

Specialty Distributors for EPKINLY

EPKINLY can be purchased from the following Specialty Distributors. If you prefer, EPKINLY can also be dispensed through an exclusive network of specialty pharmacies. Contact a *MyNavCare™* Support Specialist by calling **1-866-NAV-CARI** (1-866-628-2271) Monday–Friday, 8 AM–8 PM ET to determine whether your patient is eligible to access this medication through Genmab's specialty pharmacy partners.



SPECIALTY DISTRIBUTORS

Specialty Distributor	Telephone Number	Email Address	Distributor Ordering Numbers	
			EPKINLY 4 mg/0.8 mL NDC 82705-0002-01	EPKINLY 48 mg/0.8 mL NDC 82705-0010-01
ASD Healthcare	800-746-6273	service@asdhealthcare.com	10280264	10280198
BioCare SD (Institutional)	800-304-3064	order@biocaresd.com	1000364	1000365
BioCare SD (Clinic)	800-304-3064	order@biocaresd.com	1000368	1000369
Cardinal SPD Acute	855-855-0708	GMB-spd-csorderentry@cardinalhealth.com	5849179	5849187
Cardinal SPD Provider	877-453-3972	spdoncologyteam@cardinalhealth.com	5849195	5849203
McKesson Plasma and Biologics	877-625-2566	mpborders@mckesson.com	2821452	2821460
McKesson Specialty Care Distribution	800-482-6700	oncologycustomersupport@mckesson.com	5014883	5014884
Morris & Dickson Specialty	800-388-3833	customerservice@morrisdickson.com	001256	001959
Oncology Supply	800-633-7555	service@oncologysupply.com	10280263	10280254

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.

Please see additional Important Safety Information on the next page.

Please see full Prescribing Information, including Boxed Warnings.

AVAILABLE STRENGTHS FOR EPKINLY



For each step-up dose*

One 4 mg per 0.8 mL single-dose vial

*See Prescribing Information for step-up dose prep instructions.



For full doses

One 48 mg per 0.8 mL single-dose vial

Images are not to scale; for illustrative purposes only.

Administration	Healthcare provider-administered	Healthcare provider-administered
Injection Type	Subcutaneous injection	Subcutaneous injection
HCPJCS J Code	J9321	J9321
NDC Number	82705-0002-01	82705-0010-01
Distribution	Specialty distributor	Specialty distributor

IMPORTANT SAFETY INFORMATION (continued)

ICANS (continued)

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

Infections

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

Cytopenias

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

Embryo-Fetal Toxicity

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

Adverse Reactions

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

Use in Specific Populations

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

Please see full [Prescribing Information](#), including [Boxed Warnings](#).

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