YESCARTA® (axicabtagene ciloleucel) Suspension for IV infusion | TECARTUS® (brexucabtagene autoleucel) Suspension for IV infusion

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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YESCARTA Prescribing Information and Medication Guide

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 with large B-cell lymphoma (LBCL) in ZUMA-1, including ≥ Grade 3 CRS in 13%
- CRS occurred in 84% (123/146) of patients with indolent non-Hodgkin lymphoma (iNHL) in ZUMA-5, including ≥ Grade 3 CRS in 8% (11/146) of patients with iNHL
- The median time to onset of CRS was 2 days (range: 1-12 days) for patients with LBCL and 4 days (range: 1-20 days) for patients with iNHL
- The median duration of CRS was 7 days (range: 2-58 days) for patients with LBCL and 6 days (range: 1-27 days) for patients with iNHL
- Among patients who died after receiving YESCARTA, 4 patients with LBCL and 1 patient with iNHL had ongoing CRS events at the time of death
- Key manifestations of CRS (≥10%) in all patients combined include fever (80%), hypotension (38%), tachycardia (29%), hypoxia (21%), chills (21%), and headache (13%)
- 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, multi-organ failure, and hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS)

Neurologic Toxicities

- Neurologic toxicities that were fatal or life-threatening occurred following treatment with YESCARTA
- Neurologic toxicities occurred in 87% (94/108) of patients with LBCL, including ≥ Grade 3 cases in 31%
- Neurologic toxicities occurred in 77% (112/146) of patients with iNHL, including ≥ Grade 3 in 21%
- Neurologic toxicities occurred within the first 7 days of YESCARTA infusion for 89% of affected patients with LBCL and 74% of affected patients with iNHL
- The median time to onset was 4 days (range: 1-43 days) for patients with LBCL and 6 days (range: 1-79 days) for patients with iNHL
- The median duration was 17 days in patients with LBCL and 16 days in patients with iNHL
- The most common neurologic toxicities (≥10%) in all patients combined included encephalopathy (53%), headache (45%), tremor (31%), dizziness (20%), delirium (16%), aphasia (15%), and insomnia (11%)
- 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 AND TECARTUS REMS PROGRAM REQUIREMENTS

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   - YESCARTA and TECARTUS Adverse Reaction Management Guide
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   - 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 their 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.

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- Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Resources for Healthcare Professionals

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YESCARTA and TECARTUS REMS Patient Wallet Card

Chinese English Spanish

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

Hospitals and their associated clinics must report any serious adverse event* suggestive of CRS or neurologic toxicities to Kite at 1-844-454-KITE (5483) or medinfo@kitepharma.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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TECARTUS Prescribing Information and Medication Guide

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
- Among the patients who died after receiving TECARTUS, one had a fatal CRS event
- 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 (79%) 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

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   - 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 their 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

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). This indication is approved under accelerated approval based on overall response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Resources for Healthcare Professionals

Download All Resources

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YESCARTA and TECARTUS REMS Program Training

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Resources for Patients

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YESCARTA and TECARTUS REMS Patient Wallet Card

Chinese English Spanish

Where to Find YESCARTA and TECARTUS REMS Program Information and Resources

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Reporting Adverse Reactions

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Contact your institution's Authorized Representative for REMS Training.

You are now leaving YescartaTecartusREMS.com. Select CANCEL to return or OK to continue.

Cancel OK

YESCARTA® (axicabtagene ciloleucel)

YESCARTA Prescribing [illegible]

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 with large B-cell lymphoma (LBCL) in ZUMA-1, including ≥ Grade 3 CRS in 13%
- CRS occurred in 84% (123/146) of patients with indolent non-Hodgkin lymphoma (iNHL) in ZUMA-5, including ≥ Grade 3 CRS in 8% (11/146) of patients with iNHL
- The median time to onset of CRS was 2 days (range: 1-12 days) for patients with LBCL and 4 days (range: 1-20 days) for patients with iNHL
- The median duration of CRS was 7 days (range: 2-58 days) for patients with LBCL and 6 days (range: 1-27 days) for patients with iNHL
- Among patients who died after receiving YESCARTA, 4 patients with LBCL and 1 patient with iNHL had ongoing CRS events at the time of death
- Key manifestations of CRS (≥10%) in all patients combined include fever (80%), hypotension (38%), tachycardia (29%), hypoxia (21%), chills (21%), and headache (13%)
- 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, multi-organ failure, and hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS)

