



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:	ANDA
Application Number for NDA/ANDA/BLA, Med Device:	40-596
Rx Product/Proprietary Name:	Promethazine Tablets, 12.5 mg, 100 ct
NDC:	68382-040-01
UPC:	368382040015
CVX Code:	
MVX Code:	
Description:	White to off-white, round shaped, biconvex, uncoated tablets, debossed with the logo of 'ZC', '01' and bisect on one side and plain on the other side.
Active ingredients:	Pravastatin Sodium
URL for Additional Product Information:	www.zydususa.com
Address:	73 Route 31 North
Address 2:	
City:	Pennington
State:	NJ
Zip:	08534
Key Contact:	
Email:	
Phone Number:	(609) 730 1900
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="text"/>
<input type="checkbox"/>	VII. No Requirement
b. Contact for temperature excursion questions:	
Name:	<input type="text"/>
Number:	<input type="text"/>
Is this product to be shipped to customers on ice?	<input type="text" value="No"/>
Is this product to be shipped to customers on dry ice?	<input type="text" value="No"/>
c. Special regulations for product in certain states?	
Special returns requirements for this product?	<input type="text" value="No"/>
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="text" value="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:	Phenergan
III. Generic Equivalent for Brand:	Promethazine Tablets, 12.5 mg, 100 ct

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

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

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	26.00 G		3.025	1.615	4.88538	
Box/ Carton:					0	
Case:	2.75LBS	7.76	4.06	11.54	363.574624	24
Pallet:		47.24	50.39	39.37	93717.2771	144
UPC:	Case:					
	Carton:					

PHARMACY ORDER / BILL UNIT		Other Product Information	
Rec. sell unit to customer? <input type="checkbox"/>	<input type="text"/>	Size/Strength/Form:	100ct/12.5mg/Tablets
(Write-in, e.g. 1 Vial)		Product Shape:	Round
Rx billing unit to pharmacy:		Product Color:	White to off white
<input checked="" type="checkbox"/> Each		Product Imprint:	ZC 01
<input type="checkbox"/> Gram			
<input type="checkbox"/> Milliliter			

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$18.00	
As of date: <input type="text" value="9/10/2014"/>		

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: