

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014		Introduction Type: New Item				F	inal Version		Date:				
		PF	RODUCT INFORMATION						SPECIAL HAN	IDLING AND ST	TORAGE REQU	REMENTS*	
Company Name: AuroMedics Pharma LLC Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/ANDA/BLA, Med Device: 205520					I. Freezer – between -25 and -10 C (-13° – 14° F)								
Rx Product/Proprietary	lame.	ESMOLOL HYD	ROCHLORIDE INJECTIO	N 100 ma10 ml	(10 maml)				I. Cold – betwee	n 2 and 8 C (36°	, _ 46° F)		
NDC:	55150-194-10	LOMOLOLITID	TOOTILOTTIBL INGLOTIO	UPC:	355150194100			l —	II. Cool – betwee	,	,		
CVX Code:				MVX Code:						,	0 and 25 C (68°	– 77° F)	
Description:						allows for excursions between 15 and 30 C (59° – 86° F)							
Description: ESMOLOL HYDROCHLORIDE INJECTION TOO mg to mL (To mgmL)					V. Avoid Excessive Heat – above 40 C (>104° F)								
Active ingredients:					l —	/I. Other Tempe		, ,		-			
UPL Co. A LISCON I Production						(write in)	ant						
URL for Additional Product Information: Address: 6 Wheeling Road			Address 2:					VII. No Requirement					
Address: 6 Wheeling Road City: Dayton			Address 2:				b. Contact for temperature excursion questions:						
Key Contact:	Dayton		Email:	NJ Zip: 08810				Number:					
Phone Number:	888-238-7880		Fax:	732-355-9449	1				uct to be shipped	I to customers o	n ice?	No	
		FOR G	ENERIC DRUG PRODUCTS					uct to be shipped			No	_	
L Orongo Paris Batter	ΔD		_								•	110	_
I. Orange Book Rating: III. Generic Equivalent for	AP	I	II. Brand Name:					c Special rec	ulations for pro	nduct in certain	states?	No	
III. Generic Equivalent ic		CURRI V CUAII	AIN SECURITY ACT (DSCSA) INFORMATION							_			
	DRU	G SUPPLY CHAI	N SECURITY ACT (DSC	<u>'</u>				Special retu	rns requirement	s for this produc	t?	No	=
Does supplier meet DSC	SA definition of manuf		Yes	DUNS:	968961354								
Is product exempt from		No	_				d. Store product (unit of sale) upright?				No	_	
If yes, select exemption						_		Protect pr	oduct (unit of s	ale) from light?	•	Yes	=
Other exemption - Wri	te in:					1				-			
Is product repackaged?		No	If Yes, was original product purchased direct from mfr?				e. Shelf life:	24	Months			•	
Is product sold by manu			No No						Initial shelf li	fe at launch (if	different):		Months
Are any waivers granted	for product ID/barcode		No		documentation from	1 FDA							
		ADDITIONAL PI	RODUCT INFORMATION						ITEM AND	PACKING INFO	ORMATION		
Is the Product	Direct Ship Item			ORDER INFOR				Weight Lbs.	Dim	ensions (US m	smts.)	Volume	# Pieces:
Legend Device?		No	Unit of Sale		IDC selling unit?			TTOIGHT EDG.	Depth	Height	Width:	(Cube)	# T 10000.
State Control?		No	Bottle	25 vials in one	carton		Item:						
ARCOS reportable? Co-Licensed?		No No	x Box/Carton Ampule	(M/rito in o a	. 1 Box of 10 Vials)		Box/						
Controlled Substance?		No	Glass	(vviite-iii, e.g.	. I box of to viais)		Carton:	1.64 lbs	5.31 Inches	2.36 Inches	5.31 Inches		25 Vials
Schedule No.?			Tube	Minimum ord	ler quantity?	Yes	Case:	14.460 lbs	11.22 Inches	5.51 Inches	11.22 Inches		200 vials
(incl. N for non-narcot	,		Vial Liquid Sgl				Case:	14.460 IDS	11.22 Inches	5.51 Inches	11.22 Inches		(25x8)
Controlled Substance Co Hazardous Material/Cyto		No	Vial Liquid Multi Vial Powder Sql	If Yes, how m	nany of which package Each	ge type?	Pallet:	1074.16 lbs	48 Inches	44.21 Inches	40 Inches		72 Shippers
Trazar adus materiai, dyte	AOAIO AGOIR.		Vial Power Multi	8	Inner/Carton/Pack		LIBO	Case:					1
Is Item			Other: Write In	1	Case		UPC:	Carton:	35515019410	0			
If Unit Dose, is item bar co	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 customer?			ner?	Size/Strength/Form:			Regular Co	st Per Unit of	Invoice Cost (WAC) (\$)			cise Tax Per	
								Sai	e (\$)		ο. (11/10) (ψ)	Unit	of Sale
WHOLE	SALER USE ONLY:		(Write-in, e.g. 1	l Vial)	Product Shape:								
Vendor #:			Rx billing unit to pharm	acy:	Product Color:			\$110.00					
Whsl. Code #:			Each										
Fineline Code:			Gram		Product Imprint:					· -			
			Milliliter							As of date:	2/12/2016	<u> </u>	
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:								Signature:					



