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. Please call *MyNavCare*™ Support at **1-866-NAV-CAR1** (1-866-628-2271) to determine if your patient is eligible to access this medication through Genmab's specialty pharmacy partners.

epkinly™
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg | 48mg

SPECIALTY DISTRIBUTORS

Specialty Distributor	Telephone Number	Email Address	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
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

INDICATION

EPKINLY is indicated for the treatment of adult patients 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 (HGBL) 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 a confirmatory trial(s).

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 dosing 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.**

Cytokine Release Syndrome (CRS)

- EPKINLY can cause CRS, including serious or life-threatening reactions. CRS occurred in 51% of patients at the recommended dose in the clinical trial (37% grade 1, 17% grade 2, and 2.5% grade 3). Recurrent CRS occurred in 16% of patients. Of all the CRS events, most (92%) occurred during cycle 1. In cycle 1, 9% of CRS events occurred after the 0.16 mg dose (cycle 1, day 1), 16% after the 0.8 mg dose (cycle 1, day 8), 61% after the 48 mg dose (cycle 1, day 15), and 6% after the 48 mg dose (cycle 1, day 22). The median time to onset of CRS from the most recently administered EPKINLY 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 resolved in 98% of patients; the median duration of CRS events was 2 days (range, 1-27 days).
- Signs and symptoms of CRS can include pyrexia, hypotension, hypoxia, dyspnea, chills, and tachycardia. Concurrent neurological adverse reactions associated with CRS occurred in 2.5% of patients and included headache, confusional state, tremors, dizziness, and ataxia.
- Initiate EPKINLY according to the step-up dosing schedule. Administer pretreatment medications to reduce the risk of CRS and monitor patients for potential CRS. Following administration of the first 48 mg dose, patients should be hospitalized for 24 hours. At the first signs or symptoms of CRS, immediately evaluate patients for hospitalization, manage per current practice guidelines, and administer supportive care as appropriate. Withhold or discontinue EPKINLY based on the severity of CRS.
- Patients who experience CRS (or other adverse reactions that impair consciousness) should be evaluated and advised not to drive and to refrain from operating heavy or potentially dangerous machinery until resolution.

Immune Effector Cell–Associated Neurotoxicity Syndrome (ICANS)

- EPKINLY can cause life-threatening and fatal ICANS. ICANS occurred in 6% (10/157) of patients in the clinical trial (4.5% grade 1, 1.3% grade 2, 0.6% fatal: 1 event). Of the 10 ICANS events, 9 occurred in cycle 1 of treatment. The median time to onset was 16.5 days (range, 8-141 days) from the start of treatment. Relative to the most recent administration, 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.
- Signs and symptoms of ICANS can include confusional state, lethargy, tremors, dysgraphia, aphasia, and nonconvulsive status epilepticus. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS.
- Monitor for potential ICANS. At the first signs or symptoms of ICANS, immediately evaluate patient and provide supportive therapy based on severity. Withhold or discontinue EPKINLY per recommendations and consider further management per current practice guidelines.

Please see additional Important Safety Information on next page.

AVAILABLE STRENGTHS FOR EPKINLY

epkinly™
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg|48mg

For each step-up dose*

One 4 mg per 0.8 mL single-dose vial

*See Prescribing Information for Day 1 (0.16 mg) and Day 8 (0.8 mg) dose preparation instructions

For full doses

One 48 mg per 0.8 mL single-dose vial

Images not to scale; for illustrative purposes only

Administration	Healthcare provider-administered	Healthcare provider-administered
Injection Type	Subcutaneous injection	Subcutaneous injection
HCPCS J Code	Use miscellaneous drug code† J3490, J3590, or J9999	Use miscellaneous drug code† J3490, J3590, or J9999
NDC Number	82705-0002-01	82705-0010-01
Distribution	Specialty Distributor	Specialty Distributor

†EPKINLY does not currently have a unique HCPCS code. Until a unique HCPCS code is assigned, EPKINLY may be reported using one of the Miscellaneous HCPCS codes listed here. Correct coding is the responsibility of the provider submitting the claim for the item or service.

IMPORTANT SAFETY INFORMATION *(continued)*

Immune Effector Cell–Associated Neurotoxicity Syndrome (ICANS) *(continued)*

- Patients who experience signs or symptoms of ICANS or any other adverse reactions that impair cognition or consciousness should be evaluated, including potential neurology evaluation, and patients at increased risk should be advised not to drive and to refrain from operating heavy or potentially dangerous machinery until resolution.

Infections

- EPKINLY can cause serious and fatal infections. In the clinical trial, serious infections, including opportunistic infections, were reported in 15% of patients treated with EPKINLY at the recommended dose (14% grade 3 or 4, 1.3% fatal). The most common grade 3 or greater infections were sepsis, COVID-19, urinary tract infection, pneumonia, and upper respiratory tract infection.
- Monitor patients for signs and symptoms of infection prior to and during treatment with EPKINLY and treat appropriately. Avoid administration of EPKINLY in patients with active infections.
- Prior to starting EPKINLY, provide *Pneumocystis jirovecii* pneumonia (PJP) prophylaxis and consider prophylaxis against herpes virus.
- Withhold or consider permanent discontinuation of EPKINLY based on severity.

Cytopenias

- EPKINLY can cause serious or severe cytopenias, including neutropenia, anemia, and thrombocytopenia. Among patients who received the recommended dose in the clinical trial, grade 3 or 4 events occurred in 32% (decreased neutrophils), 12% (decreased hemoglobin), and 12% (decreased platelets). Febrile neutropenia occurred in 2.5%.
- 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. Advise pregnant women of the potential risk to the fetus. Verify pregnancy status in females of reproductive potential prior to initiating EPKINLY. Advise females of reproductive potential to use effective contraception during treatment with EPKINLY and for 4 months after the last dose.

Adverse Reactions

- The most common (≥20%) adverse reactions were CRS, fatigue, musculoskeletal pain, injection site reactions, pyrexia, abdominal pain, nausea, and diarrhea. The most common grade 3 to 4 laboratory abnormalities (≥10%) were decreased lymphocyte count, decreased neutrophil count, decreased white blood cell count, decreased hemoglobin, and decreased platelets.

Lactation

- Advise women not to breastfeed during treatment and for 4 months after the last dose of EPKINLY.

Please see accompanying Full Prescribing Information, including Boxed Warnings.

LEARN MORE AT EPKINLYHCP.COM

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