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 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 Leaflet, available online at http://www.medicines.ie/ or at https://www.ema.europa.eu/en/ medicines. To obtain additional copies of the Patient 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 Neurological events including immune effector cell-associated neurotoxicity syndrome (ICANS) associated with the use of BLINCYTO.**

▼ 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 treats adults, children, and young adults with acute lymphoblastic leukaemia (ALL) – a blood cancer where certain white blood cells (B-lymphocytes) grow out of control.
- It helps your immune system attack and destroy abnormal cancer cells.
- It is used when ALL has returned or not responded to previous treatment (called relapsed/refractory ALL) as well as for adults with ALL who still have small numbers of cancer cells after treatment (called minimal residual disease).
- Blincyto can also be given during consolidation therapy – a treatment phase after the first round of therapy, aimed at removing any remaining leukaemia cells and preventing relapse.

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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
  - 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 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.

2 IMPORTANT THINGS FOR YOU AND YOUR CAREGIVER TO KNOW ABOUT NEUROLOGIC EVENTS INCLUDING ICANS WHILST USING BLINCYTO

- BLINCYTO may cause neurologic events. Please refer to the Blincyto Package Leaflet for more information on possible side effects. The key signs and symptoms of these events are:
  - uncontrolled shaking (or tremor)
  - confusion
  - disturbances of brain function (encephalopathy)
  - seizure (convulsion)
  - difficulty in communicating (aphasia) and/or writing (dysgraphia)
  - feeling less alert
- Some of these may be signs of a serious immune reaction called ‘immune effector cell-associated neurotoxicity syndrome’ (ICANS). Please seek **urgent** attention from your doctor or nurse immediately if you experience any of the symptoms listed above.



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