BLINCYTO® ▼ (blinatumomab)

Important Risk Minimisation Information for Patients and Caregivers

This educational brochure contains important information you should know before receiving BLINCYTO.

This educational material is essential to ensure the safe and effective use of the drug and appropriate management of the important selected risks. Please read it carefully before taking the medicinal product.

If you have any questions about BLINCYTO please speak to your doctors or nurses, or refer to the Patient Leaflet, on the European Medicines Agency website under following link: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003731/human_med_001921.jsp&mid=WC0b01ac058001d124

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get to the Medicines Authority by post or e-mail: ADR reporting/ Sir Temi Zammit Building, Malta Life Sciences Park, San Gwann or on www.medicinesauthority.gov.mt/adrportal

By reporting a side effect, you can help provide more information on the safety of this medicine.

This information is not intended to take the place of discussions with your doctor or other healthcare professionals who are treating your acute lymphoblastic leukaemia. Read the BLINCYTO patient leaflet provided to you by the doctors or nurses, as well as this educational brochure.

Overview of BLINCYTO treatment

What is BLINCYTO?

BLINCYTO is a medicine that works by enabling your immune system to attack and destroy the abnormal white blood cancer cells.

What is BLINCYTO used for?

BLINCYTO is a treatment for adults and children (≥ 1 year old) with acute lymphoblastic leukaemia. Acute lymphoblastic leukaemia is a cancer of the blood in which a particular kind of white blood cell called "B-lymphocyte" is growing out of control. BLINCYTO is used when acute lymphoblastic leukaemia has come back or has not responded to previous treatment (referred to as relapsed/refractory acute lymphoblastic leukaemia).

It is also used in adult patients with acute lymphoblastic leukaemia who still have a small number of cancer cells remaining after previous treatment (referred to as minimal residual disease).

How is BLINCYTO given?

BLINCYTO will be given to you through a vein (intravenous) continuously for 4 weeks using an infusion pump (this is 1 treatment cycle). You will then have a 2-week break where you will not be given the infusion. Your infusion catheter will be attached to you at all times during each cycle of your treatment.

BLINCYTO is usually given for 2 treatment cycles if you have relapsed/refractory acute lymphoblastic leukaemia, or for 1 treatment cycle if you have minimal residual disease acute lymphoblastic leukaemia. If you respond to this treatment, your doctor may decide to give you up to 3 additional cycles of treatment. The number of treatment cycles which you will be given will depend on how you tolerate and respond to BLINCYTO. Your doctor will discuss with you how long your treatment will last. Your treatment may also be interrupted depending on how you tolerate BLINCYTO.

If you have relapsed/refractory acute lymphoblastic leukaemia, it is recommended that the first 9 days of the first cycle of treatment and the first 2 days of the second cycle of treatment will be given to you in a hospital or in a clinic under the supervision of a doctor or nurse experienced in the use of anti-cancer medicines.

If you have minimal residual disease acute lymphoblastic leukaemia, it is recommended that the first 3 days of the first cycle of treatment and the first 2 days of subsequent cycles of treatment will be given to you in a hospital or clinic under the supervision of a doctor or nurse experienced in the use of anti-cancer medicines.

If you have or had neurological problems, it is recommended that the first 14 days of treatment will be given to you in a hospital or clinic. Your doctor will discuss with you if you can continue treatment at home after your initial hospital stay. Treatment may include a bag change by a nurse.

Your doctor will determine when your BLINCYTO infusion bag will be changed, which may range from every day to every 4 days. The infusion rate (how quickly the medicine goes into your vein) may be faster or slower depending on how often the bag is changed.

Important things for you and/or your caregiver to know about using BLINCYTO

Infusion pump and its accessories	• You will receive BLINCYTO solution through an infusion that delivers the medicine directly through a tube inserted into a vein.
	• You will have the pump connected to you 24 hours a day for 28 days. Do not unlock the pump.
	• Make sure the tubing stays connected to the pump at all times.
	• **Do not let the tubing become tangled or twisted at any time.**
	• **Do not lie on the tubing.**
	• **Do not change the pump settings on purpose**:
	  ○ If the pump alarm goes off at any time, contact your doctor or nurse immediately.
	  ○ If the pump stops working unexpectedly or if the infusion bag empties too quickly, get help from your doctor or nurse immediately.
	• **Do not pull the tubing or unplug the pump at any time.**
	• **If you notice blood in the tubing, contact your doctor or nurse immediately.** Keep the pump, the tubing, and the covering at the site where it is inserted into your vein dry at all times.
	• If you have any concerns regarding how your pump is working, please contact your doctor or nurse.

Nervous system problems	• BLINCYTO may make you feel dizzy, confused, or cause shaky hands, fits or trouble with walking, speaking or writing. • Call your doctor or nurse immediately if you experience these symptoms. For more information, see the patient leaflet. • **Do not drive your car, use heavy machinery or engage in hazardous activities while receiving this medicine.**

Amgen is currently conducting a study to collect side effect information in patients receiving BLINCYTO including information on medication errors in some European countries. In addition, a patient survey is being conducted to assess knowledge and receipt of patient educational materials, about neurologic events and medication errors. Medication errors are unintended errors in the prescribing, dispensing, or administration of a medicinal product while in the control of the healthcare professional, patient, or consumer. Your physician will be able to tell you whether these studies are being conducted in your country.

If the studies are available in your country, your participation in these studies is encouraged. Please ask your physician for more information.