



BLINCYTO Preparation Card for Pharmacists

BLINCYTO<sup>®</sup> (blinatumomab)

## Important Risk Minimisation Information for Pharmacists

This preparation card contains important information regarding the reconstitution and preparation procedures for BLINCYTO

To ensure the safe and effective use of BLINCYTO and appropriate management of the important selected risks please read carefully before reconstitution and preparation of the medicinal product

**If you have any questions about the reconstitution and preparation of BLINCYTO please refer to the Product Information (PI) available from Amgen Australia Pty Ltd or <http://www.amgen.com.au/Blincyto.PI>**

For more information on BLINCYTO or to report any adverse events or product complaints involving BLINCYTO please contact Australia Medical Information on 1800 803 638





## BLINCYTO Preparation Card for Pharmacists

**Important information about the preparation of BLINCYTO for INTRAVENOUS administration****Note: for comprehensive preparation instructions, please refer to the Blincyto Product Information****Table 1. Preparation of BLINCYTO infusion solution for INTRAVENOUS administration for patients weighing greater than or equal to 45 kg**

Dose	Infusion duration (hours)	Normal Saline (250-mL bag) <sup>a</sup>	IV Solution Stabiliser for BLINCYTO (mL)	Number of BLINCYTO vials needed	Reconstituted BLINCYTO solution (mL)	Infusion rate (mL/hr)
<b>9 mcg/day</b>	24	1	5.5	1	0.83	10
	48	1	5.5	1	1.7	5
	72	1	5.5	1	2.5	3.3
	96	1	5.5	2	3.3	2.5
<b>28 mcg/day</b>	24	1	5.5	1	2.6	10
	48	1	5.5	2	5.2	5
	72	1	5.5	3	8.0	3.3
	96	1	5.5	4	10.7	2.5

<sup>a</sup> 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 micron in-line filter





## BLINCYTO Preparation Card for Pharmacists

**Table 2. Preparation of BLINCYTO infusion solution for INTRAVENOUS administration for patients weighing less than 45 kg for 5 micrograms/m<sup>2</sup>/day dose**

Infusion Duration	Normal Saline (250-ml bag) <sup>a</sup>	IV Solution Stabiliser for BLINCYTO (mL)	Infusion Rate	BSA (m <sup>2</sup> )	Reconstituted BLINCYTO (mL)	Number of BLINCYTO vials needed
24 hours	1	5.5	10 mL/hour	1.50 – 1.59	0.70	1
	1	5.5		1.40 – 1.49	0.65	1
	1	5.5		1.30 – 1.39	0.61	1
	1	5.5		1.20 – 1.29	0.56	1
	1	5.5		1.10 – 1.19	0.52	1
	1	5.5		1.00 – 1.09	0.47	1
	1	5.5		0.90 – 0.99	0.43	1
	1	5.5		0.80 – 0.89	0.38	1
	1	5.5		0.70 – 0.79	0.34	1
	1	5.5		0.60 – 0.69	0.29	1
	1	5.5		0.50 – 0.59	0.25	1
	1	5.5		0.40 – 0.49	0.20	1

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## BLINCYTO Preparation Card for Pharmacists

**Table 2. Preparation of BLINCYTO infusion solution for INTRAVENOUS administration for patients weighing less than 45 kg for 5 micrograms/m<sup>2</sup>/day dose**

Infusion Duration	Normal Saline (250-ml bag) <sup>a</sup>	IV Solution Stabiliser for BLINCYTO (mL)	Infusion Rate	BSA (m <sup>2</sup> )	Reconstituted BLINCYTO (mL)	Number of BLINCYTO vials needed
48 hours	1	5.5	5 mL/hour	1.50 – 1.59	1.4	1
	1	5.5		1.40 – 1.49	1.3	1
	1	5.5		1.30 – 1.39	1.2	1
	1	5.5		1.20 – 1.29	1.1	1
	1	5.5		1.10 – 1.19	1.0	1
	1	5.5		1.00 – 1.09	0.94	1
	1	5.5		0.90 – 0.99	0.85	1
	1	5.5		0.80 – 0.89	0.76	1
	1	5.5		0.70 – 0.79	0.67	1
	1	5.5		0.60 – 0.69	0.58	1
	1	5.5		0.50 – 0.59	0.49	1
	1	5.5		0.40 – 0.49	0.40	1





