



ADVERSE REACTIONS MANAGEMENT GUIDE

3L+ DIFFUSE LARGE B-CELL LYMPHOMA & HIGH-GRADE B-CELL LYMPHOMA

3L+ FOLLICULAR LYMPHOMA

3L=third line.

INDICATIONS

EPKINLY is indicated for the treatment of adults with:

- relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS), including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma (HGBCL) after 2 or more lines of systemic therapy.
- relapsed or refractory follicular lymphoma (FL) after 2 or more lines of systemic therapy.

These indications are approved under accelerated approval based on response rate and durability of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

SELECT IMPORTANT SAFETY INFORMATION

BOXED WARNINGS

- **Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving EPKINLY. Initiate treatment with the EPKINLY step-up dosage schedule to reduce the incidence and severity of CRS. Withhold EPKINLY until CRS resolves or permanently discontinue based on severity.**
- **Immune effector cell-associated neurotoxicity syndrome (ICANS), including life-threatening and fatal reactions, can occur with EPKINLY. Monitor patients for neurological signs or symptoms of ICANS during treatment. Withhold EPKINLY until ICANS resolves or permanently discontinue based on severity.**

Additional Warnings & Precautions: Infections, Cytopenias, and Embryo-Fetal Toxicity.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3-4 and throughout this brochure. Please see full [Prescribing Information](#).

Introduction

This guide was developed to help extended care teams understand more about the adverse reactions that may occur in patients who are receiving EPKINLY. You play a critical role in caring for and monitoring patients, administering drug and managing dose modifications when needed, and providing supportive care, all of which may help your patients with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL), high-grade B-cell lymphoma (HGBCL), or follicular lymphoma (FL) stay on treatment with EPKINLY.¹

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3L+ DLBCL/HGBCL

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3L+ FL

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3L+ DLBCL/HGBCL AND 3L+ FL

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Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3-4 and throughout this brochure. Please see full [Prescribing Information](#).


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IMPORTANT SAFETY INFORMATION

BOXED WARNINGS

- **Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving EPKINLY. Initiate treatment with the EPKINLY step-up dosage schedule to reduce the incidence and severity of CRS. Withhold EPKINLY until CRS resolves or permanently discontinue based on severity.**
- **Immune effector cell-associated neurotoxicity syndrome (ICANS), including life-threatening and fatal reactions, can occur with EPKINLY. Monitor patients for neurological signs or symptoms of ICANS during treatment. Withhold EPKINLY until ICANS resolves or permanently discontinue based on severity.**

CRS

- CRS occurred in 51% of patients with large B-cell lymphoma (LBCL) in the clinical trial (37% grade 1, 17% grade 2, and 2.5% grade 3) and recurred in 16% of patients. Most events (92%) occurred during cycle 1, with 61% occurring after the 48 mg dose on cycle 1, day 15.
- CRS occurred in 49% of patients with FL receiving the recommended 3-step up dosage schedule in the clinical trial (45% grade 1, 9% grade 2) and recurred in 23% of patients. Most events (88%) occurred during cycle 1, with 49% occurring after the 48 mg dose on cycle 1, day 22.
- In patients who experienced CRS, the signs and symptoms included pyrexia, hypotension, hypoxia, dyspnea, chills, and tachycardia. Concurrent neurological adverse reactions associated with CRS occurred in 2.5% of patients with LBCL (reactions included headache, confusional state, tremors, dizziness, and ataxia) and 4.7% of patients with FL (reactions included headache and dizziness).
- Administer pretreatment medications to reduce the risk of CRS.
- Patients with DLBCL or high-grade B-cell lymphoma should be hospitalized for 24 hours following administration of the first full 48 mg dose.
- Monitor patients for potential CRS. At the first signs or symptoms of CRS, manage per current practice guidelines and administer supportive care as appropriate.

ICANS

- ICANS occurred in 6% of patients with LBCL in the clinical trial (4.5% grade 1, 1.3% grade 2, 0.6% fatal). Of the 10 ICANS events, 9 occurred in cycle 1 of treatment.
- ICANS occurred in 6% of patients with FL receiving the 2-step up dosage schedule in the clinical trial (3.9% grade 1, 2.4% grade 2).
- The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. Clinical manifestations of ICANS included, but were not limited to, confusional state, lethargy, tremor, dysgraphia, aphasia, and non-convulsive status epilepticus.
- Monitor patients for potential ICANS. At the first signs or symptoms of ICANS, manage per current practice guidelines and administer supportive care as appropriate.

Please see additional Important Safety Information on page 4.
Please see full [Prescribing Information](#).



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IMPORTANT SAFETY INFORMATION (cont'd)

Infections

- EPKINLY can cause serious and fatal infections. Serious infections, including opportunistic infections, were reported in 15% of patients with LBCL in the clinical trial (most common: 4.5% sepsis, 3.2% pneumonia). Fatal infections occurred in 1.3% of patients (1.3% COVID-19).
- Serious infections, including opportunistic infections, were reported in 40% of patients with FL receiving the 2-step up dosage schedule in the clinical trial (most common: 20% COVID-19, 13% pneumonia, 3% urinary tract infections). Fatal infections occurred in 6% of patients (5% COVID-19, 0.8% pneumonia, 0.8% sepsis).
- Monitor patients for signs and symptoms of infection prior to and during treatment and treat appropriately. Avoid administration in patients with active infections. Withhold or consider permanent discontinuation of EPKINLY based on severity. Prior to starting EPKINLY, provide *Pneumocystis jirovecii* pneumonia (PJP) prophylaxis and consider prophylaxis against herpes virus.

Cytopenias

- EPKINLY can cause serious or severe cytopenias. In the clinical trial of patients with LBCL, grade 3 or 4 events occurred in 32% (neutrophils decreased), 12% (hemoglobin decreased), and 12% (platelets decreased). Febrile neutropenia occurred in 2.5%.
- In the clinical trial of patients with FL receiving the 2-step up dosage schedule, grade 3 or 4 events occurred in 30% (neutrophils decreased), 10% (hemoglobin decreased), and 8% (platelets decreased). Febrile neutropenia occurred in 3.1%.
- Monitor complete blood counts throughout treatment. Based on severity of cytopenias, temporarily withhold or permanently discontinue EPKINLY. Consider prophylactic granulocyte colony-stimulating factor administration as applicable.

