BLINCYTO®▼(blinatumomab)

Important Risk Minimisation Information for Nurses

The information in this guide is not intended as a replacement for the Summary of Product Characteristics (SmPC) or your standard infusion practice.

Please read the BLINCYTO SmPC, in conjunction with this guide.

The BLINCYTO SmPC and Patient Information Leaflet (PIL) are available online at http://www.medicines.ie/ or at https://www.ema.europa.eu/en/medicines

As part of the Risk Management Plan (RMP), this guide has been developed for nurses involved in the care of patients treated with BLINCYTO to provide you with 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. Adverse reactions/events should be reported to the Health Products Regulatory Authority (HPRA) using the available methods via www.hpra.ie. Adverse reactions/events should also be reported to Amgen Limited on +44 (0) 1223 436441 or Freephone 1800 535 160.

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1 OVERVIEW

In order to minimise the risk of neurological events and medication errors, **please make sure the patient receives and understands** the content of the following:

- Guide for Patients and Caregivers
- Patient Card
- Patient Information Leaflet

Please report any suspected adverse reactions or medication errors that your patients have encountered or experienced (refer to page 1 for instructions).

1.1 Important Information on Neurological Events

- Neurologic events, including events with a fatal outcome, have been observed during treatment with BLINCYTO. Events have included encephalopathy, seizures, speech disorders, disturbances in consciousness, confusion and disorientation, and coordination and balance disorders.
- Elderly patients can receive BLINCYTO, but may be more susceptible to serious neurologic events.
- The majority of neurologic events are clinically reversible and resolve following BLINCYTO interruption.

Action required from you beyond standard working practice to minimise or prevent neurologic events:

- Counsel the patient (see Section 2 of this guide for details)
- Prior to, and throughout the treatment cycle, assess patients for signs and symptoms of neurologic events
  - Eg, headache, tremor, aphasia, paraesthesia, seizure, cognitive disorder, memory impairment, dizziness, somnolence, hypoaesthesia, or ataxia (see Section 4.4 of the BLINCYTO SmPC for further information)
  - Regular writing tests should be considered to detect and monitor signs of neurological events

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1.1 Important Information on Neurological Events *(continued)*

- If the patient experiences convulsions or grade 3 or 4 neurologic events, stop the infusion of BLINCYTO immediately, ensure the patient's airway is clear and apply appropriate first aid as required. Please see Section 4.2 of the BLINCYTO SmPC for further details.

1.2 Important Information on 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 or patient/caregiver.
- Medication errors have been observed with BLINCYTO treatment.
- Medication errors may result in underdose or overdose of BLINCYTO. Underdose may lead to less than expected efficacy and overdose may increase the risk of adverse reactions.

Action required from you beyond standard working practice to minimise or prevent medication errors:

- Counsel the patient (see Section 2 of this guide for details)
- **Do not** flush the BLINCYTO infusion line or intravenous (IV) catheter, especially when changing bags
- Infuse BLINCYTO through a dedicated lumen when administering via a multi-lumen venous catheter
- **Do not** calculate the infusion rate yourself
- The infusion bag must be changed at least every 96 hours by a healthcare professional for sterility reasons, regardless of the remaining volume in the existing infusion bag
- BLINCYTO solution is a preservative-free solution. Aseptic technique must always be adhered to when administering BLINCYTO

2 COUNSELLING THE PATIENT

It is essential to counsel your patients on the following whilst receiving BLINCYTO.

2.1 Neurologic Events

- Advise patients to call their healthcare provider to ask for emergency medical help immediately if they experience any of the following neurologic events:
  - Shaking (or tremor), abnormal sensations, seizures, memory loss, confusion, disorientation, loss of balance, or difficult speaking
- Advise patients to travel home safely and to not drive or operate moving vehicles/heavy machinery, or engage in hazardous activities whilst receiving BLINCYTO.

2.2 Medication Errors

- Advise patients on the following:
  - **Do not** unlock the pump
  - **Do not** try to fix the pump if the pump does not appear to perform properly (eg, alarm goes off)
  - **Do not** change any pump settings on purpose, with the exception of stopping the pump in case of emergency
  - To contact their healthcare provider immediately if experiencing:
    - A problem with the pump or the pump alarm sounds
    - Unexpected stopping of the infusion pump
    - An empty infusion bag before the scheduled bag change

2.3 Provide Patient with Educational Materials

- Ensure the patient receives and understands the content of the following:
  - Guide for Patients and Caregivers
  - Patient Card
  - Patient Information Leaflet