KIMMTRAK®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I being given KIMMTRAK?

KIMMTRAK contains the active ingredient tebentafusp. KIMMTRAK is used to treat rare eye cancer called uveal melanoma.

For more information, see Section 1. Why am I being given KIMMTRAK? in the full CMI.

2. What should I know before I am given KIMMTRAK?

Do not use if you have ever had an allergic reaction to KIMMTRAK or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am given KIMMTRAK? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with KIMMTRAK and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How will I be given KIMMTRAK?

KIMMTRAK will be given to you by a healthcare professional in a hospital or clinic through an infusion (drip) into your vein (intravenous) over 15-20 minutes.

More instructions can be found in Section 4. How will I be given KIMMTRAK? in the full CMI.

5. What should I know about being given KIMMTRAK?

Things you should do	• Remind any doctor, dentist, pharmacist or nurse you visit that you have been given KIMMTRAK.
Driving or using machines	• If you feel unwell whilst being treated with KIMMTRAK, you should not drive or operate machinery until you feel well again.

For more information, see Section 5. What should I know about being given KIMMTRAK? in the full CMI.

6. Are there any side effects?

Very common side effects include decreased appetite, prickling, tingling or numbness in any section of the body, cough, diarrhoea, stomach pain, chills, and abnormal blood tests.

Serious side effects include symptoms of cytokine release syndrome (CRS) such as fever, dizziness, light headedness, difficulty breathing, nausea, vomiting, fatigue, muscle pain, joint pain, swelling, low blood pressure, rapid heart rate, and headache.

Other serious side effects include itchy skin, rash, severe hives, peeling or flaking skin, swelling of body and/or skin around the eyes.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

WARNING: CYTOKINE RELEASE SYNDROME
Cytokine Release Syndrome (CRS), which may be serious or life-threatening, can occur in patients receiving tebentafusp. Only administer in an appropriate setting. Monitor for at least 16 hours following each of the first three infusions, and then as clinically indicated.

KIMMTRAK®

Active ingredient: *tebentafusp*

Consumer Medicine Information (CMI)

This leaflet provides important information about using KIMMTRAK. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using KIMMTRAK.**

Where to find information in this leaflet:

1. Why am I being given KIMMTRAK?

KIMMTRAK contains the active ingredient tebentafusp.

KIMMTRAK is an anticancer medicine. It is made from two different proteins that are fused together. One of these proteins recognises a target protein called 'gp100'. Gp100 is found in large amounts in uveal melanoma cancer cells. Once the cancer cells are recognised, KIMMTRAK activates your immune system to destroy the cancer cells.

KIMMTRAK is used to treat a rare eye cancer called uveal melanoma.

KIMMTRAK is used when the uveal melanoma has grown despite local treatment, or has spread to other parts of the body.

2. What should I know before I am given KIMMTRAK?

Warnings

Do not use KIMMTRAK if:

- You are allergic to tebentafusp, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

If you are not sure you are allergic to any of the ingredients, talk to your doctor or nurse before you are given KIMMTRAK.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- are pregnant or plan on getting pregnant

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

KIMMTRAK should not be used in pregnancy unless you and your doctor agree the benefit of taking this medicine outweighs any potential risks. Your doctor or nurse will give you a test for pregnancy before you start treatment with KIMMTRAK. If you become pregnant during KIMMTRAK treatment, inform your doctor or nurse immediately.

If you are female and of child-bearing age, you must use effective birth control to avoid becoming pregnant during KIMMTRAK treatment and for at least 1 week after your last dose. Discuss with your doctor the most appropriate methods of birth control.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known if KIMMTRAK passes into your breast milk. Discuss with your doctor whether the risks and benefits of breast-feeding your child outweigh the benefit of KIMMTRAK treatment and whether you should stop breast-feeding.

Use in children

KIMMTRAK should not be used in children under the age of 18 years. This is because there is limited information on how well it works in this age group.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect KIMMTRAK.

4. How will I be given KIMMTRAK?

How much KIMMTRAK is given:

- This medicine will be given to you by a healthcare professional in a hospital or clinic
- The recommended dose of KIMMTRAK is:
  - 1st dose: 20 micrograms
  - 2nd dose: 30 micrograms
  - 3rd dose: 68 micrograms
  - All further doses: 68 micrograms
- You may be given fluids by infusion before each KIMMTRAK infusion to help prevent low blood pressure from cytokine release syndrome.

How KIMMTRAK is given

- Your doctor or nurse will give you KIMMTRAK through an infusion (drip) into your vein (intravenous) over 15-20 minutes. You will be given KIMMTRAK once a week, for as long your doctor thinks treatment is benefitting you.
- Your healthcare provider will keep you under observation during treatment and for at least 16 hours following your first three doses.
- If the first three doses do not cause any serious or unmanageable side effects, your next doses may be given in a clinic. You will be monitored for any side effects during treatment and for at least 30 minutes after each dose.

If you miss an appointment for your next dose of KIMMTRAK

If you miss an appointment, arrange another visit as soon as possible with your doctor or nurse.

If you are given too much KIMMTRAK

As KIMMTRAK is given under the close supervision of a doctor or nurse, it is unlikely that you will be given too much. However, if you experience any side effects after receiving KIMMTRAK, tell your doctor or nurse immediately.

5. What should I know about being given KIMMTRAK?

Driving or using machines

Be careful before you drive or use any machines or tools until you know how KIMMTRAK affects you.

Tebentafusp is unlikely to affect your ability to drive or use machines. If you feel unwell whilst being treated with this medicine, you should not drive or operate machinery until you feel well again.

Drinking alcohol

Tell your doctor if you drink alcohol.

Your doctor will perform regular blood tests to check for very common side effects such as:

- Increased levels of liver enzymes
- Increased levels of bilirubin
- Low levels of phosphate in the blood
- Increased levels of pancreatic enzyme, lipase in the blood
- Decreased levels of white blood cells in the blood
- Abnormal blood tests.

Looking after your medicine

Your doctor, pharmacist or nurse is responsible for storing KIMMTRAK and disposing of any unused product correctly.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal related: • Stomach pain • Diarrhoea • Indigestion • Decreased appetite **Nervous system related:** • Unusual mood changes including anxiety • Prickling, tingling or numbness in any section of the body **General body related:** • Cough • Chills • Mouth pain • Hair loss • Trouble sleeping • Excessive sweating during the night • Infection of nasal passages • Flu-like symptoms	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects during or after treatment	What to do
Nervous system related: • Fever • Dizziness • Light headedness • Difficulty breathing • Fatigue • Headache **Gastrointestinal related:** • Nausea • Vomiting **Body related:** • Muscle pain • Joint pain • Swelling **Heart and blood related:** • Low blood pressure • Rapid heart rate **Skin related:** • Itchy skin • Rash • Severe hives • Peeling or flaking skin • Swelling of body and/or skin around the eyes.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.** **.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What KIMMTRAK contains

Active ingredient (main ingredient)	Tebentafusp
Other ingredients (inactive ingredients)	Citric acid monohydrate Dibasic sodium phosphate Mannitol Trehalose dihydrate Polysorbate 20 Water for injections

Do not use this medicine if you are allergic to any of these ingredients.

What KIMMTRAK looks like

KIMMTRAK concentrate for solution for infusion is a clear, colourless to slightly yellowish solution in a single-dose vial.

The pack size is 1 glass vial per carton. (AUST R 375296).

Who distributes KIMMTRAK

Medison Pharma Australia Pty Ltd

1 Bligh Street

Sydney NSW 2000

Australia

Phone: 1800 566 020

Email: MedInfo.Australia@Medisonpharma.com

www.medisonpharma.com.au

This leaflet was prepared in June 2024.