

# **Standard Pharmaceutical Product Information (Rx Product Only)**

						Introduction	n Type:	New Item			Final Version			Date:				
			PRODUCT INFORMAT	ION							SPECIAL HANDLI	NG AND ST	ORAGE REQ	UIREMENTS	*			
Company Name:	AuroMedics Pharma L	LC				A	pplication:	ANDA	a. Tempe	erature – Indic	ate the USP tempera	ture range f	or this produ	ıct.				
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):									ature Range				en 20 and 25	C (68° – 77° I				
DUNS:										Other Te	emperature Range Re	quirement						
Proprietary Name (If Applica	ble) and Established N	Name: Mero	penem for Injection USP, 1 g								rite in)					1		
Selling Unit NDC:	55150-208-30		Individual Unit NDC:			UPC	355150208	302								='		
UDI CVX Code: MVX Code:								Is this product to be shipped to customers on ice?  No										
Description: Meropenem for Injection USP, 1 g								Is this product to be shipped to customers on dry ice?  No										
							b. Contac	b. Contact for temperature excursion questions:										
										Name:			Steve Lucas					
URL for Additional Product I		www.auromedics.cor	n							Number			732-823-412	22				
Address: City:	279 Princeton-Hightste East Windsor	own Road			_	Address 2:	Zip:	08520	_	Group E	:-mail:							
Key Contact:	East Willusui				Email:	NJ	zip.	06320	c Specia	al regulations	for product in any st	ates?			No			
Phone Number:	888-238-7880					732-355-9449			c. Special regulations for product in any states?  Special returns requirements for this product?  No									
Product Therapeutic Classifi	ication:				<u>L</u>				<b>-</b>		·	·				-		
•									d. Store	d. Store product (unit of sale) upright?  Yes								
ADDITIONA	AL PRODUCT INFORM	ATION			PRO	ODUCT DESCR	RIPTION INFOR	MATION			product (unit of sale	) from light?			No	_		
Is the Product									e. Shelf I	e. Shelf life:				24 Mont				
a legend device?		No		Size:						Initial sh	nelf life at launch (if	different):				Months		
reverse numbered?		No	_	Oize.	•											•		
co-licensed? Is the Product		No No	_	Stren	ngth:						0	RDER INFO	RMATION					
Is the Product		Direct-Ship Only	_						-	Unit of S	Sale		What is the	NDC selling	unit?			
			_	Dosa	age Form:						Bottle				he Carton ND	C No. is		
If Unit Dose, is item bar code	ed to unit dose for hospi	tal scanning?							<b>-</b>	х	Box/Carton		(Write-in, e	g. 1 Box of 1	0 Vials)			
•	·	g-	_	Prod	luct Shape:						Ampule		Minimum			Vee		
If Unit Dose NDC, indicate N	DC nere:		_						-		Glass Tube		winimum o	rder quantity	,,,	Yes		
Country of Origin		India		Prod	luct Color:					Vial Liquid Sgl								
Is this product covered under the Trade Agreements Act (TAA)?								Vial Liquid Multi If Yes, how many of which package type? Vial Powder Sql Each										
No No							<b>-</b>		Vial Powder Sqi Vial Power Multi		10	Eacn Inner/Cartor	/Pack					
									Other: Write In			Case	ar don					
FOR GENERIC DRUG PRODUCTS													•					
					Authoria	zed Generic	*If A th a size	ed Generic, other section			DUAD	MACY ORDE	ER / BILL UN	T				
I Occurre Barata Bartana	AP				Authoriz	zea Generic	fields are no											
II. Generic Equivalent to Wha	ange book Rating:					Rec. seii	Rec. sell unit to customer?				Rx billing unit to pharmacy:							
							(Write-in	, e.g. 1 Vial)		J		Gram						
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION Milliliter																		
Dana aumulian maat DCCCA			Yes	GLN:	Tr.	0355150000005			_		ITEM AN	ID BACKING	INFORMAT	ION				
Does supplier meet DSCSA of Is product exempt from DSC		urer ?	No	GLN:		J355 15000000C	)			ITEM AND PACKING INFORMATION								
If yes, select exemption:			·							Weight Lbs.			Dimensions (US msmts.) Volume # Pieces:					
Other exemption - Write in:											weight Lbs.	Depth	Height	Width	(Cube)	# Fleces.		
Is product repackaged?			No	If Yes, w		product purch	ased direct		Item:						0			
Is product sold by manufactu Has FDA granted waiver/exc			No No			entation from	FDA		Box/Cart	ton/Bundle/		0.37	3.02	2.04				
Tido I Diri grantou marronoxo	option, oxomption for [			,00, a.	ilaon aooaiii				Inner Pa		2 (Carton contains 1)	(Carton	(Carton	(Carton	#VALUE!	arton (10 Vial		
			GTIN PRODUCT INFORM	ATION					Case:		7.97	13.976	8.661	7.283	881.579008	(10 Cartons		
				saleable				0711144				10.070	40.31 (FU	7.200	001.010000	or 100 Wigles		
Serialized?			Level	Unit	72D F	Linear	Quantity	GTIN-14 00355150208302	Pallet:		630.794 (For Sea) 750.330 (For Air)	48	Sea)	40	#VALUE!	(75 Shippers		
If not, when?			Box/Carton/Bundle/Inner Pack		2D	Linear	10355150208302		UPC:		Case:		56 97 (For	l	l .	or 750		
Items aggregated?			Case		2D	Linear		50355150208307			Carton:	355150208	302					
Pallet 2D Linear 70355150208301																		
	2D Linear 2D Linear						COST INFORMATION				WHOLESALER USE ONLY:							
	2D Linear 2D Linear					Regular	Cost			Vendor#:								
	2D Linear						Invoice Cost (WAC) (\$) \$290.00			<del>-</del>								
							Federal Excise Tax Per Unit of Sale Fineline Code:											
			<u> </u>						As of date	e:	3/20/2017		1					
*Blooco provide env edd":	al information on	• 2	Attach copy of SAFETY DATA	SHEET (SDS) or					KODUCT PACE									
*Please provide any addition	iai imormation on pag	t 2.			:	see new p. 3 to	n pesignated t	Orop Ship Only.		Signatu	ie.							



