

Version 2020						Introduction Type:	New Item]	1 Final Versi	on		Date:	21.SEF	P.2020	
			PRODUCT INFORMA	TION					SPECIA	L HANDLING AND STO	RAGE REQUI	REMENTS*			
Company Name: AuroMedics Pharma LLC Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 209666								Temperature Range	Controlled Room	– between 20	and 25 C (68	s° – 77° F)			
DUNS:	968961354							_	Other Temperature I	Range Requirement			re 25°C (77°F)		
Proprietary Name (If Applicable) a	and Established Name: Milrinone Lactate in 5% Dextrose Injection 20mg/100mL [200mcg (0.2mg)/mL]							brief exposure up to 40°C (104°F) does not							
Selling Unit NDC:	55150-287-10		Unit of Use NDC:		55150-287-01		50287109	41	Notes						
UDI			CVX Code:			MVX Code:		<u> </u>							
Description: Milrinone Lactate in 5% Dextrose Injection 20 mg per 100 mL [200 mcg (0.2 mg)/mL] - Infusion bag Is this product to be shipped to customers on ice? No Is this product to be shipped to customers on dry ice? No															
Active Ingredient(s): Is this product to be shipped to customers on dry ice? No															
								b. Contact for	temperature excurs	ion questions:					
URL for Additional Product Inforr					1				Name:		732-823-41				
Address:	279 Princeton-Hightstov East Windsor	vn Road				Address 2: State: NJ Zip: 08520			Number:				·m		
City: Key Contact:	Edst Willusui				Email:	NJ ZIP	06520	Group E-mail: slucas@aurobindousa.com							
Phone Number:	888-238-7880				Fax:	732-355-9449		c. Special reg	ulations for product	in any states?			No		
Product Therapeutic Classification	n: Card	liac Agent – Pho	osphodiesterase Inhibitor					-	Special returns requ	rements for this product?			No		
Oppositi rotatilo rodali ottorito i allo product:															
	ADDITIONAL I	PRODUCT INF	ORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store produ	d. Store product (unit of sale) upright?						
The product is?			Is the Product	Direct-Ship C	Only				Protect product (ur	it of sale) from light?			No		
a legend device?	No		Is the Product	Neither		Size:	10 x 100 mL Single Dose Flexible Containers	e. Shelf life:					24	Months	
if yes, enter class # a product kit?	NI-		Orphan Drug Status	_					Initial shelf life at la	unch (if different):				Months	
if yes, list NDCs of	No		FDA Approval Status			Strength:	20 mg per 100 mL [200 mcg (0.2 mg)/mL]			ORDER INFOR	MATION				
component parts			. Dr. rippi o vai otatao				LIQUID								
reverse numbered?	No					Dosage Form:			Unit of Sale			NDC selling	unit?		
co-licensed?	No		Allergens Present						Bottle		1 case of 10				
latex-free? preservative-free?	Yes					Product Shape:	Infusion Bag		X Box/Cartor	l	(Write-in, e	.g. 1 Box of 1	0 Vials)		
correctional institution block?	Yes No								Ampule Glass		Minimum o	rder quantity	v2	Yes	
opioid?	No					Product Color:			Tube		······································	ruer quartit	·· .	103	
Cannabinoid?	No		Country of Origin	India		Product Imprint:			Vial Liquid	Sgl					
If Unit Dose, is item bar coded to u	unit dose for hospital					Froduct imprint.			Vial Liquid		If Yes, how		ich package t	ype?	
scanning?			Is this product covered u Trade Agreements Act (1)						Vial Powde			Each			
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	AA)!	No				Vial Power Other: Wri		1	Inner/Cartor Case	/Pack		
			FOR GENERIC DRUG PR	ODUCTS				<u> </u>	Outer: Wil		+	Joase			
FOR GENERIC DRUG PRODUCTS															
Authorized Generic *If Authorized Generic, other section										PHARMACY ORDER / BILL UNIT					
I. Orange Book Rating: AP fields are not applicable							Rec. sell unit	to customer?		Rx billing u	ınit to pharm	acy:			
II. Generic Equivalent to What Brand?: Primacor® in Dextrose 5% in Plastic Container								1 bag		x	Each				
(Write-in, e.g. 1 Vial)															
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION Milliliter															
Does supplier meet DSCSA defin	ition of manufacturer?		Yes	GL	.N:					ITEM AND PACKING	INFORMATIO	N			
Is product exempt from DSCSA? No															
If yes, select exemption:				_					181-1-1-1	Dimens	sions (US msi	nts.)	Volume	# D!	
Other exemption - Write in:									Weight	LDS. Depth	Width	Height	(Cube)	# Pieces:	
Is product repackaged?			No			nal product purchased		Item/Each:	0.374	28 6.81	5.31	0.68	24.589548	1	
Is product sold by manufacturer's Has FDA granted waiver/exceptio			No No	_	ect from mfr?	cumentation from FDA.		Box/Carton/B	undle/						
has FDA granted waiver/exceptio	invexemption for produc		NO	_ " '	es, attach dot	cumentation from FDA.		Inner Pack:	0.418	32 9.84	6.5	0.68	43.4928	1	
		GTIN	AND HIBCC PRODUCT II	NFORMATION				Case:	5.43	4 40.4	0.405	0.00	700 04574	40	
									5.17	4 12.4	8.465	6.89	723.21574	10	
Saleable Unit of Measure	Qua		HIBCC		GTIN-		Unit of Use GTIN-14	Pallet:	612.5	06 48	40	53.23	102201.6	1120	
								0121000 10 10 10 10 1120							
Box/Carton/Bundle/Inner Pack: 1 5035515028/104 x Case 10 5035515028/104							COST INFORMATION WHOLESALER USE ONLY:								
Pallet		120				150287108									
								Regular Cost			Vendor #:				
								Invoice Cost	(WAC) (\$)	\$152.00					
	+ -							As of date:			Fineline Co	oae:			
								As or uate.							
1			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza	ard letter, PACKAGE INS	ERT, LABEL AND PHOTO OF	PRODUCT PACK	AGING and BARCOD	E.	-1				
*Please provide any additional inf	formation on page 2			,02	,		gnated Drop Ship Only.		Signature:			Aravinda	Kumar A.		



