

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014			Intro	duction Type:	N	lew Item		Fi	nal Version		Date:		
		F	PRODUCT INFORMATION						SPECIAL HAN	IDLING AND S	TORAGE REQU	IREMENTS*	
Company Name: AuroMedics Pharma LLC Application: ANDA						A	a. Temperature – Indicate the USP temperature range for this product.						
Application Number for	r NDA/ANDA/BLA, Me	ed Device:	204657	<u> </u>	••			I.	Freezer – betw	een -25 and -10	C (-13° – 14° F)		
DUNS:									Cold – betwee	n 2 and 8 C (36°	° – 46° F)		
Rx Product/Proprietary N	ame:	ESOMEPRAZ(OLE SODIUM FOR INJECT	TION 40mg/Vial						en 8 and 15 C (4			
NDC:	55150-185-05	•		UPC:	355150185054			x IV	. Controlled Ro	om – between 2	0 and 25 C (68°	– 77° F)	
CVX Code:				MVX Code:				<u> </u>	allows for exc	ursions between	15 and 30 C (59	9° – 86° F)	
Description:	ESOMEPRAZOLE S	ODIUM FOR INJ	ECTION 40mg/Vial						Avoid Excessi	ve Heat – above	e 40 C (>104° F)		
								VI	. Other Tempe	rature Range Re	equirement		_
Active ingredients:									(write in)				
								VI	II. No Requirem	nent			
URL for Additional Produ		www.auromedi	cs.com										
Address:	6 Wheeling Road			Address 2:		1				xcursion quest	ions:		
City:	Dayton		State:	NJ	Zip:	08810		Name:	Steve Lucas				
Key Contact: Phone Number:	888-238-7880		Email:	732-355-9449	<u> </u>				732-823-4122		n ino?	No	
Phone Number:	866-236-7660							· ·		to customers o to customers o		No	=
		FOR	GENERIC DRUG PRODU					is this produc	or to be shipped	i to customers o	ii diyice:	No	_
	AP		II. Brand Name:	Nexium									
III. Generic Equivalent for	Brand:	esomeprazole						c. Special regu	lations for pro	oduct in certain	states?	No	_
	DRU	JG SUPPLY CH	AIN SECURITY ACT (DSC:	SA) INFORMATI	ON			Special retur	ns requirement	s for this produc	t?	No	_
Does supplier meet DSCS	SA definition of manu	ıfacturer?	Yes										
Is product exempt from D	SCSA?	No						d. Store produ	uct (unit of sale	e) upright?		No	
If yes, select exemption			_						•	ale) from light?	,	No	=
Other exemption - Write						7		Frotect pro	duct (dilit of s	ale, iroin light:		INU	=
Is product repackaged?	•	No	If Vac was arigin	al meadurat mural	hased direct from mf	1		e. Shelf life:		Months			
Is product repackaged?	acturer's exclusive d		nres, was origina	ai product purci	nased direct from mi			e. Shell life:	Initial shelf li	fe at launch (if	different):		Months
Are any waivers granted f			No	If ves. attach	documentation from	FDA			initial stien ii	ie at iaurien (ii	amerenty.		_ INIOIILIIS
			PRODUCT INFORMATION						ITEM AND	PACKING INF	ORMATION		
In the Dundant	Direct Ship Item	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		ORDER INFOR	MATION					ensions (US m		Volume	
Is the Product Legend Device?	Direct Ship item	No	Unit of Sale		IDC selling unit?			Weight Lbs.	Depth	Height	Width:	(Cube)	# Pieces:
State Control?		No	Bottle		e Carton. The Carton I	NDC No. is			Бериі	Tieigni	Width.	(Gube)	
ARCOS reportable?		No	x Box/Carton	55150-185-05			Item:						
Co-Licensed?		No	Ampule	(Write-in, e.g	. 1 Box of 10 Vials)		Box/	0.41120	5.12 (Carton	1.97 (Carton	2.05 (Carton		Carton (10
Controlled Substance?		No	Glass				Carton:	(Carton	contains 10	contains 10	contains 10		Vials)
Schedule No.?			Tube	Minimum ord	ler quantity?	Yes	Case:	10.458	11.811	6.496	11.811		Case
(incl. N for non-narcotic Controlled Substance Co	,		Vial Liquid Sgl	K Vaa haaa						44.04 /5			(Four 3 Ply
Hazardous Material/Cytot		No	Vial Liquid Multi Vial Powder Sql	ii res, now ii	nany of which packa Each	ge type r	Pallet:	785.984 (For Sea)	48	44.21 (For Sea)	40		For Sea (72 Shippers
Tiazar dous material/oytot	OXIC Agent:	140	Vial Power Multi	20	Inner/Carton/Pack			Case:		gou,			(. 2 6
Is Item			Other: Write In		Case		UPC:	Carton:	35515018505	4			
If Unit Dose, is item bar coo	ded to unit dose for							•	•				
hospital scanning?			PHARMACY ORDER	/ BILL UNIT	Other Pro	duct Information	on			COST INFO	RMATION		
Is it reverse numbered?			Rec. sell unit to custon	ner?	Size/Strength/Form	n:		Regular Cos	t Per Unit of	Invoice Co	st (WAC) (\$)	Federal Ex	cise Tax Per
								Sale	e (\$)	ilivoice co	St (VVAC) (#)	Unit	of Sale
WHOLES	SALER USE ONLY:		(Write-in, e.g.	1 Vial)	Product Shape:								
Vendor #:		Rx billing unit to pharmacy:		Product Color:				\$345.00					
Whsl. Code #:			Each										
Fineline Code:			Gram		Product Imprint:								
			Milliliter							As of date:	11/4/2016		
		Attach copy of SA	Milliliter	S) or non hazard I	etter. PACKAGE INSI	ERT. LABEL AN	ID PHOTO C	OF PRODUCT PAGE	CKAGING and		11/4/2016]	
*Please provide any addit		.,	l I———	,	etter, PACKAGE INSE		ID PHOTO C	DF PRODUCT PAG	CKAGING and		11/4/2016		



