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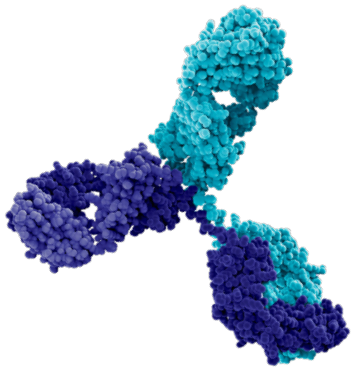
epcoritamab-bysp
SUBCUTANEOUS INJECTION 4mg | 48mg

DOSE PREPARATION OVERVIEW



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).

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 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.**

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

Please see additional Important Safety Information on pages 6-7 and throughout this brochure.
Please see full Prescribing Information.

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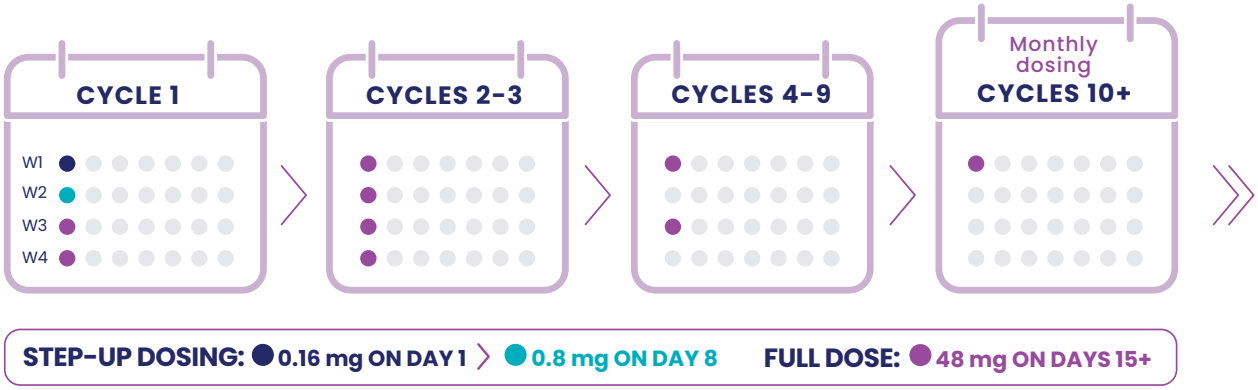
Dosage and administration for EPKINLY[1]

Your role in preparing EPKINLY is vital to patients and their care partners as key members of their care team. EPKINLY is for subcutaneous injection only. In the following pages, this brochure provides an overview of the dosage and administration of EPKINLY, including steps involved in the preparation of EPKINLY prior to administration. Please refer to Section 2 of the full US Prescribing Information for EPKINLY for complete Dosage and Administration instructions.

EPKINLY is administered according to the following 4-week dosing cycles:



- Administer EPKINLY subcutaneously in 28-day cycles to well-hydrated patients until disease progression or unacceptable toxicity
- Initiate treatment with the EPKINLY step-up dosing schedule and premedicate before each dose in cycle 1 to reduce the risk 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
- Monitor patients for potential CRS and ICANS. Due to the risk of CRS and ICANS, patients should be hospitalized for 24 hours after administration of the cycle 1, day 15 dosage of 48 mg

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

Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 6-7 and throughout this brochure. Please see full Prescribing Information.

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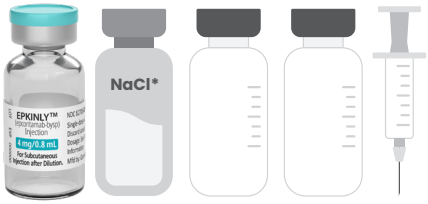
Read the entire contents of **Section 2.7 Preparation and Administration** of the full Prescribing Information carefully before preparation of EPKINLY.

- 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

Needed supplies per dose[1]

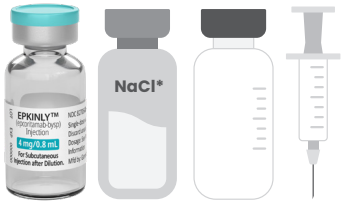
0.16 MG (STEP-UP DOSE 1)
Requires **2** dilutions



4 mg/0.8 ml vial | Empty vials

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

0.8 MG (STEP-UP DOSE 2)
Requires **1** dilution



4 mg/0.8 ml vial | Empty vial

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

48 MG (FULL DOSE)
No dilution required

48 mg/0.8 ml vial

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

- Step-up dosing may also be required if patients have a dosage delay. Please refer to Table 2 in Section 2.3 of the full Prescribing Information for recommendations on restarting EPKINLY after dosage delay
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit

SEE THE DOSING AND ADMINISTRATION GUIDE ON EPKINLYhcp.com/support-resources

*0.9% Sodium Chloride Injection, USP.

SELECT IMPORTANT SAFETY INFORMATION

EPKINLY can cause serious side effects, including **Cytokine release syndrome (CRS), Immune effector cell–associated neurotoxicity syndrome (ICANS),** Infections, Cytopenias, and Embryo-Fetal Toxicity.

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Please see additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 6-7 and throughout this brochure. Please see full Prescribing Information.

Preparing EPKINLY[1]

Read the entire contents of **Section 2.7 Preparation and Administration** of the full Prescribing Information carefully before preparation of EPKINLY.

EPKINLY is for subcutaneous injection only.

To prepare the step-up doses (0.16 mg and 0.8 mg), EPKINLY 4 mg/0.8 mL must be diluted by a healthcare provider **using aseptic technique.** Filtration of the diluted solution is not required.

0.16 mg (STEP-UP DOSE 1)

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, USP** 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, USP** 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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Please see Important Safety Information, including Boxed Warnings for CRS and ICANS, on pages 6-7 and throughout this brochure. Please see full Prescribing Information.

0.8 mg (STEP-UP DOSE 2)

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, USP** 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.

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 6-7 and throughout this brochure. Please see full Prescribing Information.

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 page 7.
Please see full Prescribing Information.

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- 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 additional Important Safety Information, including Boxed Warnings for CRS and ICANS, on page 6. Please see full Prescribing Information, including Boxed Warnings.

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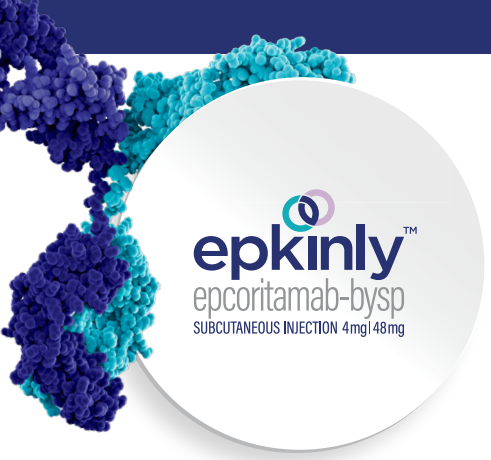
Reference: 1. EPKINLY [package insert]. Plainsboro, NJ: Genmab US, Inc. and North Chicago, IL: AbbVie Inc. 2023.



Storage and handling of EPKINLY[1]

Before dilution and preparation

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

After dilution and preparation

- Diluted EPKINLY solution should be used immediately or be stored
  - 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 hour
- Total storage time from the start of dose preparation to administration should not exceed 24 hours
- Protect from direct sunlight
- Allow EPKINLY solution to equilibrate to room temperature for no more than 1 hour before administration
- Discard unused EPKINLY solution beyond the allowable storage time

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 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.**

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

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