



Starting KIMMTRAK[®]

What to expect with your treatment

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.

Please see additional Important Safety Information including **BOXED WARNING for Cytokine Release Syndrome (CRS)** throughout and [KIMMTRAK Patient Information](#).

Why KIMMTRAK?

You're on your way to getting started on KIMMTRAK. Your doctor has confirmed you're HLA-A*02:01 positive and discussed the potential benefits and safety considerations of KIMMTRAK.

Before you start your weekly infusions, use this guide as a resource for what to expect.

KIMMTRAK is the only immunotherapy approved by the FDA to treat adults with metastatic uveal melanoma (mUM) who are HLA-A*02:01 positive

KIMMTRAK was compared to other treatments* in a clinical trial to see if there was an overall survival benefit.



- The median[†] time that someone who received KIMMTRAK lived was 21.7 months compared to 16.0 months with other treatments studied.*

Patients had a median[†] follow-up time of 14.1 months.

These results were statistically significant.

KIMMTRAK may not work for everyone. Individual results may vary.

* Other treatments studied in the trial included immunotherapies (pembrolizumab or ipilimumab) or chemotherapy (dacarbazine).

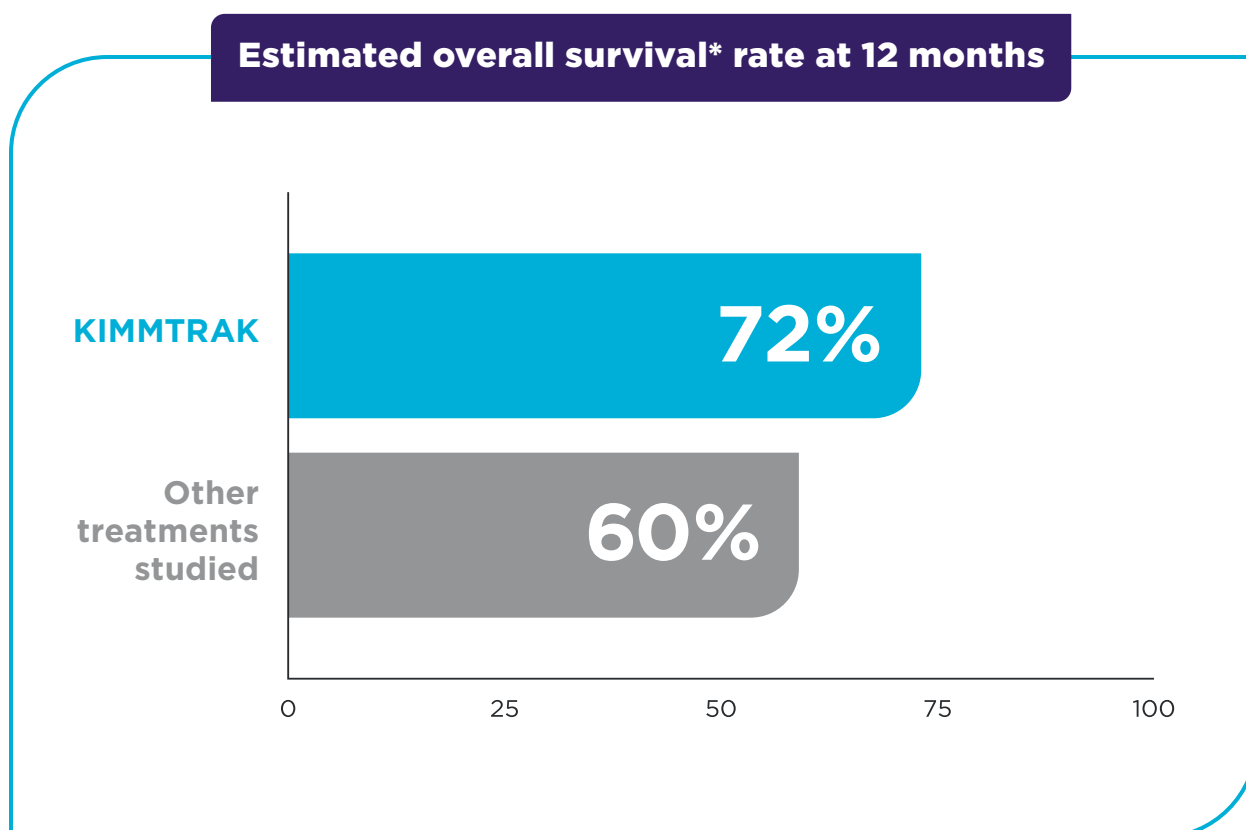
[†] Median is one number in the middle of a series of numbers that have been put in order.
HLA-A, human leukocyte antigen-A.

