



Standard Pharmaceutical Product Information

copyright Aug 2013

Release 08-09-13

Final Version

New Item Promotion/Deal Open Stock Post Launch Change

Date: 9/4/2013

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																																																												
Company Name: Zydus Pharmaceuticals USA Inc.		<input type="checkbox"/> NDA <input checked="" type="checkbox"/> ANDA <input type="checkbox"/> BLA <input type="checkbox"/> Med Device		a. Temperature – Indicate the USP temperature range for this product.																																																																												
Application number for NDA/ ANDA/ BLA, Med Device: 79-029				<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																																																																												
Rx Product / Proprietary Name: Amiodarone Hydrochloride Tablets, 200mg, 60 count				b. Contact for temperature excursion questions:																																																																												
NDC: 68382-227-14	UPC: 368382227140			Name: _____ Number: _____																																																																												
CVX Code:	MVX Code:			Is this product to be shipped to customers on ice? <input type="radio"/> Yes <input checked="" type="radio"/> No																																																																												
Description: white to off-white, round-shaped, flat beveled-edge, uncoated tablets with bisect on one side and other side is plain; one side of bisect is debossed with "ZE" and other side is				Is this product to be shipped to customers on dry ice? <input type="radio"/> Yes <input checked="" type="radio"/> No																																																																												
Active ingredients: Amiodarone				c. Special regulations for this product in certain states? <input type="radio"/> *Yes <input checked="" type="radio"/> No																																																																												
URL for additional product information: www.zydususa.com				Special returns requirements for this product? <input type="radio"/> *Yes <input checked="" type="radio"/> No																																																																												
Address: 73 Route 31 North	Address 2:			d. Store product (unit of sale) upright? <input checked="" type="radio"/> Yes <input type="radio"/> No																																																																												
City: Pennington	State: NJ	8534		Protect product (unit of sale) from light? <input type="radio"/> Yes <input checked="" type="radio"/> No																																																																												
Key Contact:	Email:			e. Shelf life: <input type="text" value="24"/> Months																																																																												
Phone Number: (609) 730 1900	Fax: (609) 730 1991			Initial shelf life at launch (if different): _____ Months																																																																												
FOR GENERIC DRUG PRODUCTS																																																																																
I. Orange Book Rating: AB		II. Brand Name: Cordarone																																																																														
III. Generic Equivalent for Brand: Amiodarone Hydrochloride Tablets, 200mg																																																																																
ADDITIONAL PRODUCT INFORMATION																																																																																
Serialized? <input checked="" type="radio"/> Yes <input type="radio"/> No	Level	How?	GTIN-14																																																																													
	<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/> 2D <input type="checkbox"/> Linear <input type="checkbox"/> RFID	10368382227147																																																																													
	<input checked="" type="checkbox"/> Case	<input type="checkbox"/> 2D <input type="checkbox"/> Linear <input type="checkbox"/> RFID																																																																														
	<input checked="" type="checkbox"/> Pallet	<input type="checkbox"/> 2D <input type="checkbox"/> Linear <input type="checkbox"/> RFID																																																																														
Is the Product... <input checked="" type="checkbox"/> Direct Ship Item <input type="checkbox"/> Direct and Drop Ship <input type="checkbox"/> Drop Ship only item (See new page 3.)																																																																																
a Legend Device? <input type="radio"/> Yes <input checked="" type="radio"/> No				ITEM AND PACKING INFORMATION <table border="1"> <thead> <tr> <th rowspan="2">Order Information</th> <th rowspan="2">Weight Lbs.</th> <th colspan="3">Dimensions (US msmts.)