Version 2020 For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): SDS Hazard Classification a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No Organic Corrosive No Inorganic Oxidizer Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? No Steroid/Androgen Contact Hazard Aerosol Class; Identify NFPA Storage Level: c. Contact Hazard? No d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) Is the product a NIOSH hazardous drug? e. Does the product contain DEHP? If yes, indicate which: Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) Hazardous Waste Identification a. UN/Identification Number b. Proper Shipping Name EPA Hazardous Waste Code: c. DOT Hazard Class Waste Characteristics d. Packing Group e. Inhalation Hazard? Is this product regulated for shipment by IATA? REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? (if ves. answer a-e below and provide SDS) a. UN/Identification Number If Yes, is it managed with a pharmacy registry? Website URL: b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? Med Guide Required Is the product restricted for air shipment? If so, indicate restriction: Limited Distribution Requirement Passenger Comments / Details: (For example, iPledge program?) Cargo Passenger & Cargo Is this a reportable quantity? REMS: RQ Threshold: REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit? Wholesale distributor support: (if yes, identify method below) Provider Name: DEA# Limited Quantity Site Enrollment Number assigned PCPDP# Consumer Commodity, ORM-D by Supplier: NPI#: Small Quantity (49 CFR 173.4) Special Permit: DOT-SP Comments Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Registry: Phone: Registry Program Contact Name: ADD'L STORAGE INFORMATION Comments Is the Product... RETURN INSTRUCTIONS Controlled Substance? Controlled Substance Code Controlled by State(s)? Listed Chemical (List I or II) ARCOS Reportable? If yes, indicate which: Contact tel. # if product received damaged: 888-238-7880 Schedule No. Is it a scheduled listed chemical product?: Yes Is product returnable for credit: CLASS OF TRADE RESTRICTION: URL/Link to returns policy: http://auromedics.com/policies/return-policy/ No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes Restricted to retail pharmacy only: No Special regulations or returns requirements for this product in certain states? No Restricted to hospital, clinics, and physician offices only: If so, which states? Other requirements? Comments? Restricted from US territories? (explain in comments) Comments: MISCELLANEOUS NOTES and/or Image of Product Barcode



Version 2020

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 b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:							
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 Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: Fax #: Covernight Fees apply: Other fees apply:							
Other Data Information Required to Process PO:	Return Instructions							
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty: Miscellaneous Notes:	Contact # if product is 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?							
	ADDITIONAL INFORMATION							
	Is product order for scheduled patient procedure? Is product order for restocking purposes?							



