

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrEPKINLY®

Epcoritamab injection (solution for subcutaneous injection) / **Epcoritamab for injection** (concentrate for solution for subcutaneous injection)

This patient medication information is written for the person who will be taking **EPKINLY**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **EPKINLY**, talk to a healthcare professional.

Serious warnings and precautions box

- Fever (38°C or higher) and chills which may be symptoms of a serious side effect called cytokine release syndrome (CRS), which can be severe or fatal. Other symptoms of CRS may include difficulty in breathing, dizziness or feeling light-headed, feeling the need to throw up, headache, fast heartbeat, low blood pressure, feeling tired, vomiting, muscle pain and joint pain.
- Neurologic problems which may include symptoms like headache, confusion, difficulty with memory, difficulty speaking or slow speech, difficulty understanding speech, difficulty in writing, confused about time or surroundings, being less alert, or excessive sleepiness, and seizures (fits) which can be serious or life-threatening. Some of these may be signs of a serious immune reaction called 'immune effector cell associated neurotoxicity syndrome' (ICANS). These effects can occur days or weeks after you receive the injection, and may not be serious right away.
- Blurry vision, loss of vision or seeing two things when there is only one (double vision) may be symptoms of serious and potentially fatal brain condition called progressive multifocal leukoencephalopathy (PML). Other symptoms of PML are trouble speaking, feeling weak or clumsy in an arm or leg, changes in the way you walk or problems with your balance, changes in your personality, thinking or memory, which may lead to confusion.
- Fever (38°C or higher), low blood cell counts, bruising (dark mark on the skin) more easily, liver problems which may be symptoms of serious side effect called Haemophagocytic lymphohistiocytosis (HLH)

Your healthcare professional will monitor for signs and symptoms of CRS and neurological problems during treatment with **EPKINLY**. Call your doctor or get emergency help right away if you develop any of these signs and symptoms of CRS or neurologic problems at any time during your treatment with **EPKINLY**.

What EPKINLY is used for:

For the following indication(s) EPKINLY has been approved with conditions (NOC/c). This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more information, talk to your healthcare professional.

- EPKINLY is used to treat some forms of large B-cell lymphomas – a cancer of blood cells (cancerous B cells), mostly in the lymph nodes. EPKINLY can be used in adults when the cancerous B cells have returned after other treatments or when other treatments did not work. It may be used if you are not able to receive or have previously received a treatment called CAR-T cell therapy.

For the following indication(s) EPKINLY has been approved without conditions. This means it has passed Health Canada's review and can be bought and sold in Canada.

- EPKINLY is used together with lenalidomide and rituximab to treat adult patients with follicular lymphoma (FL) that has come back or did not respond to previous treatment.

What is a Notice of Compliance with Conditions (NOC/c)?

A Notice of Compliance with Conditions (NOC/c) is a type of approval to sell a drug in Canada.

Health Canada only gives an NOC/c to a drug that treats, prevents, or helps identify a serious or life-threatening illness. The drug must show promising proof that it works well, is of high quality, and is reasonably safe. Also, the drug must either respond to a serious medical need in Canada, or be much safer than existing treatments.

Drug makers must agree in writing to clearly state on the label that the drug was given an NOC/c, to complete more testing to make sure the drug works the way it should, to actively monitor the drug's performance after it has been sold, and to report their findings to Health Canada.

How EPKINLY works:

EPKINLY is a cancer medicine (bispecific antibody) that binds to the surface of cancerous B cells and also to the surface of T cells (another type of white blood cell). This binding on two targets activates T cells, which causes them to multiply, and in turn helps kill the cancerous B cells.

The ingredients in EPKINLY are:

Medicinal ingredients: epcoritamab

Non-medicinal ingredients: acetic acid, polysorbate 80, sodium acetate trihydrate, sorbitol, and water for injection

EPKINLY comes in the following dosage forms:

EPKINLY is available as single-dose vials: 4 mg in 0.8 mL sterile solution (5 mg/mL) or 48 mg in 0.8 mL sterile solution (60 mg/mL).

