



DOSE PREPARATION AND ADMINISTRATION GUIDE

The first-and-only bispecific antibody
approved in 3L+ DLBCL/HGBCL and 2L+ FL¹

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

2L+ FOLLICULAR LYMPHOMA

2L=second line; 3L=third line.

INDICATIONS

DLBCL and High-grade B-cell Lymphoma

- 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.

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

Follicular Lymphoma

- EPKINLY is indicated in combination with lenalidomide and rituximab for the treatment of adults with relapsed or refractory follicular lymphoma (FL).
- EPKINLY is indicated as monotherapy for the treatment of adults with relapsed or refractory FL after 2 or more lines of systemic therapy.

SELECT IMPORTANT SAFETY INFORMATION

BOXED WARNINGS

- **Cytokine release syndrome (CRS), including serious or fatal 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 3–5 and throughout this brochure. Please see full [Prescribing Information](#), including Boxed Warnings.

TABLE OF CONTENTS

Indications and Important Safety Information	3–5
Dosing in patients with 3L+ DLBCL/HGBCL	6–9
Dosing in patients with 2L+ FL	10–13
Dosing in patients with 3L+ FL	14–17
Recommended pre- and post-administration medications	18
Recommended prophylaxis	19
Dosage modifications and management of adverse reactions	20–27
How EPKINLY is supplied	28
Storage and handling	29
Needed supplies (Empty Sterile Vial Method)	30–31
Preparing EPKINLY (Empty Sterile Vial Method)	32–33
Needed supplies (Sterile Syringe Method)	34–35
Preparing EPKINLY (Sterile Syringe Method)	36–37
Needed supplies per dose	38
Preparation of 3 mg and 48 mg EPKINLY doses	39
Treatment reminders	40–42
Navigating access	43

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

INDICATIONS

DLBCL and High-grade B-cell Lymphoma

- 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.

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

Follicular Lymphoma

- EPKINLY is indicated in combination with lenalidomide and rituximab for the treatment of adults with relapsed or refractory follicular lymphoma (FL).
- EPKINLY is indicated as monotherapy for the treatment of adults with relapsed or refractory FL after 2 or more lines of systemic therapy.

IMPORTANT SAFETY INFORMATION

BOXED WARNINGS

- **Cytokine release syndrome (CRS), including serious or fatal 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% (80/157) of patients with large B-cell lymphoma (LBCL) receiving EPKINLY at the recommended dosage schedule in EPCORE NHL-1 (37% Grade 1, 17% Grade 2, and 2.5% Grade 3) and recurred in 31% of patients. Most events (92%) occurred during Cycle 1. In Cycle 1, CRS events occurred in 6% of patients after the 0.16 mg dose (Cycle 1, day 1), 12% after the 0.8 mg dose (Cycle 1, day 8), 43% after the first 48 mg dose (Cycle 1, day 15), and 5% after the next 48 mg dose (Cycle 1, day 22). The median time to onset of CRS from the most recent administered dose across all doses was 24 hours (range: 0–10 days). The median time to onset after the first full 48 mg dose was 21 hours (range: 0–7 days).
- CRS occurred in 49% (42/86) of patients with FL receiving EPKINLY monotherapy at the recommended dosage schedule in EPCORE NHL-1 (45% Grade 1, 9% Grade 2) and recurred in 48% of patients. Most events (88%) occurred during Cycle 1. In Cycle 1, CRS events occurred in 12% of patients after the 0.16 mg dose (Cycle 1, day 1), 6% after the 0.8 mg dose (Cycle 1, day 8), 15% after the 3 mg dose (Cycle 1, day 15), and 37% after the first 48 mg dose (Cycle 1, day 22). The median time to onset of CRS from the most recent administered dose across all doses was 59 hours (range: 0.1–7 days). The median time to onset after the first full 48 mg dose was 61 hours (range: 0.1–7 days).
- CRS occurred in 24% (32/131) of patients with FL receiving EPKINLY at the recommended dosage schedule in combination with lenalidomide and rituximab in EPCORE FL-1 (19% Grade 1, 5% Grade 2, and 12% serious adverse reactions due to CRS) and recurred in 41% of patients. Most events (88%) occurred during Cycle 1. In Cycle 1, CRS occurred in 5% of patients after the 0.16 mg dose (Cycle 1, day 1), 3.8% after the 0.8 mg dose (Cycle 1, day 8), 2.3% after the 3 mg dose (Cycle 1, day 15), and 18% after the first 48 mg dose (Cycle 1, day 22). The median time to onset of CRS from the most recent EPKINLY dose was 78 hours (range: 0.2–12 days). The median time to onset after the first 48 mg dose was 41 hours (range: 0.3–12 days).
- For patients with LBCL and FL, assess whether hospitalization or outpatient monitoring for the first 48 mg dose is appropriate based on comorbidities or other situational factors. During outpatient monitoring after the first 48 mg dose, patients should remain in proximity to a healthcare facility that can assess and manage CRS.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.



epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg/48mg

IMPORTANT SAFETY INFORMATION (CONTINUED)

CRS (CONTINUED)

- In patients who experienced CRS, the signs and symptoms included pyrexia, hypotension, hypoxia, dyspnea, chills, and tachycardia. CRS resolved in 98% of patients; the median duration of CRS events was 2 days (range: <1–27 days). Concurrent neurological adverse reactions associated with CRS occurred in 2.5% of patients with LBCL, 4.7% of patients with FL receiving EPKINLY monotherapy, and 1.5% of patients receiving EPKINLY in combination with lenalidomide and rituximab (reactions included headache, confusional state, tremors, dizziness, and ataxia).
- Administer pretreatment medications to reduce the risk of CRS.
- Monitor patients for potential CRS. At the first signs or symptoms of CRS, immediately evaluate patients for hospitalization, manage per current practice guidelines, and administer supportive care as appropriate.

ICANS

- ICANS occurred in 6% (10/157) of patients with LBCL receiving EPKINLY at the recommended dosage schedule in EPCORE NHL-1 (4.5% Grade 1, 1.3% Grade 2, 0.6% fatal). Of the 10 ICANS events, 9 occurred within Cycle 1 of treatment, with a median time to onset of 16.5 days (range: 8–141 days) from the start of treatment. Relative to the most recent administered dose, the median time to onset was 3 days (range: 1–13 days). The median duration of ICANS was 4 days (range: 0–8 days), with ICANS resolving in 90% of patients with supportive care.
- ICANS occurred in 6% (8/127) of patients with FL receiving EPKINLY monotherapy following the 2-step up dosage schedule in EPCORE NHL-1 (3.9% Grade 1, 2.4% Grade 2). The median time to onset was 22 days (range: 14–66 days) from the start of treatment. Relative to the most recent administered dose, the median time to onset of ICANS was 3 days (range: 0.4–7 days). The median duration of ICANS was 2 days (range: 1–7 days), with ICANS resolving in 100% of patients.
- Among patients with FL who received EPKINLY at the recommended dosage schedule in combination with lenalidomide and rituximab in EPCORE FL-1, ICANS occurred in 0.8% (1/131, Grade 1).
- 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, immediately evaluate patient, provide supportive therapy based on severity, and manage per current practice guidelines.

Infections

- EPKINLY can cause fatal and serious infections. Serious infections, including opportunistic infections, were reported in 15% of patients with LBCL in EPCORE NHL-1 (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 EPKINLY monotherapy following the 2-step up dosage schedule in EPCORE NHL-1 (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).
- Among 243 patients with FL who received EPKINLY in combination with lenalidomide and rituximab in EPCORE FL-1, serious infections occurred in 28% of patients. The most common serious infections were pneumonia (15%), COVID-19 (7%), opportunistic infections (5%) and upper respiratory infections (3.3%). The most common opportunistic infections of any grade were cytomegalovirus (CMV) infection (7%) and herpesvirus infection (7%).
- Progressive multifocal leukoencephalopathy (PML), including fatal cases, has occurred in patients treated with EPKINLY. Across a broader clinical trial population, PML was reported in 0.4% (11/3,072) of patients, including in the first-line treatment setting. Of the 11 cases of PML, 6 resulted in fatal outcomes and 1 was unresolved at the time of death.
- Monitor patients for signs and symptoms of infection and treat appropriately. Avoid administration in patients with active infections. Withhold or consider permanent discontinuation of EPKINLY based on severity. Provide *Pneumocystis jirovecii* pneumonia (PJP) prophylaxis during treatment with EPKINLY and consider prophylaxis against herpesvirus.
- Consider monitoring immunoglobulin levels during treatment and administration of immunoglobulin treatment as appropriate.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.


epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg/48mg

IMPORTANT SAFETY INFORMATION (CONTINUED)

Cytopenias

- EPKINLY can cause serious or severe cytopenias. In the clinical trial of patients with LBCL, Grade 3 or 4 decreased neutrophils occurred in 32% (Grade 4, 14%), decreased hemoglobin in 12% (Grade 4, 0%), and decreased platelets in 12% (Grade 4, 7%) of patients. Febrile neutropenia occurred in 2.5% (Grade 4, 0.6%).
- In the clinical trial of patients with FL who received EPKINLY monotherapy following the 2-step up dosage schedule, Grade 3 or 4 decreased neutrophils occurred in 30% (Grade 4, 17%), decreased hemoglobin in 10% (Grade 4, 0%), and decreased platelets in 8% (Grade 4, 4%) of patients. Febrile neutropenia occurred in 3.1% (Grade 4, 0%).
- In patients with FL who received EPKINLY in combination with lenalidomide and rituximab, Grade 3 or 4 decreased neutrophils occurred in 67% (Grade 4, 41%), decreased lymphocytes in 62% (Grade 4, 13%), decreased hemoglobin in 7%, and decreased platelets in 10% (Grade 4, 4.1%) of patients. Febrile neutropenia occurred in 6% (Grade 4, 2.1%).
- 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.