Embryo-Fetal Toxicity

- EPKINLY may cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with EPKINLY and for 4 months after the last dose. Verify pregnancy status in females of reproductive potential prior to initiating EPKINLY.

Adverse Reactions

- DLBCL/HGBCL: Most common ($\geq 20\%$) adverse reactions were CRS, fatigue, musculoskeletal pain, injection site reactions, pyrexia, abdominal pain, nausea, and diarrhea. Most common grade 3 to 4 laboratory abnormalities ($\geq 10\%$) were decreased lymphocytes, decreased neutrophils, decreased white blood cells, decreased hemoglobin, and decreased platelets.
- FL: Most common ($\geq 20\%$) adverse reactions were injection site reactions, CRS, COVID-19, fatigue, upper respiratory tract infection, musculoskeletal pain, rash, diarrhea, pyrexia, cough, and headache. The most common grade 3 to 4 laboratory abnormalities ($\geq 10\%$) were decreased lymphocytes, decreased neutrophils, decreased white blood cells, and decreased hemoglobin.

Use in Specific Populations

- **Lactation:** Advise women not to breastfeed during treatment and for 4 months after the last dose of EPKINLY.
- **Geriatric Use:** In patients with relapsed or refractory FL who received EPKINLY in the clinical trial, 52% were ≥ 65 years old, and 13% were ≥ 75 years old. A higher rate of fatal adverse reactions, primarily infections, including COVID-19, was observed in patients ≥ 65 years old compared to younger adult patients. No overall difference in efficacy was observed.

Adverse reactions in the EPCORE[®] NHL-1 trial¹

The safety of EPKINLY was evaluated in EPCORE[®] NHL-1, a single-arm trial of 157 patients with R/R LBCL after 2 or more lines of systemic therapy, including DLBCL NOS, DLBCL arising from indolent lymphoma, HGBCL, and other B-cell lymphomas.

Majority of adverse reactions were mild to moderate (grade 1 or 2)

Most common treatment-related adverse reactions (≥10%)

Adverse Reactions ^a	All Grades (%)	Grade 3 or 4 ^b (%)
Cytokine release syndrome ^c	51	2.5
Fatigue ^d	29	2.5
Musculoskeletal pain ^d	28	1.3
Injection site reactions ^d	27	0
Pyrexia	24	0
Abdominal pain ^d	23	1.9
Nausea	20	1.3
Diarrhea	20	0
Rash ^d	15	0.6
Edema ^d	14	1.9
Headache	13	0.6
Vomiting	12	0.6
Decreased appetite	12	0.6
Cardiac arrhythmias ^d	10	0.6

^a Adverse reactions were graded based on CTCAE Version 5.0.

^b Only grade 3 adverse reactions occurred.

^c CRS was graded using ASTCT consensus criteria (Lee et al, 2019).

^d Term includes other related terms. See Prescribing Information.

- Median duration of exposure was 5 cycles (range: 1 to 20 cycles)
- Serious adverse reactions occurred in 54% of patients (reactions occurring ≥2%: CRS, infections,* pleural effusion, febrile neutropenia, fever, and ICANS)
- Fatal adverse reactions occurred in 3.8% of patients (1.3% COVID-19, 0.6% hepatotoxicity, 0.6% ICANS, 0.6% myocardial infarction, 0.6% pulmonary embolism)
- Discontinuation due to an adverse reaction occurred in 3.8% of patients (reactions included COVID-19, CRS, ICANS, pleural effusion, and fatigue)
- Dosage interruptions due to an adverse reaction occurred in 34% of patients (reactions occurring ≥3%: CRS, neutropenia, sepsis, and thrombocytopenia)
- The most common grade 3 to 4 laboratory abnormalities (≥10%) were decreased lymphocyte count, decreased neutrophil count, decreased white blood cell count, decreased hemoglobin, and decreased platelets
- Clinically relevant adverse reactions in <10% of patients included ICANS, sepsis, pleural effusion, COVID-19, pneumonia (including pneumonia and COVID-19 pneumonia), tumor flare, febrile neutropenia, upper respiratory tract infections, and tumor lysis syndrome

*Infections included sepsis, COVID-19, pneumonia, and upper respiratory tract infections.

ASTCT=American Society for Transplantation and Cellular Therapy; CTCAE=Common Terminology Criteria for Adverse Events; LBCL=large B-cell lymphoma; NHL=non-Hodgkin lymphoma; NOS=not otherwise specified.

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3-4 and throughout this brochure.
Please see full Prescribing Information.


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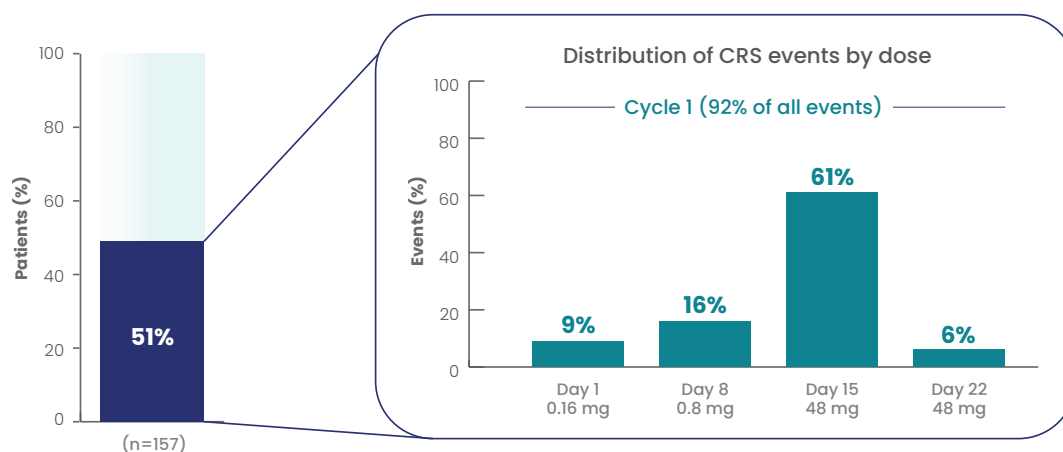
CRS considerations prior to treatment¹

CRS events in EPCORE[®] NHL-1 trial

Most CRS events (92%) occurred in cycle 1 and 61% were associated with the first full dose

- CRS occurred in 51% of patients receiving EPKINLY in the clinical trial. Recurrent CRS occurred in 16% of patients

