



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):	208719
DUNS:	156861945
Proprietary Name (If Applicable) and Established Name:	DOXAZOSIN TABLETS USP, 8MG
Selling Unit NDC:	6838278601
Individual Unit NDC:	
UDI	
CVX Code:	
UPC:	368382786012
MX Code:	
Description:	light purple to purple, mottled, round biconvex scored tablets debossed with '786' on one side and score line on another side.
Active Ingredient(s):	DOXAZOSIN
URL for Additional Product Information:	
Address:	73 ROUTE 31 NORTH
City:	PENNINGTON
State:	NJ
Zip:	08534
Key Contact:	
Phone Number:	(609) 730 1900
Fax:	(609) 730 1998
Product Therapeutic Classification:	

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

PRODUCT DESCRIPTION INFORMATION	
Size:	100 COUNT
Strength:	8MG
Dosage Form:	TABLETS
Product Shape:	ROUND
Product Color:	LIGHT PURPLE TO PURPLE
Product Imprint:	786 & SCORE LINE

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	Controlled Room – between 20 and 25 C (68° – 77°)
Temperature Range	
Other Temperature Range Requirement (write in)	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
b. Contact for temperature excursion questions:	
Name:	
Number:	
Group E-mail:	
c. Special regulations for product in any states?	No
Special returns requirements for this product?	
d. Store product (unit of sale) upright?	No
Protect product (unit of sale) from light?	No
e. Shelf life:	24 Months
Initial shelf life at launch (if different):	

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 BOTTLE OF 100 TABLETS
<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	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	
<input type="checkbox"/> Vial Powder Sgl	
<input type="checkbox"/> Vial Power Multi	
<input type="checkbox"/> Other: Write in	
	Minimum order quantity? Yes
	If Yes, how many of which package type?
	<input type="checkbox"/> Each
	<input type="checkbox"/> Inner/ Carton/ Pack
	<input checked="" type="checkbox"/> Case

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

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text" value="(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?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	No
Has FDA granted waiver/exception/exemption for product?	No
GLN:	036382000002
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/ Carton/ Bundle/ Inner Pack:	0.09	1.609	2.982	1.609	7.72004314	1
Case:	3.57	9.72	3.82	6.5	241.3476	24
Pallet:	588	48	40	48	92160	3840
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION			
Serialized?	No		
If not, when?	1/1/2018		
Items aggregated?	Yes		
Level	Unit	Quantity	GTIN-14
<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/>	1	00368382786012
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack	<input checked="" type="checkbox"/>		
<input checked="" type="checkbox"/> Case	<input checked="" type="checkbox"/>	24	40368382786010
<input checked="" type="checkbox"/> Pallet	<input checked="" type="checkbox"/>		80368382786018

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$48.01	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:	1/10/2018		



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Selling Unit NDC:	6838278610
Individual Unit NDC:	
UDI	
CVX Code:	
UPC:	368382786104
MX Code:	
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Product Color:	LIGHT PURPLE TO PURPLE
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Number:	
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<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? Yes
	If Yes, how many of which package type?
	<input type="checkbox"/> Each
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Has FDA granted waiver/exception/exemption for product?	No
GLN:	036382000002
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/ Carton/ Bundle/ Inner Pack:	0.62	1.609	2.982	1.609	7.72004314	1
Case:	10.31	11.53	8.66	8.86	884.669228	12
Pallet:	636	48	40	48	92160	720
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION			
Serialized?	No		
If not, when?	1/1/2018		
Items aggregated?	Yes		
Level	Unit	Quantity	GTIN-14
<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/>	1	00368382786104
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack	<input type="checkbox"/>		
<input checked="" type="checkbox"/> Case	<input type="checkbox"/>	12	40368382786102
<input checked="" type="checkbox"/> Pallet	<input type="checkbox"/>		80368382786100

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$456.10	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:	1/10/2018		