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 and available online at http://www.medicines.org.uk/emc/

Important information about the preparation of BLINCYTO® intravenous administration

Table 1. Materials required for the preparation of BLINCYTO® infusion solution

List of Materials	Dose	Infusion duration	Required Number of BLINCYTO® vials	Reconstituted BLINCYTO® solution (mL) from step 1	Infusion rate (mL/hr)
• A vial(s) of BLINCYTO® (see across table for required number of vials). • Water for injections. • A 250mL bag of normal saline solution (0.9% NaCl). • A vial of Solution (Stabiliser). 5.5mL needed for all preparations.	9 microgram/day	24 hours	1	0.83	10
		48 hours	1	1.7	5
		72 hours	1	2.5	3.3
		96 hours	2	3.3	2.5
	28 microgram/day	24 hours	1	2.6	10
		48 hours	2	5.2	5
		72 hours	3	8	3.3
		96 hours	4	10.7	2.5

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	• Reconstitute each vial of BLINCYTO® powder for concentrate with 3 mL of Water for Injection. **(Do not use saline solution, Stabiliser solution or any other liquids.)** • Gently swirl contents to avoid excess foaming. Do not shake. • Visually inspect the reconstituted solution for particulate matter and to confirm colour. The solution should be clear to slightly opalescent, colourless to slightly yellow. • Repeat this step according to the required number of BLINCYTO® vials as reported in table 1 above.
Step 2	• Add 5.5mLof Stabiliser Solution to a 250mL bag of normal saline solution (0.9%) sodium chloride. • Gently mix the contents of the bag avoid foaming. • Discard remaining Stabiliser Solution vial if applicable.
Step 3	• According to the desired dose and infusion duration reported in table 1 above, transfer appropriate amount of reconstituted BLINCYTO® solution from step 1 into the stabilised Normal Saline (0.9% Sodium Chloride) infusion bag from step 2. • 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. 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.