Patients with CRS



- The median time to onset of CRS from the most recently administered EPKINLY dose across all doses was 24 hours (range: 0 to 10 days)
 - The median time to onset after the first full 48-mg dose was 21 hours (range: 0 to 7 days)
- CRS resolved in 98% of patients; the median duration of CRS events was 2 days (range: 1 to 27 days)

CRS events by grade (% patients)

- Any grade=51%
- Grade 1=37%
- Grade 2=17%
- Grade 3=2.5%
- Grade 4=0%

SELECT IMPORTANT SAFETY INFORMATION

BOXED WARNING

- Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving EPKINLY. Initiate treatment with the EPKINLY step-up dosage schedule to reduce the incidence and severity of CRS. Withhold EPKINLY until CRS resolves or permanently discontinue based on severity.**

SEE THE "MANAGING CRS IF IT OCCURS" SECTION IF YOU SUSPECT YOUR PATIENT IS EXPERIENCING SYMPTOMS (PAGES 16-17)

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3-4 and throughout this brochure. Please see full [Prescribing Information](#).

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CRS considerations prior to treatment¹ (cont'd)

EPKINLY dosing considerations for CRS

- Administer EPKINLY subcutaneously according to the step up dosage schedule below, for patients with DLBCL or HGBCL to reduce the incidence and severity of CRS
- EPKINLY should only be administered by a qualified healthcare professional with appropriate medical support to manage severe reactions such as CRS
- Administer EPKINLY subcutaneously in 28-day cycles until disease progression or unacceptable toxicity:
 - Cycle 1: 0.16 mg (step up dose 1) on day 1, 0.8 mg (step up dose 2) on day 8, 48 mg (full dose) on days 15 and 22
 - Cycles 2-3: 48 mg weekly
 - Cycles 4-9: 48 mg every 2 weeks
 - Cycles 10+: 48 mg every 4 weeks

Recommended pre- and post-administration medications to reduce the risk of CRS

Between 30 and 120 minutes prior to administration of EPKINLY, administer the following medications:

- Cycle 1: For all patients, administer prior to each weekly administration of EPKINLY
 - **Dexamethasone*** (15 mg oral or IV) or **prednisolone** (100 mg oral or IV) or equivalent
 - Continue for 3 consecutive days following each weekly administration
 - **Diphenhydramine** (50 mg oral or IV) or equivalent
 - **Acetaminophen** (650 mg–1000 mg oral)
- Cycles 2+: For patients who experienced grade 2 or 3[†] CRS with previous dose, administer prior to next administration until EPKINLY is given without subsequent CRS of grade 2 or higher
 - **Dexamethasone*** (15 mg oral or IV) or **prednisolone** (100 mg oral or IV) or equivalent
 - Continue for 3 consecutive days following administration of EPKINLY

*Dexamethasone is the preferred corticosteroid when available.

[†]Patients will be permanently discontinued from EPKINLY after a grade 4 CRS event.

Monitoring patients for CRS

- Due to the risk of CRS and ICANS, monitor all patients for signs and symptoms
 - Patients with DLBCL or HGBCL should be hospitalized for 24 hours after administration of the cycle 1, day 15 dosage of 48 mg
- Signs and symptoms of CRS can include pyrexia, hypotension, hypoxia, dyspnea, chills, and tachycardia
- Concurrent neurological adverse reactions associated with CRS occurred in 2.5% of patients and included headache, confusional state, tremors, dizziness, and ataxia
- At the first signs or symptoms of CRS, immediately evaluate patients for hospitalization, manage per current practice guidelines, and administer supportive care as appropriate. Withhold or discontinue EPKINLY based on the severity of CRS

Counseling patients about CRS

- Inform patients and their care partners of the risk of CRS
- Advise them to immediately contact their healthcare provider should signs and symptoms associated with CRS occur. These can include pyrexia, hypotension, hypoxia, chills, tachycardia, headache, and dyspnea
- Advise patients with DLBCL or HGBCL that they should be hospitalized for 24 hours after administration of the cycle 1, day 15 dosage of 48 mg
- Advise patients who experience symptoms that impair consciousness not to drive and refrain from operating heavy or potentially dangerous machinery until events resolve

IV=intravenous.

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3-4 and throughout this brochure.
Please see full Prescribing Information.



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ICANS considerations prior to treatment¹

ICANS events in the EPCORE[®] NHL-1 clinical trial

- ICANS occurred in 6% (10/157) of patients. Of the 10 events, 9 occurred within cycle 1
- Median time to onset was 3 days (range: 1 to 13 days) relative to the most recent administration
- Median time to onset was 16.5 days (range: 8 to 141 days) from the start of treatment
- Median duration of ICANS was 4 days (range: 0 to 8 days)

ICANS events by grade (% patients)

- Grade 1=4.5%
- Grade 2=1.3%
- Grade 3=0%
- Grade 4=0%
- Grade 5=0.6% (fatal)
- ICANS resolved in 90% (9/10) of patients with supportive care

SELECT IMPORTANT SAFETY INFORMATION

BOXED WARNING

- **Immune effector cell–associated neurotoxicity syndrome (ICANS), including life-threatening and fatal reactions, can occur with EPKINLY. Monitor patients for neurological signs or symptoms of ICANS during treatment. Withhold EPKINLY until ICANS resolves or permanently discontinue based on severity.**

EPKINLY dosing considerations for ICANS

- EPKINLY should only be administered by a qualified healthcare professional with appropriate medical support to manage severe reactions such as ICANS
- Administer EPKINLY subcutaneously in 28-day cycles until disease progression or unacceptable toxicity according to the 2-step up dosage schedule:
 - Cycle 1: 0.16 mg (step up dose 1) on day 1, 0.8 mg (step up dose 2) on day 8, 48 mg (full dose) on days 15 and 22
 - Cycles 2–3: 48 mg weekly
 - Cycles 4–9: 48 mg every 2 weeks
 - Cycles 10+: 48 mg every 4 weeks

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–4 and throughout this brochure. Please see full Prescribing Information.


