HOW TO CHECK YESCARTA OR TECARTUS PRIOR TO ADMINISTRATION

- Verify that the patient's identity (ID) matches the patient identifiers on the Yescarta or Tecartus cassette.
- Do not remove the bag from the cassette if the information on the patient-specific label does not match the intended patient.
- Once the patient's ID is confirmed, remove the Yescarta or Tecartus product bag from the cassette.
- Check that the patient information on the cassette label matches that on the bag label.
- Inspect the product bag for any breaches of container integrity before thawing. If the bag is compromised, follow the local guidelines (or immediately contact Kite).
- Place the infusion bag inside a second sterile bag per local guidelines.

HOW TO THAW YESCARTA OR TECARTUS

- Thaw Yescarta or Tecartus at approximately 37°C using either a water bath or a dry thaw method until there is no visible ice in the infusion bag.
- Gently mix the contents of the bag to disperse clumps of cellular material. If visible cell clumps remain, continue to gently mix the contents of the bag.
- Small clumps of cellular material should disperse with gentle manual mixing. You should not wash, spin down, and/or resuspend with one of the Kite cellular therapy products in new media prior to infusion. Thawing should take approximately 3 to 5 minutes.
- Once thawed, Yescarta or Tecartus are stable at room temperature (20°C-25°C) for up to 3 hours. However, Yescarta or Tecartus infusion should begin within 30 minutes of thaw completion and the total infusion time should not exceed 30 minutes.

The SmPC, Patient Information, and Healthcare Professional Educational Material and Patient Alert Card can be found on the Health Products Regulatory Authority (HPRA) website and medicines.ie and can be obtained by contacting Kite, a Gilead Company, Medical Information at UKMed.Info@gilead.com or by telephone on +353 214825999.

Reporting of side effects

Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, website: **www.hpra.ie**

Any suspected adverse reactions to Yescarta and Tecartus should be reported to Gilead via email to **Safety_FC@gilead.com** or by telephone + 353 (0) 214 825 999.

When reporting a suspected adverse reaction, please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment date.

Please see the Yescarta and Tecartus Summary of Product Characteristics for full information on handling and administration.

UK-TEC-0418 Date of preparation: February 2023

Kite
A GILEAD Company

Kite cellular therapy products:

Yescarta® ▼(axicabtagene ciloleucel) Dispersion for infusion

Tecartus® ▼(brexucabtagene autoleucel) Dispersion for infusion

GUIDE TO HANDLING AND METHOD OF ADMINISTRATION, AND SAMPLING RECOMMENDATION FOR SECONDARY MALIGNANCIES

Yescarta and Tecartus , hereafter referred to as Kite cellular therapy products are solely intended for autologous use via intravenous infusion.

These two Kite cellular therapy products must not be irradiated as this could lead to inactivation of the product.

Do NOT use a leukodepleting filter.

▼ THESE MEDICINAL PRODUCTS ARE SUBJECT TO ADDITIONAL MONITORING. THIS WILL ALLOW QUICK IDENTIFICATION OF NEW SAFETY INFORMATION. HEALTHCARE PROFESSIONALS ARE ASKED TO REPORT ANY SUSPECTED ADVERSE REACTIONS.

SECTION 1: GUIDE TO HANDLING AND METHOD OF ADMINISTRATION

PRECAUTIONS TO TAKE BEFORE HANDLING OR ADMINISTERING YESCARTA OR TECARTUS

Yescarta and Tecartus are prepared from autologous blood of the patient collected by leukapheresis. Patient leukapheresis material and these two Kite cellular therapy products may carry a risk of transmitting infectious viruses to healthcare professionals (HCPs) handling the product. Accordingly, HCPs handling leukapheresis material of these two Kite cellular therapy products must take appropriate precautions (wearing gloves and eye protection) to avoid potential transmission of infectious diseases.

These two Kite cellular therapy products contain genetically-modified human blood cells. Local guidelines on handling of biological waste should be followed for disposal.

All material that has been in contact with these two Kite cellular therapy products (solid and liquid waste) should be handled and disposed of in accordance with local guidelines on handling of biological waste.

Yescarta and Tecartus should be transported within the facility in closed, break-proof, leak-proof containers.

HOW TO ADMINISTER YESCARTA OR TECARTUS

- Yescarta and Tecartus therapy should be initiated under the direction of and supervised by a HCP experienced in the treatment of haematological malignancies and trained for administration and management of patients treated with these two Kite cellular therapy products.
- Ensure that at least one dose of tocilizumab per patient and emergency equipment are available prior to infusion and during the recovery period. Hospitals must have access to an additional dose of tocilizumab within 8 hours of each previous dose. In the exceptional case where tocilizumab is not available due to a shortage that is listed in the European Medicines Agency shortage catalogue, the treatment centre must have access to suitable alternative measures instead of tocilizumab to treat CRS.
- A leukodepleting filter must not be used.
- Yescarta and Tecartus are for autologous use only.
- The patient's identity should be matched with the patient identifiers on the infusion bag.
- Central venous access is recommended for administration of these two Kite cellular therapy products.
- Kite cellular therapy products should be administered as an intravenous infusion using latex-free intravenous tubing without a leukodepleting filter within 30 minutes by either gravity or a peristaltic pump.
- Gently agitate the product bag during Yescarta or Tecartus infusion to prevent cell clumping. All contents of the product infusion bag should be infused.
- Sterile sodium chloride 9 mg/mL (0.9%) (0.154 mmol sodium per mL) solution for injection should be used to prime the tubing prior to infusion as well as rinse it afterwards. When the full volume of Kite cellular therapy product has been infused, the infusion bag should be rinsed with 10 to 30 mL sodium chloride 9 mg/mL (0.9%) solution for injection by back priming to ensure as many cells as possible are infused into the patient.

SECTION 2: SAMPLING RECOMMENDATION FOR SECONDARY MALIGNANCIES

The Summary of Product Characteristics recommends centers to contact the company if a secondary malignancy is diagnosed.

All secondary tumors, including solid and new hematologic malignancies, for which insertional mutagenesis is suspected should undergo thorough investigation.

The Marketing Authorisation Holder Kite Pharma EU B.V. will direct centers to collect samples for testing of peripheral blood or tumor tissue. Recognizing the complex technology and methodologies associated with these assays, upon occurrence of a secondary malignancy, the company will instruct the center in accordance with the most up to date approaches for testing and the appropriate sampling methodology.

At the current state of technology, peripheral blood is the appropriate sample type for monitoring potential replication competent retrovirus (RCR) related to secondary malignancy, solid or haematologic, and for assay of vector sequences. In addition, a core needle biopsy will be the appropriate sample type for monitoring of theoretical risk of insertional mutagenesis in T cell lymphoma.