

Standard Pharmaceutical Product Information (Rx Product Only)

			intro	duction Type:	New Item		F	inal Version		Date:		
		F	RODUCT INFORMATION					SPECIAL HA	NDLING AND S	TORAGE REQU	IREMENTS*	
Company Name: AuroMedics Pharma LLC Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.						
Application Number fo			204657	Į.	7 .			Freezer – hetw	een -25 and -10	C (-13° – 14° F		
• • •	,	ou Device.	20.00.									
DUNS:	<u> </u>	I COMEDDA 7	DLE SODIUM FOR INJECT	II. Cold – between 2 and 8 C (36° – 46° F) III. Cool – between 8 and 15 C (46° – 59° F)								
Rx Product/Proprietary I	55150-185-05	ESUMEPRAZI	JLE SODIOW FOR INJECT	UPC:	355150185054		l —		,	,	77° F\	
NDC: CVX Code:	33130-163-03			MVX Code:	333130183034		<u>x</u> \			20 and 25 C (68° n 15 and 30 C (5	,	
									,	,		
Description: ESOMEPRAZOLE SODIUM FOR INJECTION 40mg/Vial							V. Avoid Excessive Heat – above 40 C (>104° F)					
							L v		rature Range Re	equirement		1
Active ingredients:								(write in)]
URL for Additional Product Information: www.auromedics.com						L v	II. No Requiren	ient				
		www.auromeu	CS.COIII									
Address:	6 Wheeling Road		Address 2:				b. Contact for temperature excursion questions:					
City:	Dayton			State: NJ Zip: 08810			Name: Steve Lucas					
Key Contact:	200 000 7000		Email:	700 055 0440				732-823-4122				
Phone Number: 888-238-7880			Fax: 732-355-9449				Is this product to be shipped to customers on ice?					-
		FOR	GENERIC DRUG PRODU	CTS			Is this produ	ict to be shippe	d to customers of	on dry ice?	No	_
I. Orange Book Rating:	AP		II. Brand Name:	Nexium								
III. Generic Equivalent for Brand: esomeprazole							c. Special reg	ulations for pr	oduct in certair	n states?	No	
			AIN SECURITY ACT (DSCSA) INFORMATION				Special retu	rne requiremen	ts for this produc	n+2	No	-
· · · · · · · · · · · · · · · · · · ·						Special retu	ins requiremen	is for this produc	J.:	INU	-	
Does supplier meet DSC	SA definition of man	ufacturer?	Yes									
Is product exempt from DSCSA? No		<u>_</u>				d. Store product (unit of sale) upright?				No	_	
If yes, select exemption:							Protect product (unit of sale) from light?				No	
Other exemption - Wri									,g			=
			If Yes, was original product purchased direct from mfr?				e. Shelf life:		Months			
Is product repackaged? Is product sold by manufacturer's exclusive distributor?			No				e. Silen ille.	Initial shalf li	fe at launch (if	different):		Months
Are any waivers granted			No	If yos attach	documentation from FDA			illitiai Sileli li	ie at launen (ii	amerenty.		WOILIIS
rac any manere grantes	p											
					documentation from PDA			ITEM AND	D BACKING INE	OPMATION		
			PRODUCT INFORMATION	N					PACKING INF			
Is the Product	Direct Ship Item	ADDITIONAL	PRODUCT INFORMATION	ORDER INFOR	RMATION		Weight Lbs.	Dim	nensions (US m	smts.)	Volume	# Pieces:
Legend Device?	Direct Ship Item	ADDITIONAL No	PRODUCT INFORMATION Unit of Sale	ORDER INFOR	RMATION IDC selling unit?□		Weight Lbs.				Volume (Cube)	# Pieces:
Legend Device? State Control?	Direct Ship Item	No No	Unit of Sale Bottle	ORDER INFOR What is the N 10 Vials in one	RMATION IDC selling unit? December 2015 and 2015	Item:	Weight Lbs.	Dim	nensions (US m	smts.)		# Pieces:
Legend Device? State Control? ARCOS reportable?	Direct Ship Item	No No No	Unit of Sale Bottle X Box/Carton	ORDER INFOR What is the N 10 Vials in one 55150-185-05	RMATION IDC selling unit? e Carton. The Carton NDC No. is		Weight Lbs.	Dim	nensions (US m	smts.)		# Pieces:
Legend Device? State Control? ARCOS reportable? Co-Licensed?	Direct Ship Item	No No No No	Unit of Sale Bottle Box/Carton Ampule	ORDER INFOR What is the N 10 Vials in one 55150-185-05	RMATION IDC selling unit? December 2015 and 2015	Box/	0.41120 (Carton	Dim Depth	nensions (US m Height	smts.) Width:		
Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance?	Direct Ship Item	No No No	Unit of Sale Bottle Box/Carton Ampule Glass	ORDER INFOR What is the N 10 Vials in one 55150-185-05 (Write-in, e.g.	RMATION IDC selling unit? e Carton. The Carton NDC No. is 1. 1 Box of 10 Vials)		0.41120 (Carton	Dim Depth	Height	smts.) Width:		Carton (10
Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.?	·	No No No No	Unit of Sale Bottle Sex/Carton Ampule Glass Tube	ORDER INFOR What is the N 10 Vials in one 55150-185-05	RMATION IDC selling unit? e Carton. The Carton NDC No. is 1.1 Box of 10 Vials)	Box/	0.41120 (Carton	Dim Depth	Height 1.97 (Carton contains 10	width:		Carton (10 Vials) 3 Ply Roy (Four 3 Ply
Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot	ic)	No No No No	Unit of Sale Bottle X Box/Carton Ampule Glass Tube Vial Liquid Sgl	ORDER INFOR What is the N 10 Vials in one 55150-185-05 (Write-in, e.g.	RMATION IDC selling unit? e Carton. The Carton NDC No. is 1 Box of 10 Vials) Ider quantity? Yes	Box/ Carton:	U.41120 (Carton	Dim Depth 5.12 (Carton contains 10 Vials) 11.811	Height 1.97 (Carton contains 10 Vials)	width: 2.05 (Canton contains 10 Vials) 11.811		Carton (10 Vials) 3 Ply Rox
Legend Device? State Control? ARCOS reportable? Co-Licensed? Controlled Substance? Schedule No.? (incl. N for non-narcot Controlled Substance Co	ic)	No No No No	Unit of Sale Bottle Box/Carton Ampule Glass Tube Vial Liquid Sgl Vial Liquid Multi	ORDER INFOR What is the N 10 Vials in one 55150-185-05 (Write-in, e.g.	RMATION IDC selling unit? e Carton. The Carton NDC No. is 1 Box of 10 Vials) Ider quantity? Yes Inany of which package type?	Box/ Carton:	0.41120 (Carton contains 10 10.458 700.904 (FUI	Dim Depth 5.12 (Calton contains 10 Vials)	Height 1.97 (Carton contains 10 Vials) 6.496 44.21 (For Sea)	width: 2.03 (Carton contains 10 Vials)		Carton (10 Vials) 3 Ply Box (Four 3 Ply Boxes gra20 (72 Shippers
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