# Patient Guide

## What you should know about ▼KIMMTRAK® (tebentafusp)

**Important safety information for patients receiving tebentafusp therapy:**

- 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.**

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# 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 – the risk of 'Cytokine Release Syndrome' or CRS.
- Tell you what the signs and symptoms of CRS are.
- Tell you what to do if you think you are getting CRS.
- 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 it would be likely that certain serious side effects may 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 **60 minutes** after your infusions for at least 3 months.
        - If you tolerate the infusions well for at least 3 months, your monitoring might be decreased to a minimum of 30 minutes.
        - Your vital signs (temperature, pulse rate, respiratory rate, oxygen levels and blood pressure) will be taken at least twice after infusion.
    - If you have significant side effects, you may need to be monitored for longer, in a similar way to the first 3 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.**

**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 side effects that can be severe or life threatening. This includes 'Cytokine release syndrome' (CRS) – which is an expected adverse reaction related to immune cell activation caused by tebentafusp. When immune cells are activated, they produce proteins called cytokines. This can cause some of the below listed signs:

- fever
- tiredness or weakness
- vomiting
- chills
- headache
- nausea
- low blood pressure
- dizziness and light-headedness

**Call or see your doctor right away if you develop any symptoms.**

Side effects such as CRS are most likely to occur during 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, 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:

- perform heart tests, check heart rhythm, body temperature, oxygen levels and relevant vital signs.
- 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 seek medical attention immediately.**

# 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, suspected adverse reactions should be reported to the Health Products Regulatory Authority via:**

- Telephoning (01) 676 4971
- https://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form
  By downloading the form at http://www.hpra.ie/homepage/medicines/safety-information/reporting-suspected-side-effects and emailing it to medsafe@hpra.ie or post it to Freepost, Pharmacovigilance Sections, Health Products Regulatory Authority, Earlsfort Centre, Earlsfort Terrace, Dublin 2, DO2 XP77.

# Further Information

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

**For electronic copies of the Patient Guide, visit:**

http://www.hpra.ie/homepage/medicines/medicines-information/find-a-medicine

Or

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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