Version 2020						Introduction Type:	New Item]	1 Final	Version			Date:	21.SEF	P.2020
			PRODUCT INFORMA	TION					SF	PECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name: AuroMedics Pharma LLC Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 209666]	Temperature R	ange	Controlled Room -	between 20	and 25 C (68	° – 77° F)		
DUNS:	968961354							_	Other Tempera	ture Range F	Requirement			e 25°C (77°F)	
Proprietary Name (If Applicable) a		me: Milrin	one Lactate in 5% Dextrose I	njection 40 mg/		cg (0.2 mg)/mL]			(write in)			brief exposu	re up to 40°C	(104°F) does	not
Selling Unit NDC:	55150-288-10		Unit of Use NDC:		55150-288-01		0288106	41	Notes						
UDI			CVX Code:			MVX Code:		41							
Description:	Milrinone Lactate in	n 5% Dextrose Inj	ection 40 mg/200 mL [200 mc	g (0.2 mg)/mL]	- Infusion bag						to customers on ic			No	
Active Ingredient(s): Milrinone Lactate Is this product to be shipped to customers on dry ice? No															
								b. Contact for	r temperature e	xcursion qu	estions:	-			
URL for Additional Product Inform Address:		stateur Daad				Address 2:		41	Name: Number:			Steve Lucas 732-823-412			
City:	279 Princeton-Hightstown Road East Windsor				State:				Group E-mail:				obindousa.co	m	
Key Contact:					Email:		111111	Stoup E mail.							
Phone Number:	888-238-7880				Fax:	732-355-9449		c. Special reg	ulations for pro	oduct in any	states?			No	
Product Therapeutic Classificatio	n:	Cardiac Agent – F	Phosphodiesterase Inhibitor						Special returns	requirement	s for this product?			No	
	ADDITION	NAL PRODUCT IN				PRODUCT DESC	RIPTION INFORMATION	d. Store prod	uct (unit of sale					No	
The product is?			Is the Product	Direct-Ship (Only		10 100 10: 10		Protect produ	ct (unit of sa	ale) from light?			No	
a legend device? if yes, enter class #		No	Is the Product Orphan Drug Status	Neither		Size:	10 x 100 mL Single Dose Flexible Containers	e. Shelf life:	Initial shelf life	at launch (i	if different\:			24	Months Months
a product kit?		No	Orphian Drug Status				40 mg/200 mL [200 mcg		illitiai Sileli illi	at laulich (i	ii uiiieieiit).				WOTHIS
if yes, list NDCs of			FDA Approval Status			Strength:	(0.2 mg)/mL]				ORDER INFORM	ATION			
component parts						Dosage Form:	LIQUID								
reverse numbered?		No							Unit of Sale				NDC selling	unit?	
co-licensed? latex-free?		No Yes	Allergens Present				Infusion Bag		X Box/0	e Carton		1 case of 10	g. 1 Box of 1) \/iale)	
preservative-free?		Yes				Product Shape:	midolon bag		Ampi			(**************************************	g. 1 box of 1	o viais)	
correctional institution block?		No				Product Color:			Glass			Minimum o	rder quantity	?	Yes
opioid?		No				Froduct Color.			Tube						
Cannabinoid?		No	Country of Origin	India		Product Imprint:				iquid Sgl					
If Unit Dose, is item bar coded to u scanning?	unit dose for hospital		Is this product covered u	nder the						iquid Multi Powder Sql		If Yes, now	many of whi Each	ch package t	ype?
If Unit Dose, indicate NDC here:	İ		Trade Agreements Act (T		No					Power Multi			Inner/Carton	/Pack	
	ļ									r: Write In		1	Case		
FOR GENERIC DRUG PRODUCTS															
Authorized Generic *If Authorized Generic, other section fields are not applicable										PH	ARMACY ORDER				
I. Orange Book Rating: II. Generic Equivalent to What Brand?: Primacor® in Dextrose 5% in Plastic Container						licius	Rec. sell unit to customer?				Rx billing unit to pharmacy: x Each				
II. Generic Equivalent to What Brand?: Primacor® in Dextrose 5% in Plastic Container I bag (Write-in, e.g. 1 Vial) Gram															
		DRUG SUPP	LY CHAIN SECURITY ACT (DSCSA) INFO	RMATION			(Willo III, Olg.	·····				Milliliter		
Does supplier meet DSCSA defini Is product exempt from DSCSA?	ition of manufacture	er /	Yes No	_ GL	-N:					IIEM	AND PACKING IN	FORMATION	V		
If yes, select exemption:			110	_				-			Dimensi	ons (US msm	nte \	Volume	
Other exemption - Write in:	ĺ								W	eight Lbs.	Depth	Width	Height	(Cube)	# Pieces:
Is product repackaged?	ļ		No			nal product purchased		Item/Each:		0.37428	8.39	5.31	0.79	35.195211	1
Is product sold by manufacturer's			No		ect from mfr?					0.37420	0.39	5.51	0.79	33.193211	'
Has FDA granted waiver/exceptio	n/exemption for pro	oduct?	No	If y	es, attach doo	cumentation from FDA.		Box/Carton/B	Bundle/	0.41832	11.42	6.89	0.79	62.160202	1
		GT	IN AND HIBCC PRODUCT IF	JEOPMATION				Inner Pack: Case:							
		- 31	IN AND THE COT NO DOCT II	II OKWATION				Case.		5.174	12.4	8.465	6.89	723.21574	10
Saleable Unit of Measure		Quantity	HIBCC		GTIN-	14	Unit of Use GTIN-14	Pallet:		612.506	48	40	53,23	102201.6	1120
Item/Each		1				150288101	50355150288101			012.500	40	40	55.25	102201.0	1120
Box/Carton/Bundle/ Inner Pack: 1 50355150288101 50355150288101							COST INFORMATION WHOLESALER USE ONLY:								
X Case Pallet	┪	1120				150288101			COST INFO	JAWATION			WHOLESAL	ER USE UNL	ı. —
	1	25						Regular Cost				Vendor #:			
								Invoice Cost			\$304.00	Whsl. Code			
												Fineline Co	de:		
								As of date:							
1			Attach conv of SAFETY DA	TA SHEET (ST	S) or non haza	ard letter PACKAGE INICI	ERT, LABEL AND PHOTO OF	DBUDITET DVCR	AGING and BAE	CODE		l			
*Please provide any additional inf	formation on page 3	2	ALLACTICOPY OF SAFETY DA	IIA OHEET (OL	o non naza		nated Drop Ship Only.	. NODOGI FACK	Signature:	CODE.			Aravinda	Kumar A.	