## BLINCYTO Preparation Card for Pharmacists

**Table 2. Preparation of BLINCYTO infusion solution for INTRAVENOUS administration for patients weighing less than 45 kg for 5 micrograms/m<sup>2</sup>/day dose**

Infusion Duration	Normal Saline (250-ml bag) <sup>a</sup>	IV Solution Stabiliser for BLINCYTO (mL)	Infusion Rate	BSA (m <sup>2</sup> )	Reconstituted BLINCYTO (mL)	Number of BLINCYTO vials needed
72 hours	1	5.5	3.3 mL/hour	1.50 – 1.59	2.1	1
	1	5.5		1.40 – 1.49	2.0	1
	1	5.5		1.30 – 1.39	1.8	1
	1	5.5		1.20 – 1.29	1.7	1
	1	5.5		1.10 – 1.19	1.5	1
	1	5.5		1.00 – 1.09	1.4	1
	1	5.5		0.90 – 0.99	1.3	1
	1	5.5		0.80 – 0.89	1.1	1
	1	5.5		0.70 – 0.79	1.01	1
	1	5.5		0.60 – 0.69	0.87	1
	1	5.5		0.50 – 0.59	0.74	1
	1	5.5		0.40 – 0.49	0.60	1

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## BLINCYTO Preparation Card for Pharmacists

**Table 2. Preparation of BLINCYTO infusion solution for INTRAVENOUS administration for patients weighing less than 45 kg for 5 micrograms/m<sup>2</sup>/day dose**

Infusion Duration	Normal Saline (250-ml bag) <sup>a</sup>	IV Solution Stabiliser for BLINCYTO (mL)	Infusion Rate	BSA (m <sup>2</sup> )	Reconstituted BLINCYTO (mL)	Number of BLINCYTO vials needed
96 hours	1	5.5	2.5 mL/hour	1.50 – 1.59	2.8	1
	1	5.5		1.40 – 1.49	2.6	1
	1	5.5		1.30 – 1.39	2.4	1
	1	5.5		1.20 – 1.29	2.2	1
	1	5.5		1.10 – 1.19	2.1	1
	1	5.5		1.00 – 1.09	1.9	1
	1	5.5		0.90 – 0.99	1.7	1
	1	5.5		0.80 – 0.89	1.5	1
	1	5.5		0.70 – 0.79	1.3	1
	1	5.5		0.60 – 0.69	1.2	1
	1	5.5		0.50 – 0.59	0.98	1
	1	5.5		0.40 – 0.49	0.80	1

<sup>a</sup> 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 micron in-line filter





## BLINCYTO Preparation Card for Pharmacists

**Table 3. Preparation of BLINCYTO infusion solution for INTRAVENOUS administration for patients weighing less than 45 kg for 15 micrograms/m<sup>2</sup>/day dose**

Infusion Duration	Normal Saline (250-ml bag) <sup>a</sup>	IV Solution Stabiliser for BLINCYTO (mL)	Infusion Rate	BSA (m <sup>2</sup> )	Reconstituted BLINCYTO (mL)	Number of BLINCYTO vials needed
24 hours	1	5.5	10 mL/hour	1.50 – 1.59	2.1	1
	1	5.5		1.40 – 1.49	2.0	1
	1	5.5		1.30 – 1.39	1.8	1
	1	5.5		1.20 – 1.29	1.7	1
	1	5.5		1.10 – 1.19	1.5	1
	1	5.5		1.00 – 1.09	1.4	1
	1	5.5		0.90 – 0.99	1.3	1
	1	5.5		0.80 – 0.89	1.1	1
	1	5.5		0.70 – 0.79	1.01	1
	1	5.5		0.60 – 0.69	0.87	1
	1	5.5		0.50 – 0.59	0.74	1
	1	5.5		0.40 – 0.49	0.60	1





