



Product Name	BICNU 100 mg	Sap code :	510310085IN03	Reference Artwork	Party Artwork
Packaging Material	Label	Reason of change :	_____	Proof 1	28.01.2016
Size : Foil Width	_____	Country :	_____	Proof 2	29.01.2016
Size : Foil Repeat Length	_____	Pack Size :	_____	Final	02.02.2016
Size : Strip Size	_____	Barcode No. :	323155261318	Proof 4	
Size : PI - Open Size	_____	Pharmacode :	1514	Proof 5	
Size : Carton/Label	101.6 x 38.1 mm	No. of colours :	3	Proof 6 Proof 7	
PM Style/Type :	_____	Min. Font Size :	4.75	Proof 8 Proof 9	
Remark (If any) :	_____			Developed For :	Emcure (b) (4)

(b) (4)

<p style="text-align: center;">← S1S1</p> <p style="text-align: center;">NON VARNISHED AREA 20 x 85 mm Space for 2D Barcode</p> <p style="text-align: center;">NON VARNISHED AREA 15 x 85 mm</p>			510310088IN04
<p>NDC 23155-261-41 Rx only</p> <p style="text-align: center;">BiCNU[®] (carmustine for injection)</p> <p style="text-align: center;">100 mg per vial</p> <p style="text-align: center;">Each carton contains: 1 vial BiCNU (carmustine) for injection 100 mg, 1 vial Sterile Diluent for BiCNU 3 mL For intravenous infusion after reconstitution</p> <p style="text-align: center;">REFRIGERATE IMMEDIATELY</p> <p style="text-align: center;">Single Dose Vial - Discard Unused Portion</p> <p style="text-align: center;"></p>	<p>Wear gloves at all times when handling containers.</p> <p>STORE IN A REFRIGERATOR (2°-8°C, 36°-46°F)</p> <p>NOT RETURNABLE.</p> <p style="text-align: center;"> N 3 12 3 1 5 5 12 6 1 4 1 7</p> <p>Manufactured by: Emcure Pharmaceuticals Ltd., Hinjawadi, Pune, India.</p> <p>Manufactured for: Heritage Pharmaceuticals Inc. Eatontown, NJ 07724 1.866.901.DRUG (3784)</p> <p>Mfg. Lic. No.: PD/93 Rev. 01/16</p>	<p>NDC 23155-261-41 Rx only</p> <p style="text-align: center;">BiCNU[®] (carmustine for injection)</p> <p style="text-align: center;">100 mg per vial</p> <p style="text-align: center;">Each carton contains: 1 vial BiCNU (carmustine) for injection 100 mg, 1 vial Sterile Diluent for BiCNU 3 mL For intravenous infusion after reconstitution</p> <p style="text-align: center;">REFRIGERATE IMMEDIATELY</p> <p style="text-align: center;">Single Dose Vial - Discard Unused Portion</p> <p style="text-align: center;"></p>	<p>First, dissolve BiCNU (carmustine for injection) with 3 mL of the sterile diluent supplied. Second, aseptically add 27 mL Sterile Water for Injection, USP. Each mL of resulting solution contains 3.3 mg of BiCNU in 10% ethanol.</p> <p>After reconstitution as recommended, BiCNU is stable for 24 hours under refrigeration (2°-8°C, 36°-46°F). Reconstituted vials should be examined for crystal formation prior to use. If crystals are observed, they may be redissolved by warming the vial to room temperature with agitation. Protect from light.</p> <p>USUAL DOSAGE: Read enclosed package insert for indications, dosage, directions for use, and precautions.</p>

VIN 8
29116

Product Name	BiCNU 100 mg & Diluent	Sap code :	510310088IN04	Reference Artwork	Party Artwork
Packaging Material	Carton	Reason of change :	_____	Proof 1	28.01.2016
Size : Foil Width	_____	Country :	US	Proof 2	29.01.2016
Size : Foil Repeat Length	_____	Pack Size :	1 Vial of Product & 1Vial of Diluent	Proof 3	
Size : Strip Size	_____	Barcode No. :	323155261417	Final	
Size : Pl - Open Size	_____	Pharmacode :	1515	Proof 4	
Size : Carton/Label	L. 85 x W. 48 x H. 82 mm	No. of colours :	3	Proof 5 Proof 6	
PM Style/Type :	_____	Min. Font Size :	7	Proof 5 Proof 6	
Remark (if any) :	_____	Developed For :	Emcure - (b) (4)		(b) (4)

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/s/

ANN T FARRELL
04/28/2016