

# Yescarta<sup>®</sup> (axicabtagene ciloleucel)

## Primary or Secondary CNS Nervous System Lymphoma

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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>

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## Relevant Prescribing Information<sup>1</sup>

YESCARTA is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of:<sup>1</sup>

- Adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy.
- 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 (FL).

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

- Adult patients with relapsed or refractory 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).

Per the YESCARTA US Prescribing Information (USPI), YESCARTA is not indicated for the treatment of patients with primary central nervous system (CNS) lymphoma.<sup>1</sup>

In the ZUMA-1, ZUMA-5, and ZUMA-7 studies, patients with a history of CNS disorders or a history of CNS lymphoma were ineligible and excluded.<sup>1</sup>

There is no information in the YESCARTA USPI regarding the use of YESCARTA in patients with secondary CNS lymphoma.

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## Clinical Studies

### ZUMA-1, ZUMA-5, and ZUMA-7 Studies

ZUMA-1 is a phase 1/2 multicenter, single-arm, open-label study which evaluated the safety and efficacy of axi-cel in patients with chemorefractory DLBCL, primary mediastinal B-cell lymphoma, or transformed follicular lymphoma.<sup>2</sup> ZUMA-5 is a multicenter, single arm, phase 2 study to evaluate the safety and efficacy of axi-cel in patients with relapsed/refractory indolent non-Hodgkin lymphoma (iNHL), including FL (Grades 1-3a) and marginal zone lymphoma (MZL, nodal or extranodal).<sup>3</sup> Additionally, ZUMA-7 study is an international, multicenter, randomized, phase 3 trial comparing axi-cel with standard care as second-line treatment in patients with early relapsed ( $\leq 12$  months from first-line treatment) or refractory large B-cell lymphoma (LBCL).<sup>4</sup>

In ZUMA-1, ZUMA-5, and ZUMA-7 studies, patients with primary or secondary CNS lymphoma were not studied.<sup>5-7</sup> In ZUMA-1, all patients underwent a baseline brain magnetic resonance imaging (MRI) to rule out any evidence of CNS lymphoma, and patients with history of CNS lymphoma, detectable cerebrospinal fluid (CSF) malignant cells, or brain metastases were excluded from the ZUMA-1 study.<sup>5</sup> In ZUMA-5 and ZUMA-7, patients must have had no known history or suspicion of CNS involvement by lymphoma, and patients with detectable CSF malignant cells, known brain metastases, or with a history of CSF malignant cells or brain metastases were excluded.<sup>6,7</sup> There are no clinical trial data available on the use of axi-cel in patients with CNS lymphoma from the ZUMA-1, ZUMA-5, or ZUMA-7 studies.

### Primary/Secondary CNS Lymphoma (PCNSL/SCNSL)

Jacobson and colleagues reported outcomes from a prospective pilot study in patients with relapsed/refractory (R/R) primary and secondary CNS lymphoma who were treated with axi-cel.<sup>8</sup> Efficacy endpoints include objective response rate (ORR, by IPCG and Lugano), complete response (CR) rate, duration of response (DOR), progression-free survival (PFS), and overall survival (OS) rates. Safety endpoints include rate of treatment limiting toxicities (TLTs) and rate of grade  $\geq 3$  adverse events regardless of attribution.

Axi-cel was successfully manufactured in 9/9 patients who underwent leukapheresis. Patients were followed at Day 28 and Months 3, 6, 9, 12, 18, and 24. Key baseline characteristics of patients who received axi-cel (n=9) are summarized in Table 1.

**Table 1. Baseline Characteristics<sup>8</sup>**

Characteristic	Patients Treated With Axi-cel (N=9)
Age, years, median (range)	60 (33–74)
Male, n (%)	4 (44)
CNS lymphoma type, n (%)	
Primary CNS lymphoma	6 (67)
Secondary CNS lymphoma	3 (33)
Time from CNS lymphoma diagnosis to enrollment, days, median (range)	281 (121–8666)
Disease status to last treatment, n (%)	
Relapsed	4 (44)
Refractory	5 (56)

Characteristic	Patients Treated With Axi-cel (N=9)
Number of prior systemic treatments, median (range)	2 (1–6)
Time from last systemic treatment, days, median (range)	57 (16–392)

Abbreviations: CNS=central nervous system.

Of the 9 patients who received axi-cel, 6 had primary CNS lymphoma and 3 had secondary CNS lymphoma. Bridging therapy was not permitted, however stable steroid doses were allowed but were tapered to dexamethasone 2 mg daily or equivalent by Day 0. Two patients were receiving steroid therapy at the time of axi-cel infusion.