## BLINCYTO Preparation Card for Pharmacists

**Table 3. Preparation of BLINCYTO infusion solution for INTRAVENOUS administration for patients weighing less than 45 kg for 15 micrograms/m<sup>2</sup>/day dose**

Infusion Duration	Normal Saline (250-ml bag) <sup>a</sup>	IV Solution Stabiliser for BLINCYTO (mL)	Infusion Rate	BSA (m <sup>2</sup> )	Reconstituted BLINCYTO (mL)	Number of BLINCYTO vials needed
48 hours	1	5.5	5 mL/hour	1.50 – 1.59	4.2	2
	1	5.5		1.40 – 1.49	3.9	2
	1	5.5		1.30 – 1.39	3.6	2
	1	5.5		1.20 – 1.29	3.4	2
	1	5.5		1.10 – 1.19	3.1	2
	1	5.5		1.00 – 1.09	2.8	1
	1	5.5		0.90 – 0.99	2.6	1
	1	5.5		0.80 – 0.89	2.3	1
	1	5.5		0.70 – 0.79	2.0	1
	1	5.5		0.60 – 0.69	1.7	1
	1	5.5		0.50 – 0.59	1.5	1
	1	5.5		0.40 – 0.49	1.2	1

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## BLINCYTO Preparation Card for Pharmacists

**Table 3. Preparation of BLINCYTO infusion solution for INTRAVENOUS administration for patients weighing less than 45 kg for 15 micrograms/m<sup>2</sup>/day dose**

Infusion Duration	Normal Saline (250-ml bag) <sup>a</sup>	IV Solution Stabiliser for BLINCYTO (mL)	Infusion Rate	BSA (m <sup>2</sup> )	Reconstituted BLINCYTO (mL)	Number of BLINCYTO vials needed
72 hours	1	5.5	3.3 mL/hour	1.50 – 1.59	6.3	3
	1	5.5		1.40 – 1.49	5.9	3
	1	5.5		1.30 – 1.39	5.4	2
	1	5.5		1.20 – 1.29	5.0	2
	1	5.5		1.10 – 1.19	4.6	2
	1	5.5		1.00 – 1.09	4.2	2
	1	5.5		0.90 – 0.99	3.8	2
	1	5.5		0.80 – 0.89	3.4	2
	1	5.5		0.70 – 0.79	3.0	2
	1	5.5		0.60 – 0.69	2.6	1
	1	5.5		0.50 – 0.59	2.2	1
	1	5.5		0.40 – 0.49	1.8	1

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## BLINCYTO Preparation Card for Pharmacists

**Table 3. Preparation of BLINCYTO infusion solution for INTRAVENOUS administration for patients weighing less than 45 kg for 15 micrograms/m<sup>2</sup>/day dose**

Infusion Duration	Normal Saline (250-ml bag) <sup>a</sup>	IV Solution Stabiliser for BLINCYTO (mL)	Infusion Rate	BSA (m <sup>2</sup> )	Reconstituted BLINCYTO (mL)	Number of BLINCYTO vials needed
96 hours	1	5.5	2.5 mL/hour	1.50 – 1.59	8.3	3
	1	5.5		1.40 – 1.49	7.8	3
	1	5.5		1.30 – 1.39	7.3	3
	1	5.5		1.20 – 1.29	6.7	3
	1	5.5		1.10 – 1.19	6.2	3
	1	5.5		1.00 – 1.09	5.6	3
	1	5.5		0.90 – 0.99	5.1	2
	1	5.5		0.80 – 0.89	4.6	2
	1	5.5		0.70 – 0.79	4.0	2
	1	5.5		0.60 – 0.69	3.5	2
	1	5.5		0.50 – 0.59	2.9	2
	1	5.5		0.40 – 0.49	2.4	1

<sup>a</sup> 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 micron in-line filter





