

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

Version 2020				Introduction Type:	New Item] [Final Version			Date:	15.APF	R.2021	
		PRODUCT INFORMATION					SPECIAL HANI	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/AN	NDA/BLA (drug); PMA/510(k)(med de	evice): 21	3874		•] т	Temperature Range	Controlled Room -	- between 20	and 25 C (68	° – 77° F)		
DUNS:	968961354						Other Temperature Range R	Requirement		to 25°C (68°			
Proprietary Name (If Applicable)		nocobalamin Injection, USP					(write in)				d Room Temp	perature].	
Selling Unit NDC:	55150-364-25	Unit of Use NDC:	55150-364-01	UPC: 355150 MVX Code:	0364251		Notes		Protect from	Light.			
UDI		CVX Code:		WVX Code.									
Description:	Cyanocobalamin Injection, USP 100	00 mcg per mL (25 Vials)					s this product to be shipped s this product to be shipped				No No		
Active Ingredient(s):	Cyanocobalamir	n Injection USP				1	s this product to be shipped	to customers on a	ly ice:		INU		
3 44 (4)		,				b. Contact for to	emperature excursion que	estions:					
URL for Additional Product Infor							Name:		Steve Lucas				
Address:	279 Princeton-Hightstown Road Address 2:				00520		732-823-4122						
City: Key Contact:	East Windsor State: NJ Zip: 08520 Email:						Group E-mail:			slucas@aurobindousa.com			
Phone Number:	888-238-7880		Fax:	732-355-9449		c. Special regul	ations for product in any	states?			No		
Product Therapeutic Classification	Synthetic form o	f vitamin B12					Special returns requirements				No		
	ADDITIONAL PRODUCT	INFORMATION		PRODUCT DESCR	RIPTION INFORMATION	d. Store produc	t (unit of sale) upright?						
The product is?		Is the Product Direct-Ship C	Only				Protect product (unit of sa	le) from light?					
a legend device?	No	Is the Product Neither		Size:	25 x 1 mL IM or SC Vials	e. Shelf life:		f -11ff 1) -			18	Months	
if yes, enter class # a product kit?	No	Orphan Drug Status			1,000 mcg per mL		nitial shelf life at launch (i	t different):				Months	
if yes, list NDCs of	Ne	FDA Approval Status		Strength:	1,000 mag per me			ORDER INFORM	MATION				
component parts				Dosage Form:	Liquid								
reverse numbered?	No			Doodgo : c.i			Init of Sale			NDC selling	unit?		
co-licensed? latex-free?	No Yes	Allergens Present			Vial Pack	 	Bottle x Box/Carton		1 Box of 25 \	Vials g. 1 Box of 1	0 Viole)		
preservative-free?	Yes			Product Shape:	Viai Fack	H	Ampule		(write-iii, e.	g. I box of fi	J viais)		
correctional institution block?				Product Color:			Glass		Minimum o	rder quantity	/?	Yes	
opioid?	No			Product Color:			Tube				•		
Cannabinoid?	No No	Country of Origin India		Product Imprint:			Vial Liquid Sgl						
If Unit Dose, is item bar coded to a scanning?	unit dose for hospital	Is this product covered under the					Vial Liquid Multi Vial Powder Sql		If Yes, how	many of whi Each	ich package t	ype?	
If Unit Dose, indicate NDC here:		Trade Agreements Act (TAA)?	No			ll F	Vial Power Multi			Inner/Carton	/Pack		
							Other: Write In		1	Case			
FOR GENERIC DRUG PRODUCTS													
			A cath				DU	ADMACY ORDER	/ DILL LINET				
	Authorized Generic *If Authorized Generic, other section fields are not applicable												
II. Generic Equivalent to What Br	ange book Nating.					Rec. sell unit to customer? Rx billing unit to pