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EPAR summary for the public

Mekinist

trametinib

This is a summary of the European public assessment report (EPAR) for Mekinist. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Mekinist.

For practical information about using Mekinist, patients should read the package leaflet or contact their doctor or pharmacist.

What is Mekinist and what is it used for?

Mekinist is a cancer medicine used to treat adults with:

- melanoma (a type of skin cancer) that has spread or cannot be surgically removed. Mekinist is used on its own or combination with another cancer medicine, dabrafenib;
- advanced non-small cell lung cancer. It is used in combination with dabrafenib.

Mekinist is only for patients whose cancer cells have a specific genetic mutation (change) in their genes called 'BRAF V600'.

Mekinist contains the active substance trametinib.

How is Mekinist used?

Treatment with Mekinist must be started and supervised by a doctor experienced in the use of cancer medicines. The medicine can only be obtained with a prescription.

Mekinist is available as tablets (0.5, 1 and 2 mg). The dose of Mekinist either used alone or in combination with dabrafenib is 2 mg once a day, taken at around the same time every day.

Mekinist is taken at least 1 hour before or 2 hours after a meal. Treatment may need to be interrupted or stopped, or the dose reduced, if certain side effects occur. Mekinist can be continued for as long as the patient benefits from it. For further information, see the summary of product characteristics (also part of the EPAR).

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How does Mekinist work?

In melanoma and non-small cell lung cancer 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 Mekinist, trametinib, works by blocking MEK directly and by preventing its activation by BRAF thereby slowing down the growth and spread of the cancer. Mekinist is only given to patients whose cancer is caused by the BRAF V600 mutation.

What benefits of Mekinist have been shown in studies?

Melanoma

Mekinist has been shown to be more effective than the cancer medicines dacarbazine or paclitaxel at controlling melanoma that had spread to other parts of the body or could not be surgically removed, in patients whose melanoma had the BRAF V600 mutation. This was based on a main study involving 322 patients who received either Mekinist or the comparator medicine and which measured how long patients lived until their disease got worse (progression-free survival). Patients taking Mekinist lived on average for 4.8 months without their disease getting worse, compared with 1.5 months for patients given dacarbazine or paclitaxel.

In an additional study Mekinist did not show any benefit when given to patients who did not respond to previous treatment with another cancer medicine that blocked BRAF.

Two additional studies looked at using the combination of Mekinist and dabrafenib. In one study, 423 patients were given either the combination or dabrafenib alone. Patients given the combination lived for 11 months without their disease worsening, while those given dabrafenib alone lived for 8.8 months without their disease worsening. In a second study involving 704 patients, Mekinist with dabrafenib was compared with another medicine for melanoma, vemurafenib. Patients given the combination lived longer on average, 25.6 months versus 18 months with vemurafenib.

Non-small cell lung cancer

In one main study, 171 patients with BRAF V600 mutated non-small cell lung cancer either received dabrafenib combined with Mekinist or dabrafenib 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 Mekinist and dabrafenib led to a response in over 60% of the patients, compared with 23% of patients using dabrafenib alone.

What are the risks associated with Mekinist?

The most common side effects with Mekinist (which may affect more than 1 in 5 people) are rash, diarrhoea, tiredness, peripheral oedema (swelling, especially of ankles and feet), nausea and dermatitis acneiform (acne-like inflammation of the skin).

When Mekinist is taken in combination with dabrafenib the most common side effects (seen more than 1 in 5 people) are fever, tiredness, nausea, headache, chills, diarrhoea, rash, joint pain, high blood pressure, vomiting and cough.

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

Why is Mekinist approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Mekinist's benefits are greater than its risks and recommended that it be approved for use in the EU. The Committee considered that Mekinist when used alone or in combination with dabrafenib had shown a clinically relevant benefit in patients with melanoma or small cell lung-cancer who had a BRAF V600 mutation. In terms of safety, the side effects were considered acceptable and manageable with appropriate measures.

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

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

Other information about Mekinist

The European Commission granted a marketing authorisation valid throughout the European Union for Mekinist on 30 June 2014.

The full EPAR and risk management plan summary for Mekinist can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Mekinist, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 03-2017.