

## 24-Hour or 48-Hour Infusion

### INSTRUCTIONS FOR USE: 24-HOUR OR 48-HOUR INFUSION

**The preparation steps differ based on the infusion duration.**  
**Follow the steps specific to the infusion duration you are preparing.**

**It is very important that the instructions for preparation (including admixing) and administration provided in this section are strictly followed to minimize medication errors (including underdose and overdose) [see Dosage and Administration (2.5), Warnings and Precautions (5.10)].**

#### **Aseptic Preparation**

Strictly observe aseptic technique when preparing the solution for infusion since BLINCYTO vials do not contain antimicrobial preservatives. To prevent accidental contamination, prepare BLINCYTO according to aseptic standards, including but not limited to:

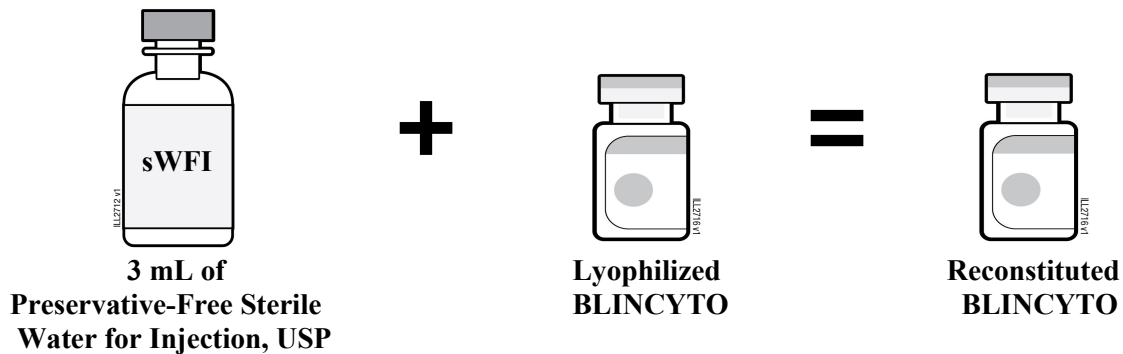
- Prepare BLINCYTO in a USP <797> compliant facility.
- Prepare BLINCYTO in an ISO Class 5 laminar flow hood or better.
- Ensure that the admixing area has appropriate environmental specifications, confirmed by periodic monitoring.
- Ensure that personnel are appropriately trained in aseptic manipulations and admixing of oncology drugs.
- Ensure that personnel wear appropriate protective clothing and gloves.
- Ensure that gloves and surfaces are disinfected.

#### **Gather Equipment and Supplies for 24-Hour or 48-Hour Infusion**

- Preservative-Free Sterile Water for Injection, USP.
- Preservative-Free 0.9% Sodium Chloride Injection, USP.
- Sterile, non-pyrogenic, low protein-binding, 0.2 micron in-line filter.
- Infusion bags/pump cassettes and intravenous tubing sets: Use either polyolefin, DEHP-free PVC, or ethyl vinyl acetate (EVA).
  - **BLINCYTO is incompatible with diethylhexylphthalate (DEHP)** due to the possibility of particle formation, leading to a cloudy solution.
- BLINCYTO package(s), each BLINCYTO package contains:
  - One BLINCYTO for injection 35 mcg single-dose vial containing a sterile, preservative-free, white to off-white lyophilized powder.
    - More than one vial of BLINCYTO may be needed to prepare the recommended dose.
  - One IV Solution Stabilizer 10 mL single-dose glass vial containing a sterile, preservative-free, colorless to slightly yellow, clear solution.
    - **Do not** use IV Solution Stabilizer for reconstitution of BLINCYTO.
    - IV Solution Stabilizer is used to coat the intravenous bag prior to addition of reconstituted BLINCYTO to prevent adhesion of BLINCYTO to intravenous bags and intravenous tubing.

### Preparation of BLINCYTO: Reconstitution

1. **Determine the number of BLINCYTO vials needed for a dose and infusion duration.**
  - Refer to Table 1 (patients weighing 45 kg or more) or Table 2 (patients weighing less than 45 kg).
- a. Reconstitute each BLINCYTO vial with **3 mL of preservative-free Sterile Water for Injection, USP** by directing the water along the walls of the BLINCYTO vial and not directly on the lyophilized powder. The resulting concentration per BLINCYTO vial is 12.5 mcg/mL.
  - **Do not** reconstitute BLINCYTO vials with the IV Solution Stabilizer (IVSS).



