



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Kimmtrak (*tebentafusp*)

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

What is Kimmtrak and what is it used for?

Kimmtrak is a medicine used to treat adults with a type of eye cancer called 'uveal melanoma'. It is used when the uveal melanoma cannot be removed by surgery or has spread to other parts of the body.

Uveal melanoma is rare, and Kimmtrak was designated an 'orphan medicine' (a medicine used in rare diseases) on 19 February 2021. Further information on the orphan designation can be found here: <https://www.ema.europa.eu/en/medicines/human/orphan-designations/eu-3-21-2397>.

Kimmtrak contains the active substance tebentafusp.

How is Kimmtrak used?

The medicine can only be obtained with a prescription and should be given under the supervision of a doctor experienced in the use of cancer medicines and the treatment of cytokine release syndrome (CRS - a potentially life-threatening condition that can cause fever, vomiting, shortness of breath, headache and low blood pressure), which can occur after treatment with Kimmtrak. It should be given in a setting where CRS can be managed.

Kimmtrak is given as an infusion (drip) into a vein. The recommended dose is 20 micrograms on day 1, 30 micrograms on day 8, 68 micrograms on day 15, and 68 micrograms once every week thereafter. The patient should be hospitalised while receiving the first three doses of Kimmtrak.

To reduce the risk of low blood pressure linked to CRS the patient may be given fluids into a vein before receiving Kimmtrak.

Treatment can continue for as long as the patient benefits from it and does not develop unacceptable side effects.

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

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How does Kimmtrak work?

The active substance in Kimmtrak is tebentafusp, a protein that recognises and attaches to two targets simultaneously: the proteins gp100 on the surface of uveal melanoma cancer cells and CD3 on the surface of T cells (which are part of the body's natural defences). By attaching to these proteins, tebentafusp brings the tumour cells and T cells into contact, which triggers killing of melanoma cells by T cells.

What benefits of Kimmtrak have been shown in studies?

A study in 378 adults with advanced uveal melanoma investigated Kimmtrak and compared it with other medicines (either dacarbazine, ipilimumab or pembrolizumab). Patients given Kimmtrak survived for 21.7 months compared with 16.0 months for patients given a comparator medicine. Patients treated with Kimmtrak lived on average 3.3 months before their cancer came back, a new melanoma occurred or they died, compared with 2.9 months for patients treated with comparator medicines.

What are the risks associated with Kimmtrak?

The most common side effects with Kimmtrak (which may affect more than 3 in 10 people) are cytokine release syndrome, rash, fever, itching, tiredness, nausea, chills, abdominal (belly) pain, oedema (swelling), hypo/hyperpigmentation (change in colouring of the skin), hypotension (low blood pressure), dry skin, headache and vomiting.

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

Why is Kimmtrak authorised in the EU?

There is no standard of care for patients with uveal melanoma, and therefore a high unmet medical need exists for new and effective treatments. The main study showed meaningful improvements with Kimmtrak in terms of overall survival. The side effects are considered manageable but can be serious, especially during the first 3 treatments and patients should therefore be hospitalised for their first 3 doses.

The European Medicines Agency decided that Kimmtrak'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 Kimmtrak?

The company that markets Kimmtrak will provide educational materials for healthcare professionals expected to use the medicine with information on its safety, including the potential risk of CRS and how to manage the risks. Patients will also receive a guide describing the symptoms of CRS and when to seek medical attention.

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

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

Other information about Kimmtrak

Kimmtrak received a marketing authorisation valid throughout the EU on 01 April 2022.

Further information on Kimmtrak can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/kimmtrak.

This overview was last updated in 04-2022.