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ICANS considerations prior to treatment¹ (cont'd)

Monitoring patients for ICANS

- Due to the risk of CRS and ICANS, monitor all patients for signs and symptoms
 - Patients with DLBCL or HGBCL should be hospitalized for 24 hours after administration of the cycle 1, day 15 dosage of 48 mg
- Signs and symptoms of ICANS can include confusional state, lethargy, tremor, dysgraphia, aphasia, and nonconvulsive status epilepticus
- The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS
- At the first signs or symptoms of ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold or discontinue EPKINLY per recommendations and consider further management per current practice guidelines

Counseling patients about ICANS

- Advise patients and their care partners of the risks of ICANS, and to immediately contact their healthcare provider for signs and symptoms of ICANS. The onset of events may be delayed and can include:

- | | |
|---------------------|------------------------------------|
| — confusional state | — dysgraphia |
| — lethargy | — aphasia |
| — tremor | — nonconvulsive status epilepticus |

- Advise patients who experience symptoms of ICANS that impair consciousness to refrain from driving or operating heavy or potentially dangerous machinery until symptoms of ICANS resolve

SEE THE "MANAGING ICANS IF IT OCCURS" SECTION IF YOU SUSPECT YOUR PATIENT IS EXPERIENCING SYMPTOMS (PAGES 18–20)

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–4 and throughout this brochure. Please see full [Prescribing Information](#).


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Adverse reactions in the EPCORE[®] NHL-1 trial¹

The safety of EPKINLY was evaluated in EPCORE[®] NHL-1, an open-label, multicohort, multicenter, single-arm trial that included patients with R/R FL after 2 or more lines of systemic therapy. A total of 213 patients received EPKINLY; 86 patients received EPKINLY at the recommended 3-step up dosage schedule and 127 patients received EPKINLY following a 2-step up dosage schedule.

Majority of adverse reactions were mild to moderate (grade 1 or 2)

Most common treatment-related adverse reactions (≥10%)

ADVERSE REACTION ^a	ALL GRADES (%)	GRADE 3 OR 4 (%)
(n=86) ^b		
Cytokine release syndrome ^{c,d}	49	0
(n=127)		
Injection site reactions ^e	58	0
COVID-19 ^f	40	19
Fatigue ^e	37	5 ^g
Upper respiratory tract infection ^f	29	2 ^g
Musculoskeletal pain ^e	28	0.8 ^g
Rash ^e	28	0
Pyrexia ^e	26	2 ^g
Diarrhea	26	1.6 ^g
Headache	20	0
Cough ^e	20	0
Pneumonia ^f	17	13 ^g
Abdominal pain ^e	17	0.8 ^g
Dyspnea ^e	17	0
Edema ^e	17	0
Nausea	17	0
Constipation	16	0
Arthralgia ^e	14	0.8 ^g
Urinary tract infection ^e	13	5 ^g
Peripheral neuropathy and paresthesia ^f	13	1.6 ^g
Neurological changes ^f	13	0
Insomnia	13	0
Herpes virus infection ^f	12	1.6 ^g
Mucositis ^f	12	0
Dizziness	11	0
Renal insufficiency ^f	10	1.6 ^g

^aAdverse reactions were graded based on CTCAE Version 5.0.

^bThe frequency of CRS is based on 86 patients with FL who received the recommended 3-step up dosage schedule in EPCORE[®] NHL-1. See Section 2.2 of the full Prescribing Information.

^cCRS was graded using ASTCT consensus criteria (Lee et al, 2019).

^dThe frequency of CRS based on the 127 patients with FL who received the 2-step up dosage schedule in EPCORE[®] NHL-1 was the following: any grade CRS 66%; grade 1 CRS: 50%; grade 2 CRS: 26%; grade 3 CRS: 1.6%.

^eIncludes related grouped terms.

^fTerm includes other related terms. See full Prescribing Information.

^gOnly grade 3 adverse reactions occurred.

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3-4 and throughout this brochure.

Please see full Prescribing Information.


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Adverse reactions in the EPCORE[®] NHL-1 trial¹ (cont'd)

In 86 patients who received EPKINLY following the recommended 3-step up dosage schedule:

- The median duration of exposure was 5 cycles (range: 1 to 12 cycles)
- CRS occurred in 49% of patients (45% grade 1, 9% grade 2)
- Serious adverse reactions due to CRS occurred in 28% of patients
- Dose interruptions due to CRS occurred in 19% of patients

In 127 patients who received EPKINLY following a 2-step up dosage schedule:

- The median duration of exposure was 8 cycles (range: 1 to 33 cycles)
- Serious adverse reactions occurred in 66% of patients (reactions occurring $\geq 5\%$ included CRS, COVID-19, pneumonia, and second primary malignancies)
- Fatal adverse reactions occurred in 9% of patients, including COVID-19 (5%), pneumonitis (1.6%), cardiac failure (0.8%), pneumonia (0.8%), and sepsis (0.8%)
- Permanent discontinuation due to any adverse reaction occurred in 19% of patients. Adverse reactions resulting in permanent discontinuation in $\geq 2\%$ of patients included COVID-19, Hepatitis E, pneumonitis, and second primary malignancy
- Dosage interruptions due to an adverse reaction occurred in 59% of patients (reactions requiring dosage interruption in $\geq 5\%$: COVID-19, CRS, pneumonia, upper respiratory tract infection, and fatigue)
- The most common grade 3 to 4 laboratory abnormalities ($\geq 10\%$) were decreased lymphocyte count, decreased neutrophil count, decreased white blood cell count, and decreased hemoglobin
- Clinically relevant adverse reactions in $<10\%$ of patients included vomiting, pruritus, hepatotoxicity, ICANS, lower respiratory tract infections, cardiac arrhythmias, respiratory tract infections, pneumonitis, second primary malignancy, vision changes, cellulitis, febrile neutropenia, cardiac failure, cytomegalovirus infection, and sepsis

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3-4 and throughout this brochure. Please see full [Prescribing Information](#).



