

Patient Guide

What to Expect with KIMMTRAK[®]



Please see Important Safety Information, including **BOXED WARNING** for Cytokine Release Syndrome (CRS) on pages 6-7 and [click here](#) for Patient Information Leaflet.

What is KIMMTRAK?

KIMMTRAK 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*02:01 positive and determine if KIMMTRAK is right for you. For more information about KIMMTRAK, visit www.KIMMTRAK.com.

How will I receive KIMMTRAK?

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

How often will I receive KIMMTRAK?

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

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

You will need to be monitored for side effects during and after receiving KIMMTRAK.

- 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 KIMMTRAK well and you didn't have significant side effects:*
 - You will be monitored during your infusions and typically for a minimum of 30 minutes after your infusions
 - Your vital signs (temperature, pulse rate, respiratory rate, and blood pressure) will be taken at least twice after each infusion
 - If you did have significant side effects, you may need to be monitored longer and your treatment may be delayed*

Before your infusion, your healthcare provider may adjust your other medications.

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

KIMMTRAK can cause side effects that can be severe or life threatening. Side effects such as CRS or skin reactions are most likely to occur during the first 3 infusions. Symptoms of CRS, skin reactions and liver issues are listed below.

Treatment-related side effects were generally predictable, manageable with appropriate treatment, and typically resolved after 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 do blood tests to check your liver before you start KIMMTRAK and during treatment with KIMMTRAK.

Call or see your healthcare provider right away if you develop any symptoms of the following problems.

Cytokine Release Syndrome (CRS)

Symptoms may include any of the following:

- Fever
- Tiredness or weakness
- Vomiting
- Chills
- Nausea
- Low blood pressure
- Dizziness and light headedness
- Headache
- Wheezing and trouble breathing
- Rash

Skin Reactions

Symptoms may include any of the following:

- Patchy or extensive redness, 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

Liver Issues

Symptoms may include any of the following:

- Right-sided abdominal pain
- Yellowing of the skin or eyes



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 after receiving your treatment with KIMMTRAK.

Why do I need to receive KIMMTRAK every week?

KIMMTRAK was shown to be effective in treating uveal melanoma that has grown or spread in people who have the HLA-A*02:01 variant gene when given every week. Your healthcare provider will decide how long you need to stay on treatment.

To increase your chances to experience the overall survival benefit seen in clinical trials, you should receive KIMMTRAK weekly, as prescribed. Call your healthcare provider if, for any reason, you are unable to go to your infusion appointment.

After infusion of KIMMTRAK, you will be required to stay at the infusion site to be monitored by healthcare providers for side effects. Ask the doctor or nurse if you have any questions or feel unwell.

Support During Treatment

Let your nurse, caregiver, support network, or loved ones help you set realistic expectations so your treatment goes as smoothly as possible.

In clinical studies, side effects usually happened less often after the first three doses.

- Treatment-related side effects were generally predictable and manageable with certain medications
- Be sure to tell your healthcare team about any side effects you may experience so they can help you manage them

Reminders for Your Appointments

The first 3 times you receive KIMMTRAK, you will need to be monitored during your infusion and for at least **16 hours** after your infusion.

Initiation



Your healthcare team will watch you during and for at least **16 hours** after you are given each of the first 3 doses.

Maintenance



If you tolerated your first 3 doses of KIMMTRAK well, you will be watched for a minimum of **30 minutes** after your next doses.

Note: If you did not tolerate KIMMTRAK well and experienced more side effects than anticipated, you may need to be monitored longer.

Starting with your 4th infusion, you may be able to move to an infusion center in your community. Talk to your care team to see if this is an option for you.

You may feel tired or fatigued for up to 24 hours after each infusion as your immune system becomes activated. Until you know how you will feel after each infusion, you may not want to make plans that day, and inform those who count on you that you may need extra rest.



Indication and Important Safety Information Including Boxed Warning

Usage

KIMMTRAK 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.

Important Safety Information

What is the most important information I should know about KIMMTRAK?

KIMMTRAK can cause serious side effects that can be severe or life threatening and usually happen within the first three infusions, including:

- **Cytokine Release Syndrome (CRS). Symptoms of CRS may include:**
 - fever
 - tiredness or weakness
 - vomiting
 - chills
 - nausea
 - low blood pressure
 - dizziness and light-headedness
 - headache
 - wheezing and trouble breathing
 - rash

Tell your healthcare provider right away if you get any of these symptoms. Your healthcare provider will check for these problems during treatment with KIMMTRAK. Your healthcare provider may temporarily stop or completely stop your treatment with KIMMTRAK if you have severe side effects.

See **“KIMMTRAK can cause other serious side effects”** for more information.

Before receiving KIMMTRAK, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. KIMMTRAK may harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with KIMMTRAK.

For females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with KIMMTRAK.
- Use an effective form of birth control during treatment with KIMMTRAK and for at least 1 week after the last dose of KIMMTRAK.

- are breastfeeding or plan to breastfeed. It is not known if KIMMTRAK passes into your breast milk. Do not breastfeed during the treatment with KIMMTRAK and for at least 1 week after the last dose of KIMMTRAK.

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

KIMMTRAK can cause other serious side effects, including:

- **Skin reactions.** KIMMTRAK may cause skin reactions that require treatment. Tell your healthcare provider if you get symptoms of skin reactions—such as rash, itching, or skin swelling—that are severe and do not go away.
- **Abnormal liver blood tests.** Your healthcare provider will do blood tests to check your liver before you start KIMMTRAK and during treatment with KIMMTRAK. Tell your healthcare provider if you get symptoms of liver problems such as right-sided abdominal pain or yellowing of the skin or eyes.

The most common side effects of KIMMTRAK include:

- cytokine release syndrome (CRS)
- rash
- fever
- itching
- tiredness
- nausea
- chills
- stomach pain
- swelling
- low blood pressure (symptoms may include dizziness or light-headedness)
- dry skin
- headache
- vomiting
- abnormal liver blood tests

These are not all the side effects possible with KIMMTRAK.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 (1-800-332-1088).

Please read the accompanying Patient Information Leaflet before you receive KIMMTRAK and discuss any questions you have with your healthcare provider.



Tips for Your Appointments

Talk to your care team to find out what to expect when you get your infusion. It is helpful to make a list of questions you may have ahead of time so you can be fully prepared.

While the infusion time for KIMMTRAK is approximately 15 to 20 minutes, you will need to be observed for at least **16 hours** following each of the first 3 doses. Consider the following:



Bring a book, audio book, iPad, laptop, or whatever you enjoy doing to pass the time or need to be able to get some work done. Remember chargers for electronic devices.



Wear comfortable clothes so you can feel relaxed. Avoid loose-fitting underwear because it may rub against your skin. Don't wear jewelry, a watch, or anything else that may be irritating if you have a skin reaction to the treatment.



Bring a snack and something to drink.



Bring your own blanket or sweater from home in case you feel cold.



Where allowed by the infusion facility, bring someone with you to keep you company.

After Your Infusion

- **Allow yourself to rest.** You may feel tired or fatigued for 24 hours after each infusion, so manage expectations with your loved ones and/or work
- If you experience Cytokine Release Syndrome (CRS) symptoms seek medical attention immediately

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For patient assistance contact:



KIMMTRAKCONNECT[®]



KIMMTRAKCONNECT.com
844-775-CARE (2273)

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