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epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg | 48mg

DOSE PREPARATION AND ADMINISTRATION GUIDE

The first-and-only bispecific antibody approved in both 3L+ DLBCL/HGBCL and 3L+ FL[1]

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

3L+ FOLLICULAR LYMPHOMA

3L=third line.

INDICATIONS

EPKINLY is indicated for the treatment of adults with:

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

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

SELECT IMPORTANT SAFETY INFORMATION

BOXED WARNINGS

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

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

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 30-31 and throughout this brochure. Please see full Prescribing Information.

About EPKINLY[1,2]

EPKINLY is a humanized IgG1, T-cell engaging bispecific antibody that binds to CD20 on B cells and to CD3 on T cells.[1]

CD20 is expressed on the surface of lymphoma cells and healthy B-lineage cells. In vitro, EPKINLY activated T cells, caused the release of proinflammatory cytokines, and induced lysis of B cells.[1]

3L+ DLBCL/HGBCL

The efficacy of EPKINLY was evaluated based on results from EPCORE® NHL-1, an open-label, multicohort, multicenter, single-arm trial in patients with R/R DLBCL after 2 or more lines of systemic therapy (N=148).[1]*

EPKINLY provided an ORR of 61% (95% CI, 53-69), including a CR rate of 38% (95% CI, 30-46) and a PR rate of 23% (95% CI, 17-31). Median DOR was 15.6 months (95% CI, 9.7-NR).[1†]

3L+ FL

The efficacy of EPKINLY was evaluated in EPCORE® NHL-1, an open-label, multicohort, multicenter, single-arm trial in 127 patients with R/R FL after at least 2 lines of systemic therapy.[1]*

EPKINLY delivered an ORR of 82% (n=104/127; 95% CI, 74-88); 60% of patients achieved a CR (n=76/127; 95% CI, 51-68) and 22% achieved a PR (n=28/127; 95% CI, 15-30). Median DOR was not reached (n=104/127; 95% CI, 13.7-NR).[1,2‡]

SELECT IMPORTANT SAFETY INFORMATION

3L+ DLBCL/HGBCL and 3L+ FL

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

*Efficacy results determined by Lugano criteria (2014) as assessed by Independent Review Committee.
†Based on Kaplan-Meier estimate. Among responders, the median follow-up for DOR was 9.8 months (range: 0 to 17.3 months).
‡Based on Kaplan-Meier estimate. The median follow-up for DOR was 14.8 months.

CD3=cluster of differentiation 3; CD20=cluster of differentiation 20; CI=confidence interval; CR=complete response; CRS=cytokine release syndrome; DOR=duration of response; IgG1=immunoglobulin G1; NHL=non-Hodgkin lymphoma; NR=not reached; ORR=overall response rate; PR=partial response; R/R=relapsed/refractory.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 30-31 and throughout this brochure. Please see full Prescribing Information.

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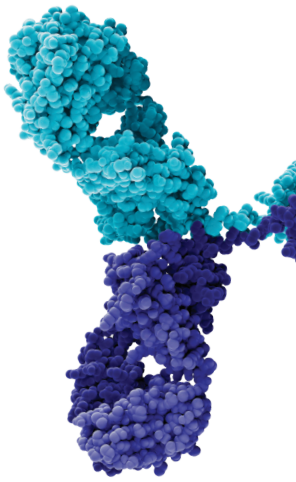

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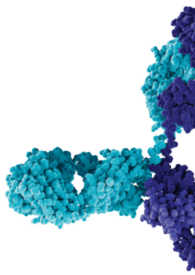

