Prescribing Information and Medication Guide

Risk Evaluation and Mitigation Strategy (REMS)

What Is the YESCARTA® REMS Program?

A REMS (Risk Evaluation and Mitigation Strategy) is a program required by the United States (US) Food and Drug Administration (FDA). The FDA has determined that a REMS is necessary to ensure that the benefits of YESCARTA® outweigh the risks of cytokine release and neurologic toxicities. YESCARTA® is available only through the YESCARTA® REMS Program.

Boxed Warning

Cytokine Release Syndrome

- Cytokine release syndrome (CRS), including fatal or life-threatening reactions, occurred following treatment with YESCARTA®
- CRS occurred in 94% (101/108) of patients receiving YESCARTA® including Grade 3 or higher CRS in 13% (114/108) of patients
- Among patients who died after receiving YESCARTA®, 4 had ongoing CRS events at the time of death
- The median time to onset was 2 days (range: 1-12 days), and the median duration of CRS was 7 days (range: 2-58 days)
- Key manifestations of CRS include fever (78%), hypotension (41%), tachycardia (28%), hypoxia (22%), and chills (20%)
- Serious events that may be associated with CRS include cardiac arrhythmias (including atrial fibrillation and ventricular tachycardia), cardiac arrest, cardiac failure, renal insufficiency, capillary leak syndrome, hypotension, hypoxia, and hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS)
Neurologic Toxicities

- Neurologic toxicities that were fatal or life-threatening, occurred following treatment with YESCARTA®
- The median time to onset was 4 days (range: 1-43 days) following YESCARTA® infusion
- Neurologic toxicities occurred in 87% of patients with a median duration of 17 days
- 98% of all neurologic toxicities occurred within the first 8 weeks of YESCARTA® infusion
- Grade 3 or higher neurologic toxicities occurred in 31% of patients
- The most common neurologic toxicities included encephalopathy (157%), headache (44%), tremor (31%), dizziness (21%), aphasia (18%), delirium (17%), insomnia (9%), and anxiety (9%)
- Prolonged encephalopathy lasting up to 173 days was noted
- Serious events including leukoencephalopathy and seizures occurred with YESCARTA®
- Fatal and serious cases of cerebral edema have occurred in patients treated with YESCARTA®

YESCARTA® REMS Program Requirements

Hospitals and their associated clinics must be enrolled in the YESCARTA® REMS Program to be able to dispense YESCARTA®.

All relevant staff involved in the prescribing, dispensing, or administering of YESCARTA® are trained on the YESCARTA® REMS Program requirements, and must successfully complete a YESCARTA® REMS Program Knowledge Assessment.

Hospital Enrollment Instructions

An authorized representative must enroll on behalf of the hospital and its associated clinics. To be enrolled in the YESCARTA® REMS Program, the representative must:

1. Complete the training program, which includes review of:
   - YESCARTA® full Prescribing Information
   - YESCARTA® REMS Program Live Training
   - YESCARTA® Adverse Reaction Management Guide
2. Successfully complete the YESCARTA® REMS Program Knowledge Assessment.
3. Complete the YESCARTA® REMS Program Hospital Enrollment Form.
4. Oversee implementation and compliance with YESCARTA® REMS Program requirements:
   - Ensure that all relevant staff involved in the prescribing, dispensing, or administering of YESCARTA® are trained on the REMS Program requirements and successfully complete the YESCARTA® REMS Program Knowledge Assessment. The authorized representative will determine relevant staff who require training
   - Maintain training records of staff
   - Ensure that the hospital and its associated clinics have a minimum of 2 doses of tocilizumab available on-site for each patient and are ready for immediate administration (within 2 hours)
   - Prior to patient discharge, provide patients/caregivers with the Patient Wallet Card and instruct patient to remain within close proximity (within 2 hours) of the certified administering hospital and its associated clinics for at least 4 weeks following YESCARTA® infusion
   - Put processes and procedures in place to ensure that relevant new staff are trained and relevant staff are retrained if YESCARTA® has not been dispensed at least once annually from the date of certification in the YESCARTA® REMS Program

Indication

YESCARTA® is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.

Limitation of Use: YESCARTA® is not indicated for the treatment of patients with primary central nervous system lymphoma.

Where to Find YESCARTA® REMS Program Information and Resources

For more information about the YESCARTA® REMS Program, see the Program Resources or call 1-844-454-KITE.
Reporting Adverse Reactions

You are encouraged to report suspected serious adverse events associated with YESCARTA® by contacting Kite at 1-844-454-KITE (1-844-454-5483) or the FDA at www.fda.gov/medwatch or 1-800-FDA-1088.
**YE CSCAR T A® Patient Wallet Card**

All patients treated with YE CSCAR T A® receive a Patient Wallet Card listing adverse reactions and other information. Patients should show the card to any healthcare professional who treats them, including in the emergency room. Non–English-speaking patients are given Patient Wallet Cards in both English and their native language. They should carry both versions of the card with them at all times.

- Arabic
- Korean
- Chinese
- Polish
- English
- Portuguese
- French
- Russian
- German
- Spanish
- Japanese
Need Help?
If you have questions about the YESCARTA® REMS Program or need help registering, call 1-844-454-KITE, Monday through Friday.

LEFT HAND CORNER:

Resources for Healthcare Professionals

Download All Resources

YESCARTA® Prescribing Information and Medication Guide
YESCARTA® REMS Program Knowledge Assessment
YESCARTA® REMS Program Live Training
YESCARTA® REMS Program Registration Hospital Enrollment Form
YESCARTA® Adverse Reaction Management Guide

Patient Resources

YESCARTA® Patient Wallet Card

YESCARTA® Prescribing Information and Medication Guide

Adobe Reader is required to view PDFs. If you do not have it installed, download it here.

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