GILEAD | Kite

YESCARTA® (axicabtagene ciloleucel) Suspension for IV infusion

TECARTUS® (brexucabtagene autoleucel) suspension for infusion

Guide to Handling and Administration

Important Safety Information

Version 2.0 12 September 2023

Guide to Handling and Administration

This educational material is essential to ensure the proper handling of the product and the safe administration.
It is advised to read this guide carefully before prescribing/dispensing/administering the product.
Yescarta (axicabtagene ciloleucel) and Tecartus (brexucabtagene autoleucel) are solely intended for autologous use via intravenous infusion.
Yescarta and Tecartus must not be irradiated as could lead to inactivation of the product.

Do NOT use a leukodepleting filter.

Precautions to take before handling or administering Yescarta and Tecartus

Yescarta and **Tecartus** are prepared from autologous blood of the patient collected by leukapheresis. Patient leukapheresis material, Yescarta and Tecartus may carry a risk of transmitting infectious viruses to healthcare professionals (HCP) handling the product. Accordingly, HCP handling leukapheresis material, Yescarta or Tecartus should take appropriate precautions (wearing gloves and eye protection) to avoid potential transmission of infectious diseases.

Yescarta and Tecartus 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 Yescarta or Tecartus (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

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How to check Yescarta and 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 Konnect).
- Place the infusion bag inside a second sterile bag per local guidelines.

How to thaw Yescarta and Tecartus

- Thaw Yescarta and Tecartus at approximately 37°C using either a water bath or using 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 re suspend Yescarta or Tecartus in new media prior to infusion. Thawing should take approximately 3 to 5 minutes.
- Once thawed, Yescarta and Tecartus is stable at room temperature (20°C - 25°C) for up to 3 hours.
  However, Yescarta and Tecartus infusion should begin within 30 minutes of thaw completion and the total Yescarta or Tecartus infusion time should not exceed 30 minutes.

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 f hematological malignancies and trained for administration and management of patient treated with Yescarta or Tecartus.
- 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 the administration of Yescarta or Tecartus.
- Yescarta and Tecartus 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 infusion bags 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 Yescarta or Tecartus have 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.

Reporting Of Adverse Reactions:

Reporting suspected adverse reactions after authorization of the medicinal product is important.
It allows continued monitoring of the benefit-risk balance of the medicinal product.

HCPs are asked to report any suspected adverse reactions associated with axicabtagene ciloleucel or brexucabtagene autoleucel to Gilead or the competent authorities directly.

Please contact the National Pharmacovigilance Center (NPC) – Saudi Food and Drug Authority (SFDA) call center 19999, e-mail: npc.drug@sfda.gov.sa, or website: https://ade.sfda.gov.sa/
Or contact the Gilead patient safety department e-mail: DrugSafety.KSA@Gilead.com

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