No treatment limiting toxicities were reported and no patients experienced Grade 4 immune effector cell-associated neurotoxicity syndrome (ICANS). One serious adverse event was reported (*Staphylococcus meningitis* related to an infection with an implant [Ommaya] that required removal). Two patients died due to progressive disease. Adverse events of interest are shown in Table 2. Prolonged Grade  $\geq 3$  cytopenias were reported in 3 patients at 1 month and included neutropenia (n=3) and thrombocytopenia (n=1); no cases were reported at 3 months.

**Table 2. Adverse Events of Interest<sup>8</sup>**

Characteristic	CRS	ICANS
Any grade, n (%)	8 (89)	4 (44)
Grade $\geq 3$ , n (%)	0 (0)	3 (33)
Median (range) time to onset	2 days (1–6)	3.5 days (1–6)
Median (range) duration	4 days (1–8)	5.5 days (4–22)
Tocilizumab administered, n (%)	7 (78)	0 (0)
Dexamethasone administered, n (%)	6 (67)	3 (33)

Abbreviations: CRS=cytokine release syndrome; ICANS=immune effector cell-associated neurotoxicity syndrome.

After a median follow-up of 11.3 months (range, 3–19) post axi-cel treatment, best objective response rate (ORR) was 78% (median time to best response, 3 months) and 6-month ORR was 78%. Complete response (CR) was reported in 67% of patients. Median duration of response was 11.3 months, while median progression-free survival and overall survival (OS) were 11.5 and 19 months, respectively. Axi-cel pharmacokinetics were similar to those in patients from the ZUMA-1 study.

Based on the efficacy and safety results for these 9 patients, the pilot study was amended to enroll 9 additional patients with CNS lymphoma, with or without systemic involvement of their lymphoma.<sup>8</sup> Nayak and colleagues reported on this complete cohort of 18 patients with longer follow-up.<sup>9</sup>

Axi-cel was successfully manufactured for 18/18 patients who underwent leukapheresis, and patients continued to be followed at Day 28 and Months 3, 6, 9, 12, 18, and 24. Key baseline characteristics of this larger cohort who received axi-cel (N=18) are summarized in Table 3.

**Table 3. Baseline Characteristics<sup>9</sup>**

Characteristic	Patients Treated With Axi-cel (N=18)
Age, years, median (range)	62 (33–81)
Male, n (%)	10 (56)
CNS lymphoma type, n (%)	
Primary CNS lymphoma	13 (72)
Secondary CNS lymphoma	4 (22)
Systemic & VRL	1 (6)
Number of prior systemic treatments, median (range)	3 (1-7)
Prior ASCT	6 (33%)
Time from diagnosis to enrollment, days, (range)	489 (150-8665)
Time from last systemic treatment to enrollment, days, (range)	72 (4-1273)

Abbreviations: ASCT=autologous stem cell transplant.  
CNS=central nervous system. VRL=vitreoretinal lymphoma

Of the 18 patients who received axi-cel, 13 had primary CNS lymphoma, 4 had secondary CNS lymphoma, and 1 had systemic & vitreoretinal lymphoma. Bridging therapy was not permitted after consenting. However stable/lower doses of dexamethasone were allowed and were tapered to 2 mg daily by Day 0, the day of axi-cel infusion (except in 1 patient). Five patients continued steroid therapy from screening to axi-cel infusion.

No new treatment limiting toxicities were reported. There were no Grade 4/5 ICANS events reported. Three new serious adverse events were reported: new Grade 3 Ommaya infection in 1 patient that required removal (total of 2 patients), new Grade 3 electrographic focal status epilepticus in 1 patient, and new Grade 4 low-risk myelodysplastic syndrome in 1 patient at 12 months. Five additional patients died due to progressive disease, for a total of 7 patient deaths due to PD. Adverse events of interest are shown in Table 4. Prolonged Grade ≥3 cytopenias were reported in 10/18 patients at 1 month and included neutropenia (n=7), thrombocytopenia (n=1), and anemia (n=5); no cases were reported at 3 months.

**Table 4. Adverse Events of Interest<sup>9</sup>**

Characteristic	CRS	ICANS
Any grade, n (%)	16 (89)	8 (44)
Grade ≥3, n (%)	0 (0)	5 (28)
Median (range) time to onset	2 days (1–6)	6 days (3–9)
Median (range) duration	5.5 days (1–9)	4 days (1–56)
Tocilizumab administered, n (%)	14 (78)	N/A
Dexamethasone administered, n (%)	13 (72)	5 (29)

Abbreviations: CRS=cytokine release syndrome; ICANS=immune effector cell-associated neurotoxicity syndrome.