## BLINCYTO Preparation Card for Pharmacists

**Table 4. Steps to prepare BLINCYTO INTRAVENOUS solution under aseptic conditions using aseptic techniques**

Step 1	<ul style="list-style-type: none"> <li>• Transfer appropriate amount of BLINCYTO IV solution stabiliser to the 0.9% sodium chloride infusion bag</li> <li>• Gently mix the contents of the bag to avoid foaming</li> <li>• Discard remaining BLINCYTO IV solution stabiliser vial if applicable</li> </ul>
Step 2	<ul style="list-style-type: none"> <li>• Reconstitute BLINCYTO lyophilised powder vial with 3 mL of Preservative Free Sterile Water for injection</li> <li>• Do not reconstitute BLINCYTO with BLINCYTO IV solution stabiliser</li> <li>• Do not shake</li> <li>• Gently swirl contents to avoid excess foaming</li> <li>• Reconstitute the required number of BLINCYTO vials (see table above)</li> <li>• Visually inspect the reconstituted solution for particulate matter and to confirm colour, the solution should be clear to slightly opalescent, colourless to slightly yellow</li> </ul>
Step 3	<ul style="list-style-type: none"> <li>• Transfer appropriate amount of reconstituted BLINCYTO solution into the 0.9% sodium chloride infusion bag containing IV solution stabiliser</li> <li>• Gently mix the contents of the bag to avoid foaming</li> </ul>
Step 4	<ul style="list-style-type: none"> <li>• Attach the intravenous tubing with the sterile 0.2 micron in-line filter to the prepared infusion bag</li> </ul>
Step 5	<ul style="list-style-type: none"> <li>• Remove air from the prepared BLINCYTO infusion solution bag</li> </ul>
Step 6	<ul style="list-style-type: none"> <li>• Prime the intravenous tubing with the prepared BLINCYTO infusion solution</li> <li>• Do not prime the intravenous tubing with 0.9% sodium chloride solution for injection</li> </ul>
Step 7	<ul style="list-style-type: none"> <li>• Store the prepared BLINCYTO infusion solution bags at 2°C to 8°C for a maximum of 10 days if not immediately used (for further information, please see Special precautions for storage section in the Product Information)</li> <li>• Clearly label the prepared IV infusion bag or cassette with the dose, infusion rate and duration of infusion</li> </ul>





## BLINCYTO Preparation Card for Pharmacists

**Important information about the preparation of BLINCYTO CASSETTE for INTRAVENOUS administration****Note: for comprehensive preparation instructions, please refer to the BLINCYTO Product Information****Table 5. Preparation of BLINCYTO CASSETTE for patients weighing greater than or equal to 45 kg**

Dose	Infusion duration (hours)	Normal Saline (to be added to 250 mL cassette) <sup>a</sup>	IV Solution Stabiliser for BLINCYTO (mL)	Number of BLINCYTO vials needed	Reconstituted BLINCYTO solution (mL)	Infusion rate (mL/hr)
<b>9 mcg/day</b>	24	244.25	5.0	1	0.75	10
	48	243.5	5.0	1	1.5	5
	72	242.75	5.0	1	2.25	3.3
	96	242	5.0	2	3.0	2.5
<b>28 mcg/day</b>	24	242.7	5.0	1	2.3	10
	48	240.3	5.0	2	4.7	5
	72	238	5.0	3	7.0	3.3
	96	235.7	5.0	4	9.3	2.5

<sup>a</sup>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 micron in-line filter





## BLINCYTO Preparation Card for Pharmacists

Table 6. Preparation of BLINCYTO CASSETTE for patients weighing less than 45 kg for 5 mcg/m<sup>2</sup>/day dose

Cassette Duration	Normal Saline (to be added to 250 mL cassette) <sup>a</sup>	IV Solution Stabiliser for BLINCYTO (mL)	Infusion Rate	BSA (m <sup>2</sup> )	Reconstituted BLINCYTO (mL)	Number of BLINCYTO vials needed
24 hours	244.35	5.0	10 mL/hour	1.50 – 1.59	0.65	1
	244.40	5.0		1.40 – 1.49	0.60	1
	244.44	5.0		1.30 – 1.39	0.56	1
	244.48	5.0		1.20 – 1.29	0.52	1
	244.52	5.0		1.10 – 1.19	0.48	1
	244.56	5.0		1.00 – 1.09	0.44	1
	244.61	5.0		0.90 – 0.99	0.39	1
	244.65	5.0		0.80 – 0.89	0.35	1
	244.69	5.0		0.70 – 0.79	0.31	1
	244.73	5.0		0.60 – 0.69	0.27	1
	244.77	5.0		0.50 – 0.59	0.23	1
	244.81	5.0		0.40 – 0.49	0.19	1