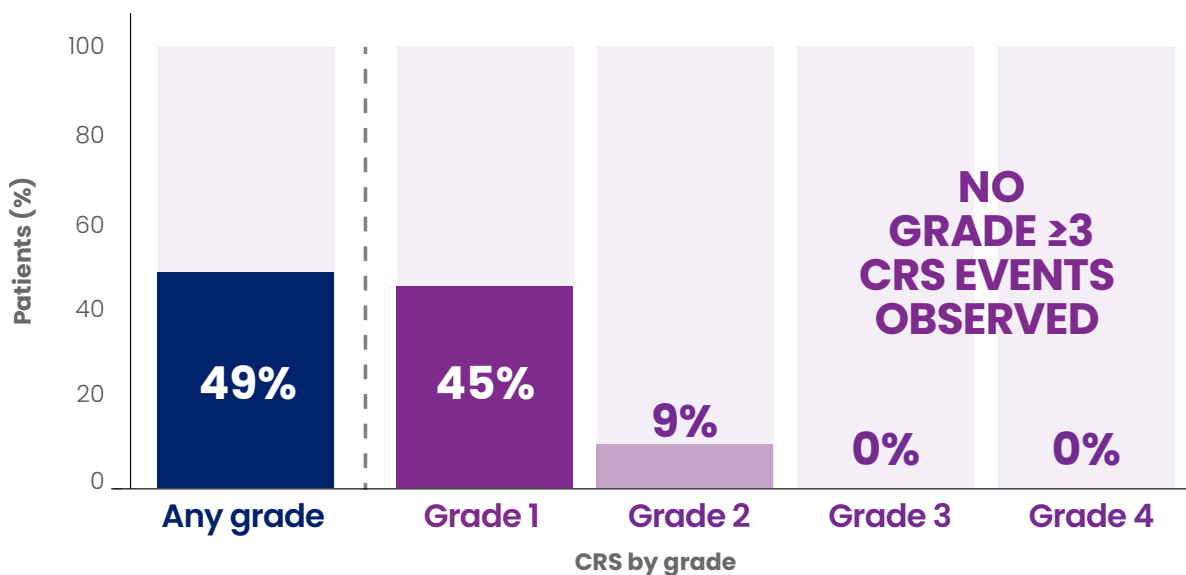
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CRS considerations prior to treatment¹

CRS in EPCORE[®] NHL-1 trial

In patients who received EPKINLY at the recommended 3-step up dosage schedule (n=86)

- Recurrent CRS occurred in 23% of patients
- Most CRS events (88%) occurred during cycle 1
 - In cycle 1, 14% of CRS events occurred after the 0.16-mg dose (day 1), 7% after the 0.8-mg dose (day 8), 17% after the 3-mg dose (day 15), and 49% after the 48-mg dose (day 22)
- The median time to onset of CRS from the most recently administered EPKINLY dose across all doses was 59 hours (range: 0.1 to 7 days)
- The median time to onset after the first full 48-mg dose was 61 hours (range: 0.1 to 7 days)
- CRS resolved in 100% of patients
 - Median duration of CRS events was 2 days (range: 1 to 14 days)



SELECT IMPORTANT SAFETY INFORMATION

Cytokine release syndrome (CRS), including serious or life-threatening reactions, can occur in patients receiving EPKINLY. Initiate treatment with the EPKINLY step-up dosage schedule to reduce the incidence and severity of CRS. Withhold EPKINLY until CRS resolves or permanently discontinue based on severity.

- In patients who experienced CRS, the signs and symptoms included pyrexia, hypotension, hypoxia, dyspnea, chills, and tachycardia. Concurrent neurological adverse reactions associated with CRS occurred in 4.7% of patients with FL and included headache and dizziness.
- Administer pretreatment medications to reduce the risk of CRS.

SEE THE "MANAGING CRS IF IT OCCURS" SECTION IF YOU SUSPECT YOUR PATIENT IS EXPERIENCING SYMPTOMS (PAGES 16-17)

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3-4 and throughout this brochure. Please see full Prescribing Information.

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CRS considerations prior to treatment¹ (cont'd)

EPKINLY dosing considerations for CRS

- Administer EPKINLY subcutaneously according to the 3-step up dosage schedule below, for patients with FL to reduce the incidence and severity of CRS
- EPKINLY should only be administered by a qualified healthcare professional with appropriate medical support to manage severe reactions such as CRS
- Administer EPKINLY subcutaneously in 28-day cycles until disease progression or unacceptable toxicity:
 - Cycle 1: 0.16 mg (step up dose 1) on day 1, 0.8 mg (step up dose 2) on day 8, 3 mg (step up dose 3) on day 15, 48 mg (full dose) on day 22
 - Cycles 2-3: 48 mg weekly
 - Cycles 4-9: 48 mg every 2 weeks
 - Cycles 10+: 48 mg every 4 weeks

Recommended pre- and post-administration medications to reduce the risk of CRS

Between 30 and 120 minutes prior to administration of EPKINLY, administer the following medications:

- Cycle 1: For all patients, administer prior to each weekly administration of EPKINLY
 - **Dexamethasone*** (15 mg oral or IV) or **prednisolone** (100 mg oral or IV) or equivalent
 - Continue for 3 consecutive days following each weekly administration
 - **Diphenhydramine** (50 mg oral or IV) or equivalent
 - **Acetaminophen** (650 mg-1000 mg oral)
- Cycles 2+: For patients who experienced grade 2 or 3[†] CRS with previous dose, administer prior to next administration until EPKINLY is given without subsequent CRS of grade 2 or higher
 - **Dexamethasone*** (15 mg oral or IV) or **prednisolone** (100 mg oral or IV) or equivalent
 - Continue for 3 consecutive days following administration of EPKINLY

*Dexamethasone is the preferred corticosteroid when available.

[†]Patients will be permanently discontinued from EPKINLY after a grade 4 CRS event.

Monitoring patients for CRS

- Due to the risk of CRS and ICANS, monitor all patients for signs and symptoms
 - Note: Hospitalization is not required to administer EPKINLY in FL. Hospitalization may be required to manage select adverse reactions in FL
- Signs and symptoms of CRS can include pyrexia, hypotension, hypoxia, dyspnea, chills, and tachycardia
- Concurrent neurological adverse reactions associated with CRS occurred in 4.7% of patients with FL and included headache and dizziness
- At the first signs or symptoms of CRS, immediately evaluate patients for hospitalization, manage per current practice guidelines, and administer supportive care as appropriate. Withhold or discontinue EPKINLY based on the severity of CRS

Counseling patients about CRS

- Inform patients and their care partners of the risk of CRS
- Advise them to immediately contact their healthcare provider should signs and symptoms associated with CRS occur. These can include pyrexia, hypotension, hypoxia, chills, tachycardia, headache, and dyspnea
- Advise patients who experience symptoms that impair consciousness not to drive and refrain from operating heavy or potentially dangerous machinery until events resolve

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3-4 and throughout this brochure.
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ICANS events in EPCORE® NHL-1 in 3L+ FL patients^{1,2}

In patients with FL who received EPKINLY following the 2-step up dosage schedule (n=127)¹

