



# Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:  New Item

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	ZYDUS PHARMACEUTICALS (USA) INC.
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	210179
DUNS:	156861945
Proprietary Name (If Applicable) and Established Name:	CARMUSTINE FOR INJECTION 100MG (1 Kit)
Selling Unit NDC:	70710-1525-9
Individual Unit NDC:	
UPC:	370710152598
UDI	
CVX Code:	
MVX Code:	
Description:	Carmustine for injection, USP. Each package includes a vial containing 100 mg carmustine and a vial containing 3 mL sterile diluent.
Active Ingredient(s):	CARMUSTINE
URL for Additional Product Information:	www.zydususa.com
Address:	73 ROUTE 31 NORTH
City:	PENNINGTON
Key Contact:	
Phone Number:	(609) 730 1900
Product Therapeutic Classification:	
Application:	ANDA

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
Temperature Range	Cold – between 2 and 8 C (36° – 46° F)
Other Temperature Range Requirement (write in)	
Is this product to be shipped to customers on ice?	<input type="checkbox"/> No
Is this product to be shipped to customers on dry ice?	<input type="checkbox"/> No
b. Contact for temperature excursion questions:	
Name:	
Number:	
Group E-mail:	
c. Special regulations for product in any states?	<input type="checkbox"/> No
Special returns requirements for this product?	<input type="checkbox"/> No
d. Store product (unit of sale) upright?	<input type="checkbox"/> Yes
Protect product (unit of sale) from light?	<input type="checkbox"/> No
e. Shelf life:	
Initial shelf life at launch (if different):	<input type="text" value="18"/> Months

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	<input type="checkbox"/> No
reverse numbered?	<input type="checkbox"/> No
co-licensed?	<input type="checkbox"/> No
Is the Product... Direct-Ship Only	<input type="checkbox"/>
Is the Product... Neither	<input type="checkbox"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>
If Unit Dose NDC, indicate NDC here:	<input type="text"/>
Country of Origin	<input type="text"/>
Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/>

PRODUCT DESCRIPTION INFORMATION	
Size:	1 KIT
Strength:	100MG
Dosage Form:	INJECTION
Product Shape:	N/A
Product Color:	Sterile, lyophilized pale yellow
Product Imprint:	N/A

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit? <input type="checkbox"/>
<input type="checkbox"/> Bottle	<input type="text" value="1 KIT"/>
<input checked="" type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	
<input type="checkbox"/> Vial Powder Sgl	
<input type="checkbox"/> Vial Powder Multi	
<input type="checkbox"/> Other: Write In	
	Minimum order quantity? <input type="checkbox"/> Yes
	If Yes, how many of which package type?
	<input type="checkbox"/> Each
	<input checked="" type="checkbox"/> Inner/ Carton/Pack
	<input type="checkbox"/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value="AP"/> <input type="checkbox"/> Authorized Generic
II. Generic Equivalent to What Brand?:	<input type="text" value="BICNJ I.V."/> *If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer? <input type="checkbox"/>	Rx billing unit to pharmacy:
<input type="text" value="1 CARTON"/> (Write-in, e.g. 1 Vial)	<input checked="" type="checkbox"/> Each
	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="checkbox"/> Yes
Is product exempt from DSCSA?	<input type="checkbox"/> No
If yes, select exemption:	
Other exemption - Write in:	<input type="text"/>
Is product repackaged?	<input type="checkbox"/> No
Is product sold by manufacturer's exclusive distributor?	<input type="checkbox"/> No
Has FDA granted waiver/exception/exemption for product?	<input type="checkbox"/> No
GLN:	<input type="text" value="036382000002"/>
If Yes, was original product purchased direct from mfr?	<input type="checkbox"/>
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Depth	Height	Width	Volume (Cube)	# Pieces:
Item:					0	
Box/Carton/Bundle/Inner Pack:	0.014	3.41	3.84	1.41	18.463104	1
Case:	3.35	7.56	9.5	8.93	641.3526	24
Pallet:	398	48	44	40	84480	2496
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	Level	Saleable Unit	Quantity	GTIN-14		
If not, when? <input type="text" value="10/1/2018"/>	<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	00370710152598	2D	Linear
Items aggregated? <input type="checkbox"/> Yes	<input checked="" type="checkbox"/> Case	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	40370710152596	2D	Linear
	<input checked="" type="checkbox"/> Pallet	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		2D	Linear
					2D	Linear
					2D	Linear
					2D	Linear
					2D	Linear
					2D	Linear

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$3,853.70	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:	<input type="text" value="9/12/2018"/>		