PATIENT INFORMATION KIMMTRAK® (KIM-track) (tebentafusp-tebn) injection

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 happens within the first three infusions. These side effects include:

- Cytokine Release Syndrome (CRS). Tell your healthcare provider right away if you get any of the following symptoms:
 - o fever
 - tiredness or weakness
 - vomitina
 - o chills
 - o nausea

- o low blood pressure
- o dizziness and light headedness
- o headache
- wheezing and trouble breathing
- o rash

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 "What are the possible side effects of KIMMTRAK?" for more information about side effects.

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 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.

Before you receive 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.

How will I receive KIMMTRAK?

- KIMMTRAK will be given to you by intravenous (IV) infusion into your vein for 15 to 20 minutes.
- KIMMTRAK is usually given every week.
- Your healthcare provider will decide how many treatments you need.
- Your healthcare provider will keep you under observation for at least 16 hours following the first three KIMMTRAK treatments and for at least 30 minutes after future treatments.
- Your healthcare provider may delay your treatment of KIMMTRAK if you have certain side effects.

Your healthcare provider may do blood tests regularly during treatment with KIMMTRAK.

What are the possible side effects of KIMMTRAK?

KIMMTRAK can cause serious side effects, including:

- See "What is the most important information I should know about KIMMTRAK?".
- **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 possible side effects of KIMMTRAK.

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

General information about safe and effective use of KIMMTRAK.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. If you would like more information about KIMMTRAK, talk with your healthcare provider. You can ask your healthcare provider for more information about KIMMTRAK that is written for healthcare professionals.

What are the ingredients in KIMMTRAK?

Active ingredient: tebentafusp

Inactive ingredients: citric acid monohydrate, di-sodium hydrogen phosphate, mannitol, polysorbate 20, trehalose, and Water for injection.

Manufactured by:

Immunocore Limited 92 Park Drive, Milton Park Abingdon, Oxfordshire United Kingdom, OX144RY License no. 2230

at: Baxter Oncology GmbH, Kantstraße 2, 33790 Halle/Westfalen Germany.

For: Immunocore Commercial LLC 181 Washington Street Conshohocken, PA, US

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For more information, go to www.KIMMTRAK.com or call 1-844-IMMUNO1 (1-844-466-8661).

This Patient Information has been approved by the U.S. Food and Drug Administration

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