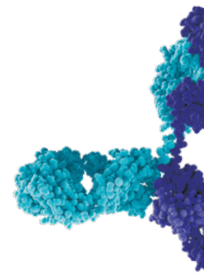
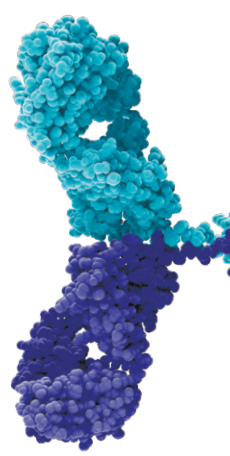
Adverse Reactions

- EPKINLY as monotherapy for LBCL or FL: Most common ($\geq 20\%$) adverse reactions were CRS, injection site reactions, fatigue, musculoskeletal pain, fever, diarrhea, COVID-19, rash, and abdominal pain. Most common Grade 3 to 4 laboratory abnormalities ($\geq 10\%$) were decreased lymphocytes, decreased neutrophils, decreased hemoglobin, and decreased platelets.
- EPKINLY in combination with lenalidomide and rituximab for FL: Most common ($\geq 20\%$) adverse reactions were rash, upper respiratory tract infections, fatigue, injection site reactions, constipation, diarrhea, CRS, pneumonia, COVID-19, and fever. The most common Grade 3 to 4 laboratory abnormalities ($\geq 10\%$) were decreased neutrophils, decreased lymphocytes, and decreased platelets.

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 EPCORE NHL-1, 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.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.



epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg/48mg

EPKINLY is administered in 28-day cycles¹

Administer EPKINLY according to the recommended 2-step up dosage schedule to reduce the incidence and severity of CRS

2-step up dosage schedule for DLBCL/HGBCL

	 EPKINLY (subcutaneous)	
CYCLE 1	Week 1	0.16 mg
	Week 2	0.8 mg
	Week 3	48 mg
	Week 4	48 mg
CYCLES 2-3	48 mg weekly	
CYCLES 4-9	48 mg every other week	
Monthly maintenance dosing CYCLES 10+	48 mg every 4 weeks	

- CRS occurred in 51% (80/157) of patients in EPCORE[®] NHL-1 (37% Grade 1, 17% Grade 2, and 2.5% Grade 3). Recurrent CRS occurred in 31% of patients
- Most CRS events (92%) occurred during Cycle 1. In Cycle 1, CRS events occurred in 6% of patients after the 0.16-mg dose (Day 1), 12% after the 0.8-mg dose (Day 8), 43% after the first 48-mg dose (Day 15), and 5% after the next 48-mg dose (Day 22)
- The median time to onset of CRS from the most recent EPKINLY dose was 24 hours (range: 0 to 10 days)
- The median time to onset of CRS after the first full 48-mg dose was 21 hours (range: 0 to 7 days)

EPKINLY is for subcutaneous injection only.

CONTINUE UNTIL DISEASE PROGRESSION OR UNACCEPTABLE TOXICITY

NHL=non-Hodgkin lymphoma.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.


 epcoritamab-bysp[®]
 SUBCUTANEOUS INJECTION 4mg/48mg

Recommendations for restarting EPKINLY after dosage delay

Last dose administered	Time since the last dose administered	Action for next dose(s) ^a
0.16 mg on Cycle 1, Day 1	More than 8 days	Repeat Cycle 1 schedule starting at step-up dose 1 (0.16 mg). Following the repeat of Cycle 1 schedule, resume the planned treatment schedule
0.8 mg on Cycle 1, Day 8	14 days or less	Administer 48 mg, then resume the planned treatment schedule
	More than 14 days	Repeat Cycle 1 schedule starting at step-up dose 1 (0.16 mg). Following the repeat of Cycle 1 schedule, resume the planned treatment schedule
48 mg on Cycle 1, Day 15 onwards	6 weeks or less	Administer 48 mg, then resume the planned treatment schedule
	More than 6 weeks	Repeat Cycle 1 schedule starting at step-up dose 1 (0.16 mg). Following the repeat of Cycle 1 schedule, resume the planned treatment schedule

^aAdminister pretreatment medication prior to EPKINLY dose and monitor patients accordingly.

SELECT IMPORTANT SAFETY INFORMATION

BOXED WARNINGS

- **Cytokine release syndrome (CRS), including serious or fatal 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.**
- 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 receiving EPKINLY monotherapy, and 1.5% of patients receiving EPKINLY in combination with lenalidomide and rituximab (reactions included headache, confusional state, tremors, dizziness, and ataxia).
- 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.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.


epkinly[®]
 epcoritamab-bysp
 SUBCUTANEOUS INJECTION 4mg/48mg

Dosing information for EPKINLY in 3L+ DLBCL

**Hospitalization is not required for monitoring with EPKINLY administration.
Assess each patient.**

- Assess whether hospitalization or outpatient monitoring for the first 48-mg dose is appropriate based on comorbidities or other situational factors
- During outpatient monitoring after the first 48-mg dose, patients should remain in proximity to a healthcare facility that can assess and manage CRS
 - Inform patients of the risk of CRS, and to immediately contact their HCP should signs and symptoms associated with CRS (eg, pyrexia, hypotension, hypoxia, chills, tachycardia, headache, and dyspnea) occur at any time
- EPKINLY should only be administered by a qualified HCP with appropriate medical support to manage severe reactions such as CRS and ICANS
- Due to the risk of CRS and ICANS, monitor all patients for signs and symptoms
- Hospitalization may be needed to manage some adverse reactions

Please see Section 2.2 of the Prescribing Information for the recommended dosage of EPKINLY.

HCP=healthcare provider.

SELECT IMPORTANT SAFETY INFORMATION

Cytokine release syndrome (CRS), including serious or fatal 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.

- Monitor patients for potential CRS. At the first signs or symptoms of CRS, immediately evaluate patients for hospitalization, manage per current practice guidelines, and administer supportive care as appropriate.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.


epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg/48mg

Important dosing information for 3L+ DLBCL/HGBCL

- Certain doses of EPKINLY require dilution prior to administration. There are 2 available methods to prepare diluted EPKINLY:
 - Empty sterile vial method
 - Sterile syringe method
- Preparation of 3-mg and 48-mg EPKINLY doses does not require dilution
- EPKINLY should only be administered by a qualified HCP with appropriate medical support to manage severe reactions such as CRS and ICANS
- Administer EPKINLY to well-hydrated patients
- Administer EPKINLY subcutaneously according to the 2-step up dosage schedule for patients with DLBCL or HGBCL and premedicate before each dose in Cycle 1 to reduce the incidence and severity of CRS

Dosing discontinuation and delays in the clinical trial

- 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 $\geq 3\%$: CRS, neutropenia, sepsis, and thrombocytopenia)

SELECT IMPORTANT SAFETY INFORMATION

BOXED WARNINGS

- **Cytokine release syndrome (CRS), including serious or fatal 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.**
- 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 receiving EPKINLY monotherapy, and 1.5% of patients receiving EPKINLY in combination with lenalidomide and rituximab (reactions included headache, confusional state, tremors, dizziness, and ataxia).
- 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.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.



epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg/48mg

EPKINLY + R² is administered in 28-day cycles¹

Administer EPKINLY according to the recommended 3-step up dosage schedule to reduce the incidence and severity of CRS

3-step up dosage schedule for FL

			R ²	
	 EPKINLY (subcutaneous)	 rituximab (IV)	 lenalidomide (oral)	
CYCLE 1	Week 1	0.16 mg	375 mg/m ² weekly	20 mg on Days 1 to 21 of each cycle through 12 cycles
	Week 2	0.8 mg		
	Week 3	3 mg		
	Week 4	48 mg		
CYCLES 2-3	48 mg weekly		375 mg/m ² every 4 weeks	
CYCLES 4-5	48 mg every 4 weeks			
CYCLES 6-12			—	

EPKINLY is for subcutaneous injection only.

Refer to the lenalidomide prescribing information and rituximab prescribing information for the respective dosage recommendations, including lenalidomide dosage recommendations for patients with renal insufficiency.