**!** **Important:** Do not reconstitute BLINCYTO vials with IV Solution Stabilizer (IVSS).

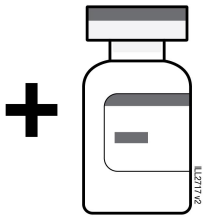
- b. Gently swirl contents to avoid excess foaming.
  - **Do not** shake.
- c. **Visually inspect the reconstituted solution for particulate matter and discoloration during reconstitution and prior to preparing the intravenous bag.** The resulting solution should be clear to slightly opalescent, colorless to slightly yellow.
  - **Do not** use if solution is cloudy or has precipitated.

### Preparation of BLINCYTO: 24-Hour or 48-Hour Intravenous Bag

2. Aseptically add **270 mL of preservative-free 0.9% Sodium Chloride Injection, USP** to the empty intravenous bag.



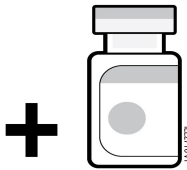
3. Aseptically **transfer 5.5 mL of IV Solution Stabilizer (IVSS)** to the intravenous bag containing preservative-free 0.9% Sodium Chloride Injection, USP.
  - Gently mix the contents of the bag to avoid foaming.



**IV Solution Stabilizer**

- For 24-hour infusion, **transfer 5.5 mL IV Solution Stabilizer.**
- For 48-hour infusion, **transfer 5.5 mL IV Solution Stabilizer.**
- Discard the vial containing the unused IV Solution Stabilizer.

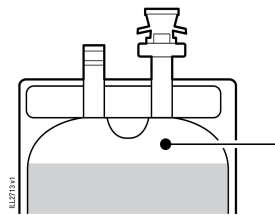
4. Aseptically **transfer the required volume of reconstituted BLINCYTO solution** into the intravenous bag containing preservative-free 0.9% Sodium Chloride Injection, USP and IV Solution Stabilizer.
  - Gently mix the contents of the bag to avoid foaming.



**Reconstituted BLINCYTO**

- Refer to Table 1 for patients weighing 45 kg or more for the specific volume of reconstituted BLINCYTO.
- Refer to Table 2 for patients weighing less than 45 kg (dose based on BSA) for the specific volume of reconstituted BLINCYTO.
- Discard the vial containing unused BLINCYTO.

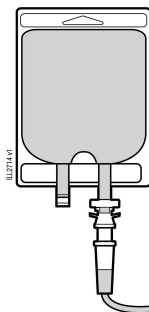
5. **Remove air from the intravenous bag.** This is particularly important for use with an ambulatory infusion pump.



**Remove air from the IV Bag**

6. Under aseptic conditions, attach the intravenous tubing to the intravenous bag with the sterile **0.2 micron in-line filter.**
  - Ensure that the intravenous tubing is compatible with the infusion pump.
  - Use either polyolefin, DEHP-free PVC or EVA intravenous tubing sets.

7. **Prime the intravenous tubing only with the solution in the bag containing the FINAL prepared BLINCYTO solution for infusion.**



**Prime with FINAL prepared BLINCYTO solution**

8. Store refrigerated at 2°C to 8°C (36°F to 46°F) if not used immediately [see Dosage and Administration (2.6)].

Table 1. For 24-Hour and 48-Hour Infusion: Patients Weighing **45 kg or More**

Infusion Duration	Dose	Reconstituted BLINCYTO	
		Volume	Vials
24 hours	9 mcg/day	0.83 mL	1
	28 mcg/day	2.6 mL	1
48 hours	9 mcg/day	1.7 mL	1
	28 mcg/day	5.2 mL	2

