KIMMTRAK
(tebentafusp-tebn)
Injection for Intravenous Use 100 mcg/0.5 mL

Patient Guide

What you should know about Kimmtrak®

Important safety information for patients receiving treatment with Kimmtrak:

- This leaflet contains important safety information only.
- In case of any further questions, refer to your attending physician.

This medication is subject to additional monitoring. This enables the rapid identification of new safety findings. You can help by reporting any side effects that occur. See the last page for information about reporting side effects.

This guide is phrased in the masculine form for reasons of convenience only, and is designed for both men and women.

MEDISON

About this leaflet

The information in this leaflet is intended for patients who are receiving Kimmtrak.

The product is administered by the attending physician. The attending physician will discuss this leaflet with you, as well as important information for you, such as the benefits and the risks of treatment with Kimmtrak and what to expect regarding your follow up schedule.

This leaflet will:

- Explain what Kimmtrak is
- Describe the treatment with Kimmtrak and what kind of clinical follow up you can expect
- Describe important side effect that you need to be aware of - the risk of cytokine release syndrome (CRS)
- Describe the signs and symptoms of CRS
- Instruct you what to do if the development of CRS is suspected
- Provide you with information on how to report side effects

What you should know about Kimmtrak

What is Kimmtrak?

Kimmtrak is a prescription medication used to treat HLA-A*02:01-positive adults with uveal melanoma that is inoperable or that has spread. The attending physician will have a blood test performed for you in order to determine whether you are positive for HLA-A*02:01 and to determine whether Kimmtrak is right for you.

How will I receive Kimmtrak?

Kimmtrak will be administered to you by intravenous (IV) infusion. The duration of the infusion is 15 to 20 minutes.

How often will I receive Kimmtrak?

Kimmtrak is usually administered every week. Your dose is expected to increase over the first three treatments, and then remain unchanged. The attending physician will decide how many treatments you should receive.

What should I expect during the infusion of Kimmtrak?

- You will have to stay in the hospital overnight and undergo monitoring for side effects during and after the administration of Kimmtrak.
    - For at least the first 3 infusions, you will be monitored during the administration of the infusion and for at least **16 hours** afterwards. This is the period of time during which it is most likely that certain serious side effects will appear.
        - Your vital signs (temperature, pulse, respiratory rate, and blood pressure) will be measured at least every 4 hours

- After the first 3 infusions:
  - If you tolerated Kimmtrak well and you did not experience any significant side effects:
    - You will be monitored during your infusions for at least 3 months. The monitoring will usually last for a minimum of **60 minutes** after the completion of the infusions.
    - If you tolerated the infusions well over the course of at least 3 months, the duration of the monitoring may be reduced to a minimum of 30 minutes.
    - Your vital signs (temperature, pulse, respiratory rate, and blood pressure) will be measured at least twice after the infusion.
  - If you developed significant side effects, you may have to undergo monitoring for a longer period of time (as for the first 3 infusions), and your treatment may be postponed.

Before the administration of the infusion, the attending physician may make changes in other medications you are taking.

Before receiving Kimmtrak, tell the attending physician about all of your medical conditions.

Tell the attending physician about all of the medications you are taking, including prescription and non-prescription medications, vitamins, and herbal supplements.

Why do I need to be monitored during the treatment with Kimmtrak?

Kimmtrak can cause side effects that can be severe or life threatening.

One of these side effects may be **"cytokine release syndrome" (CRS)** - an expected side effect related to the activation of immune system cells caused by Kimmtrak.

When the immune system cells are activated, they produce proteins called cytokines. This can cause some of the signs listed below:

- Fever
- Fatigue or weakness
- Vomiting
- Chills
- Headache
- Nausea
- Low blood pressure
- Dizziness and light-headedness

Call or see the attending physician right away if you develop any symptoms.

Side effects such as CRS are most likely to develop during the first 3 infusions.

What will happen when I experience side effects?

Treatment-related side effects were generally:

- Expected,
- Manageable with appropriate treatment, and
- Usually occurred during the first 3 doses.

In order to manage potential side effects, the attending physician may give you an infusion of fluids, medication, or oxygen.

You will be monitored during and after your infusion, so that any side effects can be treated as soon as possible.

The medical team:

- Will perform heart tests, measure your heart rate, body temperature and relevant vital signs
- Will check for any problems during the treatment with Kimmtrak
- May temporarily suspend or permanently discontinue your treatment with Kimmtrak in the case of severe side effects.

What should I do if I develop a side effect when I go home after my infusion?

If you develop any symptoms whatsoever, contact your attending physician right away.

Do not wait until your next infusion or your next appointment with the attending physician.

If you develop symptoms of cytokine release syndrome (CRS), refer for medical treatment right away.

Reporting side effects

In case of any side effects (including any side effect not listed in this leaflet), refer to the attending physician.

By reporting side effects, you can help provide more information about the safety of this medication.

Side effects can be reported to the Ministry of Health via the portal for the report of side effects on the Ministry of Health homepage, at: www.health.gov.il,
or using the link: https://sideeffects.health.gov.il.

Side effects can be reported to Medison Pharma Ltd.
at email: PVIsrael@Medisonpharma.com or at fax no: 03-9234218.

This guide was approved and reviewed by the Ministry of Health in October 2023.