BLINCYTO®▼ (blinatumomab)

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 preparing 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).

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Important information about the preparation of BLINCYTO intravenous administration

Specific reconstitution and dilution instructions are provided for each dose and infusion time. Verify the prescribed dose and infusion time of BLINCYTO and identify the appropriate dosing preparation requirements below.

- **For patients <u>weighing greater than or equal to 45kg</u> use Table 1 and Guide 1.**
  Note: For patients <u>weighing less than 45 kg</u> please use Tables 2 to 5 and Guide 2.

Table 1. Preparation of BLINCYTO infusion solution for patients <u>weighing greater than or equal to 45 kg</u>: volumes of sodium chloride 9 mg/mL (0.9%) solution for injection, solution (stabiliser), and reconstituted BLINCYTO to add to infusion bag

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 mcg/day	24 hours	1	5.5	1	0.83	10
	48 hours	1	5.5	1	1.7	5
28 mcg/day	24 hours	1	5.5	1	2.6	10
	48 hours	1	5.5	2	5.2	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

Guide 1: Steps to prepare BLINCYTO infusion solution under aseptic conditions using aseptic techniques

Step 1	• Before preparation, consult the dosing tables and assemble the correct number of vials and other excipients
Step 2	• Add 5.5 ml of Stabiliser Solution to a 250 mL bag of normal saline solution (0.9%) sodium chloride. • Gently mix the contents of the bag to avoid foaming • Discard remaining Solution (stabiliser) vial if applicable
Step 3	• 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 1). 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 4	• Transfer appropriate amount of reconstituted BLINCYTO solution into the Normal Saline (0.9% Sodium Chloride) infusion bag from step 2. • Gently mix the contents of the bag to avoid foaming
Step 5	• Attach the intravenous tubing to the prepared BLINCYTO infusion solution bag with the sterile 0.2 µm in-line filter
Step 6	• Remove air from the prepared BLINCYTO infusion solution bag
Step 7	• 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 8	• Store the prepared BLINCYTO infusion solution bag at 2ºC to 8ºC for a maximum of 10 days if not immediately used (for further information, please see section 6.3 of the SmPC)

Important information about the preparation of BLINCYTO intravenous administration

- **For patients <u>weighing less than 45 kg</u> please use Tables 2 to 5 and Guide 2.**
  Note: For patients <u>weighing greater than or equal to 45 kg</u> use Table 1 and Guide 1.

Table 2. Preparation of BLINCYTO infusion solution for patients <u>weighing less than 45 kg:</u> Volumes of sodium chloride 9 mg/mL (0.9%) solution for injection, solution (stabiliser), and reconstituted BLINCYTO to add to infusion bag <u>for 5 mcg/m²/day dose for 24 and 48 Hours infusion</u>

Dose	Infusion duration	Normal Saline (250-ml bag)[a]	Solution (Stabiliser) Volume (mL)	Required Number of BLINCYTO vials	Body Surface Area (m^2)	Reconstituted BLINCYTO solution (mL)	Infusion rate (mL/hr)
5 mcg/m²/day	**24 hours**	1	5.5	1	1.50 – 1.59	0.70 mL	10
					1.40 – 1.49	0.66 mL	
					1.30 – 1.39	0.61 mL	
					1.20 – 1.29	0.56 mL	
					1.10 – 1.19	0.52 mL	
					1.00 – 1.09	0.47 mL	
					0.90 – 0.99	0.43 mL	
					0.80 – 0.89	0.38 mL	
					0.70 – 0.79	0.33 mL	
					0.60 – 0.69	0.29 mL	
					0.50 – 0.59	0.24 mL	
					0.40 – 0.49	0.20 mL	
5 mcg/m²/day	**48 hours**	1	5.5	1	1.50 – 1.59	1.4 mL	5
					1.40 – 1.49	1.3 mL	
					1.30 – 1.39	1.2 mL	
					1.20 – 1.29	1.1 mL	
					1.10 – 1.19	1.0 mL	
					1.00 – 1.09	0.94 mL	
					0.90 – 0.99	0.85 mL	
					0.80 – 0.89	0.76 mL	
					0.70 – 0.79	0.67 mL	
					0.60 – 0.69	0.57 mL	
					0.50 – 0.59	0.48 mL	
					0.40 – 0.49	0.39 mL	

[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

Table3. Preparation of BLINCYTO infusion solution for patients weighing less than 45 kg: volumes of sodium chloride 9 mg/mL (0.9%) solution for injection, solution (stabiliser), and reconstituted BLINCYTO to add to infusion bag for 15 mcg/m²/day dose for 24 and 48 Hours infusion

Dose	Infusion duration	Normal Saline (250-ml bag)[a]	Solution (Stabiliser) Volume (mL)	Required Number of BLINCYTO vials	Body Surface Area (m^2)	Reconstituted BLINCYTO solution (mL)	Infusion rate (mL/hr)
15 mcg/m²/day	**24 hours**	1	5.5	1	1.50 – 1.59	2.1 mL	10
				1	1.40 – 1.49	2.0 mL	
				1	1.30 – 1.39	1.8 mL	
				1	1.20 – 1.29	1.7 mL	
				1	1.10 – 1.19	1.6 mL	
				1	1.00 – 1.09	1.4 mL	
				1	0.90 – 0.99	1.3 mL	
				1	0.80 – 0.89	1.1 mL	
				1	0.70 – 0.79	1.00 mL	
				1	0.60 – 0.69	0.86 mL	
				1	0.50 – 0.59	0.72 mL	
				1	0.40 – 0.49	0.59 mL	
15 mcg/m²/day	**48 hours**	1	5.5	2	1.50 – 1.59	4.2 mL	5
				2	1.40 – 1.49	3.9 mL	
				2	1.30 – 1.39	3.7 mL	
				2	1.20 – 1.29	3.4 mL	
				2	1.10 – 1.19	3.1 mL	
				1	1.00 – 1.09	2.8 mL	
				1	0.90 – 0.99	2.6 mL	
				1	0.80 – 0.89	2.3 mL	
				1	0.70 – 0.79	2.0 mL	
				1	0.60 – 0.69	1.7 mL	
				1	0.50 – 0.59	1.4 mL	
				1	0.40 – 0.49	1.2 mL	

[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

Guide 2: Steps to prepare BLINCYTO infusion solution under aseptic conditions using aseptic techniques

Step 1	• Before preparation, consult the dosing tables and assemble the correct number of vials and other excipients
Step 2	• Add 5.5 ml of Stabiliser Solution to a 250 mL bag of normal saline solution (0.9%) sodium chloride. • Gently mix the contents of the bag to avoid foaming • Discard remaining Solution (stabiliser) vial if applicable
Step 3	• 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 pages 3 to 6 and select the table which matches the required dose and infusion time). 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 4	• Transfer appropriate amount of reconstituted BLINCYTO solution into the Normal Saline (0.9% Sodium Chloride) infusion bag from step 2. • Gently mix the contents of the bag to avoid foaming
Step 5	• Attach the intravenous tubing to the prepared BLINCYTO infusion solution bag with the sterile 0.2 µm in-line filter
Step 6	• Remove air from the prepared BLINCYTO infusion solution bag
Step 7	• 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 8	• Store the prepared BLINCYTO infusion solution bag at 2ºC to 8ºC for a maximum of 8 days if not immediately used (for further information, please see section 6.3 of the SmPC)

Call for reporting;

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@sfda.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