Table 2. For 24-Hour and 48-Hour Infusion: Patients Weighing **Less Than 45 kg**

Infusion Duration	Dose	BSA (m <sup>2</sup> )	Reconstituted BLINCYTO	
			Volume	Vials
24 hours	5 mcg/m <sup>2</sup> /day	1.5 – 1.59	0.7 mL	1
		1.4 – 1.49	0.66 mL	1
		1.3 – 1.39	0.61 mL	1
		1.2 – 1.29	0.56 mL	1
		1.1 – 1.19	0.52 mL	1
		1 – 1.09	0.47 mL	1
		0.9 – 0.99	0.43 mL	1
		0.8 – 0.89	0.38 mL	1
		0.7 – 0.79	0.33 mL	1
		0.6 – 0.69	0.29 mL	1
		0.5 – 0.59	0.24 mL	1
		0.4 – 0.49	0.2 mL	1
		0.35 – 0.39	0.17 mL	1
		0.3 – 0.34	0.15 mL	1
		0.25 – 0.29	0.12 mL	1
24 hours	15 mcg/m <sup>2</sup> /day	1.5 – 1.59	2.1 mL	1
		1.4 – 1.49	2 mL	1
		1.3 – 1.39	1.8 mL	1
		1.2 – 1.29	1.7 mL	1
		1.1 – 1.19	1.6 mL	1
		1 – 1.09	1.4 mL	1
		0.9 – 0.99	1.3 mL	1
		0.8 – 0.89	1.1 mL	1
		0.7 – 0.79	1 mL	1
		0.6 – 0.69	0.86 mL	1
		0.5 – 0.59	0.72 mL	1
		0.4 – 0.49	0.59 mL	1
		0.35 – 0.39	0.51 mL	1

		0.3 – 0.34	0.44 mL	1
		0.25 – 0.29	0.37 mL	1
		0.2 – 0.24	0.3 mL	1
48 hours	5 mcg/m <sup>2</sup> /day	1.5 – 1.59	1.4 mL	1
		1.4 – 1.49	1.3 mL	1
		1.3 – 1.39	1.2 mL	1
		1.2 – 1.29	1.1 mL	1
		1.1 – 1.19	1 mL	1
		1 – 1.09	0.94 mL	1
		0.9 – 0.99	0.85 mL	1
		0.8 – 0.89	0.76 mL	1
		0.7 – 0.79	0.67 mL	1
		0.6 – 0.69	0.57 mL	1
		0.5 – 0.59	0.48 mL	1
		0.4 – 0.49	0.39 mL	1
		0.35 – 0.39	0.34 mL	1
		0.3 – 0.34	0.29 mL	1
		0.25 – 0.29	0.25 mL	1
		0.2 – 0.24	0.2 mL	1
48 hours	15 mcg/m <sup>2</sup> /day	1.5 – 1.59	4.2 mL	2
		1.4 – 1.49	3.9 mL	2
		1.3 – 1.39	3.7 mL	2
		1.2 – 1.29	3.4 mL	2
		1.1 – 1.19	3.1 mL	2
		1 – 1.09	2.8 mL	1
		0.9 – 0.99	2.6 mL	1
		0.8 – 0.89	2.3 mL	1
		0.7 – 0.79	2 mL	1
		0.6 – 0.69	1.7 mL	1
		0.5 – 0.59	1.4 mL	1
		0.4 – 0.49	1.2 mL	1
		0.35 – 0.39	1 mL	1
		0.3 – 0.34	0.88 mL	1
		0.25 – 0.29	0.75 mL	1
		0.2 – 0.24	0.61 mL	1

**Administration of BLINCYTO: 24-Hour or 48-Hour Intravenous Bag**

- Administer BLINCYTO as a continuous intravenous infusion at a constant flow rate using an infusion pump. The pump should be programmable, lockable, non-elastomeric, and have an alarm.
- The starting volume (270 mL) is more than the volume administered to the patient (240 mL) to account for the priming of the intravenous tubing and to ensure that the patient will receive the full dose of BLINCYTO.
- **Ensure that the intravenous tubing is primed only with the solution in the bag containing the FINAL prepared BLINCYTO solution for infusion.**