CONTINUE EPKINLY FOR A TOTAL OF 12 CYCLES (1 CYCLE = 28 DAYS) OR UNTIL DISEASE PROGRESSION OR UNACCEPTABLE TOXICITY, WHICHEVER OCCURS FIRST

- CRS occurred in 24% (32/131) of patients receiving EPKINLY + R² at the recommended dosage schedule in EPCORE[®] FL-1 (19% Grade 1, 5% Grade 2). Serious adverse reactions due to CRS occurred in 12% of patients; recurrent CRS occurred in 41%
- Most CRS events (88%) occurred during Cycle 1. In Cycle 1, CRS occurred in 5% of patients after the 0.16-mg dose (Day 1), 3.8% after the 0.8-mg dose (Day 8), 2.3% after the 3-mg dose (Day 15), and 18% after the first 48-mg dose (Day 22)
- The median time to onset of CRS from the most recent EPKINLY dose was 78 hours (range: 0.2 to 12 days)
- The median time to onset after the first full 48-mg dose was 41 hours (range: 0.3 to 12 days)
- **CRS resolved in 98% of DLBCL and FL patients**
 - Median duration of CRS events was 2 days (range: <1 to 27 days)

IV=intravenous; R²=rituximab + lenalidomide.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.

epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg/48mg

Recommendations for restarting EPKINLY after dosage delay

Last dose administered	Time since the last dose administered	Action for next dose(s) ^a
0.16 mg on Cycle 1, Day 1	More than 8 days	Repeat Cycle 1 schedule starting at step-up dose 1 (0.16 mg). Following the repeat of Cycle 1 schedule, resume the planned treatment schedule
0.8 mg on Cycle 1, Day 8	More than 8 days	Repeat Cycle 1 schedule starting at step-up dose 1 (0.16 mg). Following the repeat of Cycle 1 schedule, resume the planned treatment schedule
3 mg on Cycle 1, Day 15	14 days or less	Administer 48 mg, then resume the planned treatment schedule
	More than 14 days	Repeat Cycle 1 schedule starting at step-up dose 1 (0.16 mg). Following the repeat of Cycle 1 schedule, resume the planned treatment schedule
48 mg on Cycle 1, Day 22 onwards	6 weeks or less	Administer 48 mg, then resume the planned treatment schedule
	More than 6 weeks	Repeat Cycle 1 schedule starting at step-up dose 1 (0.16 mg). Following the repeat of Cycle 1 schedule, resume the planned treatment schedule

^aAdminister pretreatment medication prior to EPKINLY dose and monitor patients accordingly.

SELECT IMPORTANT SAFETY INFORMATION

BOXED WARNINGS

- **Cytokine release syndrome (CRS), including serious or fatal 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.**
- 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 receiving EPKINLY monotherapy, and 1.5% of patients receiving EPKINLY in combination with lenalidomide and rituximab (reactions included headache, confusional state, tremors, dizziness, and ataxia).
- 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.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.


epkinly[®]
 epcoritamab-bysp
 SUBCUTANEOUS INJECTION 4mg/48mg

Dosing information for EPKINLY in 2L+ FL¹

Hospitalization is not required for monitoring with EPKINLY administration. Assess each patient.

- Assess whether hospitalization or outpatient monitoring for the first 48-mg dose is appropriate based on comorbidities or other situational factors
- During outpatient monitoring after the first 48-mg dose, patients should remain in proximity to a healthcare facility that can assess and manage CRS
 - Inform patients of the risk of CRS, and to immediately contact their HCP should signs and symptoms associated with CRS (eg, pyrexia, hypotension, hypoxia, chills, tachycardia, headache, and dyspnea) occur at any time
- EPKINLY should only be administered by a qualified HCP with appropriate medical support to manage severe reactions such as CRS and ICANS
- Due to the risk of CRS and ICANS, monitor all patients for signs and symptoms
- Hospitalization may be needed to manage some adverse reactions

Please see Section 2.2 of the Prescribing Information for the recommended dosage of EPKINLY.

SELECT IMPORTANT SAFETY INFORMATION

Cytokine release syndrome (CRS), including serious or fatal 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.

- Monitor patients for potential CRS. At the first signs or symptoms of CRS, immediately evaluate patients for hospitalization, manage per current practice guidelines, and administer supportive care as appropriate.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.


epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg/48mg

Important dosing information for 2L+ FL

- Certain doses of EPKINLY require dilution prior to administration. There are 2 available methods to prepare diluted EPKINLY:
 - Empty sterile vial method
 - Sterile syringe method
- Preparation of 3-mg and 48-mg EPKINLY doses does not require dilution
- EPKINLY should only be administered by a qualified HCP with appropriate medical support to manage severe reactions such as CRS and ICANS
- Administer EPKINLY to well-hydrated patients
- Administer EPKINLY subcutaneously according to the 3-step up dosage schedule for patients with FL and premedicate before each dose in Cycle 1 to reduce the incidence and severity of CRS

Dosing discontinuation and delays in the clinical trial

- In 243 patients who received EPKINLY + R²:
 - Adverse reactions led to permanent discontinuation of EPKINLY in 6% of patients and dose interruption in 75% of patients, with infection as a leading cause. Adverse reactions leading to interruption of EPKINLY in ≥5% of patients included respiratory tract infections, CRS, and rash
 - In the EPKINLY arm, adverse reactions led to lenalidomide dose interruption in 72%, dose reduction in 22%, and permanent discontinuation in 15%

SELECT IMPORTANT SAFETY INFORMATION

BOXED WARNINGS

- **Cytokine release syndrome (CRS), including serious or fatal 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.**
- 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 receiving EPKINLY monotherapy, and 1.5% of patients receiving EPKINLY in combination with lenalidomide and rituximab (reactions included headache, confusional state, tremors, dizziness, and ataxia).
- 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.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.



epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg/48mg

EPKINLY is administered in 28-day cycles¹

Administer EPKINLY according to the recommended 3-step up dosage schedule to reduce the incidence and severity of CRS

3-step up dosage schedule for FL

	 EPKINLY (subcutaneous)	
CYCLE 1	Week 1	0.16 mg
	Week 2	0.8 mg
	Week 3	3 mg
	Week 4	48 mg
CYCLES 2-3	48 mg weekly	
CYCLES 4-9	48 mg every other week	
CYCLES 10+	48 mg every 4 weeks	

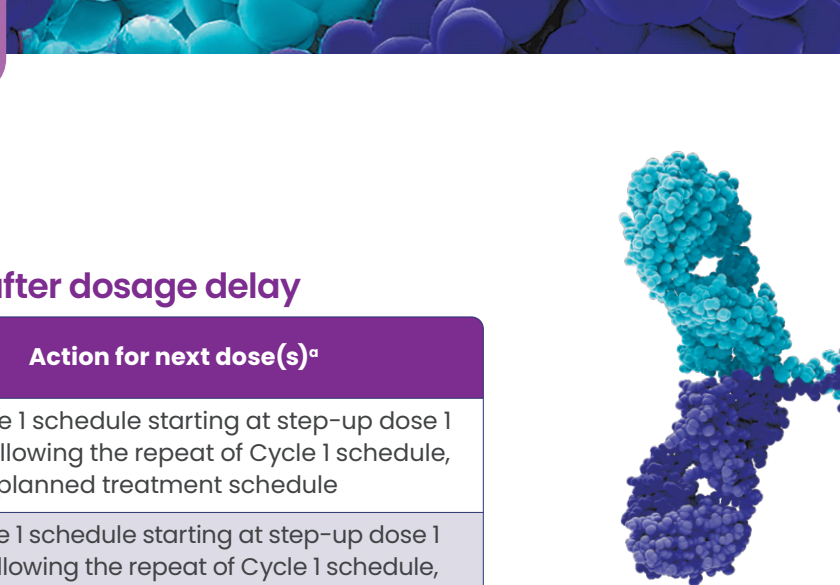
- CRS occurred in 49% (42/86) of patients receiving EPKINLY at the recommended dosage schedule in EPCORE[®] NHL-1 (45% Grade 1, 9% Grade 2). Recurrent CRS occurred in 48% of patients
- Most CRS events (88%) occurred during Cycle 1. In Cycle 1, CRS events occurred in 12% of patients after the 0.16-mg dose (Day 1), 6% after the 0.8-mg dose (Day 8), 15% after the 3-mg dose (Day 15), and 37% after the first 48-mg dose (Day 22)
- The median time to onset of CRS from the most recent EPKINLY dose 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)

EPKINLY is for subcutaneous injection only.

