PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrBLINCYTO® (blin sye' toe)

blinatumomab for injection

Read this carefully before you start taking **BLINCYTO** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **BLINCYTO**.

Serious Warnings and Precautions

BLINCYTO can cause serious side effects that can be severe, life-threatening, or lead to death, including:

- Cytokine Release Syndrome and Infusion Reactions (fever, tiredness or weakness, dizziness, headache, low blood pressure, nausea, vomiting, chills, face swelling, wheezing or trouble breathing and skin rash).
- Tumour Lysis Syndrome (complications occurring after cancer treatment leading to increased blood levels of potassium, uric acid, and phosphorus and decreased blood levels of calcium).
- Neurological problems including immune effector cell-associated neurotoxicity syndrome (disturbances of brain function such as difficulty in communicating, tingling of skin, seizure, difficulty thinking or processing thoughts, difficulty remembering).
- Infections (fever, aches, feeling tired, cough).
- Pancreatitis (inflammation of the pancreas) that includes symptoms of severe and persistent stomach pain, with or without nausea and vomiting.

What is BLINCYTO used for?

- Treatment of Philadelphia chromosome-negative B-cell precursor acute lymphoblastic leukemia who have detectable traces of cancer cells (referred to as minimal residual disease positive or MRD-positive) after treatment with chemotherapy.
- Treatment of pediatric patients with Philadelphia chromosome-negative B-cell precursor acute lymphoblastic leukemia that has come back after a previous treatment (relapsed) or if there was no response to the first treatment (refractory).
- Treatment of acute lymphoblastic leukemia in adults that has come back after a previous treatment (relapsed) or if there was no response to the first treatment (refractory). Acute lymphoblastic leukemia is a cancer of the blood in which a particular kind of white blood cell is growing out of control. Acute lymphoblastic leukemia is also referred to as ALL.

How does BLINCYTO work?

BLINCYTO helps your immune system find and kill the cancer cells in acute lymphoblastic leukemia.

What are the ingredients in BLINCYTO?

Medicinal ingredients: blinatumomab

Non-medicinal ingredients: citric acid monohydrate, lysine hydrochloride, polysorbate 80, sodium hydroxide and trehalose dihydrate.

BLINCYTO is sold with a vial containing a liquid that will be used by the healthcare professional to prepare your dose of BLINCYTO. It contains the following non-medicinal ingredients: citric acid monohydrate, lysine hydrochloride, polysorbate 80, sodium hydroxide and water for injection.

BLINCYTO comes in the following dosage forms:

BLINCYTO is sold as a lyophilized powder in a vial. One vial contains 38.5 micrograms of powder for solution for infusion. Each package of BLINCYTO also contains a vial of liquid that will be used by the healthcare professional to prepare your dose of BLINCYTO.

Do not use BLINCYTO if:

- you are allergic to blinatumomab or to any of the ingredients of BLINCYTO.

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

- have a history of radiation treatment to the brain, or chemotherapy treatment.
- have a history of neurological problems including immune effector cell-associated neurotoxicity syndrome (ICANS), for example, shaking (or tremor), abnormal sensations, seizures, memory loss, confusion, disorientation, loss of balance, or difficulty in speaking. If you are still suffering from active neurological problems or conditions, tell your doctor. If your leukemia has spread to your brain and/or spinal cord, your doctor may have to treat this first before you can start treatment with BLINCYTO. Your doctor will assess your nervous system and conduct tests before deciding if you should receive BLINCYTO. Your doctor may need to take special care of you during your treatment with BLINCYTO.
- have an infection;
- have ever had an infusion reaction after receiving BLINCYTO or other medications. Symptoms may include wheezing, flushing, face swelling, difficulty breathing, low or high blood pressure;
- have severe and persistent stomach pain, with or without nausea and vomiting, as these may be symptoms of a serious and potentially fatal condition known as pancreatitis (inflammation of the pancreas);
- are pregnant or plan to become pregnant. BLINCYTO may harm your unborn baby. Tell your healthcare professional if you become pregnant during treatment with BLINCYTO. Women who are able to become pregnant should use contraception during treatment. You must also do this for 48 hours after your last treatment. Talk to your healthcare professional about suitable methods of contraception;
- become pregnant during BLINCYTO treatment, your doctor may need to talk to you about precautions in using vaccinations for your baby;

- are breastfeeding or plan to breastfeed. It is not known if BLINCYTO passes into your breast milk. You should not breast-feed during treatment with BLINCYTO and for at least 48 hours after your last treatment. You and your healthcare professional should decide if you will take BLINCYTO or breastfeed. You should not do both.