Important Safety Information (continued)

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.

Why KIMMTRAK? (continued)

- In the clinical trial, KIMMTRAK extended the lives of adults with mUM who were HLA-A*02:01 positive.



* Overall survival means how long people in the study were alive at a given point of time after starting treatment. These are study estimates; individual results may vary.

Important Safety Information (continued)

- **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.

Please see additional Important Safety Information including **BOXED WARNING for Cytokine Release Syndrome (CRS)** throughout and [KIMMTRAK Patient Information](#).

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

Starting KIMMTRAK

How will I receive KIMMTRAK?



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

How often will I receive KIMMTRAK?



KIMMTRAK is given weekly. Your dose should increase over the first three visits so your body has a chance to get used to KIMMTRAK. This also aims to reduce your risk of side effects. After these first three visits, your doses will likely remain the same **and may be referred to as maintenance doses**. Your doctor will decide how many treatments you need.

Why do I need to receive KIMMTRAK every week?

To maximize your opportunity to experience the survival benefit seen in the clinical trial, you must receive KIMMTRAK weekly, as prescribed.

If you need to miss a dose, talk to your doctor first.

Work with your healthcare team to determine how to fit KIMMTRAK weekly infusions into your life.

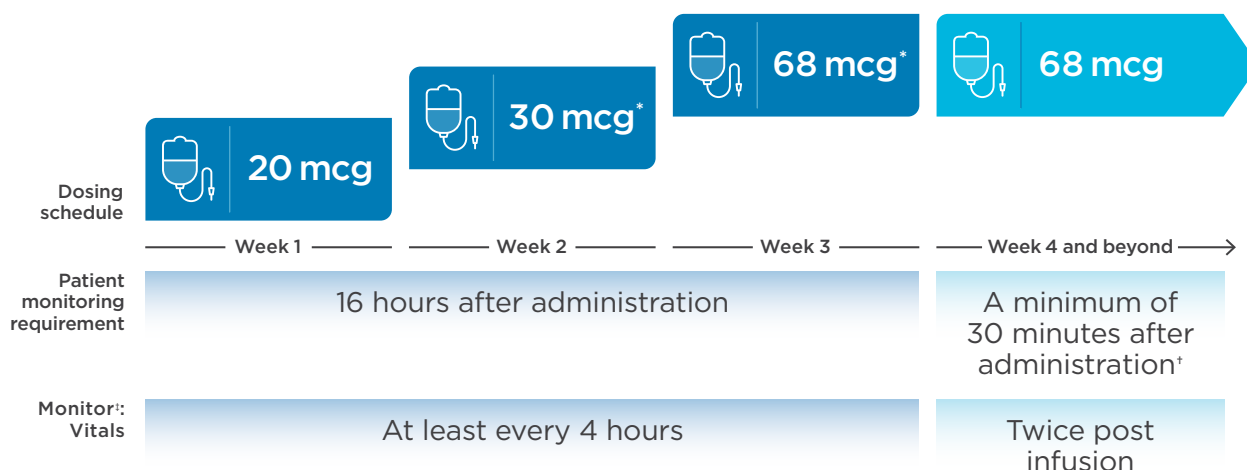


Important Safety Information (continued)

- **Abnormal liver blood tests.** Your healthcare provider will do blood tests to check your liver before you start KIMMTRAK and during treatment with KIMMTRAK.

