

Standard Pharmaceutical Product Information (Rx Product Only)

							Introduction Typ	pe.	New Item	0	Final Version			Date:	1/17/	2020
				PRODUCT INFORMAT	TION						SPECIAL HANDL	ING AND STO	ORAGE REQ	UIREMENTS	*	
Company Name:	Auromedics Pharma	LLC					Applic	cation:	ANDA	a. Temperature – Ind	cate the USP temper	rature range f	or this produ	ıct.		
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 212456					2456				rature Range				en 20 and 25	C (68° – 77° F		
DUNS:	968961354									Other 1	emperature Range R	equirement				
Proprietary Name (If Applicat		Name:	Naloxone Hvdr	rochloride Injection, USI	SP 4 mg/10 mL ((0.4 ma/mL) I	MDVI (10 Vials)				vrite in)	equirement	Store at 20°	to 25°C (68°	to 77°F).	
Selling Unit NDC:	55150-328-10			Individual Unit NDC:		150-328-10		355150328109		`	,			(, ,	
UDI				CVX Code:			MVX Code:			Is this p	product to be shipped	to customers of	on ice?		No	
Description:	Naloxone Hydrochlor	ide Injection, USF	9 4 mg/10 mL	(0.4 mg/mL) [MDV] (10	Vials)					Is this p	product to be shipped	to customers of	on dry ice?		No	
·	-	-			•								,			
Active Ingredient(s):		Naloxone Hydro	chloride							b. Contact for temper		stions:				
										Name:						
URL for Additional Product In Address:		tour Dood					Address 2:			Numbe						
City:	279 Princeton-Hightstown Road East Windsor								Group	E-maii:						
Key Contact:	Edot Willdoor					Email:			c. Special regulations	for product in any s	states?			No		
Phone Number:	888-238-7880					Fax:	732-355-9449				returns requirements		ct?		No	
Product Therapeutic Classific	ication:	Opioid Reversal	l Agent													
										d. Store product (uni	of sale) upright?				No	
ADDITIONA	AL PRODUCT INFORM	IATION				F	PRODUCT DESCRIPTI	ION INFORMATION	ION	Protec	t product (unit of sale	e) from light?			No	
Is the Product										e. Shelf life:					24	Months
a legend device?			No		Si	ze:	10 vials			Initial	shelf life at launch (if	different):				Months
reverse numbered?			No		"		- To Tidio									
co-licensed?			No		St	rength:	4 mg/10 mL	(0.4 mg/mL)			(ORDER INFOR	RMATION			
Is the Product		Direct-Ship Only Neither								Unit of	Colo		What is the	NDC salling	unit?	
is the Product		TTOTALICI			Do	osage Form:	Liquid			U CINCO	Bottle		1 box of 10		uiiit.	
Kille A Dana Ja Mana han anda		14-1								x	Box/Carton			g. 1 Box of 1	0 Vials)	
If Unit Dose, is item bar code	ed to unit dose for nosp	ital scanning?			D.	oduct Shap	0.				Ampule					
If Unit Dose NDC, indicate NI	DC here:				1	oudet onup					Glass		Minimum o	rder quantity	/?	Yes
		Decare			Pr	oduct Color	:			<u> </u>	Tube					
Country of Origin		India									Vial Liquid Sgl Vial Liquid Multi		If Voc. how	many of wh	ich package t	uno?
Is this product covered under	r the Trade Agreements	s Act (TAA)?	No		Pr	oduct Impri	nt:				Vial Powder Sql		ii res, now	Fach	icii package i	yper
		-							-		Vial Power Multi			Inner/Cartor	/Pack	
										"	Other: Write In	_	1	Case		
			FOR	R GENERIC DRUG PRO	ODUCTS						Other: Write In		1	Case		
			FOR	R GENERIC DRUG PRO	ODUCTS		anian d Compania	Elf Authorizad Con				BMACY ORDE		ı		
			FOR	R GENERIC DRUG PRO	ODUCTS	Autho			neric, other section		PHAF	RMACY ORDE	R / BILL UNI	ΙΤ		
•	AP	Maraga his esti				Autho		*If Authorized Ger fields are not appl		Rec. sell unit to custo	PHAF	RMACY ORDE		T nit to pharm	acy:	
I. Orange Book Rating: II. Generic Equivalent to Wha		Narcan® Injection		R GENERIC DRUG PRO		Autho				10	PHAF	RMACY ORDE	R / BILL UNI	T nit to pharm Each	асу:	
			ion 4 mg/10 mL	L (Adapt Pharma Opera	ations Ltd.)						PHAF	RMACY ORDE	R / BILL UNI	T nit to pharm Each Gram	асу:	
			ion 4 mg/10 mL		ations Ltd.)					10	PHAF	RMACY ORDE	R / BILL UNI	T nit to pharm Each	acy:	
	at Brand?:	DRUG	ion 4 mg/10 mL 3 SUPPLY CH/	L (Adapt Pharma Opera	ations Ltd.)					10	PHAF omer? vials	RMACY ORDE	Rx billing u	nit to pharm Each Gram Milliliter	асу:	
II. Generic Equivalent to Wha Does supplier meet DSCSA of Is product exempt from DSCS	at Brand?:	DRUG	ion 4 mg/10 mL	L (Adapt Pharma Opera	ations Ltd.)					10	PHAF omer? vials	AND PACKING	R / BILL UNI Rx billing u x	nit to pharm Each Gram Milliliter		
II. Generic Equivalent to Wha Does supplier meet DSCSA of Is product exempt from DSCS If yes, select exemption:	at Brand?: definition of manufact SA?	DRUG	ion 4 mg/10 mL 3 SUPPLY CH/	L (Adapt Pharma Opera	ations Ltd.)					10	PHAF omer? vials	AND PACKING	R / BILL UNI Rx billing u x BINFORMATI	nit to pharm Each Gram Milliliter	Volume	#Pieces:
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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? No Is the product a CA Prop 65 carcinogen? 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? If yes, indicate which: Is this product regulated for shipment by DOT or IATA? (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: Special Provision (listed in Column 7 of 49 CFR 172.101); Site Enrollment Number assigned DEA #: by Supplier: SP# PCPDP #: NPI#: ADD'L STORAGE INFORMATION Is the Product... Comments Controlled Substance? Nο No Controlled by State(s)? Registry: ARCOS Reportable? Registry Program Contact Name: Phone No Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code RETURN INSTRUCTIONS Listed Chemical (List I or II) No If yes, indicate which: 888-238-7880 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 Yes URL/Link to returns policy: http://auromedics.com/policies/return-policy/ No Restricted to retail pharmacy only: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments? Restricted to hospital, clinics, and physician offices only: No 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 c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	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: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
	Priority Overnight receipt available:
Class of Trade Restriction: 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: 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?