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EPAR summary for the public

Tafinlar

dabrafenib

This is a summary of the European public assessment report (EPAR) for Tafinlar. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Tafinlar.

For practical information about using Tafinlar, patients should read the package leaflet or contact their doctor or pharmacist.

What is Tafinlar and what is it used for?

Tafinlar is a cancer medicine used to treat adults with:

- melanoma (a type of skin cancer) that has spread or cannot be surgically removed. Tafinlar is used on its own or in combination with trametinib, another cancer medicine to treat melanoma;
- advanced non-small cell lung cancer. Tafinlar is used in combination with trametinib.

Tafinlar is only for patients whose cancer cells have a specific genetic mutation (change) called 'BRAF V600'.

Tafinlar contains the active substance dabrafenib.

How is Tafinlar used?

Treatment with Tafinlar must be started and supervised by a doctor experienced in the use of cancer medicines. The medicine can only be obtained with a prescription.

Tafinlar is available as capsules (50 and 75 mg). The dose of Tafinlar either used alone or in combination with trametinib is 150 mg twice a day.

Tafinlar is taken at least one hour before or two hours after a meal. Tafinlar can be continued for as long as the patient benefits from it. Treatment may need to be interrupted or stopped, or the dose reduced, if certain side effects occur. For further information, see the summary of product characteristics (also part of the EPAR).

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How does Tafinlar work?

The active substance in Tafinlar, dabrafenib, works by blocking BRAF, a protein involved in stimulating cell division. In melanoma and non-small cell lung cancer with the BRAF V600 mutation, the abnormal form of BRAF plays a role in the development of the cancer by allowing uncontrolled division of the tumour cells. By blocking the action of the abnormal BRAF, Tafinlar helps to slow down the growth and spread of the cancer. Tafinlar is only given to patients whose cancer is caused by the BRAF V600 mutation.

What benefits of Tafinlar have been shown in studies?

Melanoma

Tafinlar was more effective than the cancer medicine dacarbazine at controlling melanoma that had spread to other parts of the body or could not be surgically removed, in patients whose melanoma had a BRAF V600 mutation. This was based on one main study involving 250 patients which measured how long patients lived until their disease got worse (progression-free survival). In this study it took on average 6.9 months before the disease got worse in patients given Tafinlar, compared with 2.7 months in patients given dacarbazine.

Two additional studies looked at the use of the combination of Tafinlar with trametinib. In one study 423 patients were given either the combination or Tafinlar alone. Patients given the combination lived for 11 months without their disease worsening, while those given Tafinlar alone lived for 8.8 months without their disease worsening. In a second study involving 704 patients, Tafinlar with trametinib was compared with another medicine for melanoma, vemurafenib. Patients given the combination lived 25.6 months on average, versus 18 months with vemurafenib.

Non-small cell lung cancer

In one main study, 171 patients with BRAF V600 mutated non-small cell lung cancer either received Tafinlar combined with trametinib or Tafinlar alone. The main measure of effectiveness was the percentage of patients who responded completely or partially to treatment. Response to treatment was assessed using body scans and patients' clinical data. The use of Tafinlar and trametinib led to a response in over 60% of the patients, compared with 23% of patients using Tafinlar alone.

What are the risks associated with Tafinlar?

The most common side effects with Tafinlar alone (seen in more than 15% of patients) are papilloma (warts), headache, nausea, vomiting, hyperkeratosis (thickening and toughening of the skin), hair loss, rash, joint pain, fever and tiredness.

When Tafinlar is taken in combination with trametinib the most common side effects (seen in more than 20% of patients) are fever, tiredness, nausea, headache, chills, diarrhoea, rash, joint pain, high blood pressure, vomiting and cough.

For the full list of all side effects reported with Tafinlar see the package leaflet.

Why is Tafinlar approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Tafinlar's benefits are greater than its risks and recommended that it be approved for use in the EU. The Committee

considered that Tafinlar (alone or in combination with trametinib) had shown clinically relevant benefit in patients with BRAF V600 mutation who had melanoma that had spread or was not surgically removable. Similar benefits were shown when Tafinlar was used in combination with trametinib in patients who had advanced non-small cell lung cancer. The side effects were considered acceptable and manageable with appropriate measures.

What measures are being taken to ensure the safe and effective use of Tafinlar?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Tafinlar have been included in the summary of product characteristics and the package leaflet.

Other information about Tafinlar

The European Commission granted a marketing authorisation valid throughout the European Union for Tafinlar on 26 August 2013.

The full EPAR for Tafinlar can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Tafinlar, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2017.