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

Is the product clorical all that apply): a. Cytology D. C. Africagen or Reproductive Toxicant? Both Warmy appears on labed C. Correct Hearer? b. C. Dees the product regular special clean-up instructions? b. Dees the product contain Cheff? b. Dees the product regulated for all short of all product dependent without the product and product an	MATE	RIAL HAZARD CLASSIFICATION and TRANSPORTATION							
e. Does the product creditated for shipment by the DOT? Is this product regulated for shipment by the DOT? Is this a reportable quantity? RO Threshold by the product of	a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Carcinogen Reproductive Toxicant Both Warning appears on label c. Contact Hazard? d. Does this product require special clean-up instructions?								
Is this a reportable quantity? RO Threshold: Is this product shipped utilizing an authorized DOT exception or Special Permit? Is this product shipped utilizing an authorized DOT exception or Special Permit? Is this product shipped utilizing an authorized DOT exception or Special Permit? I consumer Commodity, ORM-D Small Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4) Special Permit DOT-SP Inon, when? Items aggregated to case? Cuse	· · · · · · · · · · · · · · · · · · ·	<u>_</u>							
Consumer Commodity, CRM-D Small Quantity (49 CFR 173.4) Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49 CFR 172.101); Items aggregated to case? If not, when? Items aggregated to case? REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? If Yas, is it managed with a pharmacy registry? Website URL: Comments / Details: (For example, iPledge program?) Listed Chemical (List 1 or II) (Indicate or Write-in below): Ephedrine Pactical Chemical (List 1 or II) (Indicate or Write-in below): Ephedrine Pactical Chemical (List 1 or II) (Indicate or Write-in below): Special Product received damaged: Is product returnable for credit: URL/Link to returns policy: Special requirements for this product in certain states? If so, which states? Other requirements for this product in certain states? If so, which states? Other requirements? MISCELLANEOUS NOTES and/or Image of Product Barcode: MISCELLANEOUS NOTES and/or Image of Product Barcode:	Is this a reportable quantity? RQ Threshold: Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit?	a. DOT Hazard Class b. UN/ID Number c. Packing Group							
Consumer Commodity, CRM-D Small Quantity (49 CFR 173.4) Special Promit: DOT-SP If not, when? Items aggregated to case? Items aggre	Limited Quantity	ADDITIONAL PRODUCT INFORMATION - Serialization							
Passenger Cargo Passenger & Passenger & Passenger & Passenger & Cargo Passenger & Pass	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);	Level How? GTIN-14							
Passenger Cargo Passenger & Passenger & Passenger & Passenger & Cargo Passenger & Pass	le the product restricted for air chipment? If so indicate restriction:	REMS or REGISTRY RESTRICTIONS							
Please check as appropriate for this product. Organic	Passenger Cargo Passenger & Cargo	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:							
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? 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) Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? ADDITIONAL INFORMATION If Unit Dose NDC, indicate NDC here: MISCELLANEOUS NOTES and/or Image of Product Barcode: MISCELLANEOUS NOTES and/or Image of Product Barcode:	Organic Inorganic Antineoplastic Steroid/Androgen								
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? 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) Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? ADDITIONAL INFORMATION If Unit Dose NDC, indicate NDC here: MISCELLANEOUS NOTES and/or Image of Product Barcode: MISCELLANEOUS NOTES and/or Image of Product Barcode:	Agreed Class Identify NEDA Storage Levels	DETIIDN INSTRUCTIONS							
Phenylpropanolamine Iodine (≥2.2%) Other:	Listed Chemical (List I or II) (Indicate or Write-in below):	Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy:							
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) If Unit Dose NDC, indicate NDC here: MISCELLANEOUS NOTES and/or Image of Product Barcode:	Phenylpropanolamine lodine (≥2.2%) Other:								
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	CLASS OF TRADE RESTRICTION:	ADDITIONAL INFORMATION							
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	If Unit Dose NDC, indicate NDC here:							
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)									
	Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)								



Standard Pharmaceutical Product Information (Page 3)

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI	Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only Phone No.:	Shipping lead time of PO: Hours Days
e. Supplier Web Site only Ninimum Order Quantity: Supplier's Customer Service Number:	Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #: Name: Phone:	
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:	Overnight receipt available:
Drop Ship service fee billed with each order:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:	Days of week overnight is available: Monday Tuesday
	Wednesday Thursday Friday
	Priority Overnight receipt available:
Class of Trade Restriction:	PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:
Restricted to retail pharmacy only:	PO Receipt Cut off time:
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	Order receipt method: Phone: Phone #: Fax #:
Comments:	EDI:
	Overnight Fees apply: Other fees apply:
REMS or Registry Restrictions	Return Instructions
REMS:	Contact # if product is received damaged:
REMS Program Manager Name: Phone:	Is product returnable for credit:
Supplier Manages REMS registry exclusively:	URL/Link to returns policy:
Wholesale distributor support: Provider Name:	Special regulations or returns requirements for this product in certain states?
Site Enrollment Number assigned by Supplier:	If so, which states? Other requirements? Comments?
DEA #:	
PCPDP #:	
NPI#:	
Comments: Registry:	ADDITIONAL INFORMATION
Registry Program Contact Name: Phone:	Is product order for scheduled patient procedure?
Comments	Is product order for restocking purposes?
Other Data Information Required to Process PO:	Miscellaneous Notes:
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:	