KIMMTRAK® (tebentafusp-tebn) distribution information An ImmTAC® Biologic

KIMMTRAK is indicated for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma.¹

Dosing and administration¹

KIMMTRAK is administered once weekly via continuous IV infusion over 15-20 minutes. The starting dose is 20 mcg for week 1, with an increase to 30 mcg for week 2 and 68 mcg for week 3 and subsequent weeks.

Product information

Each package contains a 100 mcg/0.5 mL single-dose vial of KIMMTRAK, which is a sterile, preservative-free, clear, colorless or slightly yellowish solution.¹

10-digit NDC: 80446-401-01 **11-digit NDC:** 80446-0401-01

Wholesale acquisition cost (WAC): \$20,480



Distributors for physician offices			
Specialty distributor	Phone orders	Fax orders and website	
Cardinal Health Specialty Pharmaceutical Distribution	877-453-3972 Monday-Friday, 7 AM-6 PM CT (24-hour emergency on call)	https://specialtyonline.cardinalhealth.com	
McKesson Specialty Health	800-482-6700 Monday-Friday, 7 дм-7 рм СТ	Fax: 800-289-9285 https://mscs.mckesson.com	
Oncology Supply	800-633-7555 Monday-Friday, 8 AM-7 PM CT	https://www.oncologysupply.com	

Distributors for hospitals and infusion centers			
Specialty distributor	Phone orders	Fax orders and website	
ASD Healthcare	800-746-6273 Monday-Thursday, 7 AM-6:30 PM CT; Friday, 7 AM-6 PM CT (24-hour emergency on call)	Fax: 800-547-9413 https://www.asdhealthcare.com	
Cardinal Health Specialty Pharmaceutical Distribution	866-677-4844 Monday-Friday, 7 AM-6 PM CT (24-hour emergency on call)	Fax: 614-553-6301 https://orderexpress.cardinalhealth.com	
McKesson Plasma and Biologics	877-625-2566 Monday-Friday, 8 AM-6:30 PM CT	Fax: 888-752-7626 https://connect.mckesson.com	

KIMMTRAK is not currently available through specialty pharmacy orders. HLA-A, human leukocyte antigen-A.



Indication and Important Safety Information Including Boxed Warning

Indication

KIMMTRAK is a bispecific gp100 peptide-HLA-directed CD3 T cell engager indicated for the treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma.

Important Safety Information Including Boxed Warning

WARNING: CYTOKINE RELEASE SYNDROME

Cytokine Release Syndrome (CRS), which may be serious or life-threatening, occurred in patients receiving KIMMTRAK. Monitor for at least 16 hours following first three infusions and then as clinically indicated. Manifestations of CRS may include fever, hypotension, hypoxia, chills, nausea, vomiting, rash, elevated transaminases, fatigue, and headache. CRS occurred in 89% of patients who received KIMMTRAK with 0.8% being grade 3 or 4. Ensure immediate access to medications and resuscitative equipment to manage CRS. Ensure patients are euvolemic prior to initiating the infusions. Closely monitor patients for signs or symptoms of CRS following infusions of KIMMTRAK. Monitor fluid status, vital signs, and oxygenation level and provide appropriate therapy. Withhold or discontinue KIMMTRAK depending on persistence and severity of CRS.

Skin Reactions

Skin reactions, including rash, pruritus, and cutaneous edema occurred in 91% of patients treated with KIMMTRAK. Monitor patients for skin reactions. If skin reactions occur, treat with antihistamine and topical or systemic steroids based on persistence and severity of symptoms. Withhold or permanently discontinue KIMMTRAK depending on the severity of skin reactions.

Elevated Liver Enzymes

Elevations in liver enzymes occurred in 65% of patients treated with KIMMTRAK. Monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), and total blood bilirubin prior to the start of and during treatment with KIMMTRAK. Withhold KIMMTRAK according to severity.

Embryo-Fetal Toxicity

KIMMTRAK may cause fetal harm. Advise pregnant patients of potential risk to the fetus and patients of reproductive potential to use effective contraception during treatment with KIMMTRAK and 1 week after the last dose.

The most common adverse reactions (≥30%) in patients who received KIMMTRAK were cytokine release syndrome, rash, pyrexia, pruritus, fatigue, nausea, chills, abdominal pain, edema, hypotension, dry skin, headache, and vomiting. The most common (≥50%) laboratory abnormalities were decreased lymphocyte count, increased creatinine, increased glucose, increased AST, increased ALT, decreased hemoglobin, and decreased phosphate.

Please see <u>full Prescribing Information</u>, including BOXED WARNING for CRS.

Reference: 1. Kimmtrak. Package insert. Immunocore Ltd; 2022.