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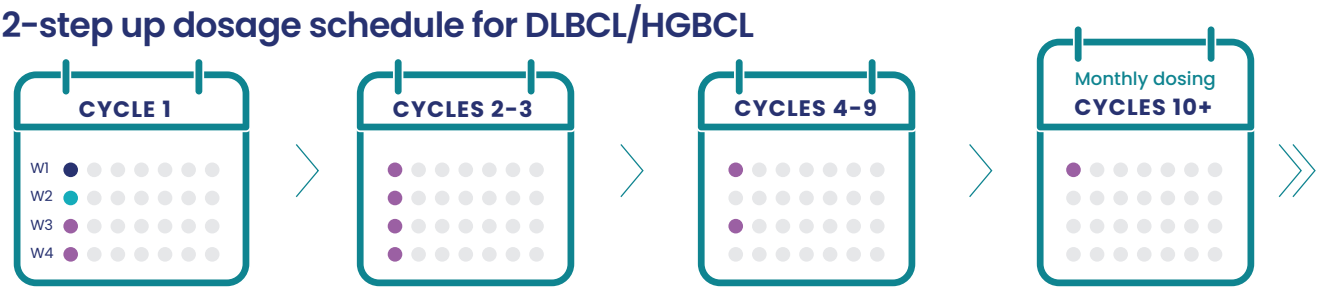
Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 30-31 and throughout this brochure. Please see full Prescribing Information.

EPKINLY is administered in 28-day cycles[1]

EPKINLY is for subcutaneous injection only.

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



STEP UP DOSING: 0.16 mg ON DAY 1 > 0.8 mg ON DAY 8 **FULL DOSE:** 48 mg ON DAYS 15+

CONTINUE UNTIL DISEASE PROGRESSION OR UNACCEPTABLE TOXICITY

W1=week 1; W2=week 2; W3=week 3; W4=week 4.

- CRS occurred in 51% of patients in the clinical trial. Recurrent CRS occurred in 16% of patients. Most CRS events (92%) occurred during cycle 1
- In cycle 1, 9% of CRS events occurred after the 0.16-mg dose on cycle 1, day 1; 16% after the 0.8-mg dose on cycle 1, day 8; 61% after the 48-mg dose on cycle 1, day 15; and 6% after the 48-mg dose on cycle 1, day 22
- The median time to onset of CRS after the first full 48-mg dose was 21 hours (range: 0 to 7 days)
- The median time to onset of CRS from the most recently administered EPKINLY dose across all doses was 24 hours (range: 0 to 10 days)
- CRS resolved in 98% of patients
  - Median duration of CRS events was 2 days (range: 1 to 27 days)

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

[a]Administer pretreatment medication prior to EPKINLY dose and monitor patients accordingly.

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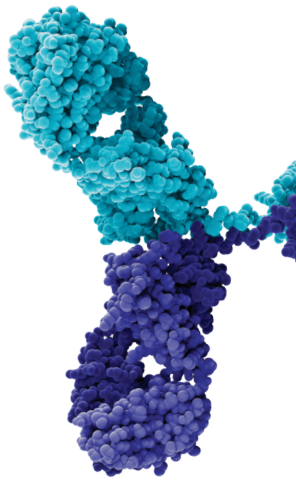
EPKINLY is administered in 28-day cycles[1] (cont'd)



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 do not require dilution
- 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
- EPKINLY should only be administered by a qualified healthcare professional 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
  - For patients with DLBCL or high-grade B-cell lymphoma: Patients should be hospitalized for 24 hours after administration of the cycle 1, day 15 dosage of 48 mg
- Hospitalization may be required to manage select adverse reactions

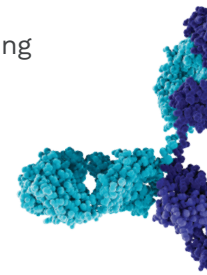
Dosing discontinuation and delays in the clinical trial

- 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 ≥3%: CRS, neutropenia, sepsis, and thrombocytopenia)

SELECT IMPORTANT SAFETY INFORMATION

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

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



Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 30-31 and throughout this brochure. Please see full Prescribing Information.