Starting KIMMTRAK (continued)

Step-up dose and monitoring schedule



The starting dose is 20 mcg for week 1. The dose increases to 30 mcg for week 2 and 68 mcg for week 3 and beyond.

* If patient has not had a $\geq$ grade 2 (moderate, severe, or life threatening) cytokine release syndrome side effect with their previous dose.

† If patient has not had low blood pressure that required medical intervention with their most recent dose.

‡ The recommendations above are based on the clinical trial protocol. Your healthcare team may adjust what to monitor and at what frequency.



Visit [KIMMTRAK.com](https://www.kimmtrak.com) to learn more.

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The first 3 doses

What can I expect when I receive KIMMTRAK?

KIMMTRAK can cause side effects that can be very serious and require management by a healthcare provider. In the clinical trial, side effects related to KIMMTRAK, such as cytokine release syndrome (CRS) and rash, were generally predictable (expected to occur), able to be managed, and usually happened during the first few 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.

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

Monitoring after the first 3 doses

Initiation



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

- This is the period of time that it would be likely that certain serious side effects may be seen.
 - Your vital signs (temperature, heart rate, breathing rate, and blood pressure) will be taken at least every 4 hours.

The first 3 doses (continued)

How can I prepare for my first 3 treatments?

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. Planning is especially important for the first few weeks. You might want to bring the following:**



A book, audio book, iPad, laptop, or whatever helps you pass the time or get some work done. Remember chargers for electronic devices.



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



A snack and something to drink.



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



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

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Common side effects

Cytokine release syndrome (CRS)

89% of patients experienced some symptoms of CRS. 84% of the time, CRS started the day of the infusion.

- 1.2% discontinued their treatment as a result.

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, and rash.

- Fever is usually the first sign of CRS, so let your healthcare team know if you are feeling feverish. They will want to track your symptoms closely so they can manage them.

CRS is a side effect that may happen with KIMMTRAK because the treatment works by activating your immune system.

Rash

Rash occurred in 83% of patients.

- None discontinued their treatment due to rash.

A red rash can appear on all or part of the body, and it may peel or feel itchy and painful. It may appear similar to a sunburn but can look and feel differently for each individual.

In the clinical trial, most rashes got better or went away over time.

Metastatic uveal melanoma cells are similar to your skin cells. In an effort to fight your cancer, KIMMTRAK may also affect some of your skin cells, resulting in a rash.

Common side effects (continued)

Liver issues

65% of patients had elevated liver enzymes.

- 0.4% discontinued their treatment as a result.

Symptoms may include right-sided abdominal pain or yellowing of the skin or eyes.

Your doctor will do blood tests to check your liver before you start KIMMTRAK and during treatment with KIMMTRAK.

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

After you've completed your post-infusion observation time and have gone home, you may develop side effects.

The first few weeks may be the most challenging as your immune system begins to work with KIMMTRAK. In the clinical trial, most patients remained on treatment.