### **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): 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 Is the product a CA Prop 65 reproductive toxicant? No Inorganic Oxidizer Does the product label bear a CA Prop 65 warning? No Steroid/Androgen Contact Hazard c. Contact Hazard? No Aerosol Class; Identify NFPA Storage Level: 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? No If yes, indicate which: Is this product regulated for shipment by DOT or IATA? No (if yes, answer a-e below and provide SDS) a. UN/Identification Number Hazardous Waste Identification b. Proper Shipping Name c. DOT Hazard Class EPA Hazardous Waste Code: d. Packing Group e. Inhalation Hazard? REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: Passenger Is there a REMS on this product? Cargo If Yes, is it managed with a pharmacy registry? Passenger & Cargo Website URL: Is this a reportable quantity? RQ Threshold: Comments / Details: (For example, iPledge program?) Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) REMS: REMS Program Manager Name: Limited Quantity Phone: Consumer Commodity, ORM-D Supplier Manages REMS registry exclusively: Small Quantity (49 CFR 173.4) Wholesale distributor support: Special Permit: DOT-SP Provider Name: Site Enrollment Number assigned Special Provision (listed in Column 7 of 49 CFR 172.101); DEA #: by Supplier: SP# PCPDP #: NPI#: ADD'L STORAGE INFORMATION Is the Product... Comments Controlled Substance? No Controlled by State(s)? No Registry: ARCOS Reportable? No Registry Program Contact Name: Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code Listed Chemical (List I or II) No RETURN INSTRUCTIONS If yes, indicate which: Is it a scheduled listed chemical product?: No Contact tel. # if product received damaged: CLASS OF TRADE RESTRICTION: Is product returnable for credit: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices URL/Link to returns policy: Restricted to retail pharmacy only: Special regulations or returns requirements for this product in certain states? 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:



## **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 d. Phone only e. Supplier Web Site only  Fax Number: Phone No.: Site Address:	Shipping lead time of PO: Hours Days  Ships same day for next day receipt:						
Minimum Order Quantity:  Supplier's Customer Service Number:  Contracted 3PL company / contact #:  Phone:	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: EDI:  Overnight 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:	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?						
Miscellaneous Notes:							
	ADDITIONAL INFORMATION						
	Is product order for scheduled patient procedure? Is product order for restocking purposes?						



