# Yescarta® (axicabtagene ciloleucel) Post-Infusion Monitoring

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**The full indication, important safety information, and boxed warnings for cytokine release syndrome, neurologic toxicities and secondary hematological malignancies are available at: https://www.gilead.com/-/media/files/pdfs/medicines/oncology/yescarta/yescarta-pi.**

## Summary


Boxed Warning, and YESCARTA and TECARTUS REMS[1,2]

Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving YESCARTA. Do not administer YESCARTA to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.

Neurologic toxicities, including fatal or life-threatening reactions, occurred in patients receiving YESCARTA, including concurrently with CRS or after CRS resolution. Monitor for neurologic toxicities after treatment with YESCARTA. Provide supportive care and/or corticosteroids, as needed.

T cell malignancies have occurred following treatment of hematologic malignancies with BCMA- and CD19-directed genetically modified autologous T cell immunotherapies, including YESCARTA.

Because of the risk of CRS and neurologic toxicities, YESCARTA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS.

Monitoring of CRS and Neurologic Toxicities[1]

Following administration of YESCARTA at a certified healthcare facility, monitor patients at least daily for 7 days at the certified healthcare facility following infusion for signs and symptoms of CRS and neurologic toxicities. Instruct patient to remain within proximity of a certified healthcare facility for at least 4 weeks following infusion.

Data from Real-World Studies[3,4]

In a multicenter, retrospective real-world analysis in 475 patients who received CAR T-cell therapies (YESCARTA, n=216), the median time to onset of CRS was 3 days and the median time to resolution was 5 days. The median time to onset of immune effector cell-associated neurotoxicity syndrome (ICANS) was 5 days and the median time to resolution

was 6 days. There were no new-onset cases of CRS or ICANS beyond 14 days following infusion in YESCARTA-treated patients.

Additionally, in a retrospective analysis of real-world outcomes following CAR T-cell therapy in 256 patients who received B-cell maturation antigen (BCMA) and CD19 CAR T-cell therapies (YESCARTA, n=91), median onset of CRS and ICANS in YESCARTA-treated patients was 2 and 6 days post-infusion, respectively. Results showed a low incidence of CRS and ICANS beyond 14 days following infusion.

# Post-Infusion Monitoring

## CRS, Neurologic Toxicities, and REMS Program

### Cytokine Release Syndrome[1]

#### *CRS Incidence, Onset, and Duration*

CRS, including fatal or life-threatening reactions, occurred following treatment with YESCARTA. CRS occurred in 90% (379/422) of patients with non-Hodgkin lymphoma (NHL) receiving YESCARTA, including ≥ Grade 3 (Lee grading system[5]) CRS in 9%. CRS occurred in 93% (256/276) of patients with large B-cell lymphoma (LBCL), including ≥ Grade 3 CRS in 9%. Among patients with LBCL who died after receiving YESCARTA, four had ongoing CRS events at the time of death. For patients with LBCL in ZUMA-1, the median time to onset of CRS was 2 days following infusion (range: 1 to 12 days) and the median duration of CRS was 7 days (range: 2 to 58 days). For patients with LBCL in ZUMA-7, the median time to onset of CRS was 3 days following infusion (range: 1 to 10 days) and the median duration was 7 days (range: 2 to 43 days).

CRS occurred in 84% (123/146) of patients with indolent non-Hodgkin lymphoma (iNHL) in ZUMA-5, including ≥ Grade 3 CRS in 8%. Among patients with iNHL who died after receiving YESCARTA, one patient had an ongoing CRS event at the time of death. The median time to onset of CRS was 4 days (range: 1 to 20 days) and the median duration was 6 days (range: 1 to 27 days) for patients with iNHL.

#### *Key Manifestations of CRS*

Key manifestations of CRS (≥10%) in all patients combined included fever (85%), hypotension (40%), tachycardia (32%), chills (22%), hypoxia (20%), headache (15%), and fatigue (12%). Serious events that may be associated with CRS include, cardiac arrhythmias (including atrial fibrillation and ventricular tachycardia), renal insufficiency, cardiac failure, respiratory failure, cardiac arrest, capillary leak syndrome, multi-organ failure, and hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS).