- ICANS events occurred in 6% (8/127) of patients with FL receiving EPKINLY, utilizing the 2-step up dosage schedule
 - 3.9% grade 1, 2.4% grade 2
- The median time to onset of ICANS was 21.5 days (range: 14 to 66 days) from the start of treatment
- Relative to the most recent administration, the median time to onset was 3 days (range: 0.4 to 7 days)
- ICANS resolved in 100% of patients
 - The median duration of ICANS was 2 days (range: 1 to 7 days)
- The median duration of exposure for patients was 8 cycles (range: 1 to 33 cycles)

In patients who received EPKINLY following the recommended 3-step up dosage schedule (n=86)^{1,2}

- No ICANS events were observed at the time of analysis. The median exposure for patients in the dose optimization cohort was 5 cycles (range: 1 to 12 cycles). No conclusions regarding the rate of ICANS can be made, as exposure may not be sufficient in this cohort

Monitor patients for potential ICANS. At first signs or symptoms of ICANS, manage per current practice guidelines and administer supportive care as appropriate. Withhold or discontinue EPKINLY as recommended.

Please see Section 2.6 of the Prescribing Information for CRS and ICANS grading and management recommendations.

SELECT IMPORTANT SAFETY INFORMATION

Immune effector cell-associated neurotoxicity syndrome (ICANS), including life-threatening and fatal reactions, can occur with EPKINLY. Monitor patients for neurological signs or symptoms of ICANS during treatment. Withhold EPKINLY until ICANS resolves or permanently discontinue based on severity.

- The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. Clinical manifestations of ICANS included, but were not limited to, confusional state, lethargy, tremor, dysgraphia, aphasia, and non-convulsive status epilepticus.

EPKINLY dosing considerations for ICANS

- EPKINLY should only be administered by a qualified healthcare professional with appropriate medical support to manage severe reactions such as ICANS
- Administer EPKINLY subcutaneously in 28-day cycles until disease progression or unacceptable toxicity according to the 3-step up dosage schedule:
 - Cycle 1: 0.16 mg (step up dose 1) on day 1, 0.8 mg (step up dose 2) on day 8, 3 mg (step up dose 3) on day 15, 48 mg (full dose) on day 22
 - Cycles 2-3: 48 mg weekly
 - Cycles 4-9: 48 mg every 2 weeks
 - Cycles 10+: 48 mg every 4 weeks

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3-4 and throughout this brochure. Please see full Prescribing Information.


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ICANS events in EPCORE[®] NHL-1 in 3L+ FL patients^{1,2} (cont'd)

Monitoring patients for ICANS

- Due to the risk of CRS and ICANS, monitor all patients for signs and symptoms
 - Note: Hospitalization is not required to administer EPKINLY in FL. Hospitalization may be required to manage select adverse reactions in FL
- Signs and symptoms of ICANS can include confusional state, lethargy, tremor, dysgraphia, aphasia, and nonconvulsive status epilepticus
- The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS
- At the first signs or symptoms of ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold or discontinue EPKINLY per recommendations and consider further management per current practice guidelines

Counseling patients about ICANS

- Advise patients and their care partners of the risks of ICANS, and to immediately contact their healthcare provider for signs and symptoms of ICANS. The onset of events may be delayed and can include:

- | | |
|---------------------|------------------------------------|
| — confusional state | — dysgraphia |
| — lethargy | — aphasia |
| — tremor | — nonconvulsive status epilepticus |

- Advise patients who experience symptoms of ICANS that impair consciousness to refrain from driving or operating heavy or potentially dangerous machinery until symptoms of ICANS resolve

SEE THE "MANAGING ICANS IF IT OCCURS" SECTION IF YOU SUSPECT YOUR PATIENT IS EXPERIENCING SYMPTOMS (PAGES 18–20)

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–4 and throughout this brochure. Please see full [Prescribing Information](#).




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Managing CRS if it occurs¹

What to do if CRS is suspected¹

- Identify CRS based on clinical presentation. Evaluate for and treat other causes of fever, hypotension, and hypoxia
- If CRS is suspected, withhold EPKINLY until CRS resolves
- Manage according to the recommendations in the following table (from Section 2.6 Table 6 of full Prescribing Information) and consider further management per current practice guidelines
- Administer supportive therapy for CRS, which may include intensive care for severe or life-threatening CRS

Recommendations for management of CRS

Grade 1 ^a	Actions
Temperature ≥ 100.4 °F (38 °C) ^b	 Withhold EPKINLY <ul style="list-style-type: none"> ● Manage per current practice guidelines ● Ensure CRS symptoms are resolved prior to next dose of EPKINLY^c
Grade 2 ^a	Actions
Temperature ≥ 100.4 °F (38 °C) ^b with Hypotension not requiring vasopressors and/or Hypoxia requiring low-flow oxygen ^e by nasal cannula or blow-by	 Withhold EPKINLY <ul style="list-style-type: none"> ● Manage per current practice guidelines ● Ensure CRS symptoms are resolved prior to next dose of EPKINLY^c ● Administer premedication^d prior to next dose of EPKINLY ● For the next dose of EPKINLY, monitor more frequently and consider hospitalization

^aBased on ASTCT 2019 grading for CRS.

^bPremedication may mask fever, therefore if clinical presentation is consistent with CRS, follow these management guidelines.

^cRefer to Table 3 or 4 in Section 2.3 of the Prescribing Information for information on restarting EPKINLY after dosage delays.

^dIf grade 2 or 3 CRS occurs with the second full dose (48 mg) or beyond, administer CRS pre- and post-administration medications with each subsequent dose until an EPKINLY dose is given without subsequent CRS of grade 2 or higher. Refer to Table 5 in Section 2.4 of the Prescribing Information for additional information on pre- and post-administration medications.

^eLow-flow oxygen defined as oxygen delivered at < 6 L/minute; high-flow oxygen defined as oxygen delivered at ≥ 6 L/minute.

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3-4 and throughout this brochure. Please see full [Prescribing Information](#).