</th> <th rowspan="2">Volume (Cube)</th> <th rowspan="2"># Pieces:</th> </tr> <tr> <th>Depth</th> <th>Height</th> <th>Width:</th> </tr> </thead> <tbody> <tr> <td>Item: <input checked="" type="checkbox"/> Bottle</td> <td>36.09 g</td> <td></td> <td>3.025</td> <td>1.615</td> <td>4.88538</td> <td></td> </tr> <tr> <td>Box/ Carton: <input type="checkbox"/> Box / Carton</td> <td></td> <td></td> <td></td> <td></td> <td>0</td> <td></td> </tr> <tr> <td>Case: <input type="checkbox"/> Ampule</td> <td>3.40lbs</td> <td>6.76</td> <td>4.06</td> <td>11.54</td> <td>316.722</td> <td>24</td> </tr> <tr> <td>Pallet: <input type="checkbox"/> Glass</td> <td></td> <td>47.24</td> <td>50.39</td> <td>39.37</td> <td>93717.3</td> <td>144</td> </tr> <tr> <td>Other: <input type="checkbox"/> Tube</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>UPC: <input type="checkbox"/> Vial Liquid Sgl</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td><input type="checkbox"/> Vial Liquid Multil</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td><input type="checkbox"/> Vial Powder Sgl</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td><input type="checkbox"/> Vial Powder Multi</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>				Order Information	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:	Depth	Height	Width:	Item: <input checked="" type="checkbox"/> Bottle	36.09 g		3.025	1.615	4.88538		Box/ Carton: <input type="checkbox"/> Box / Carton					0		Case: <input type="checkbox"/> Ampule	3.40lbs	6.76	4.06	11.54	316.722	24	Pallet: <input type="checkbox"/> Glass		47.24	50.39	39.37	93717.3	144	Other: <input type="checkbox"/> Tube							UPC: <input type="checkbox"/> Vial Liquid Sgl							<input type="checkbox"/> Vial Liquid Multil							<input type="checkbox"/> Vial Powder Sgl							<input type="checkbox"/> Vial Powder Multi						
Order Information	Weight Lbs.	Dimensions (US msmts.)								Volume (Cube)	# Pieces:																																																																					
		Depth	Height					Width:																																																																								
Item: <input checked="" type="checkbox"/> Bottle	36.09 g		3.025					1.615	4.88538																																																																							
Box/ Carton: <input type="checkbox"/> Box / Carton									0																																																																							
Case: <input type="checkbox"/> Ampule	3.40lbs	6.76	4.06					11.54	316.722	24																																																																						
Pallet: <input type="checkbox"/> Glass		47.24	50.39					39.37	93717.3	144																																																																						
Other: <input type="checkbox"/> Tube																																																																																
UPC: <input type="checkbox"/> Vial Liquid Sgl																																																																																
<input type="checkbox"/> Vial Liquid Multil																																																																																
<input type="checkbox"/> Vial Powder Sgl																																																																																
<input type="checkbox"/> Vial Powder Multi																																																																																
a State Control? <input type="radio"/> Yes <input checked="" type="radio"/> No																																																																																
ARCOS reportable? <input type="radio"/> Yes <input checked="" type="radio"/> No																																																																																
Co-Licensed? <input type="radio"/> Yes <input checked="" type="radio"/> No																																																																																
Repackaged? <input type="radio"/> Yes <input checked="" type="radio"/> No																																																																																
Controlled Substance? <input type="radio"/> Yes <input checked="" type="radio"/> No																																																																																
Schedule No.? _____ (incl. N for non-narcotic)																																																																																
Hazardous Material / Cytotoxic Agent? <input type="radio"/> *Yes <input checked="" type="radio"/> No																																																																																
Is Item... <input type="radio"/> Unit Dose <input type="radio"/> Unit of Use																																																																																
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="radio"/> Yes <input type="radio"/> No																																																																																
Is it reverse numbered? <input type="radio"/> Yes <input type="radio"/> No																																																																																
PHARMACY ORDER / BILL UNIT				COST INFORMATION																																																																												
Rec. sell unit to customer?		Size/Strength/Form:		Regular Cost Per Unit of Sale (\$)		Invoice Cost (WAC) (\$)																																																																										
(Write-in, e.g. 1 Vial)		500 mg/capsule				\$16.20																																																																										
Rx billing unit to pharmacy:		Product Shape: Round																																																																														
<input checked="" type="checkbox"/> Each <input type="checkbox"/> Gram <input type="checkbox"/> Milliliter		Product Color: White to off-white																																																																														
		Product Imprint: ZE 65																																																																														
WHOLESALE USE ONLY:																																																																																
Vendor #:																																																																																
Whsl. Code #:																																																																																
Fineline Code:																																																																																