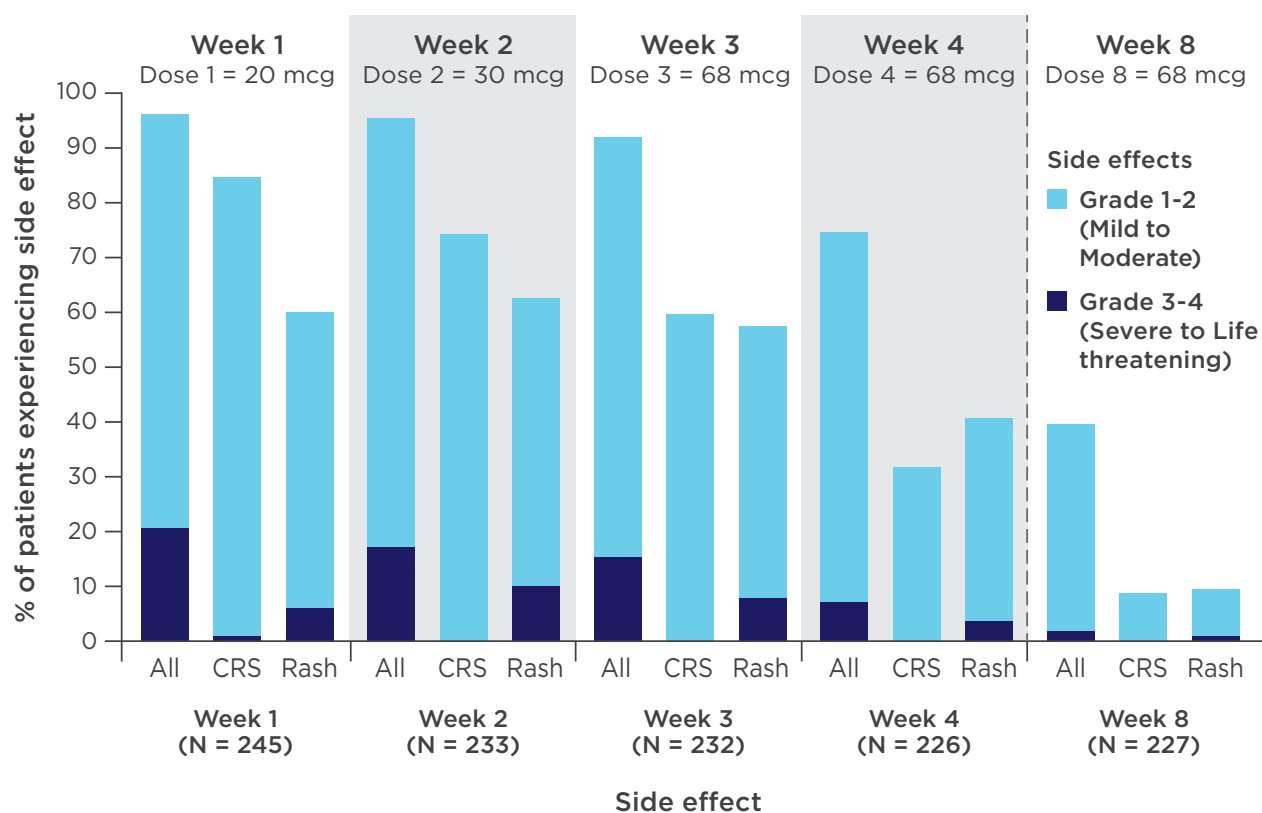
Contact your doctor right away if you develop any of the symptoms listed.

Please see additional Important Safety Information including **BOXED WARNING for Cytokine Release Syndrome (CRS)** throughout and [KIMMTRAK Patient Information](#).

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Common side effects (continued)

How often certain side effects* happened each week during treatment with KIMMTRAK



* Treatment-related side effects.

CRS was identified by using the American Society for Transplant and Cellular Therapy (ASTCT) criteria.

Rash includes a variety of skin-related side effects.

This chart was published in the *New England Journal of Medicine* in 2021.

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N = Number of patients taking KIMMTRAK.



Follow recommendations from your doctor on how to manage any side effects you may experience.

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Maintenance doses

Will I still have side effects after my maintenance doses?

Although side effects happen less frequently after the first few doses, they may still occur following maintenance doses. The most common side effects that occurred in the clinical trial included CRS, rash, fever, itching, tiredness, nausea, chills, stomach pain, swelling, low blood pressure (symptoms may include dizziness or light-headedness), dry skin, headache, vomiting, and abnormal liver blood tests.

Monitoring after maintenance doses

Maintenance



If you tolerated your first 3 doses of KIMMTRAK well and you didn't have significant side effects, you will be watched during your infusion and for **a minimum of 30 minutes** after your next doses.

