YESCARTA®
(axicabtagene ciloleucel) Dispersion for infusion

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

APPROVED BY THE MINISTRY OF HEALTH ON MAY 2021
HGUIDE : KITE YES IL HGUIDE: V1 12-11-2020

SECTION I: GUIDE TO HANDLING AND METHOD OF 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 providers (HCPs) handling the product. Accordingly, HCPs handling leukapheresis material or YESCARTA should 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 patient ID is confirmed, remove the YESCARTA product bag from the cassette.
- Check that the patient information on the cassette label matches the patient information on bag.
- Inspect the bag for any breaches of container integrity before thawing. If the bag is compromised, the local guidelines should be followed (or immediately contact Kite Konnect).
- Place the infusion bag inside a second sterile bag per local guidelines.

HOW TO THAW YESCARTA

- 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.
- 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 suspended YESCARTA in new media prior to infusion. Thawing should take approximately 3 to 5 minutes.
- 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 time and 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 patients treated with YESCARTA.
- A minimum of four doses of tocilizumab for each patient and emergency equipment for use in the event of cytokine release syndrome (CRS) must be available prior to infusion and during the monitoring period.
- 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 product 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 to rinse it 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.

SECTION 2: SAMPLING RECOMMENDATIONS FOR SECONDARY MALIGNANCIES

The Prescribing Information 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 Authorization Holder Gilead Sciences Israel Ltd will direct the 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.

To report an adverse reaction associated with YESCARTA, please contact the Ministry of Health using the link http://sideeffects.health.gov.il or through the registration holder: DrugSafety.Israel@gilead.com

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PRESCRIBING INFORMATION

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

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