Neurologic Toxicities

- Neurologic toxicities that were fatal or life-threatening occurred following treatment with YESCARTA
- Neurologic toxicities occurred in 87% (94/108) of patients with LBCL, including ≥ Grade 3 cases in 31%
- Neurologic toxicities occurred in 77% (112/146) of patients with iNHL, including ≥ Grade 3 in 21%
- Neurologic toxicities occurred within the first 7 days of YESCARTA infusion for 89% of affected patients with LBCL and 74% of affected patients with iNHL
- The median time to onset was 4 days (range: 1-43 days) for patients with LBCL and 6 days (range: 1-79 days) for patients with iNHL
- The median duration was 17 days in patients with LBCL and 16 days in patients with iNHL
- The most common neurologic toxicities (≥10%) in all patients combined included encephalopathy (53%), headache (45%), tremor (31%), dizziness (20%), delirium (16%), aphasia (15%), and insomnia (11%)
- 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 AND TECARTUS REMS PROGRAM REQUIREMENTS

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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.

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- Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

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- [illegible]ad All [illegible]es
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YESCARTA and TECARTUS REMS Patient Wallet Card

Chinese English Spanish

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YESCARTA Full Prescribing Information and Medication Guide

TECARTUS Full Prescribing Information and Medication Guide

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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.
- Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy. This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Resources for Healthcare Professionals

Download All Resources

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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://lms.gilead.com

Resources for Patients

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YESCARTA and TECARTUS REMS Patient Wallet Card

Chinese English Spanish

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

Hospitals and their associated clinics must report any serious adverse event* suggestive of CRS or neurologic toxicities to Kite at 1-844-454-KITE (5483) or medinfo@kitepharma.com or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Healthcare providers are also encouraged to report any suspected serious adverse events* associated with YESCARTA or TECARTUS as outlined above.

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YESCARTA (axicabtagene ciloleucel) | TECARTUS (brexucabtagene autoleucel)

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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.

YESCARTA (axicabtagene ciloleucel) | TECARTUS (brexucabtagene autoleucel)

TECARTUS Prescribing Information and Medication Guide

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
- Among the patients who died after receiving TECARTUS, one had a fatal CRS event
- 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 (79%) 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 their 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

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). This indication is approved under accelerated approval based on overall response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

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YESCARTA and TECARTUS REMS Patient Wallet Card

Chinese English Spanish

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YESCARTA Prescribing Information and

Contact your Institution's Authorized Representative for REMS Training.

You are now leaving YescartaTecartusREMS.com. Select CANCEL to return or OK to continue.

Cancel | OK

- YESCARTA in 84% (123/146) of patients with indolent non-Hodgkin lymphoma (iNHL) in ZUMA-5, including 2 Grade 3 CRS in 8% (11/146) of patients with iNHL
- The median time to onset of CRS was 2 days (range: 1-12 days) for patients with LBCL and 4 days (range: 1-20 days) for patients with iNHL
- The median duration of CRS was 7 days (range: 2-58 days) for patients with LBCL and 6 days (range: 1-27 days) for patients with iNHL
- Among patients who died after receiving YESCARTA, 4 patients with LBCL and 1 patient with iNHL had ongoing CRS events at the time of death
- Key manifestations of CRS (≥10%) in all patients combined include fever (80%), hypotension (38%), tachycardia (29%), hypoxia (21%), chills (21%), and headache (13%)
- 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, multi-organ failure, and hemophagocytic lymphohistiocytic/macrophage activation syndrome (HLH/MAS)

Neurologic Toxicities

- Neurologic toxicities that were fatal or life-threatening occurred following treatment with YESCARTA
- Neurologic toxicities occurred in 87% (94/108) of patients with LBCL, including 2 Grade 3 cases in 3%
- Neurologic toxicities occurred in 77% (112/146) of patients with iNHL, including 2 Grade 3 in 2%
- Neurologic toxicities occurred within the first 7 days of YESCARTA infusion for 89% of affected patients with LBCL and 74% of affected patients with iNHL
- The median time to onset was 4 days (range: 1-43 days) for patients with LBCL and 6 days (range: 1-79 days) for patients with iNHL
- The median duration was 17 days in patients with LBCL and 16 days in patients with iNHL
- The most common neurological toxicities (≥10%) in all patients combined included encephalopathy (53%), headache (45%), tremor (31%), dizziness (20%), delirium (16%), aphasia (15%), and insomnia (11%)
- 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 AND TECARTUS REMS PROGRAM REQUIREMENTS

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YESCARTA and TECARTUS REMS Patient Wallet Card

Chinese | English | Spanish

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