#### *Impact of Tocilizumab and/or Corticosteroids*

The impact of tocilizumab and/or corticosteroids on the incidence and severity of CRS was assessed in two subsequent cohorts of LBCL patients in ZUMA-1. Among patients who received tocilizumab and/or corticosteroids for ongoing Grade 1 events, CRS occurred in

93% (38/41), including 2% (1/41) with Grade 3 CRS; no patients experienced a Grade 4 or 5 event. The median time to onset of CRS was 2 days (range: 1 to 8 days) and the median duration of CRS was 7 days (range: 2 to 16 days).

Prophylactic treatment with corticosteroids was administered to a cohort of 39 patients for 3 days beginning on the day of infusion of YESCARTA. Thirty-one of the 39 patients (79%) developed CRS at which point the patients were managed with tocilizumab and/or therapeutic doses of corticosteroids with no patients developing Grade 3 or higher CRS. The median time to onset of CRS was 5 days (range: 1 to 15 days) and the median duration of CRS was 4 days (range: 1 to 10 days). Although there is no known mechanistic explanation, consider the risk and benefits of prophylactic corticosteroids in the context of pre-existing comorbidities for the individual patient and the potential for the risk of Grade 4 and prolonged neurologic toxicities.

### *Monitoring Recommendations for CRS*

Ensure that 2 doses of tocilizumab are available prior to infusion of YESCARTA. Monitor patients at least daily for 7 days at the certified healthcare facility following infusion for signs and symptoms of CRS. Monitor patients for signs or symptoms of CRS for 4 weeks after infusion. Counsel patients to seek immediate medical attention should signs or symptoms of CRS occur at any time. At the first sign of CRS, institute treatment with supportive care, tocilizumab, or tocilizumab and corticosteroids as indicated.

## Neurologic Toxicities[1]

### *Incidence, Onset, and Duration of Neurologic Toxicities*

Neurologic toxicities (including ICANS) that were fatal or life-threatening occurred following treatment with YESCARTA. Neurologic toxicities occurred in 78% (330/422) of patients with NHL receiving YESCARTA, including ≥ Grade 3 cases in 25%.

Neurologic toxicities occurred in 87% (94/108) of patients with LBCL in ZUMA-1, including ≥ Grade 3 cases in 31% and in 74% (124/168) of patients in ZUMA-7 including ≥ Grade 3 cases in 25%. The median time to onset was 4 days (range: 1 to 43 days) and the median duration was 17 days in patients with LBCL in ZUMA-1. The median time to onset for neurologic toxicity was 5 days (range:1 to 133 days) and median duration was 15 days in patients with LBCL in ZUMA-7. Neurologic toxicities occurred in 77% (112/146) of patients with iNHL, including ≥ Grade 3 in 21%. The median time to onset was 6 days (range: 1 to 79 days) and the median duration was 16 days. Ninety-eight percent of all neurologic toxicities in patients with LBCL and 99% of all neurologic toxicities in patients with iNHL occurred within the first 8 weeks of YESCARTA infusion. Neurologic toxicities occurred within the first 7 days of YESCARTA infusion in 87% of affected patients with LBCL and 74% of affected patients with iNHL.

### *Key Manifestations of Neurologic Toxicities*

The most common neurologic toxicities (≥10%) in all patients combined included encephalopathy (50%), headache (43%), tremor (29%), dizziness (21%), aphasia (17%), delirium (15%), and insomnia (10%). Prolonged encephalopathy lasting up to 173 days was noted. Serious events including aphasia, leukoencephalopathy, dysarthria, lethargy, and

seizures occurred with YESCARTA. Fatal and serious cases of cerebral edema and encephalopathy, including late-onset encephalopathy, have occurred in patients treated with YESCARTA.

