

Standard Pharmaceutical Product Information (Rx Product Only)

						Introduc	tion Type:	New Item			Final Version			Date:	1/1/2	019
			PRODUCT INFORMA	TION						1	SPECIAL HANDL	ING AND ST	ORAGE REQ	UIREMENTS	j*	
Company Name: Auromedics Pharma LLC ANDA Application: ANDA								A I	a. Temperature – Indicate the USP temperature range for this product.							
Application Number for ND	A/ANDA/BLA (drug);	PMA/510(k)(med dev	vice):	2047	/02						ture Range		Controlled F	loom – betwe	en 20 and 25 (C (68° – 77° I
DUNS:	968961354									Other Te	mperature Range Re	equirement				
Proprietary Name (If Applica		Name: Palo	nosetron Hydrochloride Injection							(wr	ite in)		Store at 20°	to 25°C (68°	to 77°F).	
Selling Unit NDC:	55150-186-05		Individual Unit NDC:		55150-186-05	MVX Cod	PC: 355150	186051								
UDI			CVX Code:			WVX COC	le:				oduct to be shipped				No	
Description:	Palonosetron Hydroc	hloride Injection 0.25	mg per 5 mL(0.05 mg / mL) (MC	ONC)						Is this pr	oduct to be shipped	to customers	on dry ice?		No	
Active Ingredient(s):									b. Contact for temperature excursion questions: Name: Steve Lucas							
URL for Additional Product I	Information:	www.auromedics.co	m							Number	:		888-238-788			
Address:	279 Princeton-Hights	town Road				Address 2:				Group E	-mail:		pvg@aurobi	ndousa.com		
City:	East Windsor				State: NJ Zip: 08520 Email:				. On a later whether a					м.		
Key Contact: Phone Number:	888-238-7880				Fax: 732-355-9449				c. Special regulations	eturns requirements		ct?		No No		
Product Therapeutic Classifi		Antiemetic				102 000 011	0			opediari	ciumo requiremento				110	
										d. Store product (unit o	of sale) upright?				Yes	
ADDITIONA	ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION									Protect product (unit of sale) from light? No						
Is the Product										e. Shelf life:					24	Months
a legend device?		No	_	5	Size:	Mon	o Vial			Initial sh	elf life at launch (if	different):				Months
reverse numbered? co-licensed?		No No	_									ORDER INFO	DMATION			
Is the Product		Direct-Ship Only		5	Strength:	0.25	mg per 5 mL(0.05 mg / mL) (MONC	D)		, c		RMATION			
Is the Product						Linu				Unit of S	ale		What is the	NDC selling	unit?	
					Dosage Form:	Liqu	u				Bottle		55150-186-0			
If Unit Dose, is item bar code	ed to unit dose for hos	bital scanning?	-							x	Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
If Unit Dose NDC, indicate N	JDC here			F	Product Shape	:					Ampule Glass		Minimum o	rder quantity	17	Yes
											Tube				-	
Country of Origin		India			Product Color:						Vial Liquid Sgl					
Is this product covered under	er the Trade Agreemen	ts Act (TAA)?		1	Product Imprin	it:				Vial Liquid Multi If Yes, how many of which package type? Vial Powder Sql Each						ype?
		No Not									Vial Powder Sql Vial Power Multi			Eacn Inner/Cartor	Pack	
]								Other: Write In		1	Case		
			FOR GENERIC DRUG PR	RODUCTS												
				г	Author	rized Generic	*16	orized Generic, other			DUAD	MACY ORD		т		
L Owner Death Detter	AP			, L	Autho	nzed Generic		re not applicable	section	Rec. sell unit to custor						
I. Orange Book Rating: II. Generic Equivalent to What	5 - 55	Aloxi								Rec. sell unit to custor	nerr	7	Rx billing u	Each	acy:	
										(Write-in, e.g. 1 Vial)		_		Gram		
		DRUG SU	PPLY CHAIN SECURITY ACT	(DSCSA) INFO	RMATION									Milliliter		
Does supplier meet DSCSA o	definition of monutor	4	Yes	GLN		0355150000	10E					ND PACKING				
Is product exempt from DSC		turer?	No	- GLN		0355150000	005				TIEWIA	ND FACKING		ION		
If yes, select exemption:				-							Weight Lbs.	Dime	nsions (US m	ismts.)	Volume	# Pieces:
Other exemption - Write in:	:										weight Lbs.	Depth	Height	Width	(Cube)	# Fleces.
Is product repackaged? Is product sold by manufactu	uror's ovclusivo distr	ibutor?	No		s, was origina mfr?	l product pur	chased direct	L		Item:	0.077	1.42	2.36	1.26	4.222512	1
Has FDA granted waiver/exc			No	-	s, attach docu	mentation fro	m FDA.			Box/Carton/Bundle/						
		·		-						Inner Pack:	3.168	9.29	3.19	8.7	257.82537	36
			GTIN PRODUCT INFOR							Case:	15.007	18.701	8.268	10.433	1613.14908	144
			Level	Saleable Unit			Quantit	v GTIN-14		Pallet:						
Serialized?		×		x	2D	Linea		003551501860	51	railet.	708.35	48	46.34	40	88972.8	6480
If not, when?		x			2D	Linea	r 36	303551501860		UPC:	Case:					
Items aggregated?		x			2D	Linea		503551501860			Carton:	355150186	051			
		x	Pallet	┟──┤┟	2D 2D	Linea		703551501860	150		INFORMATION			WHOLESA	ER USE ONL	v
					2D 2D	Linea		1		0001				WHOLESAL	ER OSE ONE	1.
					2D	Linea				Regular Cost			Vendor #:			
					2D	Linea	r			Invoice Cost (WAC) (\$)		\$227.00	Whsl. Code			
										Federal Excise Tax Per As of date:	r Unit of Sale 1/1/2019		Fineline Co	de:		
										AS OF DALE:	1/ 1/2019		ł			
			Attach copy of SAFETY DAT	TA SHEET (SD	S) or non haza	rd letter. PACk	AGE INSERT	LABEL AND PHOTO		DUCT PACKAGING and B	ARCODE.					
*Please provide any addition	nal information on pa	ge 2.			2, 55h huzdi			ted Drop Ship Only.		Signatur				Muramredd	y Penchalaiah	
		-								5			L			



