



# Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:  New Item

Final Version

Date:

PRODUCT INFORMATION			
Company Name:	AuroMedics Pharma LLC		Application: ANDA
Application Number for NDA/ANDA/BLA, Med Device:	204657		
DUNS:	<input type="text"/>		
Rx Product/Proprietary Name:	ESOMEPRAZOLE SODIUM FOR INJECTION 40mg/Vial		
NDC:	55150-185-05	UPC:	355150185054
CVX Code:	<input type="text"/>	MVX Code:	<input type="text"/>
Description:	ESOMEPRAZOLE SODIUM FOR INJECTION 40mg/Vial		
Active ingredients:	<input type="text"/>		
URL for Additional Product Information:	www.auromedics.com		
Address:	6 Wheeling Road	Address 2:	<input type="text"/>
City:	Dayton	State:	NJ
Key Contact:	<input type="text"/>	Email:	<input type="text"/>
Phone Number:	888-238-7880	Fax:	732-355-9449
		Zip:	08810

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
<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 checked="" type="checkbox"/>	III. Cool – between 8 and 15 C (46° – 59° F)
<input 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>b. Contact for temperature excursion questions:</b>	
Name:	Steve Lucas
Number:	732-823-4122
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
<b>c. Special regulations for product in certain states?</b>	
Special returns requirements for this product?	No
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	No
<b>e. Shelf life:</b>	
<input type="text"/> Months	Initial shelf life at launch (if different): <input type="text"/> Months

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AP
II. Brand Name:	Nexium
III. Generic Equivalent for Brand:	esomeprazole

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:	<input type="text"/>
Other exemption - Write in:	<input type="text"/>
Is product repackaged?	No
If Yes, was original product purchased direct from mfr?	<input type="text"/>
Is product sold by manufacturer's exclusive distributor?	No
Are any waivers granted for product ID/barcode?	No
If yes, attach documentation from FDA	<input type="text"/>

ADDITIONAL PRODUCT INFORMATION		ORDER INFORMATION	
Is the Product... Direct Ship Item	<input type="checkbox"/>	Unit of Sale	What is the NDC selling unit?
Legend Device?	No	<input checked="" type="checkbox"/> Bottle	10 Vials in one Carton. The Carton NDC No. is 55150-185-05
State Control?	No	<input checked="" type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
ARCOS reportable?	No	<input type="checkbox"/> Ampule	
Co-Licensed?	No	<input type="checkbox"/> Glass	Minimum order quantity? Yes
Controlled Substance?	No	<input type="checkbox"/> Tube	
Schedule No. ? (incl. N for non-narcotic)	<input type="text"/>	<input type="checkbox"/> Vial Liquid Sgl	
Controlled Substance Code:	<input type="text"/>	<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
Hazardous Material/Cytotoxic Agent?	No	<input type="checkbox"/> Vial Powder Sgl	<input type="text"/> Each
Is Item... <input type="text"/>		<input type="checkbox"/> Vial Power Multi	<input type="text"/> Inner/ Carton/ Pack
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>	<input type="checkbox"/> Other: Write In	<input type="text"/> Case
Is it reverse numbered?	<input type="text"/>		

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Box/ Carton:	0.41120 (Carton)	5.12 (Carton contains 10)	1.97 (Carton contains 10)	2.05 (Carton contains 10)		Carton (10 Vials)
Case:	10.458	11.811	6.496	11.811		Case (Four 3 Ply)
Pallet:	785.984 (For Sea)	48	44.21 (For Sea)	40		For Sea (72 Shippers)
UPC:	Case:					
	Carton:	355150185054				

WHOLESALE USE ONLY:		PHARMACY ORDER / BILL UNIT		Other Product Information	
Vendor #:	<input type="text"/>	Rec. sell unit to customer?	<input type="text"/>		
Whsl. Code #:	<input type="text"/>	(Write-in, e.g. 1 Vial)	Product Shape:	<input type="text"/>	
Fineline Code:	<input type="text"/>	Rx billing unit to pharmacy:	Product Color:	<input type="text"/>	
		<input type="checkbox"/> Each	Product Imprint:	<input type="text"/>	
		<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
	\$345.00	
As of date: <input type="text" value="11/4/2016"/>		

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:



# Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

## MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic?  No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  No

Carcinogen

Reproductive Toxicant

Both

Warning appears on label

c. Contact Hazard?  No

d. Does this product require special clean-up instructions?  No  
(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP?  No

### Hazardous Waste Identification

EPA Hazardous Waste Code:

Is this product regulated for shipment by the DOT?

Is this a reportable quantity?   
RQ Threshold:

Is this a marine pollutant?

Is this product shipped utilizing an authorized DOT exception or Special Permit?   
(if yes, identify method below)

Limited Quantity

Consumer Commodity, ORM-D

Small Quantity (49 CFR 173.4)

Special Permit; DOT-SP

Special Provision (listed in Column 7 of 49 CFR 172.101);  
SP#

(if yes, answer a-d below and provide SDS)

a. DOT Hazard Class

b. UN/ID Number

c. Packing Group

d. Inhalation Hazard?

ADDITIONAL PRODUCT INFORMATION - Serialization					
Level			How?		GTIN-14
Serialized?	<input type="checkbox"/>	<input type="checkbox"/> Item	<input type="checkbox"/> 2D	<input type="checkbox"/> Linear	RFID 00355150185054
If not, when?	<input type="text"/>	<input type="checkbox"/> Box/Carton	<input type="checkbox"/> 2D	<input type="checkbox"/> Linear	RFID 30355150185055
Items aggregated to case?	<input type="checkbox"/>	<input type="checkbox"/> Case	<input type="checkbox"/> 2D	<input type="checkbox"/> Linear	RFID 50355150185059
		<input type="checkbox"/> Pallet	<input type="checkbox"/> 2D	<input type="checkbox"/> Linear	RFID 70355150185053

Is the product restricted for air shipment? If so, indicate restriction:

Passenger

Cargo

Passenger & Cargo

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

If Yes, is it managed with a pharmacy registry?

Website URL:

### ADD'L STORAGE INFORMATION

Please check as appropriate for this product.

Organic  Inorganic

Antineoplastic  Steroid/Androgen

Corrosive  Oxidizer

Aerosol Class; Identify NFPA Storage Level:

Comments / Details: (For example, iPledge program?)

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit:

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?

If so, which states? Other requirements? Comments?

Listed Chemical (List I or II) (Indicate or Write-in below):

Ephedrine

Pseudoephedrine

Phenylpropanolamine

Iodine (≥2.2%)

Other:

### CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

### ADDITIONAL INFORMATION

If Unit Dose NDC, indicate NDC here:

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