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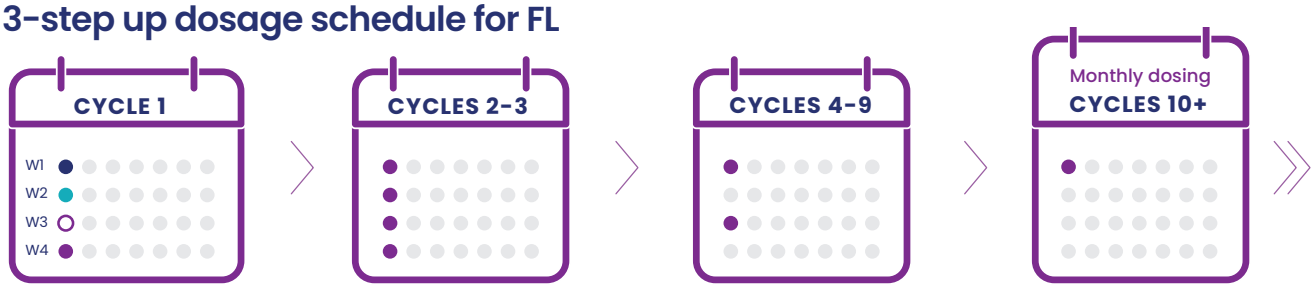
EPKINLY is administered in 28-day cycles[1]

EPKINLY is for subcutaneous injection only.

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



STEP UP DOSING: ● 0.16 mg ON DAY 1 › ● 0.8 mg ON DAY 8 › ○ 3 mg ON DAY 15 **FULL DOSE:** ● 48 mg ON DAYS 22+

CONTINUE UNTIL DISEASE PROGRESSION OR UNACCEPTABLE TOXICITY

W1=week 1; W2=week 2; W3=week 3; W4=week 4.

- CRS occurred in 49% (42/86) of patients receiving EPKINLY at the recommended 3-step up dosage schedule in the clinical trial (45% grade 1, 9% grade 2). Recurrent CRS occurred in 23% of patients
- Of all the CRS events, most (88%) occurred during cycle 1, with 14% of CRS events occurring after the 0.16-mg dose (day 1), 7% after the 0.8-mg dose (day 8), 17% after the 3-mg dose (day 15), and 49% after the 48-mg dose (day 22)
- The median time to onset of CRS from the most recently administered EPKINLY dose across all doses was 59 hours (range: 0.1 to 7 days)
- The median time to onset after the first full 48-mg dose was 61 hours (range: 0.1 to 7 days)
- CRS resolved in 100% of patients
  - Median duration of CRS events was 2 days (range: 1 to 14 days)

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

[a]Administer pretreatment medication prior to EPKINLY dose and monitor patients accordingly.

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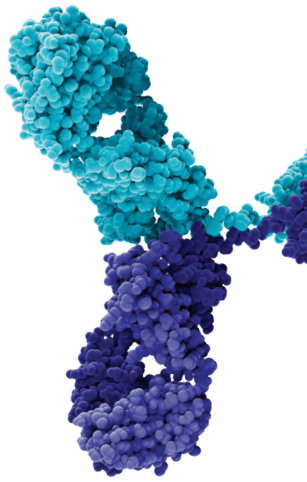
EPKINLY is administered in 28-day cycles[1] (cont'd)



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 do not require dilution
- 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
- EPKINLY should only be administered by a qualified healthcare professional 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
  - Note: Hospitalization is not required to administer EPKINLY in FL
- Hospitalization may be required to manage select adverse reactions

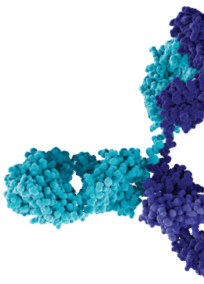
Dosing discontinuation and delays in the clinical trial

- 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

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.

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



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Recommended pre- and post-administration medications[1]

Administer pre- and post-administration medications to reduce the 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 1000 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

[a]Dexamethasone is the preferred corticosteroid when available.
[b]Patients will be permanently discontinued from EPKINLY after grade 4 CRS.

