BLINCYTO®▼(blinatumomab)

Important Risk Minimisation Information for Patients and Caregivers

The information in this guide is not intended to take the place of discussions with your doctor or other healthcare professionals who are treating your acute lymphoblastic leukaemia.

Please read the BLINCYTO Patient Information Leaflet provided to you by the doctors or nurses, as well as this guide.

If you have any questions about BLINCYTO please speak to your doctors or nurses, or refer to the Patient Information Leaflet, available online at http://www.medicines.ie/ or at https://www.ema.europa.eu/en/medicines. To obtain additional copies of the Patient Information Leaflet, please speak with your doctor or nurse.

As part of the Risk Management Plan (RMP), this guide has been developed for patients being treated with BLINCYTO or their caregivers, to provide further information about **how to minimise or prevent the following risks associated with the use of BLINCYTO:**

- **Neurologic events**
- **Medication errors**

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. Side effects can be reported directly to the Health Products Regulatory Authority (HPRA) using the available methods via www.hpra.ie By reporting side effects you can help provide more information on the safety of this medicine. Side effects should also be reported to Amgen Limited on +44 (0) 1223 436441 or Freephone 1800 535 160.

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1 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) and adolescents with B-precursor acute lymphoblastic leukaemia (ALL).
- B-precursor acute lymphoblastic leukaemia (ALL) is a cancer of the bone marrow and blood in which a particular kind of white blood cell called “B-lymphocyte” is growing out of control.
- BLINCYTO is used when B-precursor acute lymphoblastic leukaemia has come back or has not responded to previous treatment (referred to as relapsed/refractory acute lymphoblastic leukaemia or R/R ALL).
- It is also used in adult patients with B-precursor acute lymphoblastic leukaemia who still have a small number of cancer cells remaining after previous treatment (referred to as minimal residual disease or MRD+ ALL).

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How is BLINCYTO given?

- BLINCYTO is given as continuous intravenous infusion:
  - To maximise the benefits of BLINCYTO, it has to be administered continuously to patients. For this reason, BLINCYTO is delivered through a vein (intravenously) continuously using an infusion pump
  - An infusion catheter will be attached to you at all times during each cycle of your treatment
- Your doctor will discuss with you the duration of your hospitalisation stay and the number and length of cycles required for your BLINCYTO treatment.
- Your doctor will determine when your BLINCYTO infusion bag will be changed, which may range from every day to every 4 days.
- BLINCYTO will remain active in your body for a few hours.

2 IMPORTANT THINGS FOR YOU AND/OR YOUR CAREGIVER TO KNOW ABOUT USING BLINCYTO

2.1 Important Information on Neurologic Events

- BLINCYTO may cause neurologic events including:
  - Shaking (or tremor)
  - Confusion
  - Disturbances of brain function (encephalopathy)
  - Difficulty in communicating (aphasia)
  - Seizure (convulsion)

Please call your doctor or nurse immediately if you experience any of these symptoms.

- Please travel home safely and do not drive or operate moving vehicles/heavy machinery or engage in hazardous activities whilst receiving BLINCYTO

2.2 Important Information on Medication Errors

- You will receive BLINCYTO through an infusion that delivers the medicine directly through a tube inserted into a vein. The infusion pump will be connected to you 24 hours a day for 28 days.
- It is important that the infusion is administered as described by your healthcare provider to prevent medication errors and ensure that you are given the correct amount of BLINCYTO.

To prevent medication errors, it is important to remember the following:

- Please don't unlock, disconnect, or change any of settings of the infusion pump on purpose
- If the infusion pump alarm goes off, or if it stops working unexpectedly, please contact your doctor or nurse immediately
- Please don't lie on the tubing, pull the tubing, or let the tubing become tangled or twisted. Please keep the covering at the site of the infusion dry at all times.

For any concerns regarding your infusion, please contact your doctor or nurse.