Attach copy of MATERIAL SAFETY DATA SHEET (MSDS) 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: _____



Standard Pharmaceutical Product Information

copyright Aug 2013

Release 08-09-13

Final Version

New Item Promotion/Deal Open Stock Post Launch Change

Date: 9/4/2013

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																																																																			
Company Name: Zydus Pharmaceuticals USA Inc.		<input type="checkbox"/> NDA <input checked="" type="checkbox"/> ANDA <input type="checkbox"/> BLA <input type="checkbox"/> Med Device		a. Temperature – Indicate the USP temperature range for this product.																																																																																			
Application number for NDA/ ANDA/ BLA, Med Device: 79-029				<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																																																																																			
Rx Product / Proprietary Name: Amiodarone Hydrochloride Tablets, 200mg, 500 count				b. Contact for temperature excursion questions:																																																																																			
NDC: 68382-227-05	UPC: 36838227058			Name: _____ Number: _____																																																																																			
CVX Code:	MVX Code:			Is this product to be shipped to customers on ice? <input type="radio"/> Yes <input checked="" type="radio"/> No																																																																																			
Description: white to off-white, round-shaped, flat beveled-edge, uncoated tablets with bisect on one side and other side is plain; one side of bisect is debossed with "ZE" and other side is				Is this product to be shipped to customers on dry ice? <input type="radio"/> Yes <input checked="" type="radio"/> No																																																																																			
Active ingredients: Amiodarone				c. Special regulations for this product in certain states? <input type="radio"/> *Yes <input checked="" type="radio"/> No																																																																																			
URL for additional product information: www.zydususa.com				Special returns requirements for this product? <input type="radio"/> *Yes <input checked="" type="radio"/> No																																																																																			
Address: 73 Route 31 North		Address 2:		d. Store product (unit of sale) upright? <input checked="" type="radio"/> Yes <input type="radio"/> No																																																																																			
City: Pennington		State: NJ		Protect product (unit of sale) from light? <input type="radio"/> Yes <input checked="" type="radio"/> No																																																																																			
Key Contact:		Email:		e. Shelf life: <input type="text" value="24"/> Months																																																																																			
Phone Number: (609) 730 1900		Fax: (609) 730 1991		Initial shelf life at launch (if different): _____ Months																																																																																			
FOR GENERIC DRUG PRODUCTS																																																																																							
I. Orange Book Rating: AB		II. Brand Name: Cordarone																																																																																					
III. Generic Equivalent for Brand:		Amiodarone Hydrochloride Tablets, 200mg																																																																																					
ADDITIONAL PRODUCT INFORMATION																																																																																							
Serialized? <input checked="" type="radio"/> Yes <input type="radio"/> No	Level	How?	GTIN-14																																																																																				
	<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/> 2D <input type="checkbox"/> Linear <input type="checkbox"/> RFID	10368382227055																																																																																				
	<input checked="" type="checkbox"/> Case	<input type="checkbox"/> 2D <input type="checkbox"/> Linear <input type="checkbox"/> RFID																																																																																					
	<input checked="" type="checkbox"/> Pallet	<input type="checkbox"/> 2D <input type="checkbox"/> Linear <input type="checkbox"/> RFID																																																																																					
Is the Product... <input checked="" type="checkbox"/> Direct Ship Item <input type="checkbox"/> Direct and Drop Ship <input type="checkbox"/> Drop Ship only item (See new page 3.)																																																																																							
a Legend Device? <input type="radio"/> Yes <input checked="" type="radio"/> No				ITEM AND PACKING INFORMATION <table border="1"> <thead> <tr> <th rowspan="2">Order Information</th> <th rowspan="2">Weight Lbs.</th> <th colspan="3">Dimensions (US msmts.)