Patient Guide

What you should know about ▼KIMMTRAK® (tebentafusp)

Important safety information for patients receiving tebentafusp therapy:

- Cytokine Release Syndrome (CRS) as a side effect and how to recognise it.
- Acute Skin Reaction side effects.
- Importance of speaking to your doctor or nurse immediately if you have these side effects.
- Show this guide to any healthcare professional caring for you.
- This brochure contains important safety information only.
- See the KIMMTRAK Package Leaflet for more information.

▼ This medicinal product is subject to additional monitoring.

The additional risk minimisation material is provided by Immunocore (Ireland) Limited as a condition of the KIMMTRAK marketing authorisation.

Table of Contents

About this brochure

The information in this brochure is for patients who are being given tebentafusp.

It is administered by your doctor. Your doctor will also talk with you about this brochure and important information for you like the benefits and the risks of tebentafusp therapy and what to expect regarding your monitoring schedule.

This brochure will:

- Tell you about tebentafusp.
- Tell you about tebentafusp therapy and what kind of clinical monitoring you can expect.
- Tell you about important side effects that you need to be aware of – 'Cytokine Release Syndrome' or CRS, and Acute Skin Reactions.
- Tell you what the signs and symptoms of CRS and Acute Skin Reactions are.
- Tell you what to do if you think you are getting CRS or an Acute Skin Reaction.
- Provide you with information on how to report side effects.

What you should know about tebentafusp

What is tebentafusp?

Tebentafusp is a prescription medicine used to treat HLA-A*02:01-positive adults with uveal melanoma that cannot be removed by surgery or has spread. Your doctor will give you a blood test to see if you are HLA-A*2:01 positive and determine if tebentafusp is right for you.

How will I receive tebentafusp?

Tebentafusp will be given to you by intravenous (IV) infusion into your vein for 15 to 20 minutes.

How often will I receive tebentafusp?

Tebentafusp is usually given every week. Your dose should increase over the first three visits then remain consistent. Your doctor will decide how many treatments you need.

What can I expect when I receive my infusion of tebentafusp?

- You will have an overnight stay in the hospital and will need to be monitored for side effects during and after receiving tebentafusp.

  For at least your first 3 infusions, you will be monitored during your infusion and for at least **16 hours** after. This is the period of time that certain serious side effects are more likely to be seen.

  - Your vital signs (temperature, pulse rate, respiratory rate, and blood pressure) will be taken at least every 4 hours.

  After the first 3 infusions:

- If you tolerated tebentafusp well and you didn't have significant side effects:

  You will be monitored during your infusions and typically for a minimum of **30 minutes** afterwards.

  Your vital signs (temperature, pulse rate, respiratory rate, and blood pressure) will be taken at least twice after infusion.

- If you had significant side effects during the first 3 infusions you may need to be monitored for longer than 30 minutes following later infusions and your treatment may be delayed.

Before your infusion, your doctor may adjust your other medications.

Before receiving tebentafusp, tell your doctor about all of your medical conditions including any heart problems.

Tell your doctor about all medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Why do I need to be monitored when I receive tebentafusp?

Tebentafusp can cause serious side effects that can be severe or life-threatening. This includes Cytokine Release Syndrome (CRS).

CRS is an expected adverse reaction related to immune cell activation caused by tebentafusp. This can cause some of the below listed symptoms.

Tell your doctor or nurse immediately or seek urgent medical attention if you experience any of these symptoms:

Potential symptoms of CRS

- fever
- fatigue
- vomiting
- chills
- difficulty breathing or coughing
- swelling
- headache
- nausea
- low blood pressure
- dizziness and light-headedness
- muscle or joint pain
- fast heartbeat

Heart problems such as rapid or irregular heartbeat or a change in the electrical activity of the heart may occur and can present as palpitations, shortness of breath, light-headedness, dizziness, or chest pain.

Tebentafusp can cause Acute Skin Reactions. These are thought to occur due to the action of the drug on normal, healthy cells in the skin which appear similar to uveal melanoma tumour cells.

Typical acute skin reactions symptoms:

- itchy skin
- rash
- severe hives
- peeling or flaking skin
- swelling of the body
- swelling of the skin around the eyes

Speak to your doctor or nurse immediately or seek urgent medical attention if you experience any of these symptoms.

Side effects such as CRS and Acute Skin Reactions are most likely to occur following the first 3 infusions.

What happens when I experience side effects?

Treatment-related side effects are generally:

- predictable,
- manageable with appropriate treatment, and
- typically occur during the first 3 doses.

To manage potential side effects your doctor may give you IV fluids, medicine, creams, or supplemental oxygen.

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

Your healthcare provider will:

- check pulse rate, blood pressure, body temperature, oxygen levels and other monitoring as necessary.
- check for any problems during treatment with tebentafusp.
- possibly temporarily stop or completely stop your treatment with tebentafusp if you have severe side effects.

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

Call your healthcare provider right away if you develop any symptoms.

Do not wait until your next infusion or doctor's appointment. If you experience Cytokine Release Syndrome (CRS) symptoms or any Acute Skin Reactions seek medical attention immediately.

Show this guide to any healthcare professional caring for you.

Reporting of suspected adverse events or reactions

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in the Package Leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

In the event of a side effect, please report it to:

Immunocore (Ireland) Limited
Unit 1, Sky Business Centre
Dublin 17, D17 FY82
Ireland

Phone: +44 (0) 2076645100
Toll Free Number: +00 800-74451111
e-mail: medinfo.eu@immunocore.com
http://www.immunocore.com

Alternatively, side effects should be reported through the Yellow Card scheme, via the Yellow Card website

https://yellowcard.mhra.gov.uk

or the free Yellow Card app available in Apple App Store or Google Play Store. Alternatively, you can call 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

Further Information

Talk to your doctor or nurse if you have any questions or concerns.

For electronic copies of the Patient Guide, visit:

www.kimmtraksupport.eu

For Questions and medical enquiries

For more information, contact the Immunocore Medical Information Center at +44 (0)1235 438600 or via email info@immunocore.com.

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