Do not use EPKINLY if:

- you are allergic to epcoritamab or any of the other ingredients of this medicine (listed in “What are the ingredients in EPKINLY?”). Talk to your doctor before you are given EPKINLY if you are not sure.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take EPKINLY. Talk about any health conditions or problems you may have, including if you:

- have or had problems with your nervous system – such as seizures
- have or had liver, kidney or heart problems
- 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

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), immune effector cell associated neurotoxicity syndrome (ICANS), haemophagocytic lymphohistiocytosis (HLH) and progressive multifocal leukoencephalopathy (PML).

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

Cytokine Release Syndrome (CRS). Symptoms may include:

- fever (38°C or higher)
- low blood pressure
- chills
- fast heartbeat
- headache

Haemophagocytic lymphohistiocytosis (HLH). Symptoms may include:

- fever
- low blood cell counts
- bruising (dark mark on the skin) more easily
- liver problems

Progressive multifocal leukoencephalopathy (PML). Symptoms of this serious and potentially fatal brain condition may include:

- blurry vision

- loss of vision or seeing 2 things when there's only 1 (double vision)
- trouble speaking
- feeling weak or clumsy in an arm or leg
- changes in the way you walk or problems with your balance
- changes in your personality, thinking, or memory, which may lead to confusion

These symptoms may start several months after treatment has ended. They usually develop slowly over weeks or months. It is important that your relatives or caregivers know of these symptoms, since they may notice some you are not aware of.

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.

Refer to the lenalidomide and the rituximab Product Monographs for additional information.

Other warnings you should know about:

Pregnancy, contraception, breastfeeding and fertility

- 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 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 ways to avoid becoming pregnant.
- You must not breast-feed during treatment with EPKINLY and for 4 months after the last dose. EPKINLY may be passed into breast milk and could potentially harm the baby.
- The effects of EPKINLY on male and female fertility are not known.

Driving and using machines

- EPKINLY may affect your ability to drive, cycle, or use any tools or machines. If you have any symptoms that might make this difficult (such as fever, fast heartbeat, feeling dizzy or lightheaded, chills or shortness of breath, etc.) do not drive, cycle, or use any tools or machines until you feel better.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Interactions between epcoritamab and other drugs, vitamins, minerals, natural supplements or alternative medicines have not been established.

How to take EPKINLY:

Your doctor will give you EPKINLY as an injection under your skin (subcutaneous injection), on a dosing schedule, in 28 day cycles.

For patients with relapsed or refractory diffuse large B-cell lymphoma

You will be given EPKINLY according to the following schedule:

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

For patients with relapsed or refractory follicular lymphoma

You will be given EPKINLY together with lenalidomide and rituximab according to the following schedule:

Cycle	EPKINLY Dosing Schedule
Cycle 1 to 3	Weekly
Cycles 4 to 12	Every four weeks

You will be given rituximab weekly during Cycle 1 and every four weeks during Cycles 2 to 5.

You will be given lenalidomide daily (on Days 1-21) during your treatment (Cycles 1 to 12).

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

These other medicines may include:

- corticosteroids- such as prednisolone or equivalent
- an antihistamine – such as diphenhydramine
- acetaminophen

Usual dose:**Diffuse large B-cell lymphoma**

Your first two doses are small doses given to you on Day 1 of Cycle 1 (0.16 mg) and Day 8 of Cycle 1 (0.8 mg) to manage side effects of this therapy.

The first full dose (48 mg) of EPKINLY will be given to you on Cycle 1 Day 15. For 24 hours following administration of the first full dose of 48 mg, you should remain within proximity of a healthcare facility. It is also possible that your healthcare professional decides to hospitalize you.

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.

Follicular lymphoma

You will be given EPKINLY together with lenalidomide and rituximab, EPKINLY will be given in three small doses on Day 1 of Cycle 1 (0.16 mg) and Day 8 of Cycle 1 (0.8 mg) and Day 15 of Cycle 1 (3 mg) to manage potential side effects to this therapy.

The first full dose (48 mg) of EPKINLY will be given to you on Cycle 1 Day 22.

You will be given EPKINLY for up to 12 cycles, 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.

Lenalidomide 20 mg will be given orally once daily (from Day 1 to Day 21) in Cycles 1-12 and rituximab 375 mg/m² intravenously every week in Cycle 1 (on Days 1, 8, 15, and 22) and every 4 weeks in Cycles 2-5 (on Day 1). You may receive a lower dose of lenalidomide if you have kidney problems.

