EMA/372438/2024
EMEA/H/C/004579

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

.

Mektovi is used in combination with another medicine, encorafenib , to treat:

- melanoma (a skin cancer) that has spread or cannot be removed by surgery;
- 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.

Mektovi contains the active substance binimetinib.

How is Mektovi used?

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

Mektovi is available as tablets taken by mouth twice daily. The dose may be reduced or treatment may be stopped temporarily or discontinued if the patient experiences severe side effects. The dose of the other medicine, encorafenib, may also have to be reduced or treatment may have to be temporarily stopped or discontinued, in which case Mektovi should be stopped too.

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

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

How does Mektovi work?

In cancers 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.

What benefits of Mektovi have been shown in studies?

Melanoma

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.

Non-small cell lung cancer

The benefits of Mektovi given with encorafenib 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 Mektovi and encorafenib 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 Mektovi given with encorafenib, 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 Mektovi?

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 Mektovi and encorafenib 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.

Why is Mektovi authorised in the EU?

Up to 50% of patients with metastatic melanoma have a mutation in the BRAF gene, 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.

Although the study in patients with NSCLC did not directly compare Mektovi and encorafenib 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.

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/medicines/human/EPAR/mektovi.

This overview was last updated in 08-2024.