

Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2020				Introduction Type:	New Item]	Final Version			Date:	09.FE	B.2021
		PRODUCT INFORMATION					SPECIAL HANI	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name: Auromedics LLC Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/AN		(med device): 21	3279					Controlled Room -		and 25 C (68	° – 77° F)	
DUNS:	968961354					-	Other Temperature Range R	Requirement				
Proprietary Name (If Applicable) a	nd Established Name:	Naloxone Hydrochloride Injection, USP				11	(write in)	•				
Selling Unit NDC:	55150-345-10	Unit of Use NDC:	55150-345-01		345106		Notes		Protect from	light.		
UDI		CVX Code:		MVX Code:]						
Description: Naloxone Hydrochloride Injection, USP (2 mL Single Dose Disposable Prefilled Syringe) 10's Pack 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):	Naloxone	e Hydrochloride										
UDI for Additional Draduct Inform	- etien.					b. Contact for	temperature excursion que	estions:	Steve Lucas			
URL for Additional Product Inform Address:	279 Princeton-Hightstown R	oad	1	Address 2:			Name: Number:		732-823-412	2		
City:	East Windsor	oau	State:	NJ Zip:	08520	1	Group E-mail:		slucas@auro		m	
Key Contact:	East Willado.		Email:		00020	11	o.oup 2a		ora o a o ao	,Daoaoa.oo		
Phone Number:	888-238-7880		Fax:	732-355-9449		c. Special reg	ulations for product in any	states?			No	
Product Therapeutic Classification	n: Opioid R	eversal Agent					Special returns requirements				No	
	ADDITIONAL PRO	DUCT INFORMATION		PRODUCT DESCR	RIPTION INFORMATION	d. Store produ	uct (unit of sale) upright?				No	_
The product is?		Is the Product Direct-Ship (Only				Protect product (unit of sa	le) from light?			Yes	
a legend device?	No	Is the Product Neither	•	Size:	10 x 2 mL Single Dose	e. Shelf life:	, ,	,			24	Months
if yes, enter class #		Orphan Drug Status		Size:	Disposable Prefilled		Initial shelf life at launch (i	f different):			24	Months
a product kit?	No	<u> </u>		Strength:	2 mg per 2 mL							-
if yes, list NDCs of		FDA Approval Status		J	(1 mg/mL)			ORDER INFORM	IATION			
component parts reverse numbered?				Dosage Form:	Liquid		Unit of Sale		What is the	NDC salling		
co-licensed?	No No	Allergens Present					Bottle		1 Carton of 1			
latex-free?	Yes	Allergens Fresent			PFS		x Box/Carton			g. 1 Box of 10		
preservative-free?	Yes	_		Product Shape:			Ampule		(**************************************	g. 1 Dox of 11	, viaio,	
correctional institution block?	No			Product Color:			Glass		Minimum or	der quantity	/?	Yes
opioid?	No	_		Product Color:			Tube				•	
Cannabinoid?	No	Country of Origin India		Product Imprint:			Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for hospital						Vial Liquid Multi		If Yes, how		ich package t	type?
scanning?		Is this product covered under the Trade Agreements Act (TAA)?					Vial Powder Sql			Each	/D I-	
If Unit Dose, indicate NDC here:		Trade Agreements Act (TAA)?					Vial Power Multi Other: Write In		1	Inner/Carton Case	/Pack	
		FOR GENERIC DRUG PRODUCTS				1	Other. Write iii		-	Case		
		TOR GENERIC BROG PROBUCTS							1			
			Autho	orized Generic *If Auth	norized Generic, other section		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AP			fields a	re not applicable	Rec. sell unit	to customer?		Rx billing u	nit to pharm	acv:	
II. Generic Equivalent to What Bra	nd?: Narcan li	njection					Pre-Filled Syringes		X	Each		
-						(Write-in, e.g.				Gram		
	DRU	G SUPPLY CHAIN SECURITY ACT (DSCSA) INFO	RMATION						x	Milliliter		
		Yes GI				,	ITEM	AND PACKING IN	IEODMATIO			
Does supplier meet DSCSA definit Is product exempt from DSCSA?	tion of manufacturer?	No Yes GI	LN:				IIEM	AND PACKING IN	NFORMATION	V		
1 .		110				1		Di	(110	4- 1		
If yes, select exemption: Other exemption - Write in:							Weight Lbs.	Dimension	ons (US msm Width		Volume (Cube)	# Pieces:
Is product repackaged?		No If	Yos was origin	nal product purchased		Item/Each:				Height		
Is product sold by manufacturer's	exclusive distributor?		rect from mfr?			1.00	0.704	6.3	4.13	8.07	209.97333	1 pack of 10
Has FDA granted waiver/exception		No If	yes, attach doo	cumentation from FDA.		Box/Carton/B	undle/					
						Inner Pack:						
		GTIN AND HIBCC PRODUCT INFORMATION				Case:	9.4	18.701	14.37	10.24	2751.8297	8 packs
	.											V
Saleable Unit of Measure	Quantity	HIBCC	GTIN-	14 150345106	Unit of Use GTIN-14	Pallet:	315.058	48	40	56.18	107865.6	30 Cases
x Item/Each Box/Carton/Bundle/Inner Pack	1		00355	150345106								
Case Case	8		50355	150345101			COST INFORMATION			WHOL <u>ESAL</u>	ER USE ONL	Y:
Pallet	30			150345105								
	I T					Regular Cost			Vendor #:			
				•		Invoice Cost (WAC) (\$)	\$315.00	Whsl. Code			
									Fineline Co	de:		
	1					As of date:			+			
		Attach copy of SAFETY DATA SHEET (SI	DC) or non b	and letter DACKAGE INCE	DT LABEL AND DUOTO OF	DDODUCT DAGK	ACING and BARCORE		l			
*Please provide any additional info	ormation on page 2	Allacti copy of SAFETY DATA SHEET (SI	טו ווטו naza	ard letter, PACKAGE INSE		FRUDUCI PACK	Signature			Aravinda	Kumar A	



