

Medication Guide

BLINCYTO® (blin sye toe)
(blinatumomab)
for injection

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

Call your healthcare provider or get emergency medical help right away if you get any of the symptoms listed below.

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

- **Cytokine Release Syndrome (CRS) and Infusion Reactions.** Symptoms of CRS and infusion reactions may include:
 - fever
 - tiredness or weakness
 - dizziness
 - headache
 - low blood pressure
 - nausea
 - vomiting
 - chills
 - face swelling
 - wheezing or trouble breathing
 - skin rash
- **Neurologic problems.** Symptoms of neurologic problems may include:
 - seizures
 - difficulty in speaking or slurred speech
 - loss of consciousness
 - trouble sleeping
 - confusion and disorientation
 - loss of balance
 - headache
 - difficulty with facial movements, hearing, vision, or swallowing
 - tremors

People with Down Syndrome over the age of 10 years may have a higher risk of seizures with BLINCYTO treatment.

Your healthcare provider will check for these problems during treatment with BLINCYTO. Your healthcare provider may temporarily stop or completely stop your treatment with BLINCYTO, if you have severe side effects.

See “**What are the possible side effects of BLINCYTO?**” below for other side effects of BLINCYTO.

What is BLINCYTO?

BLINCYTO is a prescription medicine used to treat adults and children 1 month and older with:

- B-cell precursor acute lymphoblastic leukemia (ALL) in remission when only a small number of cancer cells remain in the body (minimal residual disease)
- B-cell precursor ALL that has come back or did not respond to previous treatments
- Philadelphia-chromosome negative B-cell precursor ALL in the consolidation phase of chemotherapy treatment with multiple phases

ALL is a cancer of the blood in which a particular kind of white blood cell is growing out of control.

It is not known if BLINCYTO is safe and effective in children less than 1 month of age.

Who should not receive BLINCYTO?

Do not receive BLINCYTO if you are allergic to blinatumomab or to any of the ingredients of BLINCYTO. See the end of this Medication Guide for a complete list of ingredients in BLINCYTO.

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

- have a history of neurological problems, such as seizures, confusion, trouble speaking or loss of balance
- have Down Syndrome
- have an infection
- have ever had an infusion reaction after receiving BLINCYTO or other medications
- have a history of radiation treatment to the brain, or chemotherapy treatment
- are scheduled to receive a vaccine. You should not receive a “live vaccine” for at least 2 weeks before you start treatment with BLINCYTO, during treatment, and until your immune system recovers after you receive your last cycle of BLINCYTO. If you are not sure about the type of vaccine, ask your healthcare provider.
- are pregnant or plan to become pregnant. BLINCYTO may harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with BLINCYTO.
 - If you are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with BLINCYTO.
 - Females who are able to become pregnant should use an effective form of birth control (contraception) during treatment with BLINCYTO, and for 48 hours after your last dose of BLINCYTO.
- are breastfeeding or plan to breastfeed. It is not known if BLINCYTO passes into your breast milk. You should not breastfeed during treatment with BLINCYTO and for 48 hours after your last dose.

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 BLINCYTO?

- BLINCYTO will be given to you by intravenous (IV) infusion into your vein by an infusion pump.
- Your healthcare provider will decide the number of treatment cycles of BLINCYTO.
 - You will receive BLINCYTO by continuous IV infusion for 4 weeks (28 days), followed by a 2-week (14 days) break during which you will not receive BLINCYTO. This is 1 treatment cycle (42 days).
- Your healthcare provider may prescribe continued therapy.
 - You will receive BLINCYTO by continuous IV infusion for 4 weeks (28 days), followed by an 8-week (56 days) break during which you will not receive BLINCYTO. This is 1 treatment cycle (84 days).
- Your healthcare provider may give you BLINCYTO in a hospital or clinic for the first 3 or 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.
- Your healthcare provider may change your dose of BLINCYTO, delay, or completely stop treatment with BLINCYTO if you have certain side effects.
- Your healthcare provider will do blood tests during treatment with BLINCYTO to check you for side effects.
- Before you receive BLINCYTO, you will be given a corticosteroid medicine to help reduce infusion reactions.
- Before and during treatment with BLINCYTO, you may be given chemotherapy as an injection into the space that surrounds the spinal cord and the brain (intrathecal injection) to help prevent central nervous system relapse of ALL.
- It is very important to keep the area around the IV catheter clean to reduce the risk of getting an infection. Your healthcare provider 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 provider or nurse right away if you have any problems with your pump or your pump alarm sounds.

What should I avoid while receiving 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.

What are the possible side effects of BLINCYTO?

BLINCYTO may cause serious side effects, including:

See **“What is the most important information I should know about BLINCYTO?”**

- **Infections.** BLINCYTO may cause life-threatening infections that may lead to death. Tell your healthcare provider right away if you develop any signs or symptoms of an infection.
- **Tumor Lysis Syndrome (TLS).** TLS is caused by the fast breakdown of cancer cells. TLS can be life-threatening and may lead to death. Tell your healthcare provider right away if you have any symptoms of TLS during treatment with BLINCYTO, including:
 - nausea and vomiting
 - confusion
 - shortness of breath
 - irregular heartbeat
 - dark or cloudy urine
 - reduced amount of urine
 - unusual tiredness
 - muscle cramps
- **Low white blood cell counts (neutropenia).** Neutropenia is common with BLINCYTO treatment and may sometimes be life-threatening. Low white blood cell counts can increase your risk of infection. Your healthcare provider will do blood tests to check your white blood cell count during treatment with BLINCYTO. Tell your healthcare provider right away if you get a fever.
- **Abnormal liver blood tests.** Your healthcare provider will do blood tests to check your liver before you start BLINCYTO and during treatment with BLINCYTO.
- **Inflammation of the pancreas (pancreatitis).** Pancreatitis may happen in people treated with BLINCYTO and corticosteroids. It may be severe and lead to death. Tell your healthcare provider right away if you have severe stomach-area pain that does not go away. The pain may happen with or without nausea and vomiting.

The most common side effects of BLINCYTO include:

- fever
- reactions related to infusion of the medicine such as face swelling, low blood pressure, and high blood pressure (infusion-related reactions)
- headache
- muscle, joint and bone pain
- low white blood cell count (neutropenia)
- nausea
- low red blood cell count (anemia)
- low platelet count (thrombocytopenia)

- infection
- diarrhea

These are not all the possible side effects of BLINCYTO.

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

How should I store BLINCYTO?

Intravenous (IV) bags containing BLINCYTO for infusion will arrive in a special package.

- Do not open the package.
- Do not freeze the package.
- The package containing BLINCYTO will be opened by your healthcare provider and stored in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Do not throw away (dispose of) any BLINCYTO in your household trash. Talk with your healthcare provider about disposal of BLINCYTO and used supplies.

Keep BLINCYTO and all medicines out of reach of children.

General information about safe and effective use of BLINCYTO.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use BLINCYTO for a condition for which it was not prescribed. Do not give BLINCYTO to other people even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about BLINCYTO that is written for health professionals.

What are the ingredients in BLINCYTO?

Active ingredient: blinatumomab

Inactive ingredients: citric acid monohydrate, lysine hydrochloride, polysorbate 80, trehalose dihydrate, sodium hydroxide and preservative-free sterile water for injection.

Inactive ingredients of IV Solution Stabilizer: citric acid monohydrate, lysine hydrochloride, polysorbate 80, sodium hydroxide and water for injection.

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For more information, go to www.blinicyto.com or call Amgen at 1-800-772-6436.