### *Impact of Tocilizumab and/or Corticosteroids*

The impact of tocilizumab and/or corticosteroids on the incidence and severity of neurologic toxicities was assessed in two subsequent cohorts of LBCL patients in ZUMA-1. Among patients who received corticosteroids at the onset of Grade 1 toxicities, neurologic toxicities occurred in 78% (32/41) and 20% (8/41) had Grade 3 neurologic toxicities; no patients experienced a Grade 4 or 5 event. The median time to onset of neurologic toxicities was 6 days (range: 1 to 93 days) with a median duration of 8 days (range: 1 to 144 days). Prophylactic treatment with corticosteroids was administered to a cohort of 39 patients for 3 days beginning on the day of infusion of YESCARTA. Of these 39 patients, 85% (33/39) developed neurologic toxicities; 8% (3/39) developed Grade 3 and 5% (2/39) developed Grade 4 neurologic toxicities. The median time to onset of neurological toxicities was 6 days (range: 1 to 274 days) with a median duration of 12 days (range: 1 to 107 days). Prophylactic corticosteroids for management of CRS and neurologic toxicities may result in higher grade of neurologic toxicities or prolongation of neurologic toxicities, delay the onset and decrease the duration of CRS.

### *Monitoring Recommendations for Neurologic Toxicities*

Monitor patients at least daily for 7 days at the certified healthcare facility following infusion for signs and symptoms of neurologic toxicities. Monitor patients for signs or symptoms of neurologic toxicities for 4 weeks after infusion and treat promptly.

## YESCARTA and TECARTUS REMS[1,2]

Because of the risk of CRS and neurologic toxicities, YESCARTA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the YESCARTA and TECARTUS REMS. The required components of the YESCARTA and TECARTUS REMS are:

- Healthcare facilities that dispense and administer YESCARTA must be enrolled and comply with the REMS requirements. Certified healthcare facilities must have on-site, immediate access to tocilizumab, and ensure that a minimum of 2 doses of tocilizumab are available for each patient for infusion within 2 hours after YESCARTA infusion, if needed for treatment of CRS.

Further information is available at www.YescartaTecartusREMS.com or 1-844-454-KITE (5483).

# Monitoring and Management of CRS and Neurologic Toxicities

## Monitoring[1]

Following administration of YESCARTA at a certified healthcare facility, monitor patients at least daily for 7 days at the certified healthcare facility following infusion for signs and symptoms of CRS and neurologic toxicities. Instruct patient to remain within close proximity of a certified administering hospital for at least 4 weeks following infusion.

## Management of CRS[1]

Identify CRS based on clinical presentation. Evaluate for and treat other causes of fever, hypoxia, and hypotension. If CRS is suspected, manage according to the recommendations in Table 1. Patients who experience Grade 2 or higher CRS (e.g., hypotension not responsive to fluids, or hypoxia requiring supplemental oxygenation) should be monitored with continuous cardiac telemetry and pulse oximetry. For patients experiencing severe CRS, consider performing an echocardiogram to assess cardiac function. For severe or life-threatening CRS, consider intensive-care supportive therapy.

**Table 1. CRS Grading and Management Guidance[1]**

| CRS Grade[a] | Tocilizumab | Corticosteroids |
|---|---|---|
| **Grade 1**<br><br>Symptoms require symptomatic treatment only (e.g., fever, nausea, fatigue, headache, myalgia, malaise). | If symptoms (e.g., fever) not improving after 24 hours, consider managing as Grade 2. | If not improving after 3 days, administer one dose of dexamethasone 10 mg intravenously. |
| **Grade 2**<br><br>Symptoms require and respond to moderate intervention.<br><br>Oxygen requirement less than 40% FiO2 or hypotension responsive to fluids or low-dose of one vasopressor or Grade 2 organ toxicity.[b] | Administer tocilizumab[c] 8 mg/kg intravenously over 1 hour (not to exceed 800 mg).<br><br>If no clinical improvement in the signs and symptoms of CRS after the first dose, repeat tocilizumab every 8 hours as needed.<br><br>Limit to a maximum of 3 doses in a 24-hour period; maximum total of 4 doses.<br><br>If improving, discontinue tocilizumab. | Administer dexamethasone 10 mg intravenously once daily.<br><br>If improving, manage as Grade 1 above and continue corticosteroids until the severity is Grade 1 or less, then quickly taper as clinically appropriate.<br><br>If not improving, manage as appropriate grade below. |
| **Grade 3** | Per Grade 2.<br><br>If improving, manage as appropriate grade above. | Dexamethasone 10 mg intravenously three times a day. |