Standard Pharmaceutical Product Information (Page 2)

	gnated Drop Ship Only Products, Please Use Page 3 L HAZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply):							
a. Cytotoxic? No	SDS Hazard Classification						
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	1						
b. Proper Shipping Name	Hazardous Waste Identification						
c. DOT Hazard Class	EPA Hazardous Waste Code:						
d. Packing Group							
e. Inhalation Hazard?	-						
	1						
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS						
Passenger	Is there a REMS on this product? No						
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:						
Limited Quantity	REMS Program Manager Name: 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:						
Special Provision (listed in Column 7 of 49 CFR 172.101);	Site Enrollment Number assigned DEA #:						
SP#	by Supplier: PCPDP #:						
	NPI#:						
ADD'L STORAGE INFORMATION	INF 177.						
Is the Product	Comments						
Controlled Substance? No	Comments						
Controlled by State(s)? No	– Registry:						
ARCOS Reportable? No	Registry Program Contact Name: Phone:						
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: 888-238-7880						
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CLASS OF TRADE RESTRICTION:	Is product returnable for credit:						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	URL/Link to returns policy: http://auromedics.com/policies/return-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:	111						
	J <u></u>						
MISCELL	ANEOUS NOTES and/or Image of Product Barcode:						



Standard Pharmaceutical Product Information (Page 3)

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if n	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 #:	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
Class of Trade Restriction:	Priority Overnight receipt available:
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:	PO Receipt Cut off time:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?