Overdose:

If you think you, or a person you are caring for, have taken too much EPKINLY, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

If you miss an appointment to have EPKINLY administered, make another one straight away. For the treatment to be fully effective, it is very important not to miss a dose.

Possible side effects from using EPKINLY:

These are not all the possible side effects you may have when taking EPKINLY. If you experience any side effects not listed here, tell your healthcare professional. You may only get one or some of these symptoms.

EPKINLY used for the treatment of diffuse large B-cell lymphoma

Very common (may affect more than 1 in 10 people):

- headache
- bacterial infection such as urinary tract infection
- decreased hunger
- viral infections such as lung infections (pneumonia)
- nausea
- diarrhea
- vomiting
- tiredness
- injection site reactions
- abdominal pain (pain in the belly area)

- back pain
- swelling
- constipation

Shown in blood tests:

- low levels of some white blood cells (neutropenia), which may lead to fever or symptoms of an infection such as chills, sore throat, shortness of breath, congestion, diarrhea
- 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)
- low levels of potassium in the blood

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)
- tender swollen lymph nodes, chest pain, cough or difficulty breathing, pain at the site of the tumour (tumour flare)
- tumour 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)
- difficulty sleeping
- extra fluid around the lungs that make it difficult to breathe (pleural effusion)
- increased heart rate
- cough
- difficulty breathing
- pain in bones and joints
- chills
- fungal infections (caused by a type of germ called a fungus)
- rash
- itching
- confusion

Shown in blood tests:

- low level of phosphates in the blood, potassium, magnesium or sodium
- increased blood level of liver proteins, which may show problems with the liver (ALT)

EPKINLY used in combination with lenalidomide and rituximab for follicular lymphoma:

Very common (may affect more than 1 in 10 people):

- upper respiratory tract infections (infection of the airways)
- COVID-19
- lung infection (pneumonia)
- hypogammaglobulinemia is a condition in which the body does not produce enough antibodies to fight infections
- difficulties sleeping
- effects on your nervous system (neurological changes)
- headache

- diarrhea
- constipation
- nausea
- rash
- feeling tired (fatigue)
- injection site reactions
- fever
- an increase in liver tests, which show how your liver is working

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)
- low levels, as measured in blood tests, of lymphocytes (a type of white blood cell; lymphopenia), that may affect the body's ability to fight infection
- low level of potassium in blood

Common (may affect up to 1 in 10 people):

- a viral infection that may cause symptoms such as fever, pain, redness, and/or difficulty breathing (cytomegalovirus infection)
- viral infection of the mouth or genitals (herpes virus infection)
- fever due to infection when you have low levels of white blood cells (febrile neutropenia), an inflammation of the mucous membranes, which are the moist lining of the digestive, respiratory and genitourinary systems

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.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Very common			
Cytokine release syndrome (CRS): fever, low blood pressure, chills, fast heartbeat, difficulty breathing, trouble breathing/low blood oxygen levels, headache		√	
Common			
Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS): difficulty speaking or writing, drowsiness,		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
confusion/disorientation, muscle weakness, seizures, memory loss			
Serious infections fever, chills, difficulty breathing, burning pain when passing urine, confusion		√	
Tumour Lysis Syndrome: kidney problems (weakness, shortness of breath, fatigue, feeling confused), heart problems (irregular heartbeat or fluttering of the heart or a faster or slower heartbeat), vomiting, diarrhea, tingling in the mouth, hands or feet, muscle cramp		√	
Uncommon			
Haemophagocytic lymphohistiocytosis (HLH): fever, low blood cell counts, bruising (dark mark on the skin) more easily, liver problems		√	
Progressive multifocal leukoencephalopathy (PML): Symptoms of this serious and potentially fatal brain condition may include blurry vision, loss of vision or seeing 2 things when there's only 1 (double vision), trouble speaking, feeling weak or clumsy in an arm or leg, changes in the way you walk or problems with your balance, changes in your personality, thinking, or memory, which may lead to confusion		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

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 to 8°C).

Keep the vial in the original carton in order to protect from light.

Do not freeze. Do not shake.

If you want more information about EPKINLY:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.abbvie.ca), or by calling 1-888-704-8271.

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