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CRS Managing CRS if it occurs¹ (cont'd)

Grade 3^a

Actions

Temperature ≥ 100.4 °F (38 °C)^b

with

Hypotension requiring a vasopressor (with or without vasopressin)

and/or

Hypoxia requiring high-flow oxygen^c by nasal cannula, face mask, non-rebreather mask, or Venturi mask



Withhold EPKINLY

- Manage per current practice guidelines, which may include intensive care
- Ensure CRS symptoms are resolved prior to next dose of EPKINLY^c
- Administer premedication^d prior to next dose of EPKINLY
- Hospitalize for next dose of EPKINLY

Recurrent grade 3 CRS



Permanently discontinue EPKINLY

- Manage CRS per current practice guidelines and provide supportive therapy, which may include intensive care

Grade 4^a

Actions

Temperature ≥ 100.4 °F (38 °C)^b

with

Hypotension requiring multiple vasopressors (excluding vasopressin)

and/or

Hypoxia requiring oxygen by positive pressure (eg, CPAP, BiPAP, intubation, and mechanical ventilation)



Permanently discontinue EPKINLY

- Manage CRS per current practice guidelines and provide supportive therapy, which may include intensive care

^aBased on ASTCT 2019 grading for CRS.

^bPremedication may mask fever, therefore if clinical presentation is consistent with CRS, follow these management guidelines.

^cRefer to Table 3 or 4 in Section 2.3 of the Prescribing Information for information on restarting EPKINLY after dosage delays.

^dIf grade 2 or 3 CRS occurs with the second full dose (48 mg) or beyond, administer CRS pre- and post-administration medications with each subsequent dose until an EPKINLY dose is given without subsequent CRS of grade 2 or higher. Refer to Table 5 in Section 2.4 of the Prescribing Information for additional information on pre- and post-administration medications.

^eLow-flow oxygen defined as oxygen delivered at <6 L/minute; high-flow oxygen defined as oxygen delivered at ≥ 6 L/minute.

BiPAP=bilevel positive airway pressure; CPAP=continuous positive airway pressure.

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3-4 and throughout this brochure. Please see full Prescribing Information.






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ICANS Managing ICANS if it occurs¹

What to do if ICANS is suspected

- At first sign of ICANS, withhold EPKINLY and consider neurology evaluation. Rule out other causes of neurologic symptoms. Provide supportive therapy, which may include intensive care, for ICANS
- Manage according to the recommendations in the table (from Section 2.6 Table 7 of full Prescribing Information) on the next page and consider further management per current practice guidelines

Recommendations for management of ICANS¹

Grade 1 ^{a,b}	Actions
ICE score 7–9^c or Depressed level of consciousness^d: <ul style="list-style-type: none"> • Awakens spontaneously 	 Withhold EPKINLY until ICANS resolves^e <ul style="list-style-type: none"> • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management, including consideration for starting nonsedating, antiseizure medicines for seizure prophylaxis
Grade 2 ^{a,b}	Actions
ICE score 3–6^c or Depressed level of consciousness^d: <ul style="list-style-type: none"> • Awakens to voice 	 Withhold EPKINLY until ICANS resolves^e <ul style="list-style-type: none"> • Administer dexamethasone^f 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to grade 1 or less, then taper • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management, including consideration for starting nonsedating, antiseizure medicines for seizure prophylaxis
Grade 3 ^{a,b}	Actions
ICE score 0–2^c or Depressed level of consciousness^d: <ul style="list-style-type: none"> • Awakens only to tactile stimulus or Seizures,^d either: <ul style="list-style-type: none"> • Any clinical seizure, focal or generalized, that resolves rapidly, or • Nonconvulsive seizures on electroencephalogram (EEG) that resolve with intervention or Raised intracranial pressure: focal/local edema on neuroimaging ^d	First occurrence of grade 3 ICANS  Withhold EPKINLY until ICANS resolves^e <ul style="list-style-type: none"> • Administer dexamethasone^f 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to grade 1 or less, then taper • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management, including consideration for starting nonsedating, antiseizure medicines for seizure prophylaxis • Provide supportive therapy, which may include intensive care Recurrent grade 3 ICANS  Permanently discontinue EPKINLY <ul style="list-style-type: none"> • Administer dexamethasone^f 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to grade 1 or less, then taper • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management, including consideration for starting nonsedating, antiseizure medicines for seizure prophylaxis • Provide supportive therapy, which may include intensive care

^aBased on ASTCT 2019 grading for ICANS.

^bManagement is determined by the most severe event, not attributable to any other cause.

^cSee ICE assessment tool on page 20. If patient is unarousable and unable to perform ICE Assessment (grade 4 ICANS) = 0 points.

^dNot attributable to any other cause.

^eSee Table 3 or 4 in Section 2.3 of the Prescribing Information for recommendations on restarting EPKINLY after dosage delays.

^fAll references to dexamethasone administration are dexamethasone or equivalent.

ICE=immune effector cell–associated encephalopathy.

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–4 and throughout this brochure.
Please see full [Prescribing Information](#).


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ICANS Managing ICANS if it occurs¹ (cont'd)

Grade 4^{a,b}

Actions

ICE score 0^c

or

Depressed level of consciousness,^d either:

- Patient is unarousable or requires vigorous or repetitive tactile stimuli to arouse, or
- Stupor or coma

or

Seizures,^d either:

- Life-threatening prolonged seizure (>5 minutes), or
- Repetitive clinical or electrical seizures without return to baseline in between

or

Motor findings^d:

- Deep focal motor weakness, such as hemiparesis or paraparesis

or

Raised intracranial pressure/cerebral edema,^d with signs/symptoms such as:

- Diffuse cerebral edema on neuroimaging, or
- Decerebrate or decorticate posturing, or
- Cranial nerve VI palsy, or
- Papilledema, or
- Cushing's triad



Permanently discontinue EPKINLY

- Administer dexamethasone^e 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to grade 1 or less, then taper
- Alternatively, consider administration of methylprednisolone 1000 mg per day intravenously and continue methylprednisolone 1000 mg per day intravenously for 2 or more days
- Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management, including consideration for starting non-sedating, antiseizure medicines for seizure prophylaxis
- Provide supportive therapy, which may include intensive care

FOR THE ICE ASSESSMENT TOOL, PLEASE SEE PAGE 20

^aBased on ASTCT 2019 grading for ICANS.

^bManagement is determined by the most severe event, not attributable to any other cause.

^cSee ICE assessment tool on page 20. If patient is unarousable and unable to perform ICE Assessment (grade 4 ICANS) = 0 points.

^dNot attributable to any other cause.

^eAll references to dexamethasone administration are dexamethasone or equivalent.

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3-4 and throughout this brochure. Please see full [Prescribing Information](#).