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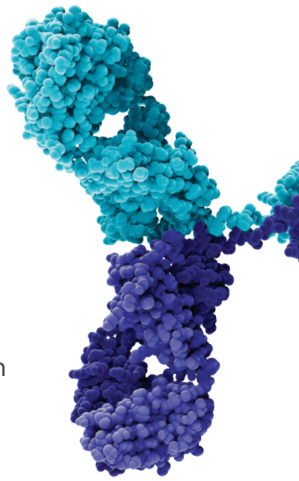
Recommended prophylaxis



- Provide *Pneumocystis jirovecii* pneumonia (PJP) prophylaxis prior to starting treatment with EPKINLY
- Consider initiating prophylaxis against herpes virus prior to starting EPKINLY to prevent herpes zoster reactivation

SELECT IMPORTANT SAFETY INFORMATION

Infections: EPKINLY can cause serious and fatal infections.

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

Cytopenias: EPKINLY can cause serious or severe cytopenias.

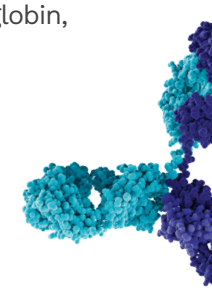
- In the clinical trial of patients with LBCL, grade 3 or 4 events occurred in 32% (neutrophils decreased), 12% (hemoglobin decreased), and 12% (platelets decreased). Febrile neutropenia occurred in 2.5%.
- In the clinical trial of patients with FL receiving the 2-step up dosage schedule, grade 3 or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

Embryo-Fetal Toxicity

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

Adverse Reactions

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



Use in Specific Populations

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

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Dosage modifications and management of adverse reactions[1]

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

[a]Based on ASTCT 2019 grading for CRS.
[b]Premedication may mask fever, therefore if clinical presentation is consistent with CRS, follow these management guidelines.
[c]Refer to Table 3 or Table 4 in Section 2.3 of the Prescribing Information for information on restarting EPKINLY after dose delays in patients with DLBCL and FL, respectively.
[d]If grade 2 or 3 CRS occurs with the second full dose (48 mg) or beyond, administer CRS pre- and post-administration medications with each subsequent dose until an EPKINLY dose is given without subsequent CRS of grade 2 or higher. Refer to Table 5 in Section 2.4 of the Prescribing Information for additional information on pre- and post-administration medications.
[e]Low-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.

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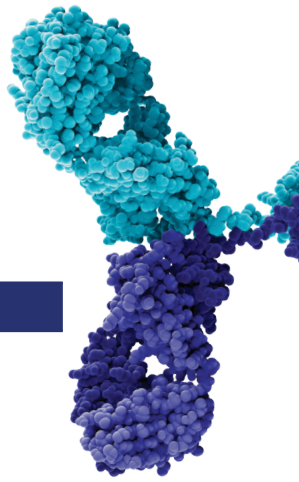
Dosage modifications and management of adverse reactions[1] (cont'd)

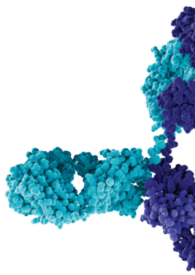


Recommendations for management of CRS (cont'd)

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

[a]Based on ASTCT 2019 grading for CRS.
[b]Premedication may mask fever, therefore if clinical presentation is consistent with CRS, follow these management guidelines.
[c]Refer to Table 3 or Table 4 in Section 2.3 of the Prescribing Information for information on restarting EPKINLY after dose delays in patients with DLBCL and FL, respectively.
[d]If grade 2 or 3 CRS occurs with the second full dose (48 mg) or beyond, administer CRS pre- and post-administration medications with each subsequent dose until an EPKINLY dose is given without subsequent CRS of grade 2 or higher. Refer to Table 5 in Section 2.4 of the Prescribing Information for additional information on pre- and post-administration medications.
[e]Low-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.



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SUBCUTANEOUS INJECTION 4mg|48mg

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 30-31 and throughout this brochure. Please see full Prescribing Information.