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| Symptoms require and respond to aggressive intervention.<br><br>Oxygen requirement greater than or equal to 40% $FiO_2$ or hypotension requiring high-dose or multiple vasopressors or Grade 3 organ toxicity or Grade 4 transaminitis. | | If improving, manage as appropriate grade above and continue corticosteroids until the severity is Grade 1 or less, then quickly taper as clinically appropriate.<br><br>If not improving, manage as Grade 4. |
| **Grade 4**<br><br>Life-threatening symptoms.<br><br>Requirements for ventilator support, CVVHD or Grade 4 organ toxicity (excluding transaminitis). | Per Grade 2.<br><br>If improving, manage as appropriate grade above. | Administer methylprednisolone 1000 mg intravenously once per day for 3 days.<br><br>If improving, manage as appropriate grade above and continue corticosteroids until the severity is Grade 1 or less, then taper as clinically appropriate.<br><br>If not improving, consider methylprednisolone 1000 mg 2-3 times a day or alternate therapy.[d] |

[a]Lee et al. 2014.[5]
[b]Refer to Table 2 for management of neurologic toxicity.
[c]Refer to tocilizumab Prescribing Information for details.
[d]Alternate therapy includes (but is not limited to): anakinra, siltuximab, ruxolitinib, cyclophosphamide, IVIG and ATG.
ATG, anti-thymocyte globulin; CRS, Cytokine Release Syndrome; CVVHD, continuous veno-venous hemodialysis; FiO2, fraction of inspired oxygen; IVIG, intravenous immunoglobulin

## Management of Neurologic Toxicity[1]

Monitor patients for signs and symptoms of neurologic toxicity/ICANS (Table 2). Rule out other causes of neurologic symptoms. Patients who experience Grade 2 or higher neurologic toxicities/ICANS should be monitored with continuous cardiac telemetry and pulse oximetry. Provide intensive-care supportive therapy for severe or life-threatening neurologic toxicities. Consider levetiracetam for seizure prophylaxis for any grade of neurologic toxicities.

**Table 2. Neurologic Toxicity/ICANS Grading and Management Guidance[1]**

| CRS Grade[a] | Concurrent CRS | No Concurrent CRS |
|---|---|---|
| **Grade 1** | Administer tocilizumab per Table 1 for management of Grade 1 CRS. | Administer one dose of dexamethasone 10 mg intravenously. |

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| | In addition, administer one dose of dexamethasone 10 mg intravenously.<br><br>If not improving after 2 days, repeat dexamethasone 10 mg intravenously. | If not improving after 2 days, repeat dexamethasone 10 mg intravenously. |
| | Consider levetiracetam for seizure prophylaxis. | |
| **Grade 2** | Administer tocilizumab per Table 1 for management of Grade 2 CRS.<br><br>In addition, administer dexamethasone 10 mg intravenously four times a day.<br><br>If improving, continue corticosteroids until the severity is Grade 1 or less, then quickly taper as clinically appropriate.<br><br>If not improving, manage as appropriate grade below. | Administer dexamethasone 10 mg intravenously four times a day.<br><br>If improving, continue corticosteroids until the severity is Grade 1 or less, then quickly taper as clinically appropriate.<br><br>If not improving, manage as appropriate grade below. |
| | Consider levetiracetam for seizure prophylaxis. | |
| **Grade 3** | Administer tocilizumab per Table 1 for management of Grade 2 CRS.<br><br>In addition, administer methylprednisolone 1000 mg intravenously once daily.<br><br>If improving, manage as appropriate grade above and continue corticosteroids until the severity is Grade 1 or less, then taper as clinically appropriate.<br><br>If not improving, manage as Grade 4. | Administer methylprednisolone 1000 mg intravenously once daily.<br><br>If improving, manage as appropriate grade above and continue corticosteroids until the severity is Grade 1 or less, then taper as clinically appropriate.<br><br>If not improving, manage as Grade 4. |
| | Consider levetiracetam for seizure prophylaxis. | |
| **Grade 4** | Administer tocilizumab per Table 1 for management of Grade 2 CRS.<br><br>In addition, administer methylprednisolone 1000 mg intravenously twice per day.<br><br>If improving, manage as appropriate grade above and continue corticosteroids until the | Administer methylprednisolone 1000 mg intravenously twice per day.<br><br>If improving, manage as appropriate grade above and continue corticosteroids until the severity is Grade 1 or less, then taper as clinically appropriate. |

| | | |
|---|---|---|
| | severity is Grade 1 or less, then taper as clinically appropriate.<br><br>If not improving, consider 1000 mg of methylprednisolone intravenously 3 times a day or alternate therapy.[b] | If not improving, consider 1000 mg of methylprednisolone intravenously 3 times a day or alternate therapy.[b] |
| | Consider levetiracetam for seizure prophylaxis. | |