</th> <th rowspan="2">Volume (Cube)</th> <th rowspan="2"># Pieces:</th> </tr> <tr> <th>Depth</th> <th>Height</th> <th>Width:</th> </tr> </thead> <tbody> <tr> <td>Unit of Sale: <input checked="" type="checkbox"/> Bottle</td> <td>Item: 211.7 g</td> <td></td> <td>4.286</td> <td>2.41</td> <td>10.3293</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Box / Carton</td> <td>Box/ Carton:</td> <td></td> <td></td> <td></td> <td>0</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Ampule</td> <td>Case: 6.93lbs</td> <td>8.11</td> <td>5.35</td> <td>10.75</td> <td>466.426</td> <td>12</td> </tr> <tr> <td><input type="checkbox"/> Glass</td> <td>Pallet:</td> <td>47.24</td> <td>49.21</td> <td>39.37</td> <td>91522.7</td> <td>112</td> </tr> <tr> <td><input type="checkbox"/> Tube</td> <td>UPC:</td> <td colspan="5"></td> </tr> <tr> <td><input type="checkbox"/> Vial Liquid Sgl</td> <td>Case:</td> <td colspan="5"></td> </tr> <tr> <td><input type="checkbox"/> Vial Liquid Multil</td> <td>Carton:</td> <td colspan="5"></td> </tr> <tr> <td><input type="checkbox"/> Vial Powder Sgl</td> <td colspan="6"></td> </tr> <tr> <td><input type="checkbox"/> Vial Powder Multi</td> <td colspan="6"></td> </tr> <tr> <td><input type="checkbox"/> Other: Write In</td> <td colspan="6"></td> </tr> </tbody> </table>				Order Information	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:	Depth	Height	Width:	Unit of Sale: <input checked="" type="checkbox"/> Bottle	Item: 211.7 g		4.286	2.41	10.3293		<input type="checkbox"/> Box / Carton	Box/ Carton:				0		<input type="checkbox"/> Ampule	Case: 6.93lbs	8.11	5.35	10.75	466.426	12	<input type="checkbox"/> Glass	Pallet:	47.24	49.21	39.37	91522.7	112	<input type="checkbox"/> Tube	UPC:						<input type="checkbox"/> Vial Liquid Sgl	Case:						<input type="checkbox"/> Vial Liquid Multil	Carton:						<input type="checkbox"/> Vial Powder Sgl							<input type="checkbox"/> Vial Powder Multi							<input type="checkbox"/> Other: Write In						
Order Information	Weight Lbs.	Dimensions (US msmts.)								Volume (Cube)	# Pieces:																																																																												
		Depth	Height					Width:																																																																															
Unit of Sale: <input checked="" type="checkbox"/> Bottle	Item: 211.7 g		4.286					2.41	10.3293																																																																														
<input type="checkbox"/> Box / Carton	Box/ Carton:								0																																																																														
<input type="checkbox"/> Ampule	Case: 6.93lbs	8.11	5.35					10.75	466.426	12																																																																													
<input type="checkbox"/> Glass	Pallet:	47.24	49.21					39.37	91522.7	112																																																																													
<input type="checkbox"/> Tube	UPC:																																																																																						
<input type="checkbox"/> Vial Liquid Sgl	Case:																																																																																						
<input type="checkbox"/> Vial Liquid Multil	Carton:																																																																																						
<input type="checkbox"/> Vial Powder Sgl																																																																																							
<input type="checkbox"/> Vial Powder Multi																																																																																							
<input type="checkbox"/> Other: Write In																																																																																							
a State Control? <input type="radio"/> Yes <input checked="" type="radio"/> No																																																																																							
ARCOS reportable? <input type="radio"/> Yes <input checked="" type="radio"/> No																																																																																							
Co-Licensed? <input type="radio"/> Yes <input checked="" type="radio"/> No																																																																																							
Repackaged? <input type="radio"/> Yes <input checked="" type="radio"/> No																																																																																							
Controlled Substance? <input type="radio"/> Yes <input checked="" type="radio"/> No																																																																																							
Schedule No.?																																																																																							
(incl. N for non-narcotic)																																																																																							
Hazardous Material / Cytotoxic Agent? <input type="radio"/> *Yes <input checked="" type="radio"/> No																																																																																							
Is Item... <input type="radio"/> Unit Dose <input type="radio"/> Unit of Use																																																																																							
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="radio"/> Yes <input type="radio"/> No																																																																																							
Is it reverse numbered? <input type="radio"/> Yes <input type="radio"/> No																																																																																							
PHARMACY ORDER / BILL UNIT		Other Product Information		COST INFORMATION																																																																																			
Rec. sell unit to customer?	Size/Strength/Form:	Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale																																																																																			
(Write-in, e.g. 1 Vial)	500 mg/capsule																																																																																						
	Product Shape: Round																																																																																						
Rx billing unit to pharmacy:	Product Color: White to off-white		\$132.26																																																																																				
<input checked="" type="checkbox"/> Each <input type="checkbox"/> Gram <input type="checkbox"/> Milliliter	Product Imprint: ZE 65																																																																																						
WHOLESALE USE ONLY:																																																																																							
Vendor #:																																																																																							
Whsl. Code #:																																																																																							
Fineline Code:																																																																																							

Attach copy of MATERIAL SAFETY DATA SHEET (MSDS) 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: _____