

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

^{Pr}KIMMTRAK[®]

Tebentafusp Solution for Intravenous Infusion

Read this carefully before you start taking ^{Pr}KIMMTRAK[®] and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about KIMMTRAK.

What is KIMMTRAK used for?

KIMMTRAK is used to treat adult patients with a type of skin cancer called uveal melanoma in adults 18 years and older whose uveal melanoma is at an advanced stage or has grown or has spread.

Your healthcare provider will test you for a presence of HLA-A*02:01 gene to make sure KIMMTRAK is right for you.

It is not known if KIMMTRAK is safe and effective in children.

How does KIMMTRAK work?

KIMMTRAK contains the active substance tebentafusp which helps your immune system attack and destroy cancer cells.

What are the ingredients in KIMMTRAK?

Medicinal ingredients: tebentafusp

Non-medicinal ingredients: Citric acid monohydrate, disodium hydrogen phosphate, mannitol, polysorbate 20, trehalose, and water for injection

KIMMTRAK comes in the following dosage forms:

Solution for infusion 100 mcg / 0.5 mL vial

Do not use KIMMTRAK if:

- You are allergic to tebentafusp or any other ingredients in KIMMTRAK.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take KIMMTRAK. Talk about any health conditions or problems you may have, including if you:

- Are pregnant or plan to become pregnant. It is not known if KIMMTRAK will harm your unborn baby. Tell your healthcare provider if you become pregnant during your treatment with KIMMTRAK.
- Are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with KIMMTRAK.
- Are able to become pregnant, you should use effective birth control (contraception) during treatment and for at least 1 week after the final dose of KIMMTRAK. Talk to your healthcare provider about birth control methods that may be right for you.
- Are breastfeeding or plan to breastfeed. It is not known if KIMMTRAK passes into your breast milk. Do not breastfeed during treatment.

Other warnings you should know about:

It is not known whether KIMMTRAK may affect your fertility. Talk to your healthcare practitioner if you are planning on having children.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with KIMMTRAK:

No relevant drug-drug interactions are known, however, initiation of treatment with KIMMTRAK may cause temporary release of cytokines (small proteins secreted by cells) which may affect the safety and effectiveness of certain types of other medications. Inform healthcare practitioner of any other medications you are taking.

How to take KIMMTRAK:

- KIMMTRAK will be given to you by a healthcare professional in a healthcare setting through an infusion (drip) into a vein (intravenously) over 15 to 20 minutes.

Usual dose:

- KIMMTRAK is usually given every week.
- Your healthcare professional will decide on how many treatments you need.
- Your healthcare professional will keep you under observation in an appropriate healthcare setting for at least 16 hours following first three KIMMTRAK treatments.
- Your healthcare professional may delay your dose of KIMMTRAK if you have certain side effects or if with subsequent dose you may require additional observation period similar to the first three doses.
- Your healthcare professional may do blood tests regularly during treatment with KIMMTRAK.

Overdose:

In case of overdose, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

It is very important for you to keep all appointments to receive KIMMTRAK. If you miss an appointment, ask your healthcare professional when to schedule your next dose.

What are possible side effects from using KIMMTRAK?

These are not all the possible side effects you may have when taking KIMMTRAK. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- rash
- fever
- tiredness
- vomiting

- chills
- patchy changes in skin and hair color
- stomach pain
- swelling
- low blood pressure (symptoms may include dizziness or light headedness)
- dry skin
- headache
- vomiting

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Cytokine Release Syndrome: Fever, tiredness or weakness, nausea, vomiting, chills, dizziness and light headedness, wheezing, trouble breathing, fatigue, muscle pain, joint pain low blood pressure, rapid heart rate and headache.		✓	
Skin Reactions: Patchy or extensive redness, severe hives, burning, pain, itching or swelling of skin rash; redness, pain or swelling around the eye, eyelid or inner lining of the eyelid; dry skin and skin peeling.		✓	
Elevated liver enzymes: Increased levels of liver enzyme in the blood		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>
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Storage:

- Store KIMMTRAK in the original package refrigerated at 2°C to 8°C.
- Protect from light until time of use. Do not freeze. Do not shake.

Keep out of reach and sight of children.

If you want more information about KIMMTRAK:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); or by calling the Importer and Distributor at 1-800- 696-1341).

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