Median follow-up for the full cohort of 18 axi-cel treated patients was 24 months. Objective response rate (ORR) was 94% (median time to best response, 3 months [range, 1–6]). Complete response (CR) was reported in 67% of patients. Median duration of response was 13.4 months (range, 1–30), while median progression-free survival and overall survival (OS) were 14.3 months (95% CI: 6.3–NR) and 26.4 months (95% CI: 11.2–NR), respectively. Axi-cel CAR T cell expansion in this cohort of CNSL patients (N=18) was comparable to the ZUMA-1 study.

High-grade ICANS was associated with baseline and peak levels of biomarkers in serum and CSF. Peak levels of IL-6 and myeloid related MCP1 were associated with Grade  $\geq 2$  ICANS, and peak IL-15 was found to be higher in patients with Grade  $\geq 2$  ICANS. Unlike in LBCL, baseline inflammatory cytokines (such as GzB, Amyloid A in serum, and CRP in CSF) and IL-1Ra in serum were associated with high-grade ICANS.

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## Real World Evidence

### Primary CNS Lymphoma

A literature search identified a retrospective study discussing the use of axi-cel in a limited number of patients with B-cell lymphomas and primary CNS lymphoma, described below. However, a literature search conducted to identify primary evidence describing outcomes of patients with FL and primary CNS lymphoma, treated with axi-cel yielded no relevant results.

In a retrospective, multicenter study of patients within the French network for oculo-cerebral lymphomas (LOC) database, Alcantara and colleagues reported results from an analysis of relapsed/refractory primary CNS lymphoma in patients treated with commercially available CAR-T cells.<sup>10</sup> The objective of this study was to evaluate the safety and efficacy of CAR T-cell therapy in patients with primary CNS lymphoma. A total of 9 patients were included in the study, and 2 of the 9 patients received axi-cel. The median follow-up after CAR T-cell infusion was 8.5 months. Among the two patients that received axi-cel, both patients achieved a CR at Month 3 after infusion, per central review. Both patients experienced adverse events, with the first patient experiencing worst Grade 2 cytokine release syndrome (CRS) and worst Grade 4 ICANS, and the second patient experiencing worst Grade 1 CRS and worst Grade 1 ICANS. Additionally, the second axi-cel treated patient experienced Grade  $\geq 3$  cytopenia that did not resolve by Day 28. Additional information from this analysis can be found via the citation link provided within the reference details, below.

### Secondary CNS Lymphoma

A literature search identified several publications discussing the use of axi-cel in a limited number of patients with B-cell lymphomas and secondary CNS lymphoma, described below. However, a literature search conducted to identify primary evidence describing outcomes of patients with FL and secondary CNS lymphoma, treated with axi-cel yielded no relevant results.

In a retrospective study, Bennani and colleagues from the US Lymphoma CAR T Consortium reported real-world experience of axi-cel in 300 patients across 17 academic centers, of which 17 patients had secondary CNS involvement at the time of leukapheresis.<sup>11</sup> With a median follow-up of 10.1 months from leukapheresis, a total of 15 patients in the CNS cohort and 262 patients in non-CNS cohort were infused, and were included in the safety and efficacy analysis. Among the 15 patients in the CNS cohort, 10 had resolution of CNS involvement, and 5 had active CNS disease at the time of infusion. In the non-CNS cohort, Grade  $\geq 3$  CRS occurred in 6% (17/262) of patients, and Grade  $\geq 3$  ICANS occurred in 31% (83/262) of patients. In the CNS cohort, Grade  $\geq 3$  CRS occurred in 20% (1/5) and 10% (1/10) of patients with active CNS and prior history of CNS involvement, respectively. Additionally, in the CNS cohort, Grade  $\geq 3$  ICANS occurred in 60% (3/5) and 20% (2/10) in patients with active CNS and prior history of CNS involvement, respectively. At data cutoff, the ITT best overall response rates (CR+PR) and ongoing responses at

Month 6 between CNS and non-CNS cohorts were 75% vs. 59%, and 41% vs. 31%, respectively. Responses for the 5 patients with active CNS disease at time of infusion included 2 CR, 1 partial response (PR), and 2 progressive disease (PD) as best response. Among the 10 patients with resolved CNS disease at time of infusion, 2 patients experienced PD and both occurred systemically. Additionally, event-free survival (EFS) at 6 months from leukapheresis was not statistically significantly different between the CNS and non-CNS cohorts (CNS cohort, 36%; non-CNS cohort, 57%) with a hazard ratio (HR) of 1.58 (95% CI: 0.83–3.01) and a *P*-value of 0.16. Furthermore, the 6-month EFS from the date of infusion for the CNS cohort was 49.9%.