**CONTINUE UNTIL DISEASE PROGRESSION
OR UNACCEPTABLE TOXICITY**

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.


 epcoritamab-bysp[®]
 SUBCUTANEOUS INJECTION 4mg/48mg



Recommendations for restarting EPKINLY after dosage delay

Last dose administered	Time since the last dose administered	Action for next dose(s) ^a
0.16 mg on Cycle 1, Day 1	More than 8 days	Repeat Cycle 1 schedule starting at step-up dose 1 (0.16 mg). Following the repeat of Cycle 1 schedule, resume the planned treatment schedule
0.8 mg on Cycle 1, Day 8	More than 8 days	Repeat Cycle 1 schedule starting at step-up dose 1 (0.16 mg). Following the repeat of Cycle 1 schedule, resume the planned treatment schedule
3 mg on Cycle 1, Day 15	14 days or less	Administer 48 mg, then resume the planned treatment schedule
	More than 14 days	Repeat Cycle 1 schedule starting at step-up dose 1 (0.16 mg). Following the repeat of Cycle 1 schedule, resume the planned treatment schedule
48 mg on Cycle 1, Day 22 onwards	6 weeks or less	Administer 48 mg, then resume the planned treatment schedule
	More than 6 weeks	Repeat Cycle 1 schedule starting at step-up dose 1 (0.16 mg). Following the repeat of Cycle 1 schedule, resume the planned treatment schedule

^aAdminister pretreatment medication prior to EPKINLY dose and monitor patients accordingly.

SELECT IMPORTANT SAFETY INFORMATION

BOXED WARNINGS

- **Cytokine release syndrome (CRS), including serious or fatal 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.**
- 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 receiving EPKINLY monotherapy, and 1.5% of patients receiving EPKINLY in combination with lenalidomide and rituximab (reactions included headache, confusional state, tremors, dizziness, and ataxia).
- 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.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.


epkinly[®]
 epcoritamab-bysp
 SUBCUTANEOUS INJECTION 4mg/48mg

Dosing information for EPKINLY in 3L+ FL

Hospitalization is not required for monitoring with EPKINLY administration. Assess each patient.

- Assess whether hospitalization or outpatient monitoring for the first 48-mg dose is appropriate based on comorbidities or other situational factors
- During outpatient monitoring after the first 48-mg dose, patients should remain in proximity to a healthcare facility that can assess and manage CRS
 - Inform patients of the risk of CRS, and to immediately contact their HCP should signs and symptoms associated with CRS (eg, pyrexia, hypotension, hypoxia, chills, tachycardia, headache, and dyspnea) occur at any time
- EPKINLY should only be administered by a qualified HCP with appropriate medical support to manage severe reactions such as CRS and ICANS
- Due to the risk of CRS and ICANS, monitor all patients for signs and symptoms
- Hospitalization may be needed to manage some adverse reactions

Please see Section 2.2 of the Prescribing Information for the recommended dosage of EPKINLY.

SELECT IMPORTANT SAFETY INFORMATION

Cytokine release syndrome (CRS), including serious or fatal 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.

- Monitor patients for potential CRS. At the first signs or symptoms of CRS, immediately evaluate patients for hospitalization, manage per current practice guidelines, and administer supportive care as appropriate.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.


epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg/48mg

Important dosing information for 3L+ FL

- Certain doses of EPKINLY require dilution prior to administration. There are 2 available methods to prepare diluted EPKINLY:
 - Empty sterile vial method
 - Sterile syringe method
- Preparation of 3-mg and 48-mg EPKINLY doses does not require dilution
- EPKINLY should only be administered by a qualified HCP with appropriate medical support to manage severe reactions such as CRS and ICANS
- Administer EPKINLY to well-hydrated patients
- Administer EPKINLY subcutaneously according to the 3-step up dosage schedule for patients with FL and premedicate before each dose in Cycle 1 to reduce the incidence and severity of CRS

Dosing discontinuation and delays in the clinical trial

- In 86 patients with FL who received the recommended 3-step up dosage schedule of EPKINLY:
 - Dose interruptions due to CRS occurred in 19% of patients
- In 127 patients with FL who received the 2-step up dosage schedule of EPKINLY:
 - Permanent discontinuation due to an adverse reaction occurred in 19% of patients
 - Adverse reactions resulting in permanent discontinuation in ≥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 occurring ≥5%: COVID-19, CRS, pneumonia, upper respiratory tract infection, and fatigue)

SELECT IMPORTANT SAFETY INFORMATION

BOXED WARNINGS

- **Cytokine release syndrome (CRS), including serious or fatal 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.**
- 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 receiving EPKINLY monotherapy, and 1.5% of patients receiving EPKINLY in combination with lenalidomide and rituximab (reactions included headache, confusional state, tremors, dizziness, and ataxia).
- 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.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.



epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg/48mg

Recommended pre- and post-administration medications¹

Administer medications as outlined below to reduce risk of CRS

Cycle	Patients requiring medication	Medication	Administration
Cycle 1	All patients	Dexamethasone^a (15 mg oral or intravenous) or prednisolone (100 mg oral or intravenous) or equivalent	30–120 minutes prior to each weekly administration of EPKINLY - And for 3 consecutive days following each weekly administration of EPKINLY in Cycle 1
		- Diphenhydramine (50 mg oral or intravenous) or equivalent - Acetaminophen (650 mg to 1,000 mg oral)	30–120 minutes prior to each weekly administration of EPKINLY
Cycles 2+	Patients who experienced Grade 2 or 3 ^b CRS with previous dose	Dexamethasone^a (15 mg oral or intravenous) or prednisolone (100 mg oral or intravenous) or equivalent	30–120 minutes prior to next administration of EPKINLY after a Grade 2 or 3^b CRS event - And for 3 consecutive days following the next administration of EPKINLY until EPKINLY is given without subsequent CRS of Grade 2 or higher

^aDexamethasone is the preferred corticosteroid when available.

^bPatients will be permanently discontinued from EPKINLY after Grade 4 CRS.

SELECT IMPORTANT SAFETY INFORMATION

Cytokine release syndrome (CRS), including serious or fatal 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.

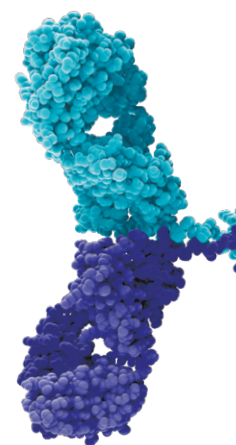
- Monitor patients for potential CRS. At the first signs or symptoms of CRS, immediately evaluate patients for hospitalization, manage per current practice guidelines, and administer supportive care as appropriate.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.


epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg/48mg

Recommended prophylaxis¹

- Provide *Pneumocystis jirovecii* pneumonia (PJP) prophylaxis during treatment with EPKINLY
- Consider providing prophylaxis against herpesvirus during treatment with EPKINLY to prevent herpes simplex and herpes zoster
- Refer to the lenalidomide prescribing information for recommendations on prophylaxis for venous and arterial thrombotic events



SELECT IMPORTANT SAFETY INFORMATION

Infections: EPKINLY can cause fatal and serious infections.

- EPKINLY can cause fatal and serious infections. Serious infections, including opportunistic infections, were reported in 15% of patients with LBCL in EPCORE NHL-1 (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 EPKINLY monotherapy following the 2-step up dosage schedule in EPCORE NHL-1 (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).
- Among 243 patients with FL who received EPKINLY in combination with lenalidomide and rituximab in EPCORE FL-1, serious infections occurred in 28% of patients. The most common serious infections were pneumonia (15%), COVID-19 (7%), opportunistic infections (5%) and upper respiratory infections (3.3%). The most common opportunistic infections of any grade were cytomegalovirus (CMV) infection (7%) and herpesvirus infection (7%).
- Progressive multifocal leukoencephalopathy (PML), including fatal cases, has occurred in patients treated with EPKINLY. Across a broader clinical trial population, PML was reported in 0.4% (11/3,072) of patients, including in the first-line treatment setting. Of the 11 cases of PML, 6 resulted in fatal outcomes and 1 was unresolved at the time of death.
- Monitor patients for signs and symptoms of infection and treat appropriately. Avoid administration in patients with active infections. Withhold or consider permanent discontinuation of EPKINLY based on severity. Provide *Pneumocystis jirovecii* pneumonia (PJP) prophylaxis during treatment with EPKINLY and consider prophylaxis against herpesvirus.
- Consider monitoring immunoglobulin levels during treatment and administration of immunoglobulin treatment as appropriate.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.



epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg/48mg

Dosage modifications and management of adverse reactions¹

Recommendations for management of CRS

- 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 below and consider further management per current practice guidelines
- Administer supportive therapy for CRS, which may include intensive care for severe or life-threatening CRS

Grade 1 ^a	Actions
Temperature ≥ 100.4 °F (38 °C) ^b	 Withhold EPKINLY ● 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 ● 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 4 or Table 5 in Section 2.3 of the Prescribing Information for information on restarting EPKINLY after dosage delays in patients with DLBCL and FL, respectively.

^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 6 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.

ASTCT=American Society for Transplantation and Cellular Therapy.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.


 epcoritamab-bysp
 SUBCUTANEOUS INJECTION 4mg/48mg

Dosage modifications and management of adverse reactions¹ (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^e 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 4 or Table 5 in Section 2.3 of the Prescribing Information for information on restarting EPKINLY after dosage delays in patients with DLBCL and FL, respectively.

