BLINCYTO® ▼ (blinatumomab)

EDUCATIONAL BROCHURE FOR PHARMACISTS

Important Risk Minimisation Information for Pharmacists

This educational brochure contains important information regarding the reconstitution and preparation procedures for blinatumomab. To ensure the safe and effective use of the medicinal product and appropriate management of the important selected risks, please carefully read this material before reconstituting and preparing of the medicinal product.

If you have any questions about the reconstitution and preparation of blinatumomab please refer to the Summary of Product Characteristics (SmPC), which is provided with this educational brochure.

Important information about the preparation of BLINCYTO® intravenous administration

Table 1. Preparation of BLINCYTO® infusion solution

Dose	Infusion duration	Normal Saline (250-ml bag)[a]	Solution (Stabiliser) Volume (mL)	Required Number of BLINCYTO® vials	Reconstituted BLINCYTO® solution (mL)	Infusion rate (mL/hr)
9 microgram/ day	24 hours	1	5.5	1	0.83	10
	48 hours	1	5.5	1	1.7	5
	72 hours	1	5.5	1	2.5	3.3
	96 hours	1	5.5	2	3.3	2.5
28 microgram/ day	24 hours	1	5.5	1	2.6	10
	48 hours	1	5.5	2	5.2	5
	72 hours	1	5.5	3	8	3.3
	96 hours	1	5.5	4	10.7	2.5

[a] Normal Saline (0.9% Sodium Chloride)

Use only polyolefin, PVC non-di-ethylhexylphthalate (non-DEHP), or ethyl vinyl acetate (EVA) infusion bags/pump cassettes and Polyolefin, PVC non-DEHP, or EVA intravenous tubing with a sterile, non-pyrogenic, low protein-binding 0.2 µm in-line filter

Table 2. Steps to prepare BLINCYTO® infusion solution under aseptic conditions using aseptic techniques

Step 1	• Transfer appropriate amount of Solution (stabiliser) to the Normal Saline (0.9% Sodium Chloride) infusion bag • Gently mix the contents of the bag to avoid foaming • Discard remaining Solution (stabiliser) vial if applicable
Step 2	• Reconstitute BLINCYTO® powder for concentrate with 3 mL of Water for Injection • Do not reconstitute BLINCYTO® with the Solution (stabiliser) • Do not shake • Gently swirl contents to avoid excess foaming • Reconstitute the required number of BLINCYTO® vials (see table above). Visually inspect the reconstituted solution for particulate matter and to confirm colour. The solution should be clear to slightly opalescent, colourless to slightly yellow.
Step 3	• Transfer appropriate amount of reconstituted BLINCYTO® solution into the Normal Saline (0.9% Sodium Chloride) infusion bag • Gently mix the contents of the bag to avoid foaming
Step 4	• Attach the intravenous tubing to the prepared BLINCYTO® infusion solution bag with the sterile 0.2 µm in-line filter
Step 5	• Remove air from the prepared BLINCYTO® infusion solution bag
Step 6	• Prime the intravenous infusion line with the prepared BLINCYTO® infusion solution • Do not prime the intravenous infusion line with Normal Saline (0.9% Sodium Chloride) solution for injection
Step 7	• Store the prepared BLINCYTO® infusion solution bag at 2°C to 8°C for a maximum of 10 days if not immediately used (for further information, please see section 6.3 of the SmPC)

▼ 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 to the Medicines Authority by post or e-mail: ADR reporting/ Sir Temi Zammit Building, Malta Life Sciences Park, San Gwann or on www.medicinesauthority.gov.mt/adrportal