Ghafouri and colleagues reported outcomes of a retrospective, single-center study at the University of California Los Angeles Medical Center for 5 adult patients with R/R NHL and secondary CNS involvement and were treated with axi-cel.<sup>12</sup> At the time of infusion, all 5 patients had CNS involvement, and 3 patients had concurrent systemic disease. All patients received CNS- directed therapies prior to lymphodepletion, and 3 patients received bridging therapy. After a median follow-up of 155 days (range, 86–208) post CAR T, two of the 5 patients did not develop any grade CRS or ICANS. For the remaining 3 patients, one patient developed worst Grade 3 ICANS without any grade CRS, another patient developed worst Grade 1 CRS without any grade ICANS, and the last patient developed both worst Grade 2 CRS and Grade 4 ICANS. Four of the 5 patients demonstrated early response to CAR T at Day +28, with 3 CRs and 1 stable disease (SD), however 3 of the 4 patients developed PD prior to 6-month post- CAR T disease reassessment. Of the 4 responders, the median PFS and OS were 134.2 days and 155.0 days (range, 86–208) respectively. As of the data cut-off, deaths occurred for 4 of the 5 patients, with one patient in sustained remission.

Ahmed and colleagues reported outcomes of a retrospective, single-center study for 7 adult patients with refractory DLBCL and CNS involvement, who underwent CAR T-cell therapy, including axi-cel.<sup>13</sup> The median follow-up for survivors was 5.1 months (range, 1.6-7.2), and 4 patients were alive at last follow-up. Three of the 7 patients received axi-cel as their CAR T-cell therapy, and all 3 axi-cel treated patients achieved a CR at the Day 28 disease assessment. The first axi-cel treated patient developed Grade 1 CRS without any grade ICANS and was alive with a CR at Day 91. The second axi-cel treated patient developed Grade 1 CRS and Grade 3 ICANS and was alive with a CR at Day 129. The third axi-cel treated patient developed Grade 2 CRS and Grade 2 ICANS, and later experienced disease relapse on Day 51 and died on Day 109 as a result of PD.

Yuen and colleagues describe the outcomes of axi-cel therapy in a bi-institutional retrospective study of 14 patients with DLBCL and with either relapsed or refractory active or nonactive SCNSL.<sup>14</sup> The median follow-up for this study was 5.9 months, and 11 of 14 patients had active CNS or systemic lymphoma (3 isolated CNS disease, 4 isolated systemic disease, 4 with both CNS and systemic disease). Of the 7 patients with active SCNSL, 3 (43%) developed neurotoxicity (NT), 2 (29%) of whom had severe NT, and all patients with NT had concurrent CRS. At data cutoff, outcomes for the 7 patients with active CNS disease included 2 CR (28.5%), 2 PD (28.5%), and 3 deceased (43%).

Additional information from the above analyses can be found via the citation links provided within the reference details, below.

Furthermore, additional studies and case reports were identified and include information regarding the use of axi-cel in a limited number of patients with a history of CNS lymphoma, which may be of interest to you:

