

EPKINLY®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I being given Epkinly?

Epkinly contains the active ingredient epcoritamab. Epkinly is used to treat diffuse large B-cell lymphoma (DLBCL).

For more information, see Section [1. Why am I being given Epkinly?](#) in the full CMI.

2. What should I know before I am given Epkinly?

Do not use if you have ever had an allergic reaction to epcoritamab or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given Epkinly?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Epkinly and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is Epkinly given?

You will receive Epkinly as an injection under your skin on a dosing schedule given to you by your healthcare professional.

More instructions can be found in Section [4. How is Epkinly given?](#) in the full CMI.

5. What should I know while being given Epkinly?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, nurse, dentist, pharmacist or any other health care
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	<p>professionals you visit that you are using Epkinly.</p> <ul style="list-style-type: none"> • Keep all your appointments relating to your treatment, including any blood tests. • Call your doctor straight away if you experience symptoms of cytokine release syndrome (CRS), haemophagocytic lymphohistiocytosis (HLH), immune effector cell-associated neurotoxicity syndrome (ICANS), serious infection, or tumour lysis syndrome (TLS) as listed in Section 6.
<p>Things you should not do</p>	<ul style="list-style-type: none"> • Do not stop your Epkinly treatment without checking with your doctor.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> • Take care when driving or using machinery until you know how Epkinly affects you. If you feel any symptoms that may affect your ability to

	drive, do not drive, or use machines until the symptoms stops.
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For more information, see Section [5. What should I know while being given Epkinly?](#) in the full CMI.

6. Are there any side effects?

The more serious side effects can include cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS).

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

EPKINLY® (ep-KIN-lee)

Active ingredient: *epcoritamab* (ep-kor-ri-ta-mab)

This medicine has **provisional registration** in Australia for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after two or more lines of systemic therapy. EPKINLY is not indicated for the treatment of patients with primary central nervous system lymphoma. The decision to provisionally register this medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to substantiate the benefit of the medicine for this use.

Consumer Medicine Information (CMI)

This leaflet provides important information about using Epkinly. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Epkinly.**

Your doctor will give you a Patient Card. Read it carefully and follow the instructions on it. Keep this Patient Card with you at all times. Always show the Patient Card to the doctor or nurse when you see them or if you go to hospital.

Where to find information in this leaflet:

1. Why am I being given Epkinly?
2. What should I know before I am given Epkinly
3. What if I am taking other medicines?
4. How is Epkinly given?
5. What should I know while being given Epkinly?
6. Are there any side effects?
7. Product details

1. Why am I being given Epkinly?

Epkinly contains the active ingredient epcoritamab.

Epcoritamab is a bispecific antibody that was specifically designed to enable your immune system to attack lymphoma cells.

Epkinly is used to treat diffuse large B-cell lymphoma (DLBCL).

2. What should I know before I am given Epkinly?

Warnings

Do not use Epkinly if:

- you are allergic to epcoritamab, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- 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
- take any medicines for any other condition.

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), haemophagocytic lymphohistiocytosis (HLH), immune effector cell-associated neurotoxicity syndrome (ICANS) and serious infection. See Section [6. Are there any side effects?](#) for the symptoms of these side effects.

Tell your doctor straight away if you get symptoms of any of the side effects listed below, during or after treatment with Epkinly. You may need additional medical treatment.

- **Cytokine Release Syndrome (CRS)**

A condition associated with medicines that stimulate T cells (a type of white blood cells). Before each injection under the skin, you may be given additional medicines, which help reduce possible side effects of CRS.

- **Haemophagocytic lymphohistiocytosis (HLH)**

A condition that is characterised by overactivity of the immune system.

- **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 ICANS.

- **Serious Infection**

You may get signs of infection, which can vary depending on where in the body the infection is. It can occur at any time, either during treatment or several months after treatment ends.

- **Tumour Lysis Syndrome (TLS)**

Your blood test may show unusual levels of some salts in the blood caused by the fast breakdown of cancer cells during treatment. This is called tumour lysis syndrome (TLS).

Your doctor or nurse will do blood tests to check for this condition. Before each injection under the skin, you should be well-hydrated and may be given other medicines that can help reduce high levels of uric acid and help reduce possible effects of tumour lysis syndrome.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Pregnancy must be ruled out before treatment. There is no information about the safety of Epkinly in pregnant women. Tell your doctor immediately if you become pregnant.

If you are a woman of child-bearing potential, use of effective contraception during treatment with Epkinly and for at least 4 months after the last dose of Epkinly. Talk to your doctor or nurse about suitable methods of contraception.

Talk to your doctor if you are breastfeeding or intend to breastfeed. You must not breastfeed during treatment with Epkinly and for at least 4 months after the last dose. It is not known whether Epkinly passes into breastmilk and could therefore affect the baby.

Fertility

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

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

4. How is Epkinly given?

How Epkinly is administered

Epkinly will be given to you by a doctor or nurse and it will be given as an injection under your skin.

