medicine is too high compared with other ways to manage this condition, and we believe that the medicine is not value for money.

Next steps

When the HSE receives our recommendation, it will look at all the relevant data about dabrafenib and trametinib. The HSE makes the final decision on reimbursement.

Where can I get more information?

You can get more information about dabrafenib and trametinib from the following online options:

- the NCPE Technical Summary Document
- Tafinlar ® Medicines Overview,
- Mekinist ® Medicine overview, or
- searching for dabrafenib and trametinib on our website (www.ncpe.ie);
- searching for dabrafenib and trametinib on the European Medicines Agency (EMA) website (www.ema.europa.eu).

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Please refer to the NCPE website for updated information on the reimbursement status of this medicine.

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