^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 6 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 additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.


epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg/48mg

Dosage modifications and management of adverse reactions¹ (cont'd)

Recommendations for management of ICANS

- Monitor patients for signs and symptoms of ICANS
- At the 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 ICANS according to the recommendations below and consider further management per current practice guidelines

Grade 1 ^{a,b}	Actions
ICE score 7–9 ^c or Depressed level of consciousness ^d : • Awakens spontaneously	 Withhold EPKINLY until ICANS resolves^e • 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 : • Awakens to voice	 Withhold EPKINLY until ICANS resolves^e • 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

^aBased on ASTCT 2019 grading for ICANS.

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

^cIf patient is arousable and able to perform the ICE Assessment, assess: orientation; naming; following commands; writing; and attention. If patient is unarousable and unable to perform ICE Assessment (Grade 4 ICANS) = 0 points. See Table 8 in Section 2.6 of the Prescribing Information for more information on the ICE Assessment.

^dNot attributable to any other cause.

^eSee Table 4 or Table 5 in Section 2.3 of the Prescribing Information for recommendations on restarting EPKINLY after dosage delays in patients with DLBCL and FL, respectively.

^fAll references to dexamethasone administration are dexamethasone or equivalent.

ICE=immune effector cell-associated encephalopathy.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.


epkinly[®]
 epcoritamab-bysp
 SUBCUTANEOUS INJECTION 4mg/48mg

Dosage modifications and management of adverse reactions¹ (cont'd)

Recommendations for management of ICANS (cont'd)

Grade 3 ^{a,b}	Actions
ICE score 0–2^c or Depressed level of consciousness^d: ● Awakens only to tactile stimulus or Seizures,^d either: ● 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 ● 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 ● 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.

^cIf patient is arousable and able to perform the ICE Assessment, assess: orientation; naming; following commands; writing; and attention. If patient is unarousable and unable to perform ICE Assessment (Grade 4 ICANS) = 0 points. See Table 8 in Section 2.6 of the Prescribing Information for more information on the ICE Assessment.

^dNot attributable to any other cause.

^eSee Table 4 or Table 5 in Section 2.3 of the Prescribing Information for recommendations on restarting EPKINLY after dosage delays in patients with DLBCL and FL, respectively.

^fAll references to dexamethasone administration are dexamethasone or equivalent.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.

epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg/48mg

Dosage modifications and management of adverse reactions¹ (cont'd)

Recommendations for management of ICANS (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 1,000 mg per day intravenously and continue methylprednisolone 1,000 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 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.

^cIf patient is arousable and able to perform the ICE Assessment, assess: orientation; naming; following commands; writing; and attention. If patient is unarousable and unable to perform ICE Assessment (Grade 4 ICANS) = 0 points. See Table 8 in Section 2.6 of the Prescribing Information for more information on the ICE Assessment.

^dNot attributable to any other cause.

^eAll references to dexamethasone administration are dexamethasone or equivalent.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.


 epcoritamab-bysp[®]
 SUBCUTANEOUS INJECTION 4mg/48mg

Dosage modifications and management of adverse reactions¹ (cont'd)

Recommended dosage modifications for other adverse reactions when EPKINLY is given as monotherapy

Adverse reaction	Severity ^a	Action
Infections	Grades 1–4	 Withhold EPKINLY • In patients with active infection, until the infection resolves^b • For Grade 4, consider permanent discontinuation of EPKINLY
Neutropenia	Absolute neutrophil count (ANC) $<0.5 \times 10^9/L$	 Withhold EPKINLY • Until ANC $\geq 0.5 \times 10^9/L$^b
Thrombocytopenia	Platelet count $<50 \times 10^9/L$	 Withhold EPKINLY • Until platelet count $\geq 50 \times 10^9/L$^b
Other adverse reactions	Grade 3 or higher	 Withhold EPKINLY • 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 Table 4 or Table 5 in Section 2.3 of the Prescribing Information for recommendations on restarting EPKINLY after dosage delays in patients with DLBCL and FL, respectively.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.


epcoritamab-bysp[®]
SUBCUTANEOUS INJECTION 4mg/48mg

Dosage modifications and management of adverse reactions¹ (cont'd)

Recommended dosage modifications for other adverse reactions when EPKINLY is given in combination with R²

Adverse reaction	Severity ^a	Action ^b
Neutropenia	ANC <0.5 x 10 ⁹ /L	- Consider G-CSF II Withhold EPKINLY - Until ANC ≥1 x 10⁹/L^c - Withhold lenalidomide for remainder of cycle. On Day 1 of next cycle, the dose of lenalidomide may be maintained if neutropenia was the only toxicity limiting lenalidomide dosing
Febrile neutropenia	Grade 3 or higher	- Consider G-CSF II Withhold EPKINLY - Until fever resolves and ANC ≥1 x 10⁹/L^c - Withhold lenalidomide for remainder of cycle. On Day 1 of next cycle, dose of lenalidomide may be maintained if febrile neutropenia was the only toxicity limiting lenalidomide dosing

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

^bRefer to lenalidomide prescribing information for additional toxicity guidelines.

^cSee Table 5 in Section 2.3 of the Prescribing Information for recommendations on restarting EPKINLY after dosage delays in patients with FL.

G-CSF=granulocyte colony-stimulating factor.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.

epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg/48mg

Dosage modifications and management of adverse reactions¹ (cont'd)

Recommended dosage modifications for other adverse reactions when EPKINLY is given in combination with R² (cont'd)

Adverse reaction	Severity ^a	Action ^b
Thrombocytopenia	Platelet count <50 x 10 ⁹ /L	 Withhold EPKINLY • Until platelet count ≥50 x 10⁹/L^c • Withhold lenalidomide for remainder of cycle. Decrease lenalidomide dose for next cycle
Other adverse reactions	Grade 3	For first episode,  Withhold EPKINLY • Until improvement to Grade 2 or less or resolution to baseline^c For second episode,  Permanently discontinue EPKINLY if clinically indicated^c
	Grade 4	 Permanently discontinue EPKINLY at discretion of HCP

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

^bRefer to lenalidomide prescribing information for additional toxicity guidelines.

^cSee Table 5 in Section 2.3 of the Prescribing Information for recommendations on restarting EPKINLY after dosage delays in patients with FL.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.


 epcoritamab-bysp
 SUBCUTANEOUS INJECTION 4mg/48mg

EPKINLY is supplied as single-dose vials in 2 strengths¹

EPKINLY is prepared and administered by an HCP as a subcutaneous injection.

Patients with DLBCL/HGBCL receive EPKINLY at a recommended 2-step up dosage schedule (0.16 and 0.8 mg).

Patients with FL receive EPKINLY at a recommended 3-step up dosage schedule (0.16, 0.8, and 3.0 mg).

4 mg/0.8 mL vial for step-up doses



- Step-up dose 1 (0.16 mg) and step-up dose 2 (0.8 mg) of EPKINLY 4 mg/0.8 mL require **dilution** by an HCP

- **For patients with FL only**
Step-up dose 3 of EPKINLY (3 mg) **does not** require dilution

48 mg/0.8 mL vial for full doses



- The 48-mg full dose of EPKINLY 48 mg/0.8 mL vial **does not** require dilution

Note: Vials are not sized to scale.

EPKINLY DILUTIONS HAVE THE FLEXIBILITY TO BE PREPARED USING 2 DIFFERENT METHODS BASED ON AVAILABLE SUPPLIES: EMPTY STERILE VIAL METHOD OR STERILE SYRINGE METHOD. SEE PAGE 30 AND PAGE 34 TO LEARN MORE.

For additional information about the dosing of R², refer to the lenalidomide prescribing information and rituximab prescribing information for the respective dosage recommendations, including lenalidomide dosage recommendations for patients with renal insufficiency.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.

epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4 mg/0.8 mL 48 mg/0.8 mL

Storage and handling for EPKINLY¹

For single-dose vials

DO	DON'T
Store refrigerated at 2 °C to 8 °C (36 °F to 46 °F)	Freeze EPKINLY
Keep in the original carton to protect from light	Shake EPKINLY

- Certain doses of EPKINLY require **dilution** prior to administration
- Follow the preparation instructions in the full Prescribing Information, as improper preparation may lead to improper dose

Storage of EPKINLY solution in the syringe

- Use EPKINLY solution in the syringe immediately
- If not used immediately, store in a refrigerator at 2 °C to 8 °C (36 °F to 46 °F) for up to **24 hours** or at room temperature at 20 °C to 25 °C (68 °F to 77 °F) for up to **12 hours**
- The total storage time from the start of dose preparation to administration should not exceed **24 hours**. Protect EPKINLY solution from direct sunlight
- Discard unused EPKINLY solution beyond the allowable storage time

Administration¹

- To minimize injection pain, allow EPKINLY solution to equilibrate to room temperature for no more than 1 hour before administration
- EPKINLY should be injected in the subcutaneous tissue of the lower part of the abdomen (preferred injection site) or the thigh
 - Change of injection site from the left or right side or vice versa is recommended, especially during the weekly administrations (Cycles 1–3)
- Do not inject into tattoos, scars, or areas where the skin is red, bruised, tender, hard, or not intact

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.


