BLINCYTO®
(blinatumomab) for injection
35 mcg single-dose vial

Learn more about neurologic problems, a side effect of BLINCYTO®[1]

Neurologic problems can be severe, life-threatening, or lead to death[2]

WHAT IS BLINCYTO® (blinatumomab)?

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.

IMPORTANT SAFETY INFORMATION

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

- **Call your health care 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, and 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, and tremors. People with Down Syndrome may have a higher risk of seizures with BLINCYTO® treatment and may be given anti-seizure medicine before starting BLINCYTO® treatment.
  - Your health care provider will check for these problems during treatment with BLINCYTO®. Your health care provider may temporarily or completely stop your treatment with BLINCYTO® if you have severe side effects.

Please see additional Important Safety Information, including **BOXED WARNINGS**, throughout.

What you should know about the risk of neurologic problems with BLINCYTO®[1]

BLINCYTO® may cause **neurologic problems** that can be severe, life-threatening, or lead to death. These are issues that could harm your brain or nerves and can be dangerous.[2,3]

Contact your health care provider or seek emergency medical help right away if you experience any of the following signs and symptoms:[2]

- 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 (shakiness)

Talk to your doctor about the signs and symptoms of neurologic problems (see examples below).[2]

Tremors (shakiness and trembling):[2] *(detail provided by your HCP)*

Shaking and trembling that can look like .....

.....

Speaking becomes difficult or speech becomes slurred while on BLINCYTO®:[1,2,4] *(detail provided by your HCP)*

This can look like .....

.....

Confusion and disorientation:[2] *(detail provided by your HCP)*

This can look like .....

.....

Difficulty with facial movements:[2] *(detail provided by your HCP)*

This can look like .....

.....

Your health care provider will check for these problems during treatment with BLINCYTO®.[2] The information provided in this brochure is intended to help you understand how your health care provider may talk to you about the signs and symptoms of neurologic problems.

Some facts to know

- In clinical trials of BLINCYTO®, around **65%** of people reported neurologic issues after starting BLINCYTO®, with **13%** having severe symptoms[1]
- In clinical trials, patients who had neurologic problems typically experienced their first symptom **within the first 2 weeks** after starting BLINCYTO®. Most of these symptoms resolved after BLINCYTO® treatment was interrupted, but some resulted in treatment being discontinued[1]

HCP, health care provider.

Please see additional Important Safety Information, including **BOXED WARNINGS**, throughout.

Important Reminders

- Neurologic problems are not the only possible side effects of BLINCYTO®. See additional Important Safety Information throughout for additional side effects. **Call your health care provider** and their team if you are having any side effects[2]
- Do not wait until symptoms get worse
- You may report side effects to the FDA at 1-800-FDA-1088
- **Do not drive** while on BLINCYTO®[2]
- BLINCYTO® is given by a continuous intravenous (IV) infusion. This means the medicine goes into your body through a vein. This happens for a 4-week (28-day) period. You must stay connected to BLINCYTO® for the whole 28-day cycle, unless your health care provider tells you otherwise[1,2]
- **Do not change the settings on your infusion pump. Any changes to your infusion pump settings may cause a dose that is too high or too low to be given**[2]

Amgen® Patient Navigators are here to help

Amgen Patient Navigators can answer questions about starting your Amgen therapy, navigating your treatment journey, and can help you start and stay on therapy as prescribed

Click here to sign up

Learn more on BLINCYTO.com

IMPORTANT SAFETY INFORMATION (cont'd)

Who should not receive BLINCYTO®?

- Do not receive BLINCYTO® if you are allergic to blinatumomab or to any of the ingredients of BLINCYTO®.

Before receiving BLINCYTO®, tell your health care 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" within 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 health care provider.
- are pregnant or plan to become pregnant. BLINCYTO® may harm your unborn baby. Tell your health care provider if you become pregnant during treatment with BLINCYTO®.
  - If you are able to become pregnant, your health care 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®.

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IMPORTANT SAFETY INFORMATION (cont'd)

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

- 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 health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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.

BLINCYTO® may cause serious side effects, including:

- **Infections.** BLINCYTO® may cause life-threatening infections that may lead to death. Tell your health care provider right away in case 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 health care provider will do blood tests to check your white blood cell counts during treatment with BLINCYTO®. Tell your health care provider right away if you get a fever.
- **Abnormal liver blood test.** Your health care 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 patients treated with BLINCYTO® and corticosteroids. It may be severe and lead to death. Tell your health care 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.

- Your health care provider will do blood tests during treatment to check for side effects.

The most common side effects

- 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
  - Infection
  - Muscle, joint, and bone pain
  - Low white blood cell count (neutropenia)
  - Nausea
  - Low red blood cell count (anemia)
  - Low platelet count (thrombocytopenia)
  - Diarrhea

These are not all the possible side effects of BLINCYTO®.

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

Please read the Medication Guide before you or your child receives BLINCYTO® and before each BLINCYTO® infusion and discuss it with your doctor.

Please see BLINCYTO® full Prescribing Information, including BOXED WARNINGS and Medication Guide.

References: 1. BLINCYTO® (blinatumomab) prescribing information, Amgen. **2.** BLINCYTO® (blinatumomab) medication guide, Amgen. **3.** Lee DW, Santomasso BD, Locke FL, et al. ASTCT consensus grading for cytokine release syndrome and neurologic toxicity associated with immune effector cells. *Biol Blood Marrow Transplant*. 2019;25:625-638. **4.** National Cancer Institute. https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTCAE_v4_Quick_Reference_8.5x11.pdf. Accessed February 12, 2026.

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