Dosage modifications and management of adverse reactions[1] (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 neurological 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

[a]Based on ASTCT 2019 grading for ICANS.
[b]Management is determined by the most severe event, not attributable to any other cause.
[c]If 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 7 in Section 2.6 of the Prescribing Information for more information on the ICE Assessment.
[d]Not attributable to any other cause.
[e]See Table 3 or Table 4 in Section 2.3 of the Prescribing Information for recommendations on restarting EPKINLY after dose delays in patients with DLBCL and FL, respectively.
[f]All references to dexamethasone administration are dexamethasone or equivalent.

ICE=Immune Effector Cell-Associated Encephalopathy.

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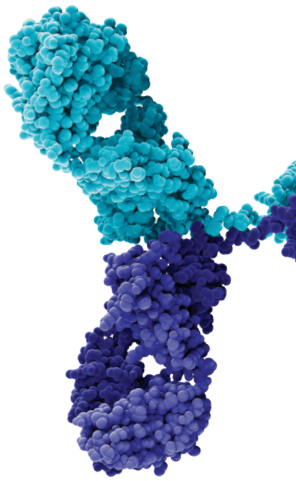
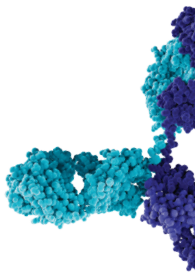
Dosage modifications and management of adverse reactions[1] (cont'd)



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

[a]Based on ASTCT 2019 grading for ICANS.
[b]Management is determined by the most severe event, not attributable to any other cause.
[c]If 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 7 in Section 2.6 of the Prescribing Information for more information on the ICE Assessment.
[d]Not attributable to any other cause.
[e]See Table 3 or Table 4 in Section 2.3 of the Prescribing Information for recommendations on restarting EPKINLY after dose delays in patients with DLBCL and FL, respectively.
[f]All references to dexamethasone administration are dexamethasone or equivalent.



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Dosage modifications and management of adverse reactions[1] (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 1000 mg per day intravenously and continue methylprednisolone 1000 mg per day intravenously for 2 or more days • Monitor neurologic symptoms and consider consultation with neurologist and other specialists for further evaluation and management, including consideration for starting nonsedating, antiseizure medicines for seizure prophylaxis • Provide supportive therapy, which may include intensive care

[a]Based on ASTCT 2019 grading for ICANS.
[b]Management is determined by the most severe event, not attributable to any other cause.
[c]If 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 7 in Section 2.6 of the Prescribing Information for more information on the ICE Assessment.
[d]Not attributable to any other cause.
[e]All references to dexamethasone administration are dexamethasone or equivalent.

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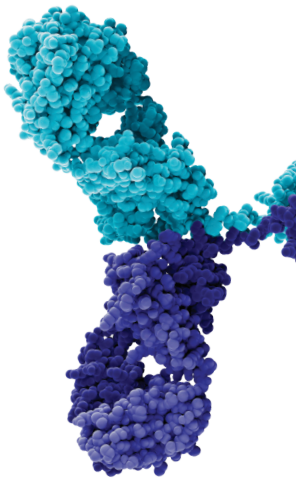
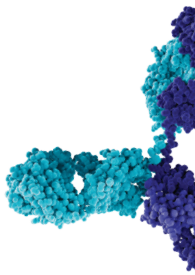
Dosage modifications and management of adverse reactions[1] (cont'd)



Recommended dosage modifications for other adverse reactions

Adverse reaction[a]	Severity[a]	Actions
Infections	Grades 1-4	**Withhold EPKINLY** • In patients with active infection, until the infection resolves[b] • For grade 4, consider permanent discontinuation
Neutropenia	Absolute neutrophil count (ANC) <0.5 x 10^9/L	**Withhold EPKINLY** • Until ANC ≥0.5 x 10^9/L[b]
Thrombocytopenia	Platelet count <50 x 10^9/L	**Withhold EPKINLY** • Until platelet count ≥50 x 10^9/L[b]
Other adverse reactions	Grade 3 or higher	**Withhold EPKINLY** • Until the toxicity resolves to grade 1 or baseline[b]

[a]Based on National Cancer Institute Common Terminology Criteria for Adverse Events, version 5.0.
[b]See Table 3 or Table 4 in Section 2.3 of the Prescribing Information for recommendations on restarting EPKINLY after dosage delays in patients with DLBCL and FL, respectively.



