YESCARTA®
(axicabtagene ciloleucel) Suspension for IV infusion

Guide to handling and administration

YESCARTA® is solely intended for autologous use via intravenous infusion.

YESCARTA® 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®

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

YESCARTA® contains 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® (solid and liquid waste) should be handled and disposed of in accordance with local guidelines on handling of biological waste.

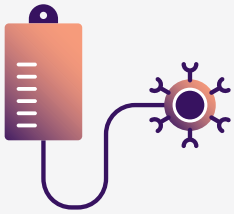
YESCARTA® should be transported within the facility in closed, break-proof, leak-proof containers.

HOW TO CHECK YESCARTA® PRIOR TO ADMINISTRATION

- Verify that the patient's identity (ID) matches the patient identifiers on the YESCARTA® 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® 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®

1. Thaw YESCARTA® 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.
2. 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.
3. Small clumps of cellular material should disperse with gentle manual mixing. You should not wash, spin down, and/or re-suspend YESCARTA® in new media prior to infusion. Thawing should take approximately 3 to 5 minutes.
4. Once thawed, YESCARTA® is stable at room temperature (20°C – 25°C) for up to 3 hours. However, YESCARTA® infusion should begin within 30 minutes of thaw completion and the total YESCARTA® infusion time should not exceed 30 minutes.



HOW TO ADMINISTER YESCARTA®

- YESCARTA® 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 patient treated with YESCARTA®.
- Ensure that a minimum of two doses of tocilizumab are available for each patient for infusion within 2 hours after YESCARTA® infusion, if required for the treatment of CRS.
- A leukodepleting filter must not be used. YESCARTA® is 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®.
- YESCARTA® 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® 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 a rinse afterwards. When the full volume of YESCARTA® 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.

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SG-YES-0019. Date of Preparation: March 2023. This document has been approved by HSA as of 01-03-2023.