## BLINCYTO Preparation Card for Pharmacists

Table 6. Preparation of BLINCYTO CASSETTE for patients weighing less than 45 kg for 5 mcg/m<sup>2</sup>/day dose

Cassette Duration	Normal Saline (to be added to 250 mL cassette) <sup>a</sup>	IV Solution Stabiliser for BLINCYTO (mL)	Infusion Rate	BSA (m <sup>2</sup> )	Reconstituted BLINCYTO (mL)	Number of BLINCYTO vials needed
48 hours	243.70	5.0	5 mL/hour	1.50 – 1.59	1.3	1
	243.80	5.0		1.40 – 1.49	1.2	1
	243.90	5.0		1.30 – 1.39	1.1	1
	244.00	5.0		1.20 – 1.29	1.0	1
	244.05	5.0		1.10 – 1.19	0.95	1
	244.13	5.0		1.00 – 1.09	0.87	1
	244.21	5.0		0.90 – 0.99	0.79	1
	244.30	5.0		0.80 – 0.89	0.70	1
	244.38	5.0		0.70 – 0.79	0.62	1
	244.46	5.0		0.60 – 0.69	0.54	1
	244.55	5.0		0.50 – 0.59	0.45	1
	244.63	5.0		0.40 – 0.49	0.37	1

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## BLINCYTO Preparation Card for Pharmacists

Table 6. Preparation of BLINCYTO CASSETTE for patients weighing less than 45 kg for 5 mcg/m<sup>2</sup>/day dose

Cassette Duration	Normal Saline (to be added to 250 mL cassette) <sup>a</sup>	IV Solution Stabiliser for BLINCYTO (mL)	Infusion Rate	BSA (m <sup>2</sup> )	Reconstituted BLINCYTO (mL)	Number of BLINCYTO vials needed
72 hours	243.10	5.0	3.3 mL/hour	1.50 – 1.59	1.9	1
	243.20	5.0		1.40 – 1.49	1.8	1
	243.30	5.0		1.30 – 1.39	1.7	1
	243.40	5.0		1.20 – 1.29	1.6	1
	243.60	5.0		1.10 – 1.19	1.4	1
	243.70	5.0		1.00 – 1.09	1.3	1
	243.80	5.0		0.90 – 0.99	1.2	1
	243.90	5.0		0.80 – 0.89	1.1	1
	244.07	5.0		0.70 – 0.79	0.93	1
	244.19	5.0		0.60 – 0.69	0.81	1
	244.32	5.0		0.50 – 0.59	0.68	1
	244.44	5.0		0.40 – 0.49	0.56	1

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## BLINCYTO Preparation Card for Pharmacists

Table 6. Preparation of BLINCYTO CASSETTE for patients weighing less than 45 kg for 5 mcg/m<sup>2</sup>/day dose

Cassette Duration	Normal Saline (to be added to 250 mL cassette) <sup>a</sup>	IV Solution Stabiliser for BLINCYTO (mL)	Infusion Rate	BSA (m <sup>2</sup> )	Reconstituted BLINCYTO (mL)	Number of BLINCYTO vials needed
96 hours	242.40	5.0	2.5 mL/hour	1.50 – 1.59	2.6	1
	242.60	5.0		1.40 – 1.49	2.4	1
	242.80	5.0		1.30 – 1.39	2.2	1
	242.90	5.0		1.20 – 1.29	2.1	1
	243.10	5.0		1.10 – 1.19	1.9	1
	243.30	5.0		1.00 – 1.09	1.7	1
	243.40	5.0		0.90 – 0.99	1.6	1
	243.60	5.0		0.80 – 0.89	1.4	1
	243.80	5.0		0.70 – 0.79	1.2	1
	243.90	5.0		0.60 – 0.69	1.1	1
	244.09	5.0		0.50 – 0.59	0.91	1
	244.26	5.0		0.40 – 0.49	0.74	1

