

# 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 <https://www.medicines.org.uk/emc>. 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 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. You can also report side effects directly via [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

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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 B-precursor acute lymphoblastic leukemia (ALL).
- B-precursor acute lymphoblastic leukemia (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.

## 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.

## 2 Important Things For You And Your Caregiver To Know About Neurologic Events Including ICANS Whilst Using BLINCYTO

Please refer to the BLINCYTO Patient Information Leaflet for more information on possible side effects.

- BLINCYTO may cause neurologic events. The key signs and symptoms of these events are:
  - uncontrolled shaking (or tremor)
  - confusion
  - disturbances of brain function (encephalopathy)
  - difficulty in communicating (aphasia) and/or writing (dysgraphia)
  - seizure (convulsion)
- 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 report any side effects you may experience. Refer to page 1 of this guide for details on how to report.