

Patient Information Leaflet (PIL)

BLINCYTO™ 35 mcg of lyophilized powder in a single-dose vial for reconstitution
blinatumomab

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or health care provider.
- 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.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or healthcare provider.

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1. What BLINCYTO is and what it is used for

BLINCYTO is a prescription medicine used to treat a certain type of acute lymphoblastic leukemia (ALL). ALL is a cancer of the blood in which a particular kind of white blood cell is growing out of control.

You can ask your pharmacist or healthcare provider for information about BLINCYTO that is written for health professionals.

2. Before you use BLINCYTO

Do not use BLINCYTO:

- if you are allergic to blinatumomab or to any of the ingredients of BLINCYTO. See the end of this leaflet for a complete list of ingredients in BLINCYTO.

Warnings and precautions

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 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 healthcare provider

Taking other medicines, herbal or dietary supplements

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Pregnancy and breast-feeding

Tell your healthcare provider if you:

- 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.
 - o If you are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with BLINCYTO.
 - o Females who are able to become pregnant should use an effective form of birth control during treatment with BLINCYTO, and for at least 48 hours after the 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 at least 48 hours after your last treatment.

Driving and using machines

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.

Important information about some of the ingredients of BLINCYTO

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. it is essentially ‘sodium- free’.

3. How to use BLINCYTO

Follow your doctor, nurse, and pharmacist's instructions when receiving BLINCYTO. If you have any further questions regarding the infusion of BLINCYTO, contact your doctor, nurse, or pharmacist.

How BLINCYTO is given

- BLINCYTO will be given to you by intravenous (IV) infusion into your vein by an infusion pump.
- 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 one treatment cycle (42 days). After the 2 week break, your healthcare provider will decide if you will be given additional treatment cycles of BLINCYTO.
- Your healthcare provider may 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.
- 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.
- 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.**

4. Possible side effects

Like all medicines, BLINCYTO can cause certain side effects, although not everybody gets them.

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
- confusion and disorientation
- loss of balance

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.

BLINCYTO may cause serious side effects, including:

- **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.
- **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 patients 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
- headache
- nausea
- swelling of hands, ankles or feet
- low blood potassium (hypokalemia)
- low red blood cell count (anemia)
- low platelet count (thrombocytopenia)
- stomach pain

Reporting of side effects: If you get any side effects, talk to your doctor or health care provider. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store BLINCYTO

If your intravenous (IV) bag is changed at home, 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 2°C to 8°C for up to 8 days.
- 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 the sight and reach of children.

6. Further information

What BLINCYTO contains

Active ingredient: blinatumomab

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

What BLINCYTO looks like and contents of the pack

Each pack of BLINCYTO contains:

- 1 single-dose BLINCYTO vial containing a sterile, preservative free, white to off-white lyophilized powder
- 1 single-dose IV Solution Stabilizer vial containing sterile, preservative free, colorless-to-slightly yellow, clear solution

IV bags containing BLINCYTO solution for infusion will be prepared by your doctor, nurse, or pharmacist.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799, USA

Site of Manufacture of the Drug Product:
Boehringer Ingelheim Pharma GmbH & Co KG
Birkendorfer Strasse 65
88397 Biberach An Der Riss, Germany

This leaflet was last revised in August 2016.

THIS MEDICINE

Is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.

Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicine.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicines out of reach of children.

Council of Arab Health Ministers,
Union of Arab Pharmacists.