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EPKINLY is supplied as single-dose vials in 2 strengths[1]

EPKINLY is prepared and administered by a healthcare provider 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 a healthcare provider
- **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 18 AND PAGE 22 TO LEARN MORE.

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 30-31 and throughout this brochure. Please see full Prescribing Information.

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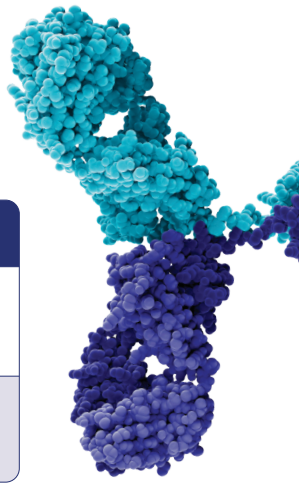
Storage and handling for EPKINLY[1]



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

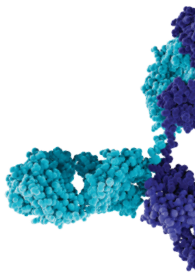
- Certain doses of EPKINLY require **dilution** prior to administration
- Follow the preparation instructions in the full Prescribing Information, as improper preparation may lead to incorrect dose

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

Administration[1]

- 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



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SUBCUTANEOUS INJECTION 4mg|48mg

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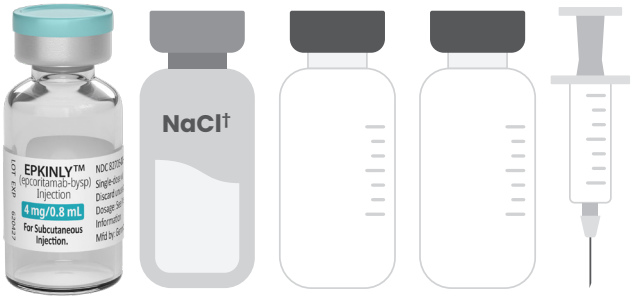
Needed supplies per dose[1]

EMPTY STERILE VIAL METHOD*

DLBCL/HGBCL AND FL

STEP UP DOSE 1 (0.16 MG)

Requires **2** dilutions



4 mg/0.8 mL vial | Empty sterile vials | Sterile syringes

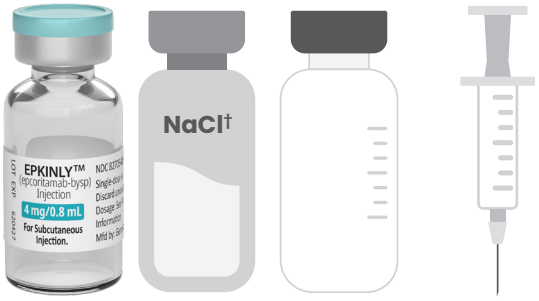
Note: Vials and syringes are not sized to scale.

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 | Empty sterile 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 3 and 4 in Section 2.3 of the full Prescribing Information for recommendations on restarting EPKINLY after dosage delay

*Use appropriately sized syringe, vial, and needle.
†0.9% Sodium Chloride Injection.

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Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 30-31 and throughout this brochure. Please see full Prescribing Information.

Needed supplies per dose[1] (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.

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Preparing EPKINLY[1]

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 a healthcare provider 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 a healthcare provider.

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 "**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 "**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.