Other warnings you should know about:

Your doctor will order blood tests to check your liver function before you start BLINCYTO and during treatment with BLINCYTO.

Before each infusion cycle of BLINCYTO, you will be given medicines which help reduce a potentially life-threatening complication known as tumour lysis syndrome, which is caused by chemical disturbances in the blood due to the breakdown of dying cancer cells.

During treatment, especially in the first few days after treatment start, you may experience a severe low white blood cell count (neutropenia), severe low white blood cell count with a fever (febrile neutropenia), elevated liver enzymes, or elevated uric acid. Your doctor will take regular blood tests to monitor your blood counts during treatment with BLINCYTO.

Do not drive, operate heavy machinery, or do other dangerous activities while you are receiving BLINCYTO because BLINCYTO can cause neurological symptoms such as dizziness, seizures, and confusion.

Benzyl alcohol preservative toxicity

If you are prescribed 7-day bags of BLINCYTO solution for infusion, they will contain benzyl alcohol as a preservative. Serious side effects (e.g., gasping syndrome) including death have happened in newborns or infants who have received benzyl alcohol intravenously. Seven-day bags of BLINCYTO solution for infusion are not recommended for use in patients weighing less than 22 kg (48 lbs).

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

Tell your healthcare professional if you think you or your child receiving BLINCYTO may need any vaccinations in the near future, including those needed to travel to other countries. Some vaccines must not be given within two weeks before, at the same time as or in the months after you receive treatment with BLINCYTO. Your doctor will check if you should have the vaccination.

The following may interact with BLINCYTO:

- It is not known which medications interact with BLINCYTO.

How to take BLINCYTO:

BLINCYTO will be given to you by a healthcare professional in a healthcare setting.

- Before you receive BLINCYTO, you will be given a medicine (corticosteroid) to help reduce side effects (infusion reactions and cytokine release syndrome). The amount of medicine and length of treatment will depend on your age and how much cancer you have (tumour burden).
- BLINCYTO will be given to you by infusion into your vein by a pump.

- You will receive BLINCYTO by continuous infusion into your vein for 4 weeks (28 days), followed by a 2-week break (14 days) during which you will not be given BLINCYTO. This is one treatment cycle (42 days). After the 2-week break, your healthcare professional will decide if you will be treated with more cycles of BLINCYTO.
- Your healthcare professional may change your dose of BLINCYTO, delay, or completely stop treatment with BLINCYTO if you have certain side effects.
- Your healthcare professional will do blood tests during treatment with BLINCYTO to check you for side effects.
- It is very important to keep the area around the IV catheter clean to reduce the risk of getting an infection. Your healthcare professional will show you how to care for your catheter site.
- Do not change the settings on your infusion pump, even if there is a problem with your pump or your pump alarm sounds. Any changes to your infusion pump settings may cause a dose that is too high or too low to be given.

Call your healthcare professional right away if you have any problems with the pump or the pump alarm sounds, if the infusion bag empties before the scheduled bag change or if the infusion pump stops unexpectedly.

Treatment of Relapsed or Refractory B-cell precursor ALL

Your healthcare professional should give you BLINCYTO in a hospital or clinic for the first 9 days of the first treatment cycle and for the first 2 days of the second cycle to check you for side effects. If you receive additional treatment cycles of BLINCYTO or if your treatment is stopped for a period of time and restarted, you may also be treated in a hospital or clinic.

Treatment of MRD-positive B-cell Precursor ALL

Your healthcare professional should give you BLINCYTO in a hospital or clinic for the first 3 days of your first treatment cycle and the first 2 days of your second cycle to check you for side effects.

Usual Dose:

Treatment of Relapsed or Refractory B-cell precursor ALL

Patients weighing 45 kilograms or more

You will be given 9 micrograms per day of BLINCYTO for the first week of your first cycle. You will be given 28 micrograms per day for the rest of the first cycle and for all other cycles. Your doctor will determine if more cycles should be given or if your dose should change.

You may not be able to tell the difference between the 9 micrograms per day and 28 micrograms per day infusions.

Patients weighing less than 45 kilograms

Your pump will be set to deliver a dose based on your body size (surface area). You will be given 5 micrograms per square meter per day for the first week of your first cycle. You will be given 15 micrograms per square meter per day for the rest of the first cycle (days 8 - 28) and for all other cycles. Your doctor will determine if more cycles should be given or if your dose should change.

You may not be able to tell the difference between the 5 micrograms per square meter per day and the 15 micrograms per square meter per day infusions.

Treatment of MRD-positive B-cell Precursor ALL

Patients weighing 45 kilograms or more

You will be given 28 micrograms per day of BLINCYTO for all treatment cycles. Your pump will be set to deliver a dose of 28 micrograms per day. Your doctor will determine the number of cycles of BLINCYTO that should be given.