<sup>a</sup> 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 micron in-line filter







## BLINCYTO Preparation Card for Pharmacists

**Table 7. Preparation of BLINCYTO CASSETTE for patients weighing less than 45 kg for 15 mcg/m<sup>2</sup>/day dose**

Cassette Duration	Normal Saline (to be added to 250 mL cassette) <sup>a</sup>	IV Solution Stabiliser for BLINCYTO (mL)	Infusion Rate	BSA (m <sup>2</sup> )	Reconstituted BLINCYTO (mL)	Number of BLINCYTO vials needed
24 hours	243.1	5.0	10 mL/hour	1.50 – 1.59	1.9	1
	243.2	5.0		1.40 – 1.49	1.8	1
	243.3	5.0		1.30 – 1.39	1.7	1
	243.4	5.0		1.20 – 1.29	1.6	1
	243.6	5.0		1.10 – 1.19	1.4	1
	243.7	5.0		1.00 – 1.09	1.3	1
	243.8	5.0		0.90 – 0.99	1.2	1
	243.9	5.0		0.80 – 0.89	1.1	1
	244.07	5.0		0.70 – 0.79	0.93	1
	244.19	5.0		0.60 – 0.69	0.81	1
	244.32	5.0		0.50 – 0.59	0.68	1
	244.44	5.0		0.40 – 0.49	0.56	1





## BLINCYTO Preparation Card for Pharmacists

**Table 7. Preparation of BLINCYTO CASSETTE for patients weighing less than 45 kg for 15 mcg/m<sup>2</sup>/day dose**

Cassette Duration	Normal Saline (to be added to 250 mL cassette) <sup>a</sup>	IV Solution Stabiliser for BLINCYTO (mL)	Infusion Rate	BSA (m <sup>2</sup> )	Reconstituted BLINCYTO (mL)	Number of BLINCYTO vials needed
48 hours	241.1	5.0	5 mL/hour	1.50 – 1.59	3.9	2
	241.4	5.0		1.40 – 1.49	3.6	2
	241.6	5.0		1.30 – 1.39	3.4	2
	241.9	5.0		1.20 – 1.29	3.1	2
	242.1	5.0		1.10 – 1.19	2.9	2
	242.4	5.0		1.00 – 1.09	2.6	1
	242.6	5.0		0.90 – 0.99	2.4	1
	242.9	5.0		0.80 – 0.89	2.1	1
	243.1	5.0		0.70 – 0.79	1.9	1
	243.4	5.0		0.60 – 0.69	1.6	1
	243.6	5.0		0.50 – 0.59	1.4	1
	243.9	5.0		0.40 – 0.49	1.1	1

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## BLINCYTO Preparation Card for Pharmacists

**Table 7. Preparation of BLINCYTO CASSETTE for patients weighing less than 45 kg for 15 mcg/m<sup>2</sup>/day dose**

Cassette Duration	Normal Saline (to be added to 250 mL cassette) <sup>a</sup>	IV Solution Stabiliser for BLINCYTO (mL)	Infusion Rate	BSA (m <sup>2</sup> )	Reconstituted BLINCYTO (mL)	Number of BLINCYTO vials needed
72 hours	239.2	5.0	3.3 mL/hour	1.50 – 1.59	5.8	3
	239.6	5.0		1.40 – 1.49	5.4	2
	240.0	5.0		1.30 – 1.39	5.0	2
	240.3	5.0		1.20 – 1.29	4.7	2
	240.7	5.0		1.10 – 1.19	4.3	2
	241.1	5.0		1.00 – 1.09	3.9	2
	241.5	5.0		0.90 – 0.99	3.5	2
	241.8	5.0		0.80 – 0.89	3.2	2
	242.2	5.0		0.70 – 0.79	2.8	1
	242.6	5.0		0.60 – 0.69	2.4	1
	243.0	5.0		0.50 – 0.59	2.0	1
	243.3	5.0		0.40 – 0.49	1.7	1