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Preparing EPKINLY[1] (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 "**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 DLBCL/HGBCL

WATCH: DOSE PREPARATION STEP-BY-STEP VIDEO FOR FL

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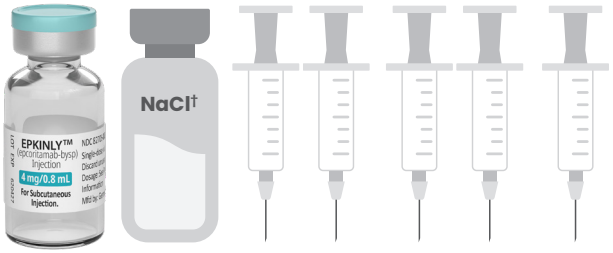
Needed supplies per dose[1]

STERILE SYRINGE METHOD*

DLBCL/HGBCL AND FL

STEP UP DOSE 1 (0.16 MG)

Requires **2** dilutions



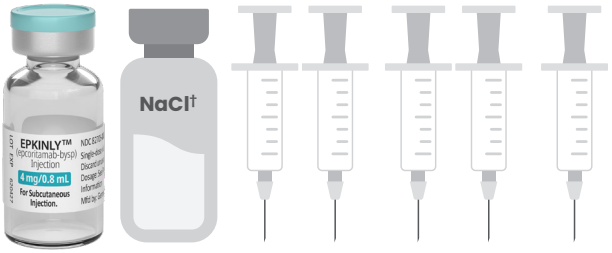
4 mg/0.8 mL vial

Sterile syringes

DLBCL/HGBCL AND FL

STEP UP DOSE 2 (0.8 MG)

Requires **1** dilution



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.

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 3 and 4 in Section 2.3 of the full Prescribing Information for recommendations on restarting EPKINLY after dosage delay

*Use appropriately sized syringe and needle.
†0.9% Sodium Chloride Injection.

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Needed supplies per dose[1] (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.

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Preparing EPKINLY[1]

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 a healthcare provider 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**"
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.

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Preparing EPKINLY[1] (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** from the **Dilution A** syringe 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 Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 30-31 and throughout this brochure. Please see full Prescribing Information.

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Needed supplies per dose[1]

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.

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Preparation of 3 mg and 48 mg EPKINLY doses[1]

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.

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Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 30-31 and throughout this brochure. Please see full Prescribing Information.

What to remember when starting EPKINLY[1]

Before treatment with EPKINLY

Treatment Reminders	Treatment Considerations
Do you and your patient understand the dosing schedule?	• Day 1: 0.16 mg • Day 8: 0.8 mg • Day 15: **DLBCL/HGBCL: 48 mg** **FL only: 3 mg** • Day 22: 48 mg
Is your patient adequately hydrated?	EPKINLY should be administered to well-hydrated patients.
Have you administered the recommended pre- and post-administration medications?	Please refer to Section 2.4 of the Full Prescribing Information or page 8 of this brochure for more information.
Have you confirmed the correct dose for the cycle and day?	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 4 and 6 of this brochure for full dose schedule information.
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?	**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.
Has the dose been allowed to come to room temperature?	To minimize injection pain, allow EPKINLY solution to equilibrate to room temperature for no more than 1 hour before administration.
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?	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.

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 30-31 and throughout this brochure. Please see full Prescribing Information.

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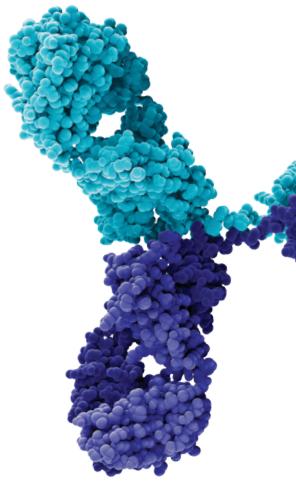
SUBCUTANEOUS INJECTION 4mg|48mg

What to remember when starting EPKINLY[1] (cont'd)



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

Due to the risk of CRS and ICANS, monitor all patients for signs and symptoms.

Patients with DLBCL and HGBCL should be hospitalized for 24 hours after administration of the cycle 1, day 15 dosage of 48 mg due to the risk of CRS and ICANS.

Hospitalization is not required for 24 hours after the first full dose of EPKINLY in patients with FL.