# **Standard Pharmaceutical Product Information (Rx Product Only)**

					Introduction	n Type:	New Item		Final Version			Date:					
			PRODUCT INFORMATION						SPECIAL HANDLI	NG AND STO	DRAGE REQ	UIREMENTS	S*				
Company Name:	AuroMedics Pharma L	LC			Ap	oplication:	ANDA	a. Temperature - Indic	ate the USP tempera	ature range f	or this produ	ıct.					
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):							Temperature Range Controlled Room – between 20 and 25 C (68° – 77° f										
ouns:						Other Temperature Range Requirement											
Proprietary Name (If Applica	roprietary Name (If Applicable) and Established Name: Meropenem for Injection USP, 500 mg							(write in)									
Selling Unit NDC:	55150-207-20		Individual Unit NDC:		UPC:	35515020720	06										
UDI CVX Code: MVX Code:						Is this product to be shipped to customers on ice?  No											
Description: Meropenem for Injection USP, 500 mg								Is this product to be shipped to customers on dry ice?  No									
Active Ingredient(s):								b. Contact for tempera Name:	ture excursion ques	tions:	Steve Lucas						
URL for Additional Product Information: www.auromedics.com				Number			732-823-4122										
Address:							Group E	<del>-</del>									
City:	East Windsor			State:	NJ	Zip:	08520							•			
Key Contact:				Email:				c. Special regulations					No	_			
Phone Number:	888-238-7880			Fax:	732-355-9449			Special returns requirements for this product?  No									
Product Therapeutic Classifi	cation:																
ADDITIONA	L PRODUCT INFORM.	ATION	1		PRODUCT DESCR	IDTION INFORM	MATION	d. Store product (unit of sale) upright?  Protect product (unit of sale) from light?  No									
	LET ROBOOT IN ORIM	ATION	1	ATION	1	, iroin iigiit:	24										
Is the Product a legend device?		No	1					e. Shelf life:	nelf life at launch (if o	difforont).			24	Months Months			
reverse numbered?		No	1	Size:				Illitial Si	ien me at launtin (ii t	unierent).				WOITIIS			
co-licensed?		No	1	Strongth	ORDER INFORMATION												
Is the Product		Direct-Ship Only	1	Strength:													
Is the Product			1	Dosage Form	:			Unit of S	-1		What is the			O Nie de			
			1					x	Bottle Box/Carton			g. 1 Box of 1	he Carton ND	C NO. IS			
If Unit Dose, is item bar code	d to unit dose for hospi	tal scanning?	1	Davidson Observ				-	Ampule		(vviite iii, e.	.g. 1 Dox 01 1	o viais)				
If Unit Dose NDC, indicate N	DC here:		1	Product Shap	e:			Glass Minimum order quantity? Yes					Yes				
	Ī	India	1	Product Colo	r:				Tube								
Country of Origin			1					Vial Liquid Sgl Vial Liquid Multi If Yes, how many of which package type?									
Is this product covered under the Trade Agreements Act (TAA)? No Product Imprint:								Vial Powder Sql		11 103, 110	Each	ion package	type.				
									Vial Power Multi		10	Inner/Cartor	/Pack				
FOR GENERIC DRUG PRODUCTS								Other: Write In	7		Case						
			FOR GENERIC DRUG PRODUCTS	•						1							
				Auth	orized Generic	*If Authorized	Generic, other section	PHARMACY ORDER / BILL UNIT									
I. Orange Book Rating:	AP			<u></u>		fields are not	applicable	Rec. sell unit to custor		Rx billing unit to pharmacy:							
II. Generic Equivalent to What Brand?:				·							Each						
DRIJE CURRI.)			( OUATH DEGUEETY 4 OF (DOGGA)	INFORMATION				(Write-in, e.g. 1 Vial)				Gram					
		DRUG SUPPLY	Y CHAIN SECURITY ACT (DSCSA)	INFORMATION								Milliliter					
Does supplier meet DSCSA definition of manufacturer?  Yes  GLN:  0355150000005									ITEM AND PACKING INFORMATION								
Is product exempt from DSC	SA?	N	No		-												
If yes, select exemption:	Ī								Weight Lbs.		ensions (US msmts.)		Volume	# Pieces:			
Other exemption - Write in: Is product repackaged?	ļ		No	If Yes, was origin	al product purcha	sed direct		Item:		Depth	Height	Width	(Cube)				
Is product sold by manufactu	urer's exclusive distrib			from mfr?	ai product parena	iscu un cot		liciii.					0				
Has FDA granted waiver/exc	eption/exemption for p	product?	No	If yes, attach doc	umentation from I	FDA.		Box/Carton/Bundle/	3 (Carton contains 10	Carton	(Carton	(Carton	#VALUE!	arton (10 Vial			
			OTIN PROPUST INFORMATION					Inner Pack:	o (ourton contains 1)	contains 10	contains 10	contains 10	#V/ILOL:	Case			
			GTIN PRODUCT INFORMATION Saleable					Case:	6.557	13.976	7.48	7.283	761.368316	(10 Cartons			
			Level Unit			Quantity	GTIN-14	Pallet:	524.783 (For Sea)		42.40 (FOI	- 10		or 100 Yégle)			
Serialized?			Item	2D	Linear		00355150207206		721.466 (For Air)	48	Sea) 57.36 (For	40	#VALUE!	(75 Shippers			
If not, when?			Box/Carton/Bundle/Inner Pack	2D	Linear		10355150207203	UPC:	Case:								
Items aggregated?			Case Pallet	2D	Linear		50355150207201	Carton: 355150207206									
		<b>├</b> ─┤┌	railet	2D 2D	Linear		70355150207205	COST	INFORMATION			WHOLESAL	ER USE ONI	Y:			
	2D Linear									MIGEORET GOL ONLI.							
	ZD Linear					Regular Cost			Vendor #:								
			2D Linear							) Whsl. Code #:							
							Federal Excise Tax Per Unit of Sale Fineline Code:  As of date: 3/20/2017			de:							
								As of date:	3/20/2017		ł						
		At	ttach copy of SAFETY DATA SHEE	T (SDS) or non haz	ard letter, PACKAG	SE INSERT, LAB	EL AND PHOTO OF PRO	DDUCT PACKAGING and B	ARCODE.		•						
*Please provide any addition	al information on page		**		See new p. 3 fo			Signatu									



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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 d. Phone only e. Supplier Web Site only  Fax Number: Phone No.: Site Address:	Shipping lead time of PO: Hours Days  Ships same day for next day receipt:						
Minimum Order Quantity:  Supplier's Customer Service Number:  Contracted 3PL company / contact #:  Phone:	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: EDI:  Overnight 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:	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?						
Miscellaneous Notes:							
	ADDITIONAL INFORMATION						
	Is product order for scheduled patient procedure? Is product order for restocking purposes?						