



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item

Final Version Date:

PRODUCT INFORMATION		SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																			
Company Name: <input type="text" value="AuroMedics Pharma LLC"/> Application: <input type="text" value="ANDA"/> Application Number for NDA/ANDA/BLA, Med Device: <input type="text" value="204657"/> DUNS: <input type="text"/> Rx Product/Proprietary Name: <input type="text" value="ESOMEPRAZOLE SODIUM FOR INJECTION 40mg/Vial"/> NDC: <input type="text" value="55150-185-05"/> UPC: <input type="text" value="355150185054"/> CVX Code: <input type="text"/> MVX Code: <input type="text"/> Description: <input type="text" value="ESOMEPRAZOLE SODIUM FOR INJECTION 40mg/Vial"/> Active ingredients: <input type="text"/> URL for Additional Product Information: <input type="text" value="www.auromedics.com"/> Address: <input type="text" value="6 Wheeling Road"/> Address 2: <input type="text"/> City: <input type="text" value="Dayton"/> State: <input type="text" value="NJ"/> Zip: <input type="text" value="08810"/> Key Contact: <input type="text"/> Email: <input type="text"/> Phone Number: <input type="text" value="888-238-7880"/> Fax: <input type="text" value="732-355-9449"/>		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" value="Steve Lucas"/> Number: <input type="text" value="732-823-4122"/> 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? <input type="text" value="No"/> Special returns requirements for this product? <input type="text" value="No"/> d. Store product (unit of sale) upright? <input type="text" value="No"/> Protect product (unit of sale) from light? <input type="text" value="No"/> e. Shelf life: <input type="text"/> Months Initial shelf life at launch (if different): <input type="text"/> Months																																			
FOR GENERIC DRUG PRODUCTS																																					
I. Orange Book Rating: <input type="text" value="AP"/> II. Brand Name: <input type="text" value="Nexium"/> III. Generic Equivalent for Brand: <input type="text" value="esomeprazole"/>																																					
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION																																					
Does supplier meet DSCSA definition of manufacturer? <input type="text" value="Yes"/> Is product exempt from DSCSA? <input type="text" value="No"/> If yes, select exemption: Other exemption - Write in: <input type="text"/> Is product repackaged? <input type="text" value="No"/> If Yes, was original product purchased direct from mfr? <input type="text" value="No"/> Is product sold by manufacturer's exclusive distributor? <input type="text" value="No"/> Are any waivers granted for product ID/barcode? <input type="text" value="No"/> If yes, attach documentation from FDA <input type="text"/>																																					
ADDITIONAL PRODUCT INFORMATION		ITEM AND PACKING INFORMATION																																			
Is the Product... <input type="text" value="Direct Ship Item"/> Legend Device? <input type="text" value="No"/> State Control? <input type="text" value="No"/> ARCOS reportable? <input type="text" value="No"/> Co-Licensed? <input type="text" value="No"/> Controlled Substance? <input type="text" value="No"/> Schedule No.? <input type="text"/> (incl. N for non-narcotic) Controlled Substance Code: <input type="text"/> Hazardous Material/Cytotoxic Agent? <input type="text" value="No"/> Is Item... <input type="text"/> If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="text"/> Is it reverse numbered? <input type="text"/>		ORDER INFORMATION Unit of Sale <input type="checkbox"/> Bottle <input checked="" type="checkbox"/> Box/Carton <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 <input type="text"/> What is the NDC selling unit? □ <input type="text" value="10 Vials in one Carton. The Carton NDC No. is 55150-185-05"/> (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? <input type="text" value="20"/> Yes If Yes, how many of which package type? <input type="text" value="20"/> Each <input type="text"/> Inner/ Carton/ Pack <input type="text"/> Case																																			
		<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2">Item:</th> <th colspan="3">Dimensions (US msmts.)</th> <th rowspan="2">Volume (Cube)</th> <th rowspan="2"># Pieces:</th> </tr> <tr> <th>Weight Lbs.</th> <th>Depth</th> <th>Height</th> <th>Width:</th> </tr> </thead> <tbody> <tr> <td>Box/ Carton:</td> <td>0.4120 (Carton contains 10)</td> <td>5.12 (Carton contains 10 Vials)</td> <td>1.97 (Carton contains 10 Vials)</td> <td>2.05 (Carton contains 10 Vials)</td> <td>Carton (10 Vials) 3 Ply Box Case</td> </tr> <tr> <td>Case:</td> <td>10.458</td> <td>11.811</td> <td>6.496</td> <td>11.811</td> <td>(Four 3 Ply Boxes or 20 Pallets)</td> </tr> <tr> <td>Pallet:</td> <td>753.964 (For Sea)</td> <td>48</td> <td>44.21 (For Sea)</td> <td>40</td> <td>(72 Shippers or 288 Nets)</td> </tr> <tr> <td>UPC:</td> <td colspan="5"> Case: <input type="text"/> Carton: <input type="text" value="355150185054"/> </td> </tr> </tbody> </table>		Item:	Dimensions (US msmts.)			Volume (Cube)	# Pieces:	Weight Lbs.	Depth	Height	Width:	Box/ Carton:	0.4120 (Carton contains 10)	5.12 (Carton contains 10 Vials)	1.97 (Carton contains 10 Vials)	2.05 (Carton contains 10 Vials)	Carton (10 Vials) 3 Ply Box Case	Case:	10.458	11.811	6.496	11.811	(Four 3 Ply Boxes or 20 Pallets)	Pallet:	753.964 (For Sea)	48	44.21 (For Sea)	40	(72 Shippers or 288 Nets)	UPC:	Case: <input type="text"/> Carton: <input type="text" value="355150185054"/>				
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Vendor #: <input type="text"/> Whsl. Code #: <input type="text"/> FineLine Code: <input type="text"/>		PHARMACY ORDER / BILL UNIT Rec. sell unit to customer? □ <input type="text"/> (Write-in, e.g. 1 Vial) Rx billing unit to pharmacy: <input type="checkbox"/> Each <input type="checkbox"/> Gram <input type="checkbox"/> Milliliter																																			
		Other Product Information Size/Strength/Form: <input type="text"/> Product Shape: <input type="text"/> Product Color: <input type="text"/> Product Imprint: <input type="text"/>																																			
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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: