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Tafinlar (*dabrafenib*)

An overview of Tafinlar and why it is authorised in the EU

What is Tafinlar and what is it used for?

Tafinlar is a cancer medicine used to treat adults whose cancer cells have a specific genetic mutation (change) called 'BRAF V600'. It is used for the treatment of:

- melanoma (a skin cancer) that has spread or cannot be removed surgically. Tafinlar is used on its own or in combination with another cancer medicine, trametinib;
- advanced (stage III) melanoma after surgery for it. Tafinlar is used in combination with trametinib;
- advanced non-small cell lung cancer. It is used in combination with trametinib.

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 taken on an empty stomach (at least 1 hour before or 2 hours after a meal).

Tafinlar can be continued for as long as the patient benefits from it. After surgery for advanced melanoma, treatment is normally continued for 12 months unless the disease comes back. Treatment may need to be interrupted or stopped, or the dose reduced, if certain side effects occur.

For more information about using Tafinlar, see the package leaflet or contact your doctor or pharmacist.

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

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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.

What benefits of Tafinlar have been shown in studies?

Tafinlar has been studied in patients whose cancer had the BRAF V600 mutation.

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 removed surgically. This was based on one main study involving 250 patients, which measured how long patients lived until their disease got worse. Patients taking Tafinlar lived on average 6.9 months before the disease got worse, compared with 2.7 months in patients given dacarbazine.

Two additional studies on melanoma that had spread to other parts of the body or could not be removed surgically looked at using 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, compared with 8.8 months for those given Tafinlar alone. 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.

In a study involving 870 patients with stage III melanoma that had been removed surgically, the combination of Tafinlar and trametinib given for 1 year was compared with placebo (a dummy treatment). Some 40% of patients treated with the combination either died or had their disease come back after an average of about 3.5 years compared with 59% of patients receiving placebo.

Non-small cell lung cancer

In one main study, 171 patients with non-small cell lung cancer received either 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 (which may affect more than 1 in 10 people) 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 (which may affect more than 1 in 5 people) are fever, tiredness, nausea, chills, headache, diarrhoea, vomiting, joint pain and rash.

For the full list of side effects and restrictions with Tafinlar, see the package leaflet.

Why is Tafinlar authorised in the EU?

The European Medicines Agency decided that Tafinlar's benefits in cancers that carry the BRAF V600 mutation are greater than its risks and it can be authorised for use in the EU. The Agency considered

that Tafinlar when used alone or in combination with trametinib had shown clinically relevant benefit in patients with advanced non-small cell lung cancer or with melanoma that had spread or could not be removed surgically. The Agency also found it to be of benefit in patients with advanced melanoma that had been removed surgically. Tafinlar's 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.

As for all medicines, data on the use of Tafinlar are continuously monitored. Side effects reported with Tafinlar are carefully evaluated and any necessary action taken to protect patients.

Other information about Tafinlar

Tafinlar received a marketing authorisation valid throughout the EU on 26 August 2013.

Further information on Tafinlar can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 08-2018.