- Administer the FINAL prepared BLINCYTO infusion solution using intravenous tubing that contains a sterile, non-pyrogenic, low protein-binding, 0.2 micron in-line filter for 24-hour or 48-hour bags.
  - For 72-hour, 96-hour, or 7-day bag administration information [see “Administration of BLINCYTO: 72-Hour, 96-Hour, or 7-Day Intravenous Bag”].
- Infuse the FINAL prepared BLINCYTO infusion solution according to the instructions on the pharmacy label on the prepared bag at one of the following constant infusion rates:
  - Infusion rate of 10 mL/hour for a duration of 24 hours, OR
  - Infusion rate of 5 mL/hour for a duration of 48 hours.
- **Important Note: Do not flush the BLINCYTO infusion line, especially when changing infusion bags. Flushing when changing bags or at completion of infusion can result in excess dosage and complications thereof. When administering via a multi-lumen venous catheter, infuse BLINCYTO through a dedicated lumen. Before flushing the catheter system, residual amounts of BLINCYTO must be aspirated from the catheter system to avoid bolus administration.**
- At the end of the infusion, any remaining solution in the intravenous bag and intravenous tubing should be discarded in accordance with local requirements.

## 72-Hour, 96-Hour, or 7-Day Infusion (Preservative)

### INSTRUCTIONS FOR USE: 72-HOUR OR 96-HOUR, OR 7-DAY INFUSION

**The preparation steps differ based on the infusion duration.**  
**Follow the steps specific to the infusion duration you are preparing.**

**It is very important that the instructions for preparation (including admixing) and administration provided in this section are strictly followed to minimize medication errors (including underdose and overdose) [see Dosage and Administration (2.5), Warnings and Precautions (5.10)].**

**The administration of BLINCYTO as a 72-hour, 96-hour, and 7-day infusion is not recommended for patients weighing less than 5.4 kg [see Warnings and Precautions (5.12)].**

#### **Aseptic Preparation**

Strictly observe aseptic technique when preparing the solution for infusion since BLINCYTO vials do not contain antimicrobial preservatives. To prevent accidental contamination, prepare BLINCYTO according to aseptic standards, including but not limited to:

- Prepare BLINCYTO in a USP <797> compliant facility.
- Prepare BLINCYTO in an ISO Class 5 laminar flow hood or better.
- Ensure that the admixing area has appropriate environmental specifications, confirmed by periodic monitoring.
- Ensure that personnel are appropriately trained in aseptic manipulations and admixing of oncology drugs.
- Ensure that personnel wear appropriate protective clothing and gloves.

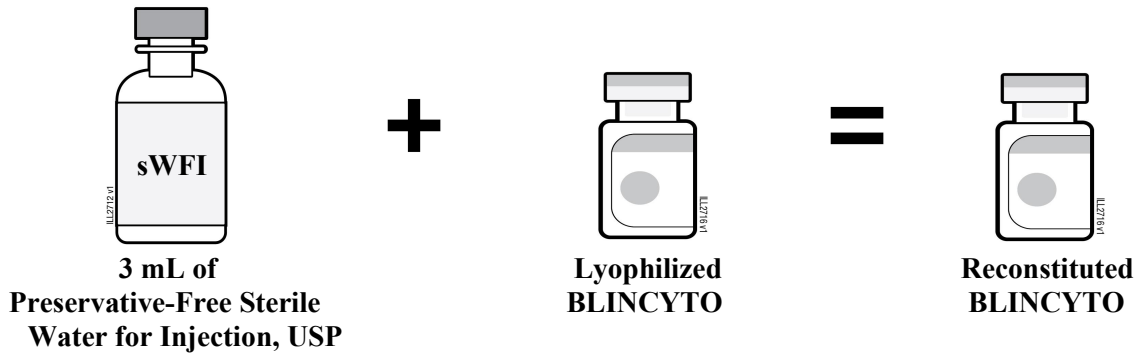
- Ensure that gloves and surfaces are disinfected.

**Gather Equipment and Supplies for 72-Hour, 96-Hour, or 7-Day Infusion**

- Preservative-Free Sterile Water for Injection, USP.
- Preservative-Free 0.9% Sodium Chloride Injection, USP.
- Bacteriostatic 0.9% Sodium Chloride Injection, USP.
- Infusion bags/pump cassettes and intravenous tubing sets: Use either polyolefin, DEHP-free PVC, or ethyl vinyl acetate (EVA).
  - **BLINCYTO is incompatible with diethylhexylphthalate (DEHP)** due to the possibility of particle formation, leading to a cloudy solution.
- BLINCYTO package(s), each BLINCYTO package contains:
  - One BLINCYTO for injection 35 mcg single-dose vial containing a sterile, preservative-free, white to off-white lyophilized powder.
    - More than one vial of BLINCYTO may be needed to prepare the recommended dose.
  - One IV Solution Stabilizer 10 mL single-dose glass vial containing a sterile, preservative-free, colorless to slightly yellow, clear solution.
    - **Do not** use IV Solution Stabilizer for reconstitution of BLINCYTO.
    - IV Solution Stabilizer is used to coat the intravenous bag prior to addition of reconstituted BLINCYTO to prevent adhesion of BLINCYTO to intravenous bags and intravenous tubing.

