

BLINCYTO® ▼ (blinatumomab)

Educational Brochure for Nurses

BLINCYTO® ▼ (blinatumomab)

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.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See below for how to report adverse reactions.

This document has been reviewed and approved by The Saudi Food and Drug Authority (SFDA).

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	<ul style="list-style-type: none"> Do not flush the infusion line or intravenous catheter into the patient, as it will cause an inadvertent bolus of BLINCYTO to be administered. When administering via a multi-lumen venous catheter, BLINCYTO should be infused through a dedicated lumen.
	Pump specifications and settings	<ul style="list-style-type: none"> Only program the pump based on the printed infusion rate on the label attached to the infusion bag. 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 may be more susceptible to serious neurological events. Counsel patients on the potential neurologic effects. Advise patients: <ul style="list-style-type: none"> 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.

BLINCYTO® ▼ (blinatumomab)

Educational Brochure for Nurses

Contact details for adverse event reporting or to request further information. Any suspected adverse reactions should be reported immediately to local Amgen safety contacts or the National Pharmacovigilance and Drug Safety Center

Amgen Local Safety Contacts

Tel: +966 112 799328

E-mail: Safety-MEA@amgen.com

The National Pharmacovigilance Centre (NPC)

Saudi Food and Drug Authority (SFDA)

SFDA call center 19999

Toll free phone: 8002490000

Fax: +966-11-2057662

E-mail: npc.drug@sfd.gov.sa Online: <http://ade.sfda.gov.sa/>

Should you have any questions or require additional information regarding the use of Blincyto, please contact Medical Information on +966 112 799366 or by e-mail at: meamedinfo@amgen.com