- Your vital signs (temperature, heart rate, breathing rate, and blood pressure) will be taken at least twice after each infusion.

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

Maintenance doses (continued)



You may be able to move to an infusion center in your community to receive your weekly treatment.

- An infusion center closer to home may be more convenient to you and anyone who helps you with your treatments.
- Talk to your healthcare team to see if this is an option for you.



You may feel tired or fatigued 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.
- Tell those who count on you that you may need extra rest.



In the clinical trial primary analysis, 2% of patients stopped taking KIMMTRAK due to treatment-related side effects.

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Maintenance doses (continued)

Your scans may not present the whole picture

- With immunotherapies, including KIMMTRAK, it is possible that tumors may not shrink, but stay the same or even appear larger on scans.
- Your doctor may determine that you are receiving benefit from the treatment based on not only your scans, but also how you are feeling, and other assessments of your overall health.



Be sure to tell your healthcare team how you are feeling. This information will help inform decisions on your care moving forward.

Important Safety Information (continued)

Tell your healthcare provider if you get symptoms of liver problems such as right-sided abdominal pain or yellowing of the skin or eyes.

Support during your treatment

How should I utilize my support network?

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

When discussing your expectations, think about:

- What help you might need during each phase of your treatment.
 - Are there additional plans that need to be made while you prepare to stay in the hospital for 16 hours of observation after the first 3 doses?
 - Do you need someone to drive you to treatments?
 - Do you need help with household tasks during your treatment?
- Which friends and family make up your support network.



Caregivers, when you are accompanying your loved one to their infusion, remember to bring snacks and something to occupy yourself as well.

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KIMMTRAK CONNECT® is here for you

You are not in this alone. If you and your doctor have decided KIMMTRAK is right for you, the KIMMTRAK CONNECT team is here. They can help you better understand your disease, know what to expect, and how to manage your treatment experience.

Every person with metastatic uveal melanoma is unique. KIMMTRAK CONNECT provides services and support tailored to your specific needs.



KIMMTRAKCONNECT®



You can call
KIMMTRAK CONNECT at
844-775-CARE (2273).

Available Monday-Friday, 9 AM-7 PM (EST)

Visit KIMMTRAKCONNECT.com
for information and support.



“It is so comforting talking to someone who understands my disease. Not everyone knows about this. Your team offers great resources on what to expect with my infusions.”

—KIMMTRAK CONNECT Patient

KIMMTRAK CONNECT[®] is here for you (continued)



Customized support

Your dedicated nurse case manager will help guide you through the services and support we offer.



Financial assistance

We identify the options that are right for you. Once we understand your needs, we may be able to help set you up with financial assistance.*

* KIMMTRAK CONNECT is not insurance and does not guarantee product coverage or reimbursement.



Care coordination

Just tell us what you need, and we will try to help you manage your care. We may help coordinate infusion appointments once you and your physician choose a treatment location. We may also be able to assist you in locating affordable transportation to and from your treatment.

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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.

Indication and Important Safety Information Including Boxed Warning (continued)

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) or at www.fda.gov/medwatch.

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

Please see KIMMTRAK Patient Information.

Living longer is an important treatment goal, and KIMMTRAK provided that possibility*



In the clinical trial, **72% of KIMMTRAK patients were alive at 1 year** compared to 60% of patients who received other treatments.[†]



Treatment-related **side effects were generally predictable** (expected to occur) and were managed with certain medications.



KIMMTRAK is a weekly infusion. Work with your healthcare team to fit your treatment schedule into your life.

* Compared with other immunotherapies or chemotherapy.

† Other treatments studied in the trial included immunotherapies (pembrolizumab or ipilimumab) or chemotherapy (dacarbazine).



For patient assistance, visit
KIMMTRAKCONNECT.com.

Enroll now! A dedicated nurse case manager is ready to work with you one-on-one to support you in your treatment journey.

Important Safety Information (continued)

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, and abnormal liver blood tests.

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