**Preparation of BLINCYTO: Reconstitution**

1. **Determine the number of BLINCYTO vials needed for a dose and infusion duration.**
  - Refer to Table 3 (patients weighing 45 kg or more) or Table 4 (patients weighing between 5.4 kg and less than 45 kg).
- a. Reconstitute each BLINCYTO vial with **3 mL of preservative-free Sterile Water for Injection, USP** by directing the water along the walls of the BLINCYTO vial and not directly on the lyophilized powder. The resulting concentration per BLINCYTO vial is 12.5 mcg/mL.
  - **Do not** reconstitute BLINCYTO vials with the IV Solution Stabilizer (IVSS).



**!** **Important:** Do not reconstitute BLINCYTO vials with IV Solution Stabilizer (IVSS).

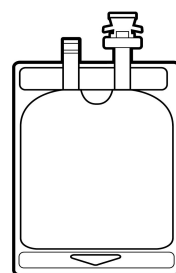
- b. Gently swirl contents to avoid excess foaming.
  - **Do not** shake.
- c. **Visually inspect the reconstituted solution for particulate matter and discoloration during reconstitution and prior to preparing the intravenous bag.** The resulting solution should be clear to slightly opalescent, colorless to slightly yellow.
  - **Do not** use if solution is cloudy or has precipitated.

**Preparation of BLINCYTO: 72-Hour, 96-Hour, or 7-Day Intravenous Bag**

2. Aseptically **add the required volume of Bacteriostatic 0.9% Sodium Chloride Injection, USP** to the empty intravenous bag.
  - For 72-hour infusion, **add 45 mL** Bacteriostatic 0.9% Sodium Chloride Injection.
  - For 96-hour infusion, **add 56 mL** Bacteriostatic 0.9% Sodium Chloride Injection.
  - For 7-day infusion, **add 90 mL** Bacteriostatic 0.9% Sodium Chloride Injection.



**Bacteriostatic  
0.9% NaCl  
Injection, USP**



**Empty IV Bag Material,  
use either:**

- Polyolefin,
- DEHP-free PVC, or
- EVA IV Bag

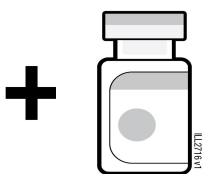
3. Aseptically **transfer the required volume of IV Solution Stabilizer (IVSS)** to the intravenous bag containing Bacteriostatic 0.9% Sodium Chloride Injection, USP.
  - Gently mix the contents of the bag to avoid foaming.



**IV Solution  
Stabilizer**

- For 72-hour infusion, **transfer 3.2 mL** IV Solution Stabilizer.
- For 96-hour infusion, **transfer 4 mL** IV Solution Stabilizer.
- For 7-day infusion, **transfer 2.2 mL** IV Solution Stabilizer.
- Discard the vial containing the unused IV Solution Stabilizer.

4. Aseptically **transfer the required volume of reconstituted BLINCYTO solution** into the intravenous bag containing Bacteriostatic 0.9% Sodium Chloride Injection, USP and IV Solution Stabilizer.
  - Gently mix the contents of the bag to avoid foaming.



**Reconstituted  
BLINCYTO**

- Refer to Table 3 for patients weighing 45 kg or more for the specific volume of reconstituted BLINCYTO.
- Refer to Table 4 for patients weighing between 5.4 kg and less than 45 kg (dose based on BSA) for the specific volume of reconstituted BLINCYTO.
- Discard the vial containing unused BLINCYTO.



5. Aseptically **add the needed volume of preservative-free 0.9% Sodium Chloride Injection, USP** to the intravenous bag to obtain **the final volumes within Table 3 and Table 4**.

