

YESCARTA Full Prescribing Information and Medication Guide
TECARTUS Full Prescribing Information and Medication Guide

Risk Evaluation and Mitigation Strategy (REMS)

This website is intended for US healthcare professionals only.

What Is the YESCARTA and TECARTUS REMS Program?

A REMS 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 and TECARTUS outweigh the risks of cytokine release syndrome and neurologic toxicities. YESCARTA and TECARTUS are available only through the YESCARTA and TECARTUS REMS Program.

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Boxed Warning for YESCARTA

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 (57%), 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

Boxed Warning for TECARTUS

Cytokine Release Syndrome

- Cytokine release syndrome (CRS), including life-threatening reactions, occurred following treatment with TECARTUS
- CRS occurred in 91% (75/82) of patients receiving TECARTUS including Grade 3 or higher CRS in 18% of patients
- The median time to onset was 3 days (range: 1-13 days), and the median duration of CRS was 10 days (range: 1-50 days)
- Key manifestations of CRS included fever (99%), hypotension (60%), hypoxia (37%), chills (33%), tachycardia (37%), headache (24%), fatigue (19%), nausea (13%), alanine aminotransferase increased (13%), aspartate aminotransferase increased (12%), and diarrhea (11%)

Serious events associated with CRS included hypotension, fever, hypoxia, acute kidney injury, and tachycardia

Neurologic Toxicities

- Neurologic events, including those that were life-threatening, occurred following treatment with TECARTUS
- The median time to onset was 6 days (range: 1-32 days) following TECARTUS infusion
- Neurologic events occurred in 81% of patients, 37% of whom experienced Grade 3 or higher (severe or life threatening) adverse reactions
- Neurologic events resolved for 52 out of 66 patients with a median duration of 21 days (range: 2 to 454 days). Three patients had ongoing neurologic events at the time of death, including one patient with serious encephalopathy. The remaining unresolved neurologic events were either Grade 1 or Grade 2
- Eighty-five percent of all treated patients experienced the first CRS or neurological event within the first 7 days after TECARTUS infusion
- The most common neurologic toxicities included encephalopathy (51%), headache (35%), tremor (38%), aphasia (23%), and delirium (16%)
- Serious events including encephalopathy, aphasia, and seizures occurred after treatment with TECARTUS

YESCARTA and TECARTUS REMS Program Requirements

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

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

Hospital Enrollment Instructions

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

1. Complete the training program, which includes review of:
 - YESCARTA and TECARTUS full Prescribing Information
 - YESCARTA and TECARTUS REMS Program Training
 - YESCARTA and TECARTUS Adverse Reaction Management Guide
2. Successfully complete the YESCARTA and TECARTUS REMS Program Knowledge Assessment.
3. Complete the YESCARTA and TECARTUS REMS Program Hospital Enrollment Form.
4. Oversee implementation and compliance with the YESCARTA and TECARTUS REMS Program requirements:
 - Ensure that all relevant staff involved in the prescribing, dispensing, or administering of YESCARTA and/or TECARTUS are trained on the REMS Program requirements and successfully complete the YESCARTA and TECARTUS 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 or TECARTUS infusion
 - Put processes and procedures in place to ensure that relevant new staff are trained, and relevant staff are retrained if YESCARTA or TECARTUS has not been dispensed at least once annually from the date of certification in the YESCARTA and TECARTUS 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.

Indication

TECARTUS is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).

Where to Find YESCARTA and TECARTUS REMS Program Information and Resources

For more information about the YESCARTA and TECARTUS REMS Program, see the Program Resources or call 1-844-454-KITE (5483).

Reporting Adverse Reactions

You are encouraged to report suspected serious adverse events associated with YESCARTA or TECARTUS by contacting Kite at 1-844-454-KITE or medinfo@kitepharma.com or the FDA at www.fda.gov/medwatch or 1-800-FDA-1088.

Need Help?

If you have questions about the YESCARTA and TECARTUS REMS Program or need help registering, call 1-844-454-KITE.

LEFT HAND CORNER:

Resources for Healthcare Professionals

Download All Resources

YESCARTA and TECARTUS REMS Program Knowledge Assessment

YESCARTA and TECARTUS REMS Program Training

YESCARTA and TECARTUS REMS Program Hospital Enrollment Form

YESCARTA and TECARTUS Adverse Reaction Management Guide

YESCARTA and TECARTUS REMS Training

Log in to the YESCARTA and TECARTUS REMS Gilead Learning Management System here:

<https://gsir.gilead.com>

[When the end user clicks on this hyperlink, an intermediary page loads which states: Contact your institution's Authorized Representative for REMS Training. You are now leaving www.YescartaTecartusREMS.com. Select CANCEL to return or OK to continue.]

Resources for Patients

All patients treated with YESCARTA or TECARTUS receive a Patient Wallet Card listing adverse reactions and other information. Patients should carry the card with them at all times and show it to any healthcare professional who treats them, including in the emergency room.

YESCARTA and TECARTUS REMS Patient Wallet Card

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

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