epkinly[®]
 epcoritamab-bysp
 SUBCUTANEOUS INJECTION 4mg/48mg

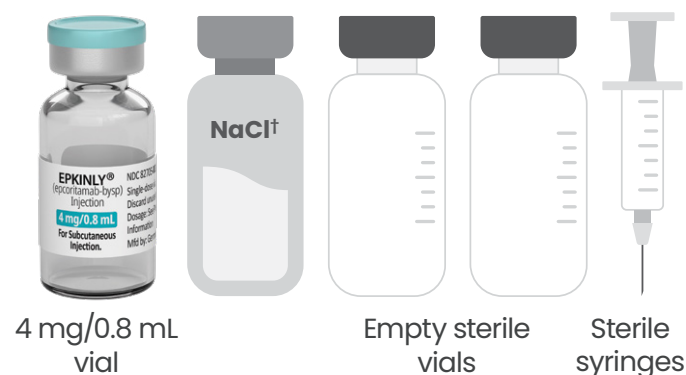
Needed supplies per dose¹

EMPTY STERILE VIAL METHOD*

DLBCL/HGBCL AND FL

STEP-UP DOSE 1 (0.16 MG)

Requires **2** dilutions

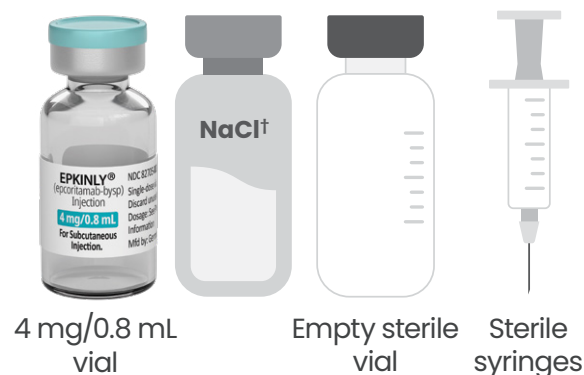


Note: Vials and syringes are not sized to scale.

DLBCL/HGBCL AND FL

STEP-UP DOSE 2 (0.8 MG)

Requires **1** dilution



Step-up dose 1 uses one EPKINLY 4 mg/0.8 mL vial. Dilute prior to use.

Step-up dose 2 uses one EPKINLY 4 mg/0.8 mL vial. Dilute prior to use.

- Step-up dosing may also be required if patients have a dosage delay. Please refer to Tables 4 and 5 in Section 2.3 of the full Prescribing Information for recommendations on restarting EPKINLY after dosage delay

For additional information about the dosing of R², refer to the lenalidomide prescribing information and rituximab prescribing information for the respective dosage recommendations, including lenalidomide dosage recommendations for patients with renal insufficiency.

*Use appropriately sized syringe, vial, and needle.

†0.9% Sodium Chloride Injection.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.

epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg/48mg

Needed supplies per dose¹ (cont'd)

FL ONLY

STEP-UP DOSE 3 (3 MG)

No dilution required



4 mg/0.8 mL
vial



Sterile
syringe

**Step-up dose 3 uses one
EPKINLY 4 mg/0.8 mL vial.
DO NOT dilute.**

DLBCL/HGBCL AND FL

FULL DOSE (48 MG)

No dilution required



48 mg/0.8 mL
vial



Sterile
syringe

**The full dose uses one
EPKINLY 48 mg/0.8 mL vial.
DO NOT dilute.**

Note: Vials and syringes are not sized to scale.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.

epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4 mg/48 mg

Preparing EPKINLY¹

EMPTY STERILE VIAL METHOD

Read the entire contents of **Section 2.7 Preparation of Diluted EPKINLY using the Vial Method** of the full Prescribing Information carefully before preparation of EPKINLY.

- EPKINLY is prepared and administered by an HCP as a subcutaneous injection
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit
- Use aseptic technique to prepare EPKINLY. Filtration of the diluted solution is not required

To prepare the first 2 step-up doses (0.16 mg and 0.8 mg), EPKINLY 4 mg/0.8 mL must be diluted by an HCP.



0.16 mg (STEP-UP DOSE 1: DLBCL/HGBCL AND FL) Requires 2 dilutions

Use an appropriately sized syringe, vial, and needle for each transfer step.



Step-up dose 1 uses one EPKINLY 4 mg/0.8 mL vial.
Dilute prior to use.

PREPARE EPKINLY VIAL

- 1 Retrieve one 4 mg/0.8 mL EPKINLY vial from the refrigerator
- 2 Allow the vial to come to room temperature for no more than 1 hour
- 3 Gently swirl the EPKINLY vial. **DO NOT** invert, vortex, or vigorously shake the vial

PERFORM FIRST DILUTION

- 4 Label an appropriately sized empty vial as "Dilution A"
- 5 Transfer **0.8 mL of EPKINLY** into the **Dilution A** vial
- 6 Transfer **4.2 mL of 0.9% Sodium Chloride Injection** into the **Dilution A** vial. The initially diluted solution contains 0.8 mg/mL of EPKINLY
- 7 Gently swirl the **Dilution A** vial for 30–45 seconds

PERFORM SECOND DILUTION

- 8 Label an appropriately sized empty vial as "Dilution B"
- 9 Transfer **2 mL of solution** from the **Dilution A** vial into the **Dilution B** vial. The **Dilution A** vial is no longer needed
- 10 Transfer **8 mL of 0.9% Sodium Chloride Injection** into the **Dilution B** vial to make a final concentration of 0.16 mg/mL
- 11 Gently swirl the **Dilution B** vial for 30–45 seconds

WITHDRAW DOSE

- 12 Withdraw **1 mL of the diluted EPKINLY** from the **Dilution B** vial into a syringe

LABEL SYRINGE

- 13 Label the syringe with the dose strength (0.16 mg) and the time of day

Discard the vial containing unused EPKINLY.

For additional information about the dosing of R², refer to the lenalidomide prescribing information and rituximab prescribing information for the respective dosage recommendations, including lenalidomide dosage recommendations for patients with renal insufficiency.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.

epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4 mg/48 mg

Preparing EPKINLY¹ (cont'd)

EMPTY STERILE VIAL METHOD



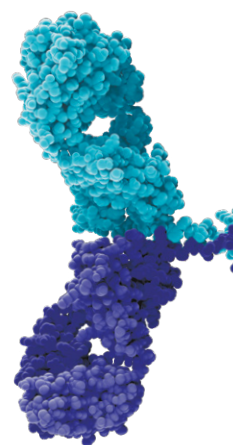
EMPTY STERILE VIAL METHOD

0.8 mg (STEP-UP DOSE 2: DLBCL/HGBCL AND FL) Requires 1 dilution

Use an appropriately sized syringe, vial, and needle for each transfer step.



Step-up dose 2 uses one EPKINLY 4 mg/0.8 mL vial.
Dilute prior to use.



PREPARE EPKINLY VIAL

- 1 Retrieve one 4 mg/0.8 mL EPKINLY vial from the refrigerator
- 2 Allow the vial to come to room temperature for no more than 1 hour
- 3 Gently swirl the EPKINLY vial. **DO NOT** invert, vortex, or vigorously shake the vial

PERFORM DILUTION

- 4 Label an appropriately sized empty vial as "Dilution A"
- 5 Transfer **0.8 mL of EPKINLY** into the **Dilution A** vial

- 6 Transfer **4.2 mL of 0.9% Sodium Chloride Injection** into the **Dilution A** vial to make a final concentration of 0.8 mg/mL
- 7 Gently swirl the **Dilution A** vial for 30–45 seconds

WITHDRAW DOSE

- 8 Withdraw **1 mL of the diluted EPKINLY** from the **Dilution A** vial into a syringe

LABEL SYRINGE

- 9 Label the syringe with the dose strength (0.8 mg) and the time of day
- Discard the vial containing unused EPKINLY.

WATCH: [DOSE PREPARATION STEP-BY-STEP VIDEO FOR 3L+ DLBCL/HGBCL](#)

WATCH: [DOSE PREPARATION STEP-BY-STEP VIDEO FOR 2L+ FL](#)

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full [Prescribing Information](#), including Boxed Warnings.

epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg/48mg

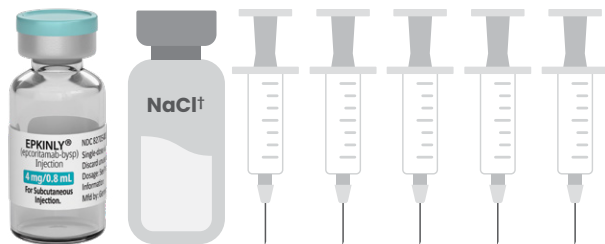
Needed supplies per dose¹

STERILE SYRINGE METHOD*

DLBCL/HGBCL AND FL

STEP-UP DOSE 1 (0.16 MG)

Requires **2** dilutions



4 mg/0.8 mL
vial

Sterile syringes

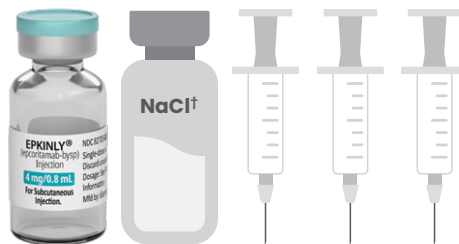
Note: Vials and syringes are not sized to scale.
Luer lock/connectors not depicted but required.