- Novo M, Ruff MW, Skrabek PJ, Lin Y. Axicabtagene ciloleucel chimeric antigen receptor T cell therapy in lymphoma with secondary central nervous system involvement. *Mayo Clin Proc.* 2019 Nov;94(11):2361-2364. DOI: [10.1016/j.mayocp.2019.09.006](https://doi.org/10.1016/j.mayocp.2019.09.006)
- Nastoupil LJ, Jain MD, Feng L, et al. Standard-of-care axicabtagene ciloleucel for relapsed or refractory large B-cell lymphoma: results from the US Lymphoma CAR T Consortium. *JCO.* 2020;38(27):3119-3128. DOI: [10.1200/JCO.19.02104](https://doi.org/10.1200/JCO.19.02104)
- Strati P, Nastoupil LJ, Westin J, et al. Clinical and radiologic correlates of neurotoxicity after axicabtagene ciloleucel in large B-cell lymphoma. *Blood Adv.* 2020;4(16):3943-3951. DOI: [10.1182/bloodadvances.2020002228](https://doi.org/10.1182/bloodadvances.2020002228)
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- Holtzman NG, Xie H, Bentzen S, et al. Immune effector cell–associated neurotoxicity syndrome after chimeric antigen receptor T-cell therapy for lymphoma: predictive biomarkers and clinical outcomes. *Neuro Oncol.* 2020;23(1):112-121. DOI: [10.1093/neuonc/noaa183](https://doi.org/10.1093/neuonc/noaa183)
- Abbasi A, Peeke S, Shah N, et al. Axicabtagene ciloleucel CD19 CAR-T cell therapy results in high rates of systemic and neurologic remissions in ten patients with refractory large B cell lymphoma including two with HIV and viral hepatitis. *J Hematol Oncol.* 2020;13(1):1. DOI: [10.1186/s13045-019-0838-y](https://doi.org/10.1186/s13045-019-0838-y)
- Vusqa UT, Asawa P, Rai M, et al. Intrathecal chemotherapy as a potential alternative treatment for steroid-refractory immune effector cell-associated neurotoxicity syndrome. *Blood.* 2021;138(Supplement 1):4816-4816. DOI: [10.1182/blood-2021-151113](https://doi.org/10.1182/blood-2021-151113)
- Alcantara M, Houillier C, Blonski M, et al. CAR T-cell therapy in primary central nervous system lymphoma: the clinical experience of the French LOC network. *Blood.* 2022;139(5):792-796. DOI: [10.1182/blood.2021012932](https://doi.org/10.1182/blood.2021012932)
- Choquet S, Soussain C, Azar N, et al. CAR T-cell therapy induces a high rate of prolonged remission in relapsed primary CNS lymphoma: Real-life results of the LOC network. *Am J Hematol.* 2024;99(7):1240-1249. DOI: [10.1002/ajh.27316](https://doi.org/10.1002/ajh.27316)
- Ayuk F, Gagelmann N, von Tresckow B, et al. Real-world results of CAR T-cell therapy for large B-cell lymphoma with CNS involvement: a GLA/DRST study. *Blood Adv.* 2023;7(18):5316-5319. DOI: [10.1182/bloodadvances.2023010336](https://doi.org/10.1182/bloodadvances.2023010336)

The decision to prescribe YESCARTA in patients with or a history of primary or secondary CNS lymphoma is at the discretion of the treating physician.

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## References

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2. Neelapu SS, Locke FL, Bartlett NL, et al. Axicabtagene ciloleucel CAR T-cell therapy in refractory large B-cell lymphoma. *N Engl J Med.* 2017. DOI: [10.1056/NEJMoa1707447](https://doi.org/10.1056/NEJMoa1707447)
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5. [Protocol] Neelapu SS, Locke FL, Bartlett NL, et al. Axicabtagene ciloleucel CAR T-cell therapy in refractory large B-cell lymphoma. *N Engl J Med.* 2017. DOI: [10.1056/NEJMoa1707447](https://doi.org/10.1056/NEJMoa1707447)

6. [Supplementary Appendix] Jacobson CA, Chavez JC, Sehgal AR, et al. Axicabtagene ciloleucel in relapsed or refractory indolent non-Hodgkin lymphoma (ZUMA-5): a single-arm, multicentre, phase 2 trial. *Lancet Oncol.* 2022;23(1):91-103. DOI: [10.1016/S1470-2045\(21\)00591-X](https://doi.org/10.1016/S1470-2045(21)00591-X)
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9. Nayak L, Chukwueke UN, Hogan S, et al. A Pilot Study of Axicabtagene Ciloleucel in Relapsed/Refractory Primary and Secondary Central Nervous System Lymphomas (PCNSL & SCNSL). Presented at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting; May 31-June 4, 2024; Chicago, IL.
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## Abbreviations

ASCT=autologous stem cell transplant  
 CAR=chimeric antigen receptor  
 CI=confidence interval  
 CNS=central nervous system  
 CR=complete response  
 CRS=cytokine release syndrome  
 CSF=cerebrospinal fluid  
 DLBCL=diffuse large B-cell lymphoma  
 EFS=event-free survival  
 FL=follicular lymphoma

HR=hazard ratio  
 ICANS= immune effector cell-associated neurotoxicity syndrome  
 iNHL= indolent non-Hodgkin lymphoma  
 ITT=intention to treat  
 LBCL=large B-cell lymphoma  
 MRI=magnetic resonance imaging  
 MZL=marginal zone lymphoma  
 NHL=non-Hodgkin lymphoma  
 NT=neurotoxicity

ORR=objective response rate  
 OS=overall survival  
 PCNSL=primary CNS lymphoma  
 PD=progressive disease  
 PFS=progression-free survival  
 PR=partial response  
 R/R=relapsed/refractory  
 SCNSL=secondary CNS lymphoma  
 SD=stable disease  
 TLT=treatment limiting toxicity  
 VRL=vitreoretinal lymphoma

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## Product Label

For the full indication, important safety information, and Boxed Warning(s), please refer to the YESCARTA® (axicabtagene ciloleucel) 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](mailto:medinfo@kitepharma.com)

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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](http://www.accessdata.fda.gov/scripts/medwatch)

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