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## BLINCYTO Preparation Card for Pharmacists

**Table 7. Preparation of BLINCYTO CASSETTE for patients weighing less than 45 kg for 15 mcg/m<sup>2</sup>/day dose**

Cassette Duration	Normal Saline (to be added to 250 mL cassette) <sup>a</sup>	IV Solution Stabiliser for BLINCYTO (mL)	Infusion Rate	BSA (m <sup>2</sup> )	Reconstituted BLINCYTO (mL)	Number of BLINCYTO vials needed
96 hours	237.3	5.0	2.5 mL/hour	1.50 – 1.59	7.7	3
	237.8	5.0		1.40 – 1.49	7.2	3
	238.3	5.0		1.30 – 1.39	6.7	3
	238.8	5.0		1.20 – 1.29	6.2	3
	239.3	5.0		1.10 – 1.19	5.7	3
	239.8	5.0		1.00 – 1.09	5.2	2
	240.3	5.0		0.90 – 0.99	4.7	2
	240.8	5.0		0.80 – 0.89	4.2	2
	241.3	5.0		0.70 – 0.79	3.7	2
	241.8	5.0		0.60 – 0.69	3.2	2
	242.3	5.0		0.50 – 0.59	2.7	1
	242.8	5.0		0.40 – 0.49	2.2	1

<sup>a</sup> 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 micron in-line filter





## BLINCYTO Preparation Card for Pharmacists

**Table 8. Steps to prepare BLINCYTO CASSETTE under aseptic conditions using aseptic techniques**

Step 1	<ul style="list-style-type: none"> <li>• Transfer appropriate amount of 0.9% sodium chloride solution to the cassette</li> </ul>
Step 2	<ul style="list-style-type: none"> <li>• Transfer appropriate amount of BLINCYTO IV solution stabiliser to the cassette</li> <li>• Gently mix the contents of the cassette to avoid foaming</li> <li>• Discard remaining BLINCYTO IV solution stabiliser vial if applicable</li> </ul>
Step 3	<ul style="list-style-type: none"> <li>• Reconstitute BLINCYTO lyophilised powder vial with 3 mL of Preservative Free Sterile Water for injection</li> <li>• Do not reconstitute BLINCYTO with BLINCYTO IV solution stabiliser</li> <li>• Do not shake</li> <li>• Gently swirl contents to avoid excess foaming</li> <li>• Reconstitute the required number of BLINCYTO vials (see table above) as needed</li> <li>• Visually inspect the reconstituted solution for particulate matter and to confirm colour, the solution should be clear to slightly opalescent, colourless to slightly yellow</li> </ul>
Step 4	<ul style="list-style-type: none"> <li>• Transfer appropriate amount of reconstituted BLINCYTO solution into the cassette</li> <li>• Gently mix the contents of the cassette to avoid foaming</li> </ul>
Step 5	<ul style="list-style-type: none"> <li>• Redraw approximately 10 mL of fluid from the cassette and inject back to ensure no BLINCYTO remains in the cassette line</li> <li>• Gently mix again</li> </ul>
Step 6	<ul style="list-style-type: none"> <li>• Remove air from the cassette</li> </ul>
Step 7	<ul style="list-style-type: none"> <li>• Attach the intravenous tubing with the sterile 0.2 micron in-line filter to the cassette</li> </ul>
Step 8	<ul style="list-style-type: none"> <li>• Prime the intravenous tubing with the prepared BLINCYTO solution for infusion</li> <li>• Do not prime the intravenous tubing with 0.9% sodium chloride solution for injection</li> </ul>
Step 9	<ul style="list-style-type: none"> <li>• Store at 2°C to 8°C for a maximum of 10 days if not used immediately</li> <li>• Clearly label the prepared IV infusion bag or cassette with the dose, infusion rate and duration of infusion</li> </ul>





## BLINCYTO Preparation Card for Pharmacists

**WARNING**

The following have occurred in patients receiving BLINCYTO:

- Cytokine Release Syndrome, which may be life-threatening or fatal
- Neurological toxicities, which may be severe, life-threatening, or fatal
- Reactivation of JC viral infection

Interrupt or discontinue BLINCYTO as recommended if any of these adverse events occur (See *Precautions and Dosage and Administration*).