Epkinly will be given to you in cycles of 28 days, on a dosing schedule selected by your doctor. Follow the treatment schedule explained to you by your doctor.

You will usually be given Epkinly according to the following schedule:

Cycle	Dosing Schedule
Cycle 1 to 3	Weekly
Cycles 4 to 9	Every other week

Cycle	Dosing Schedule
Cycles 10 and beyond	Every four weeks

You may be given other medicines before you are given Epkinly. This is to help prevent side effects of treatment.

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.

If you miss your Epkinly dose

If you miss your medical appointment for treatment, immediately contact your healthcare professional to discuss rescheduling. For the treatment to be fully effective it is very important not to miss a dose.

If you use too much Epkinly

As Epkinly is given to you by your healthcare professional, it is unlikely that you will be given too much. However, if you experience any side effects after being given Epkinly, tell your doctor or nurse immediately.

5. What should I know while being given Epkinly?

Things you should do

Call your doctor straight away if you:

- experience symptoms of CRS, ICANS or infection, listed in Section [6. Are there any side effects?](#)

Remind any doctor, dentist, pharmacist or nurse you visit that you are using Epkinly.

Things you should not do

Do not stop using this medicine without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Epkinly affects you.

Due to the potential risk of 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.

Looking after your medicine

Epkinly will be stored by your healthcare professional in the pharmacy or on the hospital ward in a refrigerator at a temperature between 2°C to 8°C.

When to discard your medicine

Your healthcare professional will throw away any unused medicine following local requirements.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, pharmacist or nurse if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• diarrhoea• fever due to infection when you have low levels of white blood cells (febrile neutropenia)• headache	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> ● injection site reactions ● itching ● nausea ● pneumonia (lung infection) ● rash ● tender swollen lymph nodes, chest pain, cough or difficulty breathing, pain at the site of the tumour (tumour flare) ● upper respiratory tract infections (infection of the airways) ● vomiting. <p>Shown in blood tests:</p> <ul style="list-style-type: none"> ● low levels of some white blood cells, which can cause infections (neutropenia) ● low number of red blood cells, which can cause tiredness (anaemia) ● low platelet count, which may make you more likely to bruise or bleed (thrombocytopenia). 	

Serious side effects

Serious side effects	What to do
<p data-bbox="204 432 727 595">Symptoms of Cytokine Release Syndrome (CRS):</p> <ul data-bbox="204 629 663 1126" style="list-style-type: none"><li data-bbox="204 629 357 674">• fever<li data-bbox="204 696 564 797">• dizziness/light-headedness<li data-bbox="204 819 357 864">• chills<li data-bbox="204 887 549 931">• fast heartbeat<li data-bbox="204 954 663 1055">• difficulty breathing/shortness of breath<li data-bbox="204 1077 472 1122">• headache. <p data-bbox="204 1155 671 1368">Symptoms of haemophagocytic lymphohistiocytosis (HLH):</p> <ul data-bbox="204 1402 727 1715" style="list-style-type: none"><li data-bbox="204 1402 357 1447">• fever<li data-bbox="204 1469 695 1514">• low blood cell counts<li data-bbox="204 1536 727 1637">• bruising (dark mark on the skin) more easily<li data-bbox="204 1659 560 1704">• liver problems. <p data-bbox="204 1771 759 1984">Symptoms of Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS):</p>	<p data-bbox="810 432 1374 819">Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● difficulty speaking or writing ● drowsiness ● confusion/disorientation ● muscle weakness ● seizures ● memory loss. <p>Symptoms of serious infection:</p> <ul style="list-style-type: none"> ● fever of 38°C or above ● chills ● cough ● chest pain ● shortness of breath ● painful rash ● sore throat ● pain with urination ● feeling weak or generally unwell ● confusion. <p>Symptoms of tumour lysis syndrome (TLS):</p> <ul style="list-style-type: none"> ● fever ● chills ● vomiting ● confusion 	

Serious side effects	What to do
<ul style="list-style-type: none"> ● shortness of breath ● seizures ● irregular heartbeat ● dark or cloudy urine ● unusual tiredness ● muscle or joint pain. 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Epkinly contains

Active ingredient (main ingredient)	epcoritamab
Other ingredients (inactive ingredients)	sodium acetate trihydrate glacial acetic acid sorbitol polysorbate 80 water for injections
Potential allergens	The vial stopper is NOT made with natural rubber latex.

Do not take this medicine if you are allergic to any of these ingredients.

What Epkinly looks like

Epkinly is a sterile preservative free, clear to slightly opalescent, colourless to slightly yellow solution, practically free of visible particles.

Epkinly is supplied in a pack size of 1 single-dose vial containing:

- 4 mg/0.8 mL concentrate solution for injection (AUST R 404978)
- 48 mg/0.8 mL solution for injection (AUST R 404977)

Who distributes Epkinly

EPKINLY is distributed in Australia by:

AbbVie Pty Ltd

241 O'Riordan Street

Mascot NSW 2020

Australia

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