



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, Med Device:	208278
Rx Product/Proprietary Name:	Amantadine Hydrochloride Capsules, USP 100 mg
NDC:	68382-512-01
CVX Code:	
UPC:	368382512017
MVX Code:	
Description:	white to off-white powder filled in size "2" empty hard gelatin capsule having red opaque colored cap imprinted with "652" in white ink and red opaque colored body
Active ingredients:	Amantadine
URL for Additional Product Information:	www.zydususa.com
Address:	73 Route 31 North
City:	Pennington
State:	NJ
Zip:	08534
Key Contact:	
Phone Number:	(609) 730 1900
Email:	
Fax:	(609) 730 1991

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
<input type="checkbox"/>	I. Freezer – between -25 and -10 C (-13° – 14° F)
<input type="checkbox"/>	II. Cold – between 2 and 8 C (36° – 46° F)
<input type="checkbox"/>	III. Cool – between 8 and 15 C (46° – 59° F)
<input checked="" type="checkbox"/>	IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
<input type="checkbox"/>	V. Avoid Excessive Heat – above 40 C (>104° F)
<input type="checkbox"/>	VI. Other Temperature Range Requirement (write in) _____
<input type="checkbox"/>	VII. No Requirement
b. Contact for temperature excursion questions:	
Name:	_____
Number:	_____
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
c. Special regulations for product in certain states?	
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	No
e. Shelf life:	
<input type="text" value="24"/> Months	
Initial shelf life at launch (if different):	<input type="text"/> Months

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Brand Name:	Amantadine HCl Capsules
III. Generic Equivalent for Brand:	Amantadine Hydrochloride Capsules, USP 100 mg

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
DUNS:	156861945
Is product exempt from DSCSA?	No
If yes, select exemption:	_____
Other exemption - Write in:	_____
Is product repackaged?	No
If Yes, was original product purchased direct from mfr?	<input type="checkbox"/>
Is product sold by manufacturer's exclusive distributor?	No
Are any waivers granted for product ID/barcode?	No
If yes, attach documentation from FDA	_____

ADDITIONAL PRODUCT INFORMATION	
Is the Product... Direct Ship Item	<input type="checkbox"/>
Legend Device?	No
State Control?	No
ARCOS reportable?	No
Co-Licensed?	No
Controlled Substance?	No
Schedule No.?	<input type="text"/>
(incl. N for non-narcotic)	
Controlled Substance Code:	<input type="text"/>
Hazardous Material/Cytotoxic Agent?	No
Is Item...	<input type="text"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>
Is it reverse numbered?	<input type="checkbox"/>

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	Each
<input 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	Minimum order quantity? <input type="checkbox"/> Yes
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="text"/> Each
<input type="checkbox"/> Vial Power Multi	<input type="text"/> Inner/Carton/Pack
<input type="checkbox"/> Other: Write In	<input type="text"/> Case
<input type="text"/> 1	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	57.5g		3.375	1.878	6.33825	
Box/ Carton:					0	
Case:	4.34 lbs	7.51	4.33	11.29	367.131607	24
Pallet:	574 lbs	47	39	47	86151	128
UPC:	Case:					
	Carton:					

PHARMACY ORDER / BILL UNIT	Other Product Information
Rec. sell unit to customer?	Size/Strength/Form:
<input type="text"/>	100/100mg/Capsule
(Write-in, e.g. 1 Vial)	Product Shape:
Rx billing unit to pharmacy:	Capsule
<input checked="" type="checkbox"/> Each	Product Color:
<input type="checkbox"/> Gram	Red
<input type="checkbox"/> Milliliter	Product Imprint:
	"652"

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$161.52	
As of date: <input type="text" value="8/11/2016"/>		

WHOLESALE USE ONLY:	
Vendor #:	<input type="text"/>
Whsl. Code #:	<input type="text"/>
Fineline Code:	<input type="text"/>

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



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<input type="checkbox"/> Other: Write In	<input type="text"/> Case
<input type="text"/> 1	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	204.5		5.11	3.21	16.4031	
Box/ Carton:					0	
Case:	7.08 lbs	9.64	6.02	12.87	746.882136	12
Pallet:	486 lbs	47	39	47	86151	66
UPC:	Case:					
	Carton:					

PHARMACY ORDER / BILL UNIT	Other Product Information
Rec. sell unit to customer?	Size/Strength/Form:
<input type="text"/> (Write-in, e.g. 1 Vial)	500/100mg/Capsule
Rx billing unit to pharmacy:	Product Shape:
<input checked="" type="checkbox"/> Each	Capsule
<input type="checkbox"/> Gram	Product Color:
<input type="checkbox"/> Milliliter	Red
	Product Imprint:
	"652"

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$807.60	
As of date: <input type="text" value="8/11/2016"/>		

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

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