Prescribing Information FOR THE UNITED KINGDOM (ENGLAND, SCOTLAND, WALES AND NORTHERN IRELAND)

KIMMTRAK▼ 200 micrograms/ mL concentrate for solution for infusion (tebentafusp)
Please refer to the Summary of Product Characteristics [SmPC] before prescribing (https://www.medicines.org.uk/emc/product/13842/smpc#about-medicine)

Presentation: One 0.5 mL vial contains 100 micrograms of tebentafusp. **Indication:** KIMMTRAK (tebentafusp) is indicated as monotherapy for the treatment of human leukocyte antigen (HLA) A*02:01 positive adult patients with unresectable or metastatic uveal melanoma.
Dosage and administration: Tebentafusp should be administered under the supervision of a physician experienced in the use of anti-cancer immunotherapy agents. Appropriate medicinal products, including anti IL 6 treatment and resuscitation equipment should be available. Hospitalisation is recommended for at least the first three infusions of tebentafusp.
Posology*:** The recommended dose of tebentafusp is 20 micrograms on Day 1, 30 micrograms on Day 8, 68 micrograms on Day 15, and 68 micrograms once every week thereafter. ***Premedication: To minimize the risk of hypotension associated with cytokine release syndrome (CRS), administer intravenous fluids prior to starting tebentafusp infusion based on clinical evaluation and volume status of patient. For patients with pre-existing adrenal insufficiency on maintenance systemic corticosteroids, adjusting the corticosteroid dose should be considered to manage the risk of hypotension.
Dose adjustments: Other causes of fever, hypoxia and hypotension should be evaluated and treated. Tebentafusp should be withheld or discontinued to manage adverse reactions **(refer to full SmPC for dose adjustment recommendations).** ***Paediatric population:*** The safety and efficacy of tebentafusp in children under the age of 18 years have not been established. ***Elderly:*** No dose adjustment is required for elderly patients (≥ 65 years of age). ***Renal impairment:*** Dose adjustment is not necessary in patients with mild to moderate renal impairment. No dose recommendations can be made for patients with severe renal impairment, dosing in patients with severe renal impairment should be done with caution. ***Hepatic impairment:*** No dose adjustment is recommended for patients with mild hepatic impairment. ***Cardiac disease*:** Patients with cardiac disease, QTc prolongation and risk factors for cardiac failure should be monitored carefully.
Method of administration: Tebentafusp is for intravenous use. It is intended for use as single dose only. Refer to the SmPC for information on dilution and administration.
Contraindications: Hypersensitivity to tebentafusp or to any of the excipients.
Special warnings and precautions for use: ***Patient selection:*** The HLA-A*02:01 positive status of a patient should be determined when considering treatment. ***Cytokine release syndrome (CRS)*:** Patients should be monitored for signs or symptoms of CRS for at least 16 hours following first three infusions of tebentafusp. If CRS is observed, prompt treatment with supportive care including antipyretics, intravenous fluids, tocilizumab, or corticosteroids should be initiated to avoid escalation to severe or life-threatening events and monitoring should be continued until resolution. If Grade 2 CRS symptoms do not rapidly improve to Grade ≤ 1 within 2-3 hours, then treat as Grade 3. At subsequent doses, patients should be closely monitored after treatment for early CRS signs and symptoms. For Grade 3 withhold KIMMTRAK until Grade ≤ 1. At next treatment, resume KIMMTRAK at same dose level (i.e. do not escalate) after appropriate risk versus benefit assessment and monitor patient accordingly. Once dose level is tolerated, can resume pre-planned dosing schedule. For Grade 2 CRS that is persistent (lasting 2-3 hours) or recurrent (occurrence of ≥ Grade 2 CRS with more than one dose), or for Grade 3 CRS administer corticosteroid premedication (e.g. dexamethasone 4 mg or equivalent) at least 30 minutes prior to next dose. For Grade 4 permanently discontinue KIMMTRAK. Patients with co-morbidities, including certain cardiovascular disorders, may be at increased risk for sequalae associated with CRS. ***Acute skin reactions*:** Rash, pruritus, erythema and cutaneous oedema have been reported. Acute skin reactions can be managed with antihistamine and topical or systemic corticosteroids. ***Elevated liver enzymes:*** Transient elevations in liver enzymes have occurred. Aspartate transaminase/alanine aminotransferase (AST/ALT) and total blood bilirubin should be monitored prior to the start of and during treatment with tebentafusp. ***Cardiac disease*:** Cardiac events such as sinus tachycardia and arrhythmia have been reported. Tebentafusp should be administered with caution in patients with history of or predisposition to QT interval prolongation and in patients who are taking medicinal products known to prolong QT interval. Patients with pre-existing cardiovascular disorders may be at increased risk for sequalae associated with CRS and should be monitored carefully. Tebentafusp should be withheld or discontinued to manage adverse reactions, according to recommendations detailed in SmPC. Refer to full SmPC for further information on warnings and precautions. **Drug interactions:** Tebentafusp treatment causes transient release of cytokines that may suppress CYP450 enzymes. Patients receiving concomitant CYP450 substrates should be monitored for toxicity or drug concentrations and the dose of concomitant medicines adjusted as needed.
Pregnancy and lactation: Tebentafusp is not recommended during pregnancy, breast-feeding and in women of childbearing potential not using contraception. Women of childbearing potential should use effective contraception during treatment and for at least 1 week after the last dose. The pregnancy status in females of reproductive potential should be verified prior to initiating tebentafusp treatment. Breast-feeding should be discontinued during treatment with tebentafusp. The effect on male and female fertility is unknown.
Effects on ability to drive and use machines: Tebentafusp has no or negligible influence on the ability to drive and use machines.
Undesirable effects: The most common adverse reactions associated in patients treated with tebentafusp were CRS, rash, pyrexia, pruritus, fatigue, nausea, chills, abdominal pain, oedema, hypo/hyperpigmentation, hypotension, dry skin, headache and vomiting.
The most common serious adverse reactions were CRS, rashes, pyrexia and hypotension.
Refer to the SmPC for further information on undesirable effects.
Overdose: In case of overdose, patients should be closely monitored for signs or symptoms of adverse reactions and appropriate symptomatic treatment should be initiated immediately.
Pack quantities and costs: Available in packs of 1 vial. **UK:** £10,114 per vial.
Legal category: POM.
Marketing Authorisation Holder: Immunocore Limited**,** 92 Park Drive, Abingdon, Oxfordshire, OX14 4RY, United Kingdom
MA Number: PLGB 36781/0001
Date of preparation: February 2026. **Job Code**: PM-UK-KIM-2600019
Date of last revision of the aPI text: February 2025

Adverse events should be reported. Reporting forms and information can be found at: https://yellowcard.mhra.gov.uk/
Adverse events should also be reported to Immunocore Limited by calling +44 203 996 7074