Patients weighing less than 45 kilograms

You will be given 15 micrograms per square meter per day for all treatment cycles. Your pump will be set to deliver a dose based on your body size (surface area). Your doctor will determine the number of cycles of BLINCYTO that should be given.

Overdose:

If you think you, or a person you are caring for, have taken too much BLINCYTO, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

Speak with your healthcare professional as soon as possible if you miss a dose of BLINCYTO.

What are possible side effects from using BLINCYTO:

These are not all the possible side effects of taking BLINCYTO. If you experience any side effects not listed here, tell your healthcare professional. Please also see **Warnings and Precautions**.

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

- infections in the blood including bacteria, fungi, viruses, or infections in other organs
- low levels of certain white blood cells with fever (febrile neutropenia), decreased levels of red blood cells (anemia), decreased levels of white blood cells (neutropenia, leukopenia), decreased levels of platelets (thrombocytopenia)
- fever, swelling, chills, decreased or increased blood pressure and fluid in the lungs, which may become severe (cytokine release syndrome)
- sleep problems (insomnia)
- headache
- rapid heart rate (tachycardia)
- low blood pressure
- cough
- rash
- back pain, bone pain

- fever (pyrexia), swelling of hands, ankles or feet
- high levels of liver enzymes (ALT, AST)
- reactions related to infusion may include, wheezing, flushing, face swelling, difficulty breathing, low blood pressure, high blood pressure

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

- high white blood cell counts, low levels of certain white blood cells (lymphopenia), swollen lymph nodes
- pain in extremity, chills, chest pain
- complications during or after cancer treatment leading to high blood levels of potassium, uric acid, and phosphorus and low blood levels of calcium (tumour lysis syndrome)
- confusion, disorientation
- shaking (or tremor), dizziness, drowsiness (somnolence), disturbances of brain function (encephalopathy) such as difficulty in communicating (aphasia), tingling of skin (paresthesia), reduced pain or touch sensation (hypoesthesia), seizure, difficulty thinking or processing thoughts, difficulty remembering. These may be symptoms of neurological problems associated with a condition called immune effector cell-associated neurotoxicity syndrome (ICANS).
- high blood pressure (hypertension), flushing
- wet cough, shortness of breath (dyspnea)
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (allergic reaction)
- low levels of antibodies called “immunoglobulins” which help the immune system fight against infections (decreased immunoglobulins)
- high levels of bilirubin and liver enzymes (GGT)
- overdose

Uncommon side effects (may affect up to 1 in 100 people):

- a condition which causes fluid to leak from the small blood vessels into your body (capillary leak syndrome)
- fever, swelling, chills, decreased or increased blood pressure and fluid in the lungs, which may be severe and can be fatal (cytokine storm)
- nerve problems affecting the head and neck such as visual disturbances, difficulty with facial movements, difficulty hearing, and trouble swallowing (cranial nerve disorders)

Some side effects more frequently seen in adolescents and children include:

- runny nose (rhinitis)
- low phosphorus levels in blood (hypophosphatemia), low calcium levels in blood (hypocalcemia)
- nose bleeds (epistaxis)
- high levels of the enzyme lactate dehydrogenase (LDH) in blood

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
VERY COMMON			
Cytokine release syndrome and infusion reactions (fever, tiredness or weakness, dizziness, headache, low blood pressure, nausea, vomiting, chills, face swelling, wheezing or trouble breathing and skin rash)		✓	
Infections (fever, aches, feeling tired, cough)		✓	
COMMON			
Tumour lysis syndrome (complications occurring after cancer treatment leading to increased blood levels of potassium, uric acid, and phosphate and decreased blood levels of calcium)		✓	
Neurological problems including ICANS (seizures, difficulty in speaking or slurred speech, loss of consciousness, confusion and disorientation and loss of balance)		✓	
UNCOMMON			
Capillary leak syndrome (a condition which causes fluid to leak from the small blood vessels into your body)		✓	

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 (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

Storage:

BLINCYTO will be prepared in a bag for intravenous infusion by a healthcare professional. Intravenous bags containing BLINCYTO will be stored in the refrigerator at 2°C to 8°C for up to 10 days (preservative-free bag) and for up to 14 days (with preservative).

Do not throw away (dispose of) any BLINCYTO in your household trash. Talk with your healthcare professional about disposal of BLINCYTO and used supplies.

Keep out of reach and sight of children.

If you want more information about BLINCYTO:

- 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.amgen.ca), or by calling 1 866-502-6436.

This leaflet was prepared by Amgen Canada Inc.

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