BLINCYTO® ▼ (blinatumomab)

EDUCATIONAL BROCHURE FOR NURSES

Important Risk Minimisation Information for Nurses

This educational brochure contains important information regarding the administration of BLINCYTO® and the risks of medication errors and neurologic events. This educational material is essential to ensure the safe and effective use of the product and appropriate management of the important selected risks and therefore it is advised to be read carefully before administering the medicinal product.

If you have any questions about the administration and the adverse events of BLINCYTO®, refer to the Summary of Product Characteristics (SmPC), provided with this brochure and available online at http://www.medicines.org.uk/emc/

Important Information Regarding BLINCYTO®

The following actions should be taken to prevent or minimize the risk of medication errors and to provide important counseling information on neurologic events.

Administration	IV lines	• **Do not flush the infusion lines into the patient, as it will cause an inadvertent bolus of BLINCYTO® to be administered. BLINCYTO® should be infused through a dedicated lumen.**
	Pump specifications and settings	• Only program the pump based on the printed infusion rate on the label attached to the infusion bag. • For the infusion rate ask the consultant pharmacist/doctor. Do not calculate the infusion rate yourself. • Lock the pump and make sure the battery is adequately charged with each bag change. • Instruct patients not to unlock the pump. • If the pump does not appear to perform properly (for example: alarm goes off) at any time, instruct patients and caregivers not to try to fix the pump and tell them to get help from the treating physician or from you immediately. • Instruct patients not to change any pump settings on purpose (with the exception of stopping the pump in case of emergency). • Remember to check if the remaining volume of infusion bag correlates with the set infusion rate prior to each bag change. If the remaining volume of infusion bag does not correlate with the set infusion rate prior to each bag change, please record discrepancy and contact the physician for further instruction.
	IV bag change	• The IV bag change must occur within 4 hours of the designated time regardless of the remaining volume in the existing infusion bag.
	Therapy interruption	• Healthcare professional supervision or hospitalisation is recommended in instances where treatment is being re-initiated following an interruption of 4 or more hours (see section 4.2 of the SmPC for more information).
	Catheter site care	• BLINCYTO® solution is a preservative-free solution. Aseptic technique must always be adhered to when administering BLINCYTO®. • Instruct the patients and/or caregivers on how to perform catheter site care as required.

Counseling	Neurologic events	• BLINCYTO® has been observed to cause neurological toxicities in approximately 52% of patients in clinical trials. Assess patients for signs and symptoms of neurological events (e.g. confusion, disorientation, dizziness, tremor, seizure) prior to and throughout the treatment cycle (see section 4.4 of the SmPC for further information). Consider using a writing test periodically to assist with monitoring for neurological events during BLINCYTO® treatment.
		• Elderly patients experience a higher rate of neurological events.
		• Counsel patients on the potential neurologic effects.
		• Advise patients:
		  • Not to drive, use heavy machinery, or engage in hazardous activities while receiving BLINCYTO®.
		  • To contact you or the doctor if they experience neurological symptoms.

▼ This medicinal product is subject to additional monitoring. Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
Adverse events should also be reported to Amgen Limited on +44 (0) 1223 436712