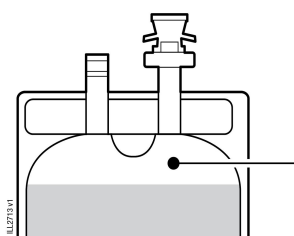
- Gently mix the contents of the bag to avoid foaming.



**Preservative-Free  
0.9% NaCl  
Injection, USP**

- Refer to Table 3 for patients weighing 45 kg or more for the specific volume of preservative-free 0.9% Sodium Chloride Injection, USP.
- Refer to Table 4 for patients weighing between 5.4 kg and less than 45 kg (dose based on BSA) for the specific volume of preservative-free 0.9% Sodium Chloride Injection, USP.

6. **Remove air from the intravenous bag.** This is particularly important for use with an ambulatory infusion pump.



**Remove air  
from the IV Bag**

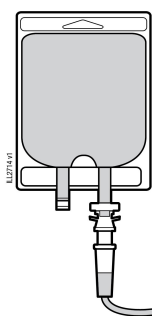
7. Under aseptic conditions, attach the intravenous tubing to the intravenous bag. **Do not** use an in-line filter for 72-hour, 96-hour, or 7-day bags.

- Ensure that the intravenous tubing is compatible with the infusion pump.
- Use either polyolefin, DEHP-free PVC or EVA intravenous tubing sets.



**Important:** Do not use an in-line filter for 72-hour, 96-hour, or 7-day bags.

8. **Prime the intravenous tubing only with the solution in the bag containing the FINAL prepared BLINCYTO solution for infusion.**



**Prime with  
FINAL prepared  
BLINCYTO solution**

9. Store refrigerated at 2°C to 8°C (36°F to 46°F) if not used immediately [see *Dosage and Administration* (2.6)].

Table 3. For 72-Hour, 96-Hour, and 7-Day Infusion: Patients Weighing **45 kg or More**

Infusion Duration	Dose	Reconstituted BLINCYTO		Volume of Preservative-Free 0.9% Sodium Chloride Injection, USP needed to q.s. to Final Volume	Final Volume of IV Bag
		Volume	Vials		
72 hours	28 mcg/day	8.4 mL	3	105 mL	162 mL
96 hours	28 mcg/day	10.4 mL	4	130 mL	200 mL
7 days	28 mcg/day	16.8 mL	6	1 mL	110 mL

Table 4. For 72-Hour, 96-Hour, and 7-Day Infusion: Patients Weighing Between 5.4 kg and Less Than 45 kg

Infusion Duration	Dose	BSA (m <sup>2</sup> )	Reconstituted BLINCYTO		Volume of Preservative-Free 0.9% Sodium Chloride Injection, USP needed to q.s. to Final Volume	Final Volume of IV Bag
			Volume	Vials		
72 hours	15 mcg/m <sup>2</sup> /day	1.5 – 1.59	6.8 mL	3	107 mL	162 mL
		1.4 – 1.49	6.4 mL	3	107 mL	162 mL
		1.30 – 1.39	6 mL	3	108 mL	162 mL
		1.20 – 1.29	5.4 mL	2	108 mL	162 mL
		1.10 – 1.19	5 mL	2	109 mL	162 mL
		1 – 1.09	4.6 mL	2	109 mL	162 mL
		0.9 – 0.99	4.2 mL	2	110 mL	162 mL
		0.8 – 0.89	3.8 mL	2	110 mL	162 mL
		0.7 – 0.79	3.2 mL	2	111 mL	162 mL
		0.6 – 0.69	2.8 mL	1	111 mL	162 mL
		0.5 – 0.59	2.3 mL	1	111 mL	162 mL
		0.4 – 0.49	2 mL	1	112 mL	162 mL
		0.35 – 0.39	1.7 mL	1	112 mL	162 mL
		0.3 – 0.34	1.4 mL	1	112 mL	162 mL
96 hours	15 mcg/m <sup>2</sup> /day	1.5 – 1.59	8.4 mL	3	132 mL	200 mL
		1.4 – 1.49	7.8 mL	3	132 mL	200 mL
		1.30 – 1.39	7.4 mL	3	133 mL	200 mL
		1.20 – 1.29	6.8 mL	3	133 mL	200 mL
		1.10 – 1.19	6.2 mL	3	134 mL	200 mL
		1 – 1.09	5.6 mL	2	134 mL	200 mL
		0.9 – 0.99	5.2 mL	2	135 mL	200 mL
		0.8 – 0.89	4.6 mL	2	135 mL	200 mL
		0.7 – 0.79	4 mL	2	136 mL	200 mL
		0.6 – 0.69	3.4 mL	2	137 mL	200 mL
		0.5 – 0.59	2.8 mL	1	137 mL	200 mL
		0.4 – 0.49	2.4 mL	1	138 mL	200 mL
		0.35 – 0.39	2.1 mL	1	138 mL	200 mL
		0.3 – 0.34	1.8 mL	1	138 mL	200 mL

