

PATIENT INFORMATION LEAFLET

EPKINLY (EPCORITAMAB) CONCENTRATE FOR SOLUTION FOR INJECTION 4 MG/0.8 ML

EPKINLY (EPCORITAMAB) SOLUTION FOR INJECTION 48 MG/0.8 ML

1. What is in this leaflet

This leaflet contains important information about the safe and effective use of this medicine. Read the entire leaflet carefully before you start taking this medicine.

2. What the most important information is

EPKINLY can cause serious side effects that can be severe or, life-threatening and can lead to death. These side effects include cytokine release syndrome (CRS) and immune effector cell associated neurotoxicity syndrome (ICANS).

Call your doctor or get emergency help right away if you get any of the following:

Cytokine Release Syndrome (CRS) symptoms may include:

- fever
- low blood pressure
- chills
- fast heartbeat
- headache

Immune effector cell-associated neurotoxicity syndrome (ICANS). Effects on your nervous system which can occur days or weeks after you receive the injection and may initially be subtle. Some of these symptoms may be signs of a serious immune reaction called “immune effector cell associated neurotoxicity syndrome” (ICANS). Symptoms of ICANS may include:

- difficulty speaking or writing
- drowsiness
- confusion/disorientation
- muscle weakness
- seizures
- memory loss

If you notice any of these symptoms listed above, call your doctor or nurse right away.

Your doctor may give you medicine to treat your side effects. Your healthcare provider will check for these problems during treatment with EPKINLY.

3. What EPKINLY is taken for and what EPKINLY does

EPKINLY is a prescription medicine used to treat adult patients with diffuse large B-cell lymphoma (DLBCL) when the disease has come back or did not respond to previous treatment and who have received at least two (2) prior therapies. EPKINLY is a bispecific antibody that was specifically designed to harness the power of your own immune system to attack lymphoma cells.

4. What you need to know about taking EPKINLY

Do not use EPKINLY if you are allergic to epcoritamab or any of the other ingredients of this medicine (listed in section 10). If you are not sure, talk to your doctor or nurse before you are given EPKINLY.

Before you take EPKINLY, tell your doctor if:

- have current or past problems with your nervous system – such as seizures
- have an infection
- are due to have a vaccine or you know you may need to have one in the near future
- are pregnant or plan to become pregnant

Once you have started EPKINLY, tell your doctor if you experience:

- Symptoms of CRS or ICANS, listed in Section 2
- Symptoms of infection, listed in Section 7

Before you start treatment with EPKINLY tell your doctor of all the medications you take.

5. Pregnancy, contraception, breastfeeding, and fertility with EPKINLY

Pregnancy

Do not use EPKINLY during pregnancy and if you are of childbearing potential and not using contraception. Pregnancy must be ruled out before treatment. This is because EPKINLY may affect your unborn baby. Tell your doctor immediately if you become pregnant.

Contraception

If you are a woman of child-bearing potential, you must use effective contraception to avoid becoming pregnant during treatment with EPKINLY and for at least 4 months after the last dose of EPKINLY. If you become pregnant during this time, you must tell your doctor immediately.

Talk to your doctor or nurse about suitable methods of contraception.

Breastfeeding

You must not breast-feed during treatment with EPKINLY until for 4 months after the last dose. It is not known whether EPKINLY passes into breast milk and could therefore affect the baby.

Fertility

The effect of epcoritamab on male and female fertility is unknown.

6. Driving and using machines with EPKINLY

Due to the potential ICANS, you should be careful while driving or using heavy or potentially dangerous machines. If you are currently having such symptoms, avoid these activities and contact your health care professional.

7. Possible side effects with EPKINLY

Serious side effects

Tell your doctor straight away if you noticed any of the symptoms of the following serious side effects. You may only get one or some of these symptoms.