Version 2020 For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): SDS Hazard Classification a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No Organic Corrosive No Inorganic Oxidizer Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? No Steroid/Androgen Contact Hazard Aerosol Class; Identify NFPA Storage Level: c. Contact Hazard? No d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) Is the product a NIOSH hazardous drug? e. Does the product contain DEHP? If yes, indicate which: Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) Hazardous Waste Identification a. UN/Identification Number b. Proper Shipping Name EPA Hazardous Waste Code: c. DOT Hazard Class Waste Characteristics d. Packing Group e. Inhalation Hazard? Is this product regulated for shipment by IATA? REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? (if ves. answer a-e below and provide SDS) a. UN/Identification Number If Yes, is it managed with a pharmacy registry? Website URL: b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? Med Guide Required Is the product restricted for air shipment? If so, indicate restriction: Limited Distribution Requirement Passenger Comments / Details: (For example, iPledge program?) Cargo Passenger & Cargo Is this a reportable quantity? REMS: RQ Threshold: REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit? Wholesale distributor support: (if yes, identify method below) Provider Name: DEA# Limited Quantity Site Enrollment Number assigned PCPDP# Consumer Commodity, ORM-D by Supplier: NPI#: Small Quantity (49 CFR 173.4) Special Permit: DOT-SP Comments Special Provision (listed in Column 7 of 49 CFR 172.101); SP# Registry: Phone: Registry Program Contact Name: ADD'L STORAGE INFORMATION Comments Is the Product... RETURN INSTRUCTIONS Controlled Substance? Controlled Substance Code Controlled by State(s)? Listed Chemical (List I or II) ARCOS Reportable? If yes, indicate which: Contact tel. # if product received damaged: 888-238-7880 Schedule No. Is it a scheduled listed chemical product?: Yes Is product returnable for credit: CLASS OF TRADE RESTRICTION: URL/Link to returns policy: http://auromedics.com/policies/return-policy/ No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes Restricted to retail pharmacy only: No Special regulations or returns requirements for this product in certain states? No Restricted to hospital, clinics, and physician offices only: If so, which states? Other requirements? Comments? Restricted from US territories? (explain in comments) Comments: MISCELLANEOUS NOTES and/or Image of Product Barcode



Version 2020

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 b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:							
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 Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: Fax #: Covernight Fees apply: Other fees apply:							
Other Data Information Required to Process PO:	Return Instructions							
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty: Miscellaneous Notes:	Contact # if product is 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?							
	ADDITIONAL INFORMATION							
	Is product order for scheduled patient procedure? Is product order for restocking purposes?							