**Step-up dose 1 uses one
EPKINLY 4 mg/0.8 mL vial.
Dilute prior to use.**

DLBCL/HGBCL AND FL

STEP-UP DOSE 2 (0.8 MG)

Requires **1** dilution



4 mg/0.8 mL
vial

Sterile syringes

**Step-up dose 2 uses one
EPKINLY 4 mg/0.8 mL vial.
Dilute prior to use.**

- Step-up dosing may also be required if patients have a dosage delay. Please refer to Tables 4 and 5 in Section 2.3 of the full Prescribing Information for recommendations on restarting EPKINLY after dosage delay

For additional information about the dosing of R², refer to the lenalidomide prescribing information and rituximab prescribing information for the respective dosage recommendations, including lenalidomide dosage recommendations for patients with renal insufficiency.

*Use appropriately sized syringe and needle.

†0.9% Sodium Chloride Injection.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.

epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4 mg/48 mg

Needed supplies per dose¹ (cont'd)

FL ONLY

STEP-UP DOSE 3 (3 MG)

No dilution required



4 mg/0.8 mL
vial



Sterile
syringe

**Step-up dose 3 uses one
EPKINLY 4 mg/0.8 mL vial.
DO NOT dilute.**

DLBCL/HGBCL AND FL

FULL DOSE (48 MG)

No dilution required



48 mg/0.8 mL
vial



Sterile
syringe

**The full dose uses one
EPKINLY 48 mg/0.8 mL vial.
DO NOT dilute.**

Note: Vials and syringes are not sized to scale.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.

epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4 mg/0.8 mL

Preparing EPKINLY¹

STERILE SYRINGE METHOD

Read the entire contents of **Section 2.8 Preparation of Diluted EPKINLY using the Syringe Method** of the full Prescribing Information carefully before preparation of EPKINLY.

- EPKINLY is prepared and administered by an HCP as a subcutaneous injection
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit
- Use aseptic technique to prepare EPKINLY. Filtration of the diluted solution is not required



0.16 mg (STEP-UP DOSE 1: DLBCL/HGBCL AND FL) Requires 2 dilutions

Use an appropriately sized syringe and needle for each transfer step.



Step-up dose 1 uses one EPKINLY 4 mg/0.8 mL vial. Dilute prior to use.

PREPARE EPKINLY VIAL

- 1 Retrieve one 4 mg/0.8 mL EPKINLY vial from the refrigerator
- 2 Allow the vial to come to room temperature for no more than 1 hour
- 3 Gently swirl the EPKINLY vial. **DO NOT** invert, vortex, or vigorously shake the vial

PERFORM FIRST DILUTION

- 4 Label an appropriately sized syringe as "Dilution A"
- 5 Withdraw **4.2 mL of 0.9% Sodium Chloride Injection** into the **Dilution A** syringe. Include approximately 0.2 mL air in the syringe
- 6 In a new syringe labeled as "**Syringe 1**," withdraw **0.8 mL of EPKINLY**
- 7 Connect the 2 syringes and push the **0.8 mL of EPKINLY** into the **Dilution A** syringe. The initially diluted solution contains 0.8 mg/mL of EPKINLY
- 8 Gently mix by inverting the connected syringes 180 degrees 5 times
- 9 Disconnect the syringes and discard **Syringe 1**

PERFORM SECOND DILUTION

- 10 Label an appropriately sized syringe as "Dilution B"

For additional information about the dosing of R², refer to the lenalidomide prescribing information and rituximab prescribing information for the respective dosage recommendations, including lenalidomide dosage recommendations for patients with renal insufficiency.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.

- 11 Withdraw **8 mL of 0.9% Sodium Chloride Injection** into the **Dilution B** syringe. Include approximately 0.2 mL air in the syringe
- 12 Label another appropriately sized syringe as "**Syringe 2**"
- 13 Connect **Syringe 2** to the **Dilution A** syringe and transfer **2 mL of solution** into **Syringe 2**. The **Dilution A** syringe is no longer needed
- 14 Connect **Syringe 2** to the **Dilution B** syringe and push the **2 mL of solution** into the **Dilution B** syringe to make a final concentration of 0.16 mg/mL
- 15 Gently mix by inverting the connected syringes 180 degrees 5 times
- 16 Disconnect the syringes and discard **Syringe 2**

WITHDRAW DOSE

- 17 Connect and transfer **1 mL of the diluted EPKINLY** from the **Dilution B** syringe into a new syringe. The **Dilution B** syringe is no longer needed

LABEL SYRINGE

- 18 Label the syringe with the dose strength (0.16 mg) and the time of day

Discard the vial containing unused EPKINLY.


epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg/48mg

Preparing EPKINLY¹ (cont'd)

STERILE SYRINGE METHOD



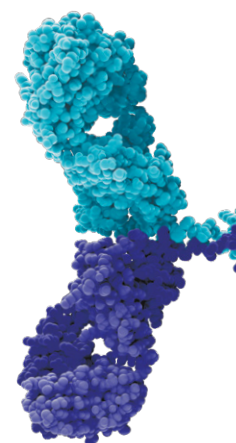
STERILE SYRINGE METHOD

0.8 mg (STEP-UP DOSE 2: DLBCL/HGBCL AND FL) Requires 1 dilution

Use an appropriately sized syringe and needle for each transfer step.



Step-up dose 2 uses one EPKINLY 4 mg/0.8 mL vial.
Dilute prior to use.



PREPARE EPKINLY VIAL

- 1 Retrieve one 4 mg/0.8 mL EPKINLY vial from the refrigerator
- 2 Allow the vial to come to room temperature for no more than 1 hour
- 3 Gently swirl the EPKINLY vial. **DO NOT** invert, vortex, or vigorously shake the vial

PERFORM FIRST DILUTION

- 4 Label an appropriately sized syringe as "Dilution A"
- 5 Withdraw **4.2 mL of 0.9% Sodium Chloride Injection** into the **Dilution A** syringe. Include approximately 0.2 mL air in the syringe
- 6 In a new syringe labeled as "**Syringe 1**," withdraw **0.8 mL of EPKINLY**

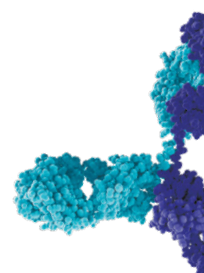
- 7 Connect the 2 syringes and push the **0.8 mL of EPKINLY** into the **Dilution A** syringe to make a final concentration of 0.8 mg/mL
- 8 Gently mix by inverting the connected syringes 180 degrees 5 times
- 9 Disconnect the syringes and discard **Syringe 1**

WITHDRAW DOSE

- 10 Connect a new syringe to the **Dilution A** syringe and transfer **1 mL of the diluted EPKINLY** into a new syringe. The **Dilution A** syringe is no longer needed

LABEL SYRINGE

- 11 Label the syringe with the dose strength (0.8 mg) and the time of day
- Discard the vial containing unused EPKINLY.



Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.

epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg/48mg

Needed supplies per dose¹

FL ONLY

STEP-UP DOSE 3 (3 MG)

No dilution required



4 mg/0.8 mL
vial



Sterile
syringe

**Step-up dose 3 uses one
EPKINLY 4 mg/0.8 mL vial.
DO NOT dilute.**

DLBCL/HGBCL AND FL

FULL DOSE (48 MG)

No dilution required



48 mg/0.8 mL
vial



Sterile
syringe

**The full dose uses one
EPKINLY 48 mg/0.8 mL vial.
DO NOT dilute.**

Note: Vials and syringes are not sized to scale.

For additional information about the dosing of R², refer to the lenalidomide prescribing information and rituximab prescribing information for the respective dosage recommendations, including lenalidomide dosage recommendations for patients with renal insufficiency.

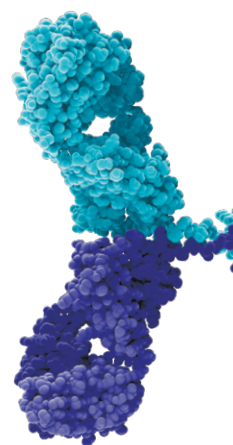
Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.

epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4 mg/48 mg

Preparation of 3 mg and 48 mg EPKINLY doses¹

Read the entire contents of **Section 2.9 Preparation of 3 mg and 48 mg EPKINLY Doses** of the full Prescribing Information carefully before preparation of EPKINLY.

- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit
- Use aseptic technique to prepare EPKINLY



FL ONLY

3 mg (STEP-UP DOSE 3) No dilution required

Step-up dose 3 uses one EPKINLY 4 mg/0.8 mL vial. **DO NOT** dilute.



PREPARE EPKINLY VIAL

- 1 Retrieve one 4 mg/0.8 mL EPKINLY vial from the refrigerator
- 2 Allow the vial to come to room temperature for no more than 1 hour
- 3 Gently swirl the EPKINLY vial. **DO NOT** invert, vortex, or vigorously shake the vial

WITHDRAW DOSE

- 4 Withdraw **0.6 mL** of EPKINLY into a syringe

LABEL SYRINGE

- 5 Label the syringe with the dose strength (3 mg) and the time of day

Discard the vial containing unused EPKINLY.

DLBCL/HGBCL AND FL

48 mg (FULL DOSE) No dilution required

The full dose uses one EPKINLY 48 mg/0.8 mL vial. **DO NOT** dilute.



PREPARE EPKINLY VIAL

- 1 Retrieve one 48 mg/0.8 mL EPKINLY vial from the refrigerator
- 2 Allow the vial to come to room temperature for no more than 1 hour
- 3 Gently swirl the EPKINLY vial. **DO NOT** invert, vortex, or vigorously shake the vial

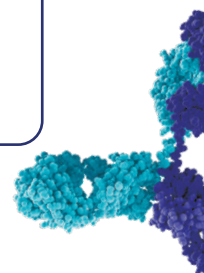
WITHDRAW DOSE

- 4 Withdraw **0.8 mL** of EPKINLY into a syringe

LABEL SYRINGE

- 5 Label the syringe with the dose strength (48 mg) and the time of day

Discard the vial containing unused EPKINLY.



Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.

epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4 mg/48 mg

What to remember when starting EPKINLY¹

Before treatment with EPKINLY

Treatment Reminders



Are you familiar with the different EPKINLY regimens for each indication?



Do you and your patient understand the Cycle 1 step-up dosing schedule?



Is your patient adequately hydrated?



Have you administered the recommended pre- and post-administration medications?



Have you confirmed the correct dose for the cycle and day?



Have you checked the label on the syringe to confirm

- Correct dose?
- Solution was prepared less than 24 hours ago if it was stored in a refrigerator?
- Solution was prepared less than 12 hours ago if it was stored at room temperature?

Treatment Considerations

- In 3L+ DLBCL/HGBCL and 3L+ FL, EPKINLY is given as **monotherapy**
- In 2L+ FL, EPKINLY is given **in combination with lenalidomide and rituximab, or R²**

- Day 1: 0.16 mg
- Day 8: 0.8 mg
- Day 15:
 - DLBCL/HGBCL: 48 mg
 - FL only: 3 mg
- Day 22: 48 mg

EPKINLY should be administered to well-hydrated patients.

Please refer to Section 2.4 of the full Prescribing Information or page 18 of this brochure for more information.

Initial dosing for patients is stepped up weekly from

- Day 1: 0.16 mg
- Day 8: 0.8 mg
- Day 15:
 - DLBCL/HGBCL: 48 mg
 - FL only: 3 mg
- Day 22: 48 mg

Please refer to Section 2.2 of the full Prescribing Information or pages 6–17 of this brochure for full dose schedule information.

Dosing is as follows:

- Day 1: 0.16 mg
- Day 8: 0.8 mg
- Day 15:
 - DLBCL/HGBCL: 48 mg
 - FL only: 3 mg
- Day 22: 48 mg

EPKINLY solution in the syringe: Use immediately or store the solution refrigerated at 2 °C to 8 °C (36 °F to 46 °F) for up to 24 hours or at room temperature at 20 °C to 25 °C (68 °F to 77 °F) for up to 12 hours. The total storage time from the start of dose preparation to administration should not exceed 24 hours.

- EPKINLY is given in combination with R² for the treatment of 2L+ FL

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.

epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg/48mg

What to remember when starting EPKINLY¹ (cont'd)

Before treatment with EPKINLY

Treatment Reminders



Has the dose been allowed to come to room temperature?



Have you determined whether the patient's last dose was on the left or right side of their body? Where would your patient prefer this injection?

Treatment Considerations

To minimize injection pain, allow EPKINLY solution to equilibrate to room temperature for no more than 1 hour before administration.

EPKINLY should be injected in the subcutaneous tissue of the lower part of the abdomen (preferred) or the thigh. Change of injection site from the left or right side or vice versa is recommended, especially during the weekly administrations (Cycles 1–3). Do not inject into tattoos, scars, or areas where the skin is red, bruised, tender, hard, or not intact.

After treatment with EPKINLY

Treatment Reminders



Have you/your staff counseled the patient to watch for side effects and to call you right away if they're experiencing symptoms such as fever of 100.4 °F (38 °C) or higher, dizziness or light-headedness, trouble breathing, chills, fast heartbeat, feeling anxious, headache, confusion, shaking (tremors), problems with balance and movement, such as trouble walking, trouble speaking or writing, confusion and disorientation, drowsiness, tiredness or lack of energy, muscle weakness, seizures, or memory loss?

Treatment Considerations

Hospitalization is not required for monitoring with EPKINLY administration. Assess each patient.

- Due to the risk of CRS and ICANS, monitor all patients for signs and symptoms
 - Assess whether hospitalization or outpatient monitoring for the first 48-mg dose is appropriate based on comorbidities or other situational factors
 - During outpatient monitoring after the first 48-mg dose, patients should remain in proximity to a healthcare facility that can assess and manage CRS
- Hospitalization may be needed to manage select adverse reactions

If you suspect your patient is showing symptoms of CRS or ICANS, withhold EPKINLY and refer to Section 2.6 of the full Prescribing Information or pages 20–27 of this brochure for more information.

Patients who experience CRS should be monitored more frequently during next scheduled administrations of EPKINLY.

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

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.


epkinly[®]
 epcoritamab-bysp
 SUBCUTANEOUS INJECTION 4mg/48mg

What to remember when starting EPKINLY¹ (cont'd)

After treatment with EPKINLY

Treatment Reminders



Have you/your staff monitored patients for signs and symptoms of infection prior to and during treatment with EPKINLY? Counsel the patient to call you if they have symptoms of an infection?



If this is the first time your patient has received EPKINLY, have you counseled your patient on use of steroids for 3 consecutive days after receiving a dose?



Does your patient understand when to come back for the next dose?

Treatment Considerations

If infection is suspected, treat patients appropriately. Avoid administration of EPKINLY in patients with active infections.

Please refer to Section 2.4 of the full Prescribing Information or page 18 of this brochure for more information.

Administer EPKINLY according to the Dosing Schedules in Section 2.2 of the full Prescribing Information or see pages 6–17 of this brochure for more information.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full Prescribing Information, including Boxed Warnings.


epkinly[®]
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg/48mg

Navigating access



With *MyNavCare Patient Support*®, your patients work with an experienced team that offers assistance throughout the treatment journey with EPKINLY® (epcoritamab-bysp).

Support & Resources *MyNavCare* Provides:

- Benefits verification
- Financial assistance
- Prior authorization support
- Coverage and claims information
- Appeals information
- Patient Engagement Liaison* ongoing support for patients throughout treatment

**MyNavCare* Patient Engagement Liaisons are part of the *MyNavCare Patient Support* Program and do not provide medical advice or work under the direction of the prescribing healthcare providers. They are trained to direct patients to speak with their healthcare provider about any treatment-related questions.

Contact a *MyNavCare* Support Specialist by calling **1-866-NAV-CAR1 (1-866-628-2271)**, Monday-Friday, 8 AM-8 PM ET, or visit www.MyNavCare.com to learn more.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full [Prescribing Information](#), including Boxed Warnings.



epkinly®
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg/48mg

Additional resources are available to help you and your patients throughout the treatment journey

- **Adverse Reactions Management Guide**

An essential guide to understanding and managing adverse reactions

- **Wallet Card (also available in Spanish)**

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

- **3L+ DLBCL/HGBCL Patient Brochure**

- **2L+ FL Patient Brochure**

- **3L+ FL Patient Brochure**

Each brochure provides an overview of EPKINLY specific to its indication, informing patients and their care partners on what they need to know about starting treatment

DOWNLOAD: [RESOURCES FOR YOUR PATIENTS AND YOUR PRACTICE](#)

EPKINLY is available directly through specialty distributors and can be dispensed through an exclusive network of specialty pharmacies. For more information, visit [EPKINLYhcp.com](https://epkinlyhcp.com).

TO LEARN MORE, VISIT [EPKINLYhcp.com](https://epkinlyhcp.com)

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 3–5 and throughout this brochure. Please see full [Prescribing Information](#), including Boxed Warnings.

Reference: 1. EPKINLY [package insert]. Plainsboro, NJ: Genmab US, Inc. and North Chicago, IL: AbbVie Inc. 2026.



Distributed and marketed by Genmab US Inc.
777 Scudders Mill Road, Plainsboro, NJ 08536.
Distributed and marketed by AbbVie Inc.
1 North Waukegan Road, North Chicago, IL 60064.
EPKINLY, EPCORE, and MyNavCare Patient Support
are trademarks of Genmab A/S.
©2026 Genmab A/S and AbbVie. All rights reserved.
08/2026 COM-US-EPK-0002939