Cytokine release syndrome (CRS) (Very common: may affect more than 1 in 10 people)

Symptoms can include:

- fever
- low blood pressure
- chills
- fast heartbeat
- difficulty breathing
- trouble breathing/low blood oxygen levels
- headache

Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) (Common: may affect up to 1 in 10 people):

- Effects on your nervous system, the symptoms of which can occur days or weeks after you receive the injection, may initially be subtle. Some of these symptoms may be signs of a serious immune reaction called “immune effector cell associated neurotoxicity syndrome” (ICANS).

Symptoms of ICANS can include:

- difficulty speaking or writing
- drowsiness
- confusion/disorientation
- muscle weakness
- seizures
- memory loss

Tumour lysis syndrome (TLS) (Common: may affect up to 1 in 10 people)

Symptoms can include:

- fever
- chills
- vomiting
- confusion
- shortness of breath
- seizures

- irregular heartbeat
- dark or cloudy urine
- unusual tiredness
- muscle or joint pain

Other side effects

Very common: may affect more than 1 in 10 people

- headache
- nausea
- diarrhea
- vomiting
- injection site reactions
- fever

Shown in blood tests

- low levels of some white blood cells (neutropenia)
- low number of red blood cells, which can cause tiredness (anemia)
- low platelet count, which may make you more likely to bruise or bleed (thrombocytopenia)

Common: may affect up to 1 in 10 people

- pneumonia (lung infection)
- fever due to infection when you have low levels of white blood cells (febrile neutropenia)
- upper respiratory tract infections (infection of the airways)
- tender swollen lymph nodes, chest pain, cough or difficulty breathing, pain at the site of the tumour (tumour flare)
- tumor lysis syndrome (A rapid breakdown of tumour cells resulting in chemical changes in the blood and damage to organs, including the kidneys, heart, and liver)
- rash
- itching

8. How EPKINLY is administered

You will receive EPKINLY as an injection under your skin (subcutaneous injection) in 28-day cycles, on a dosing schedule given to you by your healthcare provider.

You will be given EPKINLY according to the following schedule:

Cycle	Dosing Schedule
Cycle 1 to 3	Weekly
Cycles 4 to 9	Every other week
Cycles 10 and beyond	Every four weeks

You may be given other medicines before you are given EPKINLY. This is to help prevent reactions and fever in Cycle 1 (and potentially future Cycles).

These other medicines may include:

- Corticosteroids- such as prednisolone or equivalent
- An antihistamine – such as diphenhydramine
- Paracetamol

The first full dose (48 mg) of EPKINLY will be given to you on Cycle 1 Day 15. Stay within close proximity to a healthcare facility for at least 24 hours after the first full dose (48 mg).

You will be given EPKINLY for as long as your doctor thinks you are benefitting from the treatment.

Your doctor may delay or completely stop your treatment with EPKINLY if you have certain side effects.

9. How to store EPKINLY

EPKINLY will be stored by the doctor, nurse, or pharmacist at the hospital or clinic. To correctly store EPKINLY:

- Keep this medicine out of the sight and reach of children
- Store and transport refrigerated (2°C - 8°C).
- Keep the vial in the original carton in order to protect from light.
- Do not freeze.
- Do not shake.

10. Contents of the pack and other information

What EPKINLY contains:

The active substance is epcoritamab.

- Each 0.8 ml vial of EPKINLY 4mg/0.8mL contains 4 mg of epcoritamab at a concentration of 5 mg/ml.
- Each 0.8 ml vial of EPKINLY 48mg/0.8mL contains 48 mg of epcoritamab at a concentration of 60 mg/ml.

The other excipients are sodium acetate trihydrate, acetic acid, D-sorbitol, polysorbate 80, water for injections.

What EPKINLY looks like and contents of the pack:

- EPKINLY 4mg/0.8mL is a concentrate for solution for injection,
- EPKINLY 48mg/0.8mL is a solution for injection.

It is a colourless to slightly yellow solution provided in a glass vial.

Each carton contains 1 vial.

Product Registrant:

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Date of issue: DD MMM YYYY