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Mekinist (*trametinib*)

A plain-language overview of Mekinist and why it is authorised in the EU

What is Mekinist and what is it used for?

Mekinist is a cancer medicine used to treat people whose cancer cells have a specific genetic mutation (change) in their genes called 'BRAF V600'. It is used:

- in adults and adolescents aged 12 years and older for the treatment of melanoma (a skin cancer) that has spread or cannot be removed surgically. Mekinist is used on its own or in combination with another cancer medicine, dabrafenib;
- in adults and adolescents aged 12 years and older for the treatment of advanced (stage III) melanoma after surgery for it. Mekinist is used in combination with dabrafenib;
- in adults for the treatment of advanced non-small cell lung cancer. It is used in combination with dabrafenib;
- in adults for the treatment of differentiated thyroid carcinoma, a type of cancer originating from the follicular cells of the thyroid gland. Mekinist is used in combination with dabrafenib when the cancer has progressed or spread locally or to other parts of the body during or after previous treatment with systemic therapy (treatment affecting the whole body), and does not respond to, or is not suitable for, treatment with radioactive iodine.

Mekinist contains the active substance trametinib.

How is Mekinist used?

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

Mekinist is available as tablets that are taken once a day on an empty stomach (at least 1 hour before or 2 hours after a meal) and at around the same time every day. For adolescents aged 12 to less than 18 years the dose depends on the patient's body weight. For adults a standard dose is taken daily.

Mekinist treatment can be continued for as long as the patient benefits from it. After surgery for advanced melanoma, treatment is normally continued for 12 months unless the disease comes back. Treatment may need to be interrupted or stopped, or the dose reduced, if certain side effects occur.

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

How does Mekinist work?

In melanoma, non-small cell lung cancer and differentiated thyroid cancer with the BRAF V600 mutation, an abnormal form of the protein BRAF is present. This abnormal protein switches on another protein called MEK involved in stimulating cell division. This leads to the uncontrolled division of cells and cancer development. The active substance in Mekinist, trametinib, works by blocking MEK and by preventing its activation by BRAF, thereby slowing down the growth and spread of the cancer.

What benefits of Mekinist have been shown in studies?

Mekinist has been studied in patients whose cancer had the BRAF V600 mutation.

Melanoma

Mekinist was 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 removed surgically. 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. Patients taking Mekinist lived on average for 4.8 months without their disease worsening, 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 on melanoma that had spread to other parts of the body or could not be removed surgically 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 compared with 8.8 months for those given dabrafenib alone. In a second study involving 704 patients, Mekinist with dabrafenib was compared with another medicine for melanoma, vemurafenib. Patients given the combination lived on average 25.6 months versus 18 months with vemurafenib.

In a study involving 870 patients with stage III melanoma that had been removed surgically, the combination of Mekinist and dabrafenib given for 1 year was compared with placebo (a dummy treatment). Around 40% of patients treated with the combination either died or had their disease come back after an average of about 3.5 years compared with 59% of patients receiving placebo.

Data showed that Mekinist behaves in a similar way in adolescents aged 12 years and older, as it does in adults. A study in the scientific literature also provided data supporting the effectiveness of Mekinist given with dabrafenib for the treatment of melanoma that has a BRAF V600 mutation in adolescents aged 6 years and older who were 15 years old at the time of diagnosis. The study included 6 children and adolescents who received treatment through a compassionate use programme. These findings, together with information on how Mekinist behaves in the body, suggest that similar effects would be expected in adolescents receiving the recommended doses.

Non-small cell lung cancer

In one main study, 171 patients with non-small cell lung cancer received either 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.

Differentiated thyroid cancer

Mekinist given in combination with dabrafenib was shown to be more effective than placebo at slowing down the progression of the cancer in one main study. The study involved 153 adults with differentiated thyroid cancer that had progressed or spread locally or to other parts of the body despite previous treatment, and that did not respond to or was not suitable for treatment with radioactive iodine. Patients treated with Mekinist together with dabrafenib lived on average for around 13 months without their cancer getting worse compared with around 4 months for those given placebo.

Studies carried out with Mekinist are described in more detail in the medicine's assessment reports.

What are the risks associated with Mekinist?

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

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

When Mekinist is taken in combination with dabrafenib, the most common side effects (which may affect more than 1 in 5 people) include fever, tiredness, nausea, chills, headache, diarrhoea, cough, bleeding, vomiting, joint pain, peripheral oedema and rash.

Why is Mekinist authorised in the EU?

Mekinist when used alone or in combination with dabrafenib has been shown to provide a clinically relevant benefit in patients with non-small cell lung cancer or with melanoma that had spread or could not be removed surgically. It is also of benefit in patients with advanced melanoma that has been removed surgically. At the time of approval of Mekinist for the treatment of differentiated thyroid cancer, there were no therapies that targeted this type of cancer when it has mutations in the 'BRAF V600' gene. Mekinist given together with dabrafenib prolonged the time patients with differentiated thyroid cancer lived without their disease getting worse. Mekinist's side effects were considered acceptable and manageable with appropriate measures.

The European Medicines Agency therefore decided that Mekinist's benefits in the aforementioned cancers that carry the BRAF V600 mutation 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 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.

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

Other information about Mekinist

Mekinist received a marketing authorisation valid throughout the EU on 30 June 2014.

Further information on Mekinist, including the package leaflet and assessment report, can be found on the Agency's website: ema.europa.eu/en/medicines/human/EPAR/mekinist.

For information about the availability of this medicine in your country, contact your national competent authority.

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