BLINCYTO®▼(blinatumomab)

Important Risk Minimisation Information for Pharmacists

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

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 pharmacists involved in the reconstitution and preparation of BLINCYTO to provide you with further information about **how to minimise or prevent 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

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 (HCP) or patient/caregiver.
- Medication errors, including preparation 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.

How to minimise the risk of medication errors:

- Please read through the instructions for preparation and administration of BLINCYTO in Section 6.6 of the BLINCYTO SmPC and appended to the Patient Information Leaflet (PIL), and ensure that these instructions are strictly followed to minimise medication errors.

2 IMPORTANT INFORMATION ABOUT BLINCYTO DOSAGE

- The recommended daily dose of BLINCYTO is by patient weight:
  - Patients greater than or equal to 45 kg receive a fixed-dose
  - For patients less than 45 kg, the dose is calculated using the patient's body surface area.
- Please carefully read the instructions for reconstitution and dilution of BLINCYTO based on the patient's weight or body surface area and refer to the dosing tables, which are provided in Section 6.6 of the BLINCYTO SmPC and also at the end of the PIL in the section intended for HCPs only.

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3 IMPORTANT INFORMATION ABOUT THE PREPARATION OF BLINCYTO FOR INTRAVENOUS ADMINISTRATION

- The detailed steps for BLINCYTO reconstitution and preparation of the infusion bags using aseptic preparation, as well as the equipment required to prepare BLINCYTO, are included in the BLINCYTO SmPC and also at the end of the PIL in the section intended for HCPs only.

Key reminders:

- Before BLINCYTO is infused, please strictly follow **all** steps described in the BLINCYTO SmPC to avoid medication errors occurring
- BLINCYTO dosage is based on the patient's weight or body surface area
- Before preparation of BLINCYTO:
  - Consult the dosing tables in Section 6.6 of the BLINCYTO SmPC
  - Assemble the appropriate materials, which include:
    - BLINCYTO pack(s) (containing BLINCYTO powder vial and solution [stabiliser] vial), sterile single-use disposable syringes, 21 to 23 gauge needle(s), water (for reconstituting BLINCYTO), infusion bag with sodium chloride 9 mg/mL (0.9%) solution for infusion, and intravenous tubing (compatible with infusion pump)
  - Establish the patient's weight or body surface area and confirm the dosage
- When reconstituting and preparing BLINCYTO, remember the following:
  - BLINCYTO is preservative free
  - Use aseptic technique when preparing BLINCYTO
  - **Do not** reconstitute BLINCYTO powder for concentrate with solution (stabiliser)
  - **Do not** shake the contents; gently swirl to avoid excessive foaming
  - Visually inspect the reconstituted solution; it should be clear to slightly opalescent, colourless to slightly yellow. It should not be cloudy or precipitated
  - Remove all air from the prepared BLINCYTO infusion bag
  - Prime the intravenous line only with the prepared solution for infusion. Do not prime with normal saline (0.9% sodium chloride) solution for injection
  - Depending on the dosage, infusion bags will have different infusion durations
  - Store the prepared BLINCYTO infusion solution bag as described in Section 6.3 of the BLINCYTO SmPC

Please report any suspected adverse reactions or medication errors (refer to page 1 for instructions).