		0.25 – 0.29	1.5 mL	1	139 mL	200 mL
7 days	15 mcg/m <sup>2</sup> /day	1.5 – 1.59	14 mL	5	3.8 mL	110 mL
		1.4 – 1.49	13.1 mL	5	4.7 mL	110 mL
		1.30 – 1.39	12.2 mL	5	5.6 mL	110 mL
		1.20 – 1.29	11.3 mL	5	6.5 mL	110 mL
		1.10 – 1.19	10.4 mL	4	7.4 mL	110 mL
		1 – 1.09	9.5 mL	4	8.3 mL	110 mL
		0.9 – 0.99	8.6 mL	4	9.2 mL	110 mL
		0.8 – 0.89	7.7 mL	3	10.1 mL	110 mL
		0.7 – 0.79	6.8 mL	3	11 mL	110 mL
		0.6 – 0.69	5.9 mL	3	11.9 mL	110 mL
		0.5 – 0.59	5 mL	2	12.8 mL	110 mL
		0.4 – 0.49	4.1 mL	2	13.7 mL	110 mL
		0.35 – 0.39	3.4 mL	2	14.4 mL	110 mL
		0.3 – 0.34	2.8 mL	1	15 mL	110 mL
		0.25 – 0.29	2.5 mL	1	15.3 mL	110 mL

**The administration of BLINCYTO as a 72-hour, 96-hour, and 7-day infusion is not recommended for patients weighing less than 5.4 kg.**

**Administration of BLINCYTO: 72-Hour, 96-Hour, or 7-Day Intravenous Bag**

- Administer BLINCYTO as a continuous intravenous infusion at a constant flow rate using an infusion pump. The pump should be programmable, lockable, non-elastomeric, and have an alarm.
- The final volume of infusion solution will be more than the volume administered to the patient to account for the priming of the intravenous tubing and to ensure that the patient will receive the full dose of BLINCYTO.
  - For 72-hour infusion (162 mL) will be more than the volume administered to the patient (130 mL).
  - For 96-hour infusion (200 mL) will be more than the volume administered to the patient (173 mL).
  - For 7-day infusion (110 mL) will be more than the volume administered to the patient (100 mL).
- **Ensure that the intravenous tubing is primed only with the solution in the bag containing the FINAL prepared BLINCYTO solution for infusion.**
- **Do not** use an in-line filter for 72-hour, 96-hour, or 7-day bags.
- Infuse the FINAL prepared BLINCYTO infusion solution according to the instructions on the pharmacy label on the prepared bag at one of the following constant infusion rates:
  - Infusion rate of 1.8 mL/hour for a duration of 72 hours or 96 hours, OR
  - Infusion rate of 0.6 mL/hour for a duration of 7 days.
- **Important Note: Do not flush the BLINCYTO infusion line, especially when changing infusion bags. Flushing when changing bags or at completion of infusion can result in excess dosage and complications thereof. When administering via a multi-lumen venous catheter, infuse BLINCYTO through a dedicated lumen. Before flushing the catheter system, residual amounts of BLINCYTO must be aspirated from the catheter system to avoid bolus administration.**

- At the end of the infusion, any remaining solution in the intravenous bag and intravenous tubing should be discarded in accordance with local requirements.

**Manufactured by:**

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U.S. License No. 1080



BLINCYTO® (blinatumomab)

Patent: <http://pat.amgen.com/blincyto/>

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V2

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