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Braftovi (*encorafenib*)

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

What is Braftovi and what is it used for?

Braftovi is a medicine used in adults for treating certain cancers when their cells have a mutation (change) in their genes called 'BRAF V600'.

Braftovi is used in combination with another medicine, binimetinib to treat:

- melanoma (a skin cancer) that cannot be removed by surgery or has spread;
- a type of lung cancer called non-small cell lung cancer (NSCLC). It is used when the cancer is advanced and has the BRAF V600E version of the mutation.

Braftovi is also used in combination with the medicine cetuximab to treat colorectal cancer (cancer of the large bowel or rectum) with the BRAF V600E version of the mutation, when it has spread elsewhere in the body and has previously been treated with other systemic (given by mouth or injection) medicines.

Braftovi contains the active substance encorafenib.

How is Braftovi used?

Braftovi can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in using cancer medicines.

The medicine is available as capsules taken by mouth once daily and the dose depends on the condition being treated. The dose may be reduced, or treatment may be stopped temporarily, if the patient experiences severe side effects. The dose of the other medicine, binimetinib or cetuximab, may also be reduced but if the other medicine is stopped Braftovi must be stopped too.

Treatment with Braftovi can last for as long as the patient benefits from it and does not have unacceptable side effects.

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

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How does Braftovi work?

In cancers with a BRAF V600 mutation, an abnormal form of the protein BRAF is present, which switches on another protein called MEK involved in stimulating cell division. This encourages cancers to develop by allowing uncontrolled division of cells. The active substance in Braftovi, encorafenib, works by blocking the BRAF protein thereby stopping its activation of cell division and slowing down the growth and spread of the cancer.

What benefits of Braftovi have been shown in studies?

Melanoma

A study of 577 patients with melanoma with a BRAF V600 mutation that had spread or could not be removed surgically showed that Braftovi with binimetinib can prolong the length of time patients lived without their disease getting worse.

Patients who took this combination lived on average for nearly 15 months without the disease getting worse. This compared with over 9.5 months for patients who took Braftovi alone and just over 7 months for patients taking a different medicine called vemurafenib.

Colorectal cancer

In a study involving 665 patients with previously treated colorectal cancer with the BRAF V600E mutation that had spread to other parts of the body, Braftovi with cetuximab improved response rates and prolonged the length of time that patients lived compared with treatment using cetuximab with other cancer medicines. Around 20% of patients given Braftovi with cetuximab responded to treatment, compared with about 2% in those not given Braftovi. The average length of time that patients given Braftovi and cetuximab lived was 9.3 months, compared with 5.9 months among those given other medicines.

Non-small cell lung cancer

The benefits of Braftovi given with binimetinib were evaluated in a main study involving 98 patients who had advanced NSCLC with the BRAF V600E mutation, which included patients who had not received prior treatment for NSCLC and those who had. The study did not compare the combination of Braftovi and binimetinib with other medicines or placebo (a dummy treatment). The main measure of effectiveness was the percentage of patients who responded to treatment, with either no sign of cancer or a decrease in the extent of the cancer after treatment. Around 75% of patients who had not received prior treatment responded to Braftovi given with binimetinib, and they lived for an average of 40 months without their cancer getting worse. Around 46% of patients who had received prior treatment responded to this combination, and they lived for an average of around 17 months without their cancer getting worse.

What are the risks associated with Braftovi?

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

The most common side effects (which can affect more than 1 in 4 people) with Braftovi and binimetinib taken together at the highest recommended doses include tiredness, nausea (feeling sick), diarrhoea, vomiting, abdominal (belly) pain, muscle pain or problems with the muscles, and joint pain

The most common side effects with Braftovi and cetuximab (which can affect more than 1 in 4 people) include tiredness, nausea (feeling sick), diarrhoea, dermatitis acneiform (a skin condition that causes

small, raised, acne-like bumps to form, usually on the face, scalp, chest, and upper back), abdominal pain, joint pain or pain in the muscles and bones, decreased appetite, rash and vomiting.

Why is Braftovi authorised in the EU?

Up to 50% of patients with metastatic melanoma have a mutation in the BRAF gene, with forms of the V600 mutation being the most common. Braftovi, in combination with binimetinib, can help prolong the time that these patients live without their cancer getting worse.

Although the study in patients with NSCLC did not directly compare Braftovi and binimetinib with any other treatment, the benefits in patients with advanced NSCLC with a BRAF V600E mutation who had not received prior treatment were similar to those seen with the current standard of care (treatment that medical experts consider most appropriate). While the treatment effect of this combination was lower in patients who had received previous treatment, it was still considered beneficial for these patients.

In patients with previously-treated colorectal cancer and a BRAF V600E mutation, Braftovi with cetuximab has been shown to produce a meaningful improvement in the length of time they live. The side effects seen with Braftovi are similar to those seen with other medicines in the same class and are considered manageable.

The European Medicines Agency therefore decided that Braftovi's benefits are greater than its risks and it can be authorised for use in the EU.

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

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

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

Other information about Braftovi

Braftovi received a marketing authorisation valid throughout the EU on 20 September 2018.

Further information on Braftovi can be found on the Agency's website:
https://www.ema.europa.eu/en/medicines/human/EPAR/braftovi

This overview was last updated in 08-2024.