

MEDICATION GUIDE
EPKINLY® (ep-KIN-lee)
(epcoritamab-bysp)
injection, for subcutaneous use

What is the most important information I should know about EPKINLY?

EPKINLY can cause serious side effects, including:

- **Cytokine Release Syndrome (CRS).** CRS is common during treatment with EPKINLY and can also be serious or life-threatening. Tell your healthcare provider or get medical help right away if you develop any signs or symptoms of CRS, including:
 - 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

Due to the risk of CRS, you will receive EPKINLY on a “step-up dosing schedule”.

- The step-up dosing schedule is when you receive 2 or 3 smaller “step-up” doses of EPKINLY during your first cycle of treatment (Cycle 1).
- You will receive your first full dose of EPKINLY a week after your last step-up dose (this will be Day 15 or Day 22 of Cycle 1).
- If your dose of EPKINLY is delayed for any reason, you may need to repeat the “step-up dosing schedule”.
- Before each dose in Cycle 1, you will receive medicines to help reduce your risk of CRS. You will also receive medicine for 3 days after each dose in Cycle 1. Your healthcare provider will decide if you need to receive medicine to help reduce your risk of CRS with future cycles.
- See **“How will I receive EPKINLY?”** for more information about how you will receive EPKINLY.
- **Neurologic problems.** EPKINLY can cause serious neurologic problems that can be life-threatening and lead to death. Neurologic problems may happen days or weeks after you receive EPKINLY. Your healthcare provider may refer you to a healthcare provider who specializes in neurologic problems. Tell your healthcare provider right away if you develop any signs or symptoms of neurologic problems, including:
 - trouble speaking or writing
 - confusion and disorientation
 - drowsiness
 - tiredness or lack of energy
 - muscle weakness
 - shaking (tremors)
 - seizures
 - memory loss

Your healthcare provider will monitor you for signs and symptoms of CRS and neurologic problems during treatment with EPKINLY, as well as other side effects and treat you if needed. Your healthcare provider may temporarily stop or completely stop your treatment with EPKINLY if you develop CRS, neurologic problems, or any other side effects that are severe.

People with diffuse large B-cell lymphoma (DLBCL) or high-grade B-cell lymphoma should be hospitalized for 24 hours after receiving their first full dose of EPKINLY on Day 15 of Cycle 1 due to the risk of CRS and neurologic problems.

See **“What are the possible side effects of EPKINLY?”** for more information about side effects.

What is EPKINLY?

EPKINLY is a prescription medicine used to treat adults with certain types of DLBCL, high-grade B-cell lymphoma, or follicular lymphoma:

- that has come back (relapsed) or that did not respond to previous treatment (refractory), **and**
- who have already received 2 or more treatments for their cancer.

It is not known if EPKINLY is safe and effective in children.

Before receiving EPKINLY, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection.
- are pregnant or plan to become pregnant. EPKINLY may harm your unborn baby.
Females who are able to become pregnant:
 - Your healthcare provider should do a pregnancy test before you start treatment with EPKINLY.
 - You should use effective birth control (contraception) during treatment and for 4 months after your last dose of EPKINLY.
 - Tell your healthcare provider if you become pregnant or think that you may be pregnant during treatment with EPKINLY.
- are breastfeeding or plan to breastfeed. It is not known if EPKINLY passes into your breast milk. Do not breastfeed during treatment and for 4 months after your last dose of EPKINLY.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive EPKINLY?

- EPKINLY will be given to you by your healthcare provider as an injection under your skin (subcutaneous injection), usually in the lower part of your stomach-area (abdomen) or thigh.
- Your EPKINLY treatment schedule is divided into cycles that are usually 28 days (4 weeks) long.
- EPKINLY is usually given every week during Cycles 1 to 3, every 2 weeks during Cycles 4 to 9, and every 4 weeks starting with Cycle 10.
- Your healthcare provider will decide how many treatment cycles you will receive.
- See **“What is the most important information I should know about EPKINLY?”** for more information about how you will receive EPKINLY.

What should I avoid while receiving EPKINLY?

Do not drive, operate heavy machinery, or do other dangerous activities if you develop dizziness, confusion, tremors, sleepiness, or any other symptoms that impair consciousness until your signs and symptoms go away. These may be signs and symptoms of CRS or neurologic problems.

See **“What is the most important information I should know about EPKINLY?”** for more information about signs and symptoms of CRS and neurologic problems.

What are the possible side effects of EPKINLY?

EPKINLY can cause serious side effects, including:

- See **“What is the most important information I should know about EPKINLY?”**
- **Infections.** EPKINLY can cause serious infections that may lead to death. Your healthcare provider will check you for signs and symptoms of infection before and during treatment with EPKINLY. Your healthcare provider should prescribe medicines before you start treatment to help prevent infection and treat you as needed if you develop an infection during treatment with EPKINLY. Tell your healthcare provider right away if you develop any signs or symptoms of infection during treatment with EPKINLY, including:
 - fever of 100.4°F (38°C) or higher
 - cough
 - chest pain
 - tiredness
 - shortness of breath
 - painful rash
 - sore throat
 - pain during urination
 - feeling weak or generally unwell
- **Low blood cell counts.** EPKINLY can cause low blood cell counts which can be serious or severe. Your healthcare provider will check your blood cell counts during treatment with EPKINLY. EPKINLY may cause the following low blood cell counts:
 - **low white blood cell counts (neutropenia).** Low white blood cells can increase your risk for infection.
 - **low red blood cell counts (anemia).** Low red blood cells can cause tiredness and shortness of breath.
 - **low platelet counts (thrombocytopenia).** Low platelet counts can cause bruising or bleeding problems.

Your healthcare provider may temporarily stop or completely stop treatment with EPKINLY if you develop certain side effects.

The most common side effects of EPKINLY in DLBCL or high-grade B-cell lymphoma include:

- tiredness
- muscle and bone pain
- injection site reactions
- fever
- stomach-area (abdominal) pain
- nausea
- diarrhea

The most common severe abnormal laboratory test results with EPKINLY in DLBCL or high-grade B-cell lymphoma include: decreased white blood cells, decreased red blood cells, and decreased platelets.

The most common side effects of EPKINLY in follicular lymphoma include:

- injection site reactions
- COVID-19
- tiredness
- upper respiratory tract infection
- muscle and bone pain
- rash
- diarrhea
- fever
- cough
- headache

The most common severe abnormal laboratory test results with EPKINLY in follicular lymphoma include: decreased white blood cells and decreased red blood cells.

These are not all of the possible side effects of EPKINLY.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about safe and effective use of EPKINLY.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about EPKINLY that is written for health professionals.

What are the ingredients in EPKINLY?

Active ingredient: epcoritamab-bysp

Inactive ingredients: acetic acid, polysorbate 80, sodium acetate, sorbitol and Water for Injection.

Manufactured by: Genmab US, Inc., Plainsboro, NJ 08536

U.S. License Number: 2293

Marketed by: Genmab US, Inc., Plainsboro, NJ 08536 and AbbVie Inc., North Chicago, IL 60064

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For more information, go to www.EPKINLY.com or call 1-855-4GENMAB (1-855-443-6622)

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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