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Mektovi (*binimetinib*)

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

What is Mektovi and what is it used for?

Mektovi is a medicine for treating melanoma (a skin cancer) that has spread or cannot be removed by surgery.

Mektovi is used in combination with another medicine, encorafenib (Braftovi), and is only for patients whose cancer cells have a specific mutation (change) in their genes called 'BRAF V600'.

It contains the active substance binimetinib.

How is Mektovi used?

Mektovi is available as 15 mg tablets. Patients normally take 45 mg (3 tablets) by mouth twice a day but can have the dose reduced or treatment stopped temporarily if they experience troublesome side effects. The dose of the other medicine, encorafenib, may also have to be reduced.

Treatment with Mektovi can last for as long as the patient is benefiting from it and does not have unacceptable side effects.

Mektovi 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 Mektovi, see the package leaflet or contact your doctor or pharmacist.

How does Mektovi work?

In melanoma tumours with the 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 Mektovi, binimetinib, works by blocking MEK directly and by preventing its activation by BRAF thereby slowing down the growth and spread of the cancer.

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What benefits of Mektovi have been shown in studies?

A study of 577 patients with melanoma with the BRAF V600 mutation that had spread or could not be removed surgically showed that Mektovi with encorafenib prolongs the length of time patients live 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 encorafenib alone and just over 7 months for patients taking a different medicine called vemurafenib.

What are the risks associated with Mektovi?

The most common side effects with Mektovi and encorafenib taken together at the highest recommended doses are tiredness, nausea (feeling sick), diarrhoea, vomiting, retinal detachment (an eye problem that leads to poor vision), abdominal pain, 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.

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

Why is Mektovi authorised in the EU?

Up to 50% of patients with metastatic melanoma have a mutation in BRAF with the V600 mutation being the most common. Mektovi in combination with encorafenib can help prolong the time these patients live without their disease getting worse. The side effects seen with Mektovi are similar to those seen with other medicines in the same class and are considered manageable.

The European Medicines Agency therefore decided that Mektovi'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 Mektovi?

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

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

Other information about Mektovi

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

Further information on Mektovi 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 09-2018.