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ICANS Managing ICANS if it occurs¹ (cont'd)

ICE assessment tool^{1,3}

Cognitive domain	Task	Points
Orientation	Orientation to year	1
	Orientation to month	1
	Orientation to city	1
	Orientation to hospital	1
Naming	Ability to name 3 common objects (eg, point to clock, pen, button)	3
Following commands	Ability to follow simple commands (eg, "Show me 2 fingers" or "Close your eyes and stick out your tongue")	1
Writing	Ability to write a standard sentence (eg, "Our national bird is the bald eagle")	1
Attention	Ability to count backward from 100 by 10	1
Maximum ICE score		10

Managing other adverse reactions¹

Infection and cytopenia events in the EPCORE[®] NHL-1 clinical trial

Infections: EPKINLY can cause serious and fatal infections.

3L+ DLBCL/HGBCL

In patients receiving EPKINLY at the recommended 2-step up dosage schedule:

- Serious infections, including opportunistic infections, were reported in 15% of patients with LBCL and were most commonly due to sepsis (4.5%) and pneumonia (3.2%)
- Fatal infections occurred in 1.3% of patients and included COVID-19 (1.3%)
- EPKINLY can cause serious and fatal infections, and serious or severe cytopenias, including neutropenia, anemia, and thrombocytopenia

3L+ FL

In patients following the 2-step up dosage schedule:

- Serious infections, including opportunistic infections, were reported in 40% of patients with FL and were most commonly due to COVID-19 (20%), pneumonia (13%), and urinary tract infections (3%)
- Fatal infections occurred in 6% of patients and included COVID-19 (5%), pneumonia (0.8%), and sepsis (0.8%)

Cytopenias: EPKINLY can cause serious or severe cytopenias.

3L+ DLBCL/HGBCL

- Among LBCL patients receiving EPKINLY at the recommended 2-step up dosage schedule, grade 3 or 4 decreased neutrophils occurred in 32%, decreased hemoglobin in 12%, and decreased platelets in 12% of patients. Febrile neutropenia occurred in 2.5%

3L+ FL

- In patients with FL who received EPKINLY following the 2-step up dosage schedule, grade 3 or 4 decreased neutrophils occurred in 30%, decreased hemoglobin in 10%, and decreased platelets in 8%. Febrile neutropenia occurred in 3.1%

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3-4 and throughout this brochure. Please see full [Prescribing Information](#).


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Managing other adverse reactions¹ (cont'd)





Prior to and after administration

- Avoid administration of EPKINLY in patients with active infections
- Provide *Pneumocystis jirovecii* pneumonia (PJP) prophylaxis prior to initiating treatment with EPKINLY
- Consider initiating prophylaxis against herpes virus prior to starting EPKINLY to prevent herpes zoster reactivation
- Monitor patients for signs and symptoms of infection prior to and during treatment with EPKINLY and treat appropriately
- Monitor complete blood counts throughout treatment
- Based on the severity of cytopenias, temporarily withhold or permanently discontinue EPKINLY. Consider prophylactic granulocyte colony-stimulating factor administration as applicable

Counseling patients

- Advise patients of the risk of serious infections, and to contact their healthcare professional for signs or symptoms of serious infection
- Discuss the signs and symptoms associated with cytopenias, including neutropenia and febrile neutropenia, anemia, and thrombocytopenia

Recommended dosage modification for other adverse reactions

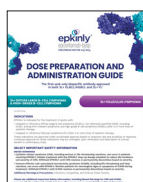
Adverse reaction ^a	Severity ^a	Action
Infections	Grades 1–4	 Withhold EPKINLY <ul style="list-style-type: none"> • In patients with active infection, until the infection resolves^b • For grade 4, consider permanent discontinuation of EPKINLY
Neutropenia	Absolute neutrophil count (ANC) <0.5 x 10 ⁹ /L	 Withhold EPKINLY <ul style="list-style-type: none"> • Until ANC ≥0.5 x 10⁹/L^b
Thrombocytopenia	Platelet count <50 x 10 ⁹ /L	 Withhold EPKINLY <ul style="list-style-type: none"> • Until platelet count ≥50 x 10⁹/L^b
Other adverse reactions	Grade 3 or higher	 Withhold EPKINLY <ul style="list-style-type: none"> • Until the toxicity resolves to grade 1 or baseline^b

^aBased on National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), version 5.0.

^bSee Tables 3 or 4 in Section 2.3 of the Prescribing Information for recommendations on restarting EPKINLY after dosage delays.

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–4 and throughout this brochure. Please see full [Prescribing Information](#).

Additional resources are available to help you, your patients, and their care partners



Dose Preparation and Administration Guide

A comprehensive resource that explains how EPKINLY is supplied, prepared, and administered, and provides recommendations on premedications and dosing schedule



Wallet Card

A card for patients or care partners to fill out and to keep with them in case a healthcare provider needs quick access to their important treatment-related information



3L+ DLBCL/HGBCL Patient Brochure

An overview of EPKINLY that informs patients and their care partners on what they need to know about starting treatment



3L+ FL Patient Brochure

An overview of EPKINLY that informs patients and their care partners on what they need to know about starting treatment

TO DOWNLOAD THESE RESOURCES, VISIT
[EPKINLYHCP.COM/SUPPORT-RESOURCES](https://epkinlyhcp.com/support-resources)

Please see Indications and Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3-4 and throughout this brochure. Please see full [Prescribing Information](#).

References: **1.** EPKINLY [package insert]. Plainsboro, NJ: Genmab US, Inc. and North Chicago, IL: AbbVie Inc. 2024. **2.** Linton KM, Vitolo U, Jurczak W, et al. Epcoritamab monotherapy in patients with relapsed or refractory follicular lymphoma (EPCORE NHL-1): a phase 2 cohort of a single-arm, multicentre study. *Lancet*. Published online June 15, 2024. [https://doi.org/10.1016/S2352-3026\(24\)00166-2](https://doi.org/10.1016/S2352-3026(24)00166-2) **3.** Thieblemont C, Phillips T, Ghesquieres H, et al. Clinical trial protocol for: Epcoritamab, a novel, subcutaneous CD3xCD20 bispecific T-cell-engaging antibody, in relapsed or refractory large B-cell lymphoma: dose expansion in a phase I/II trial. *J Clin Oncol*. Published online December 22, 2022. doi:10.1200/JCO.22.01725



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