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

	WATERIAL	L HAZARD CLASSIFICATION at	IU TRANSFORTATIO	/19					
Is this product (check all that apply):									
a. Cytotoxic?	No								
	No								
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	No								
Carcinogen									
Reproductive Toxicant									
Both									
			He and a Mark	Libert Control					
Warning appears on label		Hazardous Waste Identification							
c. Contact Hazard?	No	EPA Hazardous Waste Code:							
d. Does this product require special clean-up instructions?	No		•				<u>-</u> -		
(If yes, attach SDS with special instructions.)									
e. Does the product contain DEHP?	No								
e. Does the product contain DETT:	140								
Is this product regulated for shipment by the DOT?	No	(if yes, answer a-d below	and provide SDS)						
is this product regulated for shipment by the DOT:	140		and provide 3D3)						
		a. DOT Hazard Class							
Is this a reportable quantity?		b. UN/ID Number							
RQ Threshold:		 c. Packing Group 							
Is this a marine pollutant?		d. Inhalation Hazard?							
Is this product shipped utilizing an authorized DOT exception or Special Permit	2								
	:								
(if yes, identify method below)									
Limited Quantity			ADDITIONAL	PRODUCT INFO	ORMATIO	N - Serialization	on		
Consumer Commodity, ORM-D			<u></u>	Level		How?		GTIN-14	
l ——		0		Titem [2D	Linear	RFID	10355150194107	
Small Quantity (49 CFR 173.4)		Serialized?							
Special Permit; DOT-SP		If not, when?		Box/Carton	2D	Linear	RFID	00355150221004	
Special Provision (listed in Column 7 of 49 CFR 172.101);		Items aggregated to case?		Case	2D	Linear	RFID	50355150221009	
SP#				Pallet	2D	Linear	RFID	70355150221003	
			<u> </u>						
Is the product restricted for air shipment? If so, indicate restriction:		REMS or REGISTRY RESTRICTIONS							
Bossenger		le there e DEMC on this produc	a+?						
Passenger		Is there a REMS on this product?							
Cargo	If Yes, is it managed with a pharmacy registry?								
Passenger & Cargo	Website URL:								
ADD'L STORAGE INFORMATION	Comments / Details: (For example, iPledge program?)								
		Commente / Betaile: (1 of exam	inplo, il lougo program	.,					
Please check as appropriate for this product.									
Organic Inorganic									
Antineoplastic Steroid/Androgen									
Corrosive Oxidizer									
Assess Class Identify NEDA Characa Laval			RETURN INST	DUCTION	•				
Aerosol Class; Identify NFPA Storage Level:		<u> </u>	KETUKNINST	RUCTION	ა				
		Contact tel. # if product receive	•						
	Is product returnable for credit:								
Listed Chemical (List I or II) (Indicate or Write-in below):	URL/Link to returns policy:								
Ephedrine	Special regulations or returns requirements for this product in certain states?								
l <u> </u>	If so, which states? Other requirements? Comments?								
Pseudoephedrine	ii so, which states? Other requ	inements? Comments) <u>f</u>						
Phenylpropanolamine									
Iodine (≥2.2%)									
Other:									
CLASS OF TRADE RESTRICTION:				ADDITIONAL IN	FORMATI	ON			
						···			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	If Unit Dose NDC, indicate ND	C here:							
Restricted to retail pharmacy only:	MISCELLANEOUS NOTES and/or Image of Product Barcode:								
Restricted to hospital, clinics, and physician offices only:									
Restricted from US territories? (explain in comments)									
Comments:									
CONTINUENTS.									



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 Fax Number: c. Fax Fax Number: d. Phone only Phone No.:	Shipping lead time of PO: Hours Days					
e. Supplier Web Site only Minimum 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					
	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: REMS Program Manager Name: Phone:	Contact # if product is received damaged:					
Supplier Manages REMS registry exclusively:	Is product returnable for credit: URL/Link to returns policy:					
Wholesale distributor support:	Special regulations or returns requirements for this product in certain states?					
Provider Name:	If so, which states? Other requirements? Comments?					
Site Enrollment Number assigned by Supplier: DEA #: PCPDP #: NPI #:						
Comments:						
Registry:	ADDITIONAL INFORMATION					
Registry Program Contact Name: Phone: Comments	Is product order for scheduled patient procedure? Is product order for restocking purposes?					
Other Data Information Required to Process PO:	Miscellaneous Notes:					
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician/Clinic DEA #: Physician/Clinic Specialty:						