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For Designated Drop Ship Only Products, Please Use Page 3

	AT LIVIAL HAE	ARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply):							
a. Cytotoxic?	No	SDS Hazard Classification					
•		ODO TRAZAND CIASSINCATION					
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				
1			→ *				
c. Contact Hazard?	NI=	Aerosol Class; Identify NFPA Storage Level:					
	No	Aerosoi Class; identiliy 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?	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:	Waste Characteristics				
d. Packing Group		Er A riazardous waste dode.					
e. Inhalation Hazard?	No						
Is this product regulated for shipment by IATA?	No	REMS o	r REGISTRY RESTRICTIONS				
(if yes, answer a-e below and provide SDS)		Is there a REMS on this product?	No				
a. UN/Identification Number		If Yes, is it managed with a pharmacy registry?					
b. Proper Shipping Name		Website URL:					
c. DOT Hazard Class							
d. Packing Group							
e. Inhalation Hazard?	No	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:	No				
RQ Threshold:		REMS Program Manager Name:	Phone:				
Is this a marine pollutant?		Supplier Manages REMS registry exclusively:					
Is this product shipped utilizing an authorized DOT exception or Special Permit?		Wholesale distributor support:					
(if yes, identify method below)		Provider Name:	DEA#:				
			PCPDP#:				
Limited Quantity		Site Enrollment Number assigned					
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);							
		Building					
SP#		Registry:					
		Registry Program Contact Name:	Phone:				
ADD'L STORAGE INFORMATION		Comments					
Is the Product							
			ETUDN INCTRUCTIONS				
Controlled Substance? No Controlled Substance Code		R	ETURN INSTRUCTIONS				
Controlled by State(s)? No Listed Chemical (List I or II)	No						
ARCOS Reportable? No If yes, indicate which:		Contact tel. # if product received damaged:	888-238-7880				
Schedule No. Is it a scheduled listed chemical product?:	No	Is product returnable for credit:	Yes				
<u> </u>		· · · · · · · · · · · · · · · · · · ·					
CLASS OF TRADE RESTRICTION:		URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes	http://auromedic	cs.com/policies/return-policy/				
Restricted to retail pharmacy only:	No	Special regulations or returns requirements for this					
Restricted to hospital, clinics, and physician offices only:	No	product in certain states?					
Restricted from US territories? (explain in comments)	No	If so, which states? Other requirements? Comments?					
	.10	55,ion states. Other requirements: Comments:					
Comments:							
N N	MISCELLANEO	OUS NOTES and/or Image of Product Barcode:					



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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: 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: 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: 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?				