



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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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 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.

It 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 medicines.

It contains the active substance encorafenib.

### How is Braftovi used?

Braftovi is available as capsules (50 mg and 75 mg). For melanoma, patients normally take 450 mg (six 75-mg capsules) once a day and for colorectal cancer the recommended dose is 300 mg (four 75-mg capsules). The dose may be reduced or treatment stopped temporarily if patients experience troublesome 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 is benefiting from it and does not have unacceptable side effects.

Braftovi can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in prescribing cancer medicines. For more information about using Braftovi, see the package leaflet or contact your doctor or pharmacist.

### How does Braftovi work?

In tumours 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

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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.

## **What are the risks associated with Braftovi?**

The most common side effects with Braftovi and binimetinib taken together at the highest recommended doses are tiredness, nausea (feeling sick) and vomiting, abdominal pain, diarrhoea, retinal detachment (an eye problem that leads to poor vision), joint pain, muscle pain and high levels of an enzyme called creatine kinase, which may indicate muscle problems. These side effects occurred in more than 1 in 4 patients.

The most common side effects with Braftovi and cetuximab, also seen in more than 1 in 4 patients, are tiredness, nausea (feeling sick) and vomiting, abdominal pain, diarrhoea, decreased appetite, rashes (including an acne-like rash), joint pain and muscle pain.

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

## **Why is Braftovi authorised in the EU?**

Up to 50% of patients with metastatic melanoma have a mutation in BRAF 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 disease getting worse. Similarly, 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: [ema.europa.eu/Find/medicine/Human medicines/European public assessment reports](https://ema.europa.eu/Find/medicine/Human%20medicines/European%20public%20assessment%20reports).

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