**Indication:** treatment of relapsed or refractory (R/R) B-cell precursor acute lymphoblastic leukaemia (ALL); treatment of minimal residual disease (MRD) positive ALL in patients in complete haematological remission.

**Contraindications:** hypersensitivity to blinatumomab, CHO-derived proteins or any excipient. **Precautions:** neurologic events; increased risk for serious infections; cytokine release syndrome; infusion reactions; tumour lysis syndrome, pancreatitis. Management of these adverse reactions may require interruption or discontinuation of treatment. Neutropenia and febrile neutropenia; elevated liver enzymes; leukoencephalopathy; medication errors – strictly follow preparation and administration instructions. Pregnancy Category: C. Use contraception during and for 48 hours after treatment. Discontinue breast-feeding during and for at least 48 hours after treatment. Do not use recommended adult fixed dose in paediatric patients. No data in patients aged less than 28 days. **Interactions:** low potential of clinically meaningful drug interaction with BLINCYTO-mediated cytokine elevation. Vaccination with live viral vaccines not recommended 2 weeks prior to or during treatment, and until recovery of B lymphocytes to normal range following last treatment cycle. **Adverse Reactions:** Common: infections, pyrexia, infusion-related reactions, headache, anaemia, febrile neutropenia, neutropenia, thrombocytopenia, oedema, increased liver enzymes, fatigue, nausea, tremor, hypokalaemia, diarrhoea, chills. See also Precautions for serious adverse reactions. **Dosage & Administration:** **R/R ALL:** Single cycle is 4 weeks continuous intravenous (cIV) infusion then 2 week treatment free interval. *For patients greater than or equal to 45 kg (fixed dose):* Cycle 1 - starting dose 9 micrograms/day for days 1-7, then 28 micrograms/day for days 8-28. All other cycles 28 micrograms/day for 4 weeks. *For patients less than 45 kg (body surface area based dose):* Cycle 1 - starting dose 5 micrograms/m<sup>2</sup>/day for days 1-7 (do not exceed 9 micrograms/day), then 15 micrograms/m<sup>2</sup>/day (do not exceed 28 micrograms/day); all other cycles, 15 micrograms/m<sup>2</sup>/day (do not exceed 28 micrograms/day). For maintenance, 28 day cIV infusion, then 56 days treatment free. Hospitalise at least first 9 days of Cycle 1 and first 2 days of Cycle 2. Supervision or hospitalisation for other cycle starts and reinitiation. Adults: premedicate with 20 mg IV dexamethasone prior to initiation of each cycle. Intrathecal chemotherapy prophylaxis recommended before and during therapy. Treat with dexamethasone (≤ 24 mg/day) if high tumour burden. Paediatrics: premedicate with dexamethasone 10 mg/m<sup>2</sup> (not to exceed 20 mg) oral or IV 6 to 12 hours prior to start of BLINCYTO (Cycle 1 day 1), followed by premedication with dexamethasone 5 mg/m<sup>2</sup> oral or IV within 30 minutes of start of BLINCYTO (Cycle 1 day 1). **MRD+ ALL:** 28 day cIV infusion then 14 days treatment free, for up to 4 cycles; premedicate with prednisone 100 mg IV or equivalent 1 hour prior to start of BLINCYTO each cycle; hospitalise first 3 days Cycle 1 and first 2 days Cycle 2, supervise/hospital for subsequent cycle starts and reinitiation – see full PI. **R/R & MRD+ ALL** - Interrupt Blincyto if grade 3 neurological events, Cytokine Release Syndrome or other clinically relevant adverse reactions occur see full PI. Refer to full Product Information before prescribing; available from Amgen Australia Pty Ltd, Ph: 1800 803 638 or at [www.amgen.com.au/Blincyto.PI](http://www.amgen.com.au/Blincyto.PI)