[a]Severity based on Common Terminology Criteria for Adverse Events.
[b]Alternate therapy includes (but is not limited to): anakinra, siltuximab, ruxolitinib, cyclophosphamide, IVIG and ATG.
ADLs, activities of daily living; CRS, Cytokine Release Syndrome

# Real-World Studies

## A Cell Therapy Consortium Study; *Wesson et al.*[3]

A multicenter, retrospective real-world analysis evaluated outcomes, including the timing of CRS and ICANS, in 475 patients from the Cell Therapy Consortium registry in the US who received CAR T-cell therapy between April 2016 and May 2023. Patients who received YESCARTA (n=216) were followed for a median (IQR) of 13 (5–21) months.

In the YESCARTA group, CRS and ICANS were reported in 163 (75%) and 88 (41%) patients during Days 0–7 following infusion, and 8 and 24 patients during Days 8–14 following infusion, respectively. There were no new-onset cases of CRS or ICANS beyond 14 days following infusion in the YESCARTA group. Unresolved CRS and ICANS beyond 14 days were reported in 9% and 18% of YESCARTA patients, respectively. Unresolved CRS and ICANS beyond 28 days were reported in 1.4% and 4% of YESCARTA patients, respectively. Median onset and duration of CRS and ICANS in the YESCARTA group are summarized in Table 3.

**Table 3. CRS and ICANS Outcomes in YESCARTA Patients[3]**

| Characteristic | YESCARTA (n=216) |
|---|---|
| **CRS** | |
| Incidence, n (%) | 172 (80) |
| Median time to onset, days (IQR) | 3 (1–5) |
| Median time to resolution, days (IQR) | 5 (3–7) |
| Onset beyond Day 14, n (%) | 0 |
| **ICANS** | |
| Incidence, n (%) | 112 (53) |
| Median time to onset, days (IQR) | 5 (4–7) |
| Median time to resolution, days (IQR) | 6 (3–10) |
| Onset beyond Day 14, n (%) | 0 |
| **Tocilizumab Use** | |
| ≥1 dose, n (%) | 134 (62) |
| Median doses, n (IQR) | 2 (1–3) |
| **Steroid Use** | |
| ≥1 dose, n (%) | 108 (50) |

CRS, Cytokine Release Syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; IQR, interquartile range

## A Multicenter Experience; *Wesson et al.*[4]

A retrospective multicenter analysis evaluated real-world outcomes following CAR T-cell therapy in 256 patients from four US medical centers who received BCMA and CD19 CAR T-cell therapies, including 91 patients who received YESCARTA for treatment of NHL.

Median onset of CRS and ICANS in YESCARTA-treated patients were 2 and 6 days post-infusion, respectively. Onset of CRS and ICANS on Days 0–6, 7–14, 15–28, and 28–90 in patients who received YESCARTA is shown in Table 4.

**Table 4. Onset of CRS and ICANS in YESCARTA Patients[4]**

| Characteristic | YESCARTA (n=91) |
|---|---|
| **CRS** | |
| Median time to onset, days | 2 |
| Time to onset | |
| Days 0–6, n | 69 |
| Days 7–14, n | 8 |
| Days 15–28, n | 1 |
| Days 28–90, n | 1 |
| **ICANS** | |
| Median time to onset, days | 6 |
| Time to onset | |
| Days 0–6, n | 30 |
| Days 7–14, n | 13 |
| Days 15–28, n | 1 |
| Days 28–90, n | 0 |

CRS, Cytokine Release Syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome

Median onset and duration of CRS and ICANS in the overall study group of all CAR T-cell therapies (including YESCARTA) are summarized in Table 5. Incidence of CRS and ICANS onset beyond 14 days was low (Table 5).