Hospitalization may be required to manage select adverse reactions in patients with DLBCL/HGBCL or FL.

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 10–15 of this brochure for more information.

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

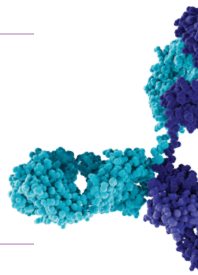
Advise patients who experience symptoms of CRS and ICANS that impair consciousness to refrain from driving or operating heavy or potentially dangerous machinery until events resolve.

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

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

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?

Please refer to Section 2.4 of the full Prescribing Information or page 8 of this brochure for more information.



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

Administer EPKINLY according to the Dosing Schedules in Section 2.2 of the full Prescribing Information or see pages 4–7 of this brochure for more information.

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Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 30–31 and throughout this brochure. Please see full Prescribing Information.

Indications and Important Safety Information

INDICATIONS

EPKINLY is indicated for the treatment of adults with:

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

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

IMPORTANT SAFETY INFORMATION

BOXED WARNINGS

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

CRS

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

ICANS

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

Please see additional Important Safety Information on page 31.

Please see full Prescribing Information.

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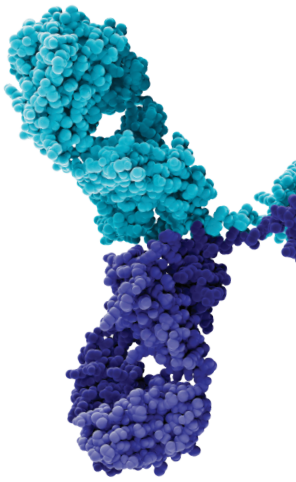
Important Safety Information (cont'd)



IMPORTANT SAFETY INFORMATION (CONTINUED)

Infections

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

Cytopenias

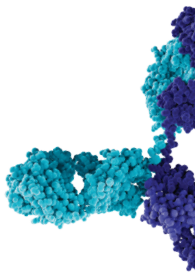
- EPKINLY can cause serious or severe cytopenias. In the clinical trial of patients with LBCL, grade 3 or 4 events occurred in 32% (neutrophils decreased), 12% (hemoglobin decreased), and 12% (platelets decreased). Febrile neutropenia occurred in 2.5%.
- In the clinical trial of patients with FL receiving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

Embryo-Fetal Toxicity

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

Adverse Reactions

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



Use in Specific Populations

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

Please see full Prescribing Information, including Boxed Warnings.

Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on page 30. Please see full Prescribing Information.

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Navigating access

MyNavCare™
PATIENT SUPPORT

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 HCP 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 Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 30-31 and throughout this brochure. Please see full Prescribing Information.

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Notes

Please see Indications and Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 30-31 and throughout this brochure. Please see full Prescribing Information.

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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

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

3L+ DLBCL/HGBCL Patient Brochure

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

3L+ FL Patient Brochure

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

TO DOWNLOAD THESE RESOURCES, VISIT EPKINLYHCP.COM/SUPPORT-RESOURCES

EPKINLY is available directly through specialty distributors and can be dispensed through an exclusive network of specialty pharmacies. For more information, visit **EPKINLYhcp.com**.

TO LEARN MORE, VISIT **EPKINLYhcp.com**

Please see Indications and Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 30-31 and throughout this brochure. Please see full Prescribing Information.

References: 1. EPKINLY [package insert]. Plainsboro, NJ: Genmab US, Inc. and North Chicago, IL: AbbVie Inc. 2024. **2.** Data on file. Plainsboro, NJ: Genmab US, Inc. and North Chicago, IL: AbbVie Inc. 2024. **3.** Linton KM, Vitolo U, Jurczak W, et al. Epcoritamab monotherapy in patients with relapsed or refractory follicular lymphoma (EPCORE NHL-1): a phase 2 cohort of a single-arm, multicentre study. *Lancet*. Published online June 15, 2024. https://doi.org/10.1016/S2352-3026(24)00166-2

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