**Table 5. CRS and ICANS Outcomes in All CAR T-cell Therapy[a] Patients (N=256)[4]**

| Characteristic | Events Days 0–6 | Events Day ≥7 | *P*-value |
|---|---|---|---|
| **CRS** | | | |
| Incidence, n (%) | 163 (75) | 35 (92) | 0.020 |
| Median time to onset, days (IQR) | 1 (1–3) | 5 (2–8) | <0.001 |
| Median time to resolution, days (IQR) | 5 (2–6) | 7 (4–10) | 0.002 |
| Onset beyond Day 14, n (%) | 1 (<1) | 1 (3) | 0.277 |
| **ICANS** | | | |
| Incidence, n (%) | 61 (28) | 31 (82) | <0.001 |
| Median time to onset, days (IQR) | 3 (2–5) | 9 (7–12) | <0.001 |
| Median time to resolution, days (IQR) | 7 (3–12) | 11 (4–18) | 0.064 |
| Onset beyond Day 14, n (%) | 1 (<1) | 1 (3) | 0.277 |

[a]CAR T-cell therapies included axi-cel, brexu-cel, cilta-cel, ide-cel, liso-cel, and tisa-cel.
Axi-cel, axicabtagene ciloleucel; brexu-cel, brexucabtagene autoleucel; cilta-cel, ciltacabtagene autoleucel; CRS, Cytokine Release Syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; ide-cel, idecabtagene vicleucel; liso-cel, lisocabtagene maraleucel; tisa-cel, tisagenlecleucel

# References


1. YESCARTA® (axicabtagene ciloleucel) Prescribing Information. Kite Pharma, Inc. Santa Monica, CA. 2024.
2. YESCARTA Risk Evaluation and Mitigation Strategy (REMS). YESCARTA® and TECARTUS® REMS (yescartatecartusrems.com). Kite Pharma, Inc. Santa Monica, CA. 2024. Accessed June 19, 2024
3. Wesson W, Riedell PA, Porter DL, et al. Defining the optimal post-CAR T monitoring period in recipients of axicabtagene ciloleucel, tisagenlecleucel, and lisocabtagene maraleucel: a cell therapy consortium study. *Transplant Cell Ther*. 2024; 30(2): S206-S207.
4. Wesson W, Dima D, Davis J, et al. A multicenter experience: duration of mandatory CRS and ICANS monitoring for myeloma and lymphoma CAR-T recipients. *Transplant Cell Ther*. 2024; 30(2): S207-S208.
5. Lee DW, Gardner R, Porter DL, et al. Current concepts in the diagnosis and management of cytokine release syndrome. *Blood*. 2014;124(2):188-195. doi: 10.1182/blood-2014-05-552729


# Abbreviations

ADLs=activities of daily living
ATG=anti-thymocyte globulin
Axi-cel=axicabtagene ciloleucel
Brexu-cel=brexucabtagene autoleucel
CAR=chimeric antigen receptor
Cilta-cel=ciltacabtagene autoleucel
CRS=cytokine release syndrome
HLH/MAS=hemophagocytic lymphohistiocytosis/macrophage activation syndrome
ICANS= immune effector cell-associated neurotoxicity syndrome
Ide-cel=idecabtagene vicleucel
iNHL=indolent non-Hodgkin lymphoma
IQR=interquartile range
IVIG=intravenous immunoglobulin
LBCL=large B-cell lymphoma
Liso-cel=lisocabtagene maraleucel
NHL=non-Hodgkin lymphoma
REMS=Risk Evaluation and Mitigation Strategy
Tisa-cel=tisagenlecleucel

# Product Label

For the full indication, important safety information, and Boxed Warning(s), please refer to the YESCARTA US Prescribing Information available at:
https://www.gilead.com/-/media/files/pdfs/medicines/oncology/yescarta/yescarta-pi.pdf

# Follow Up

For any additional questions, please contact Kite Medical Information at:

☎1-844-454-KITE (1-844-454-5483) or ✉ medinfo@kitepharma.com

# Adverse Event Reporting

Please report all adverse events to:

Kite ☎ 1-844-454-KITE (1-844-454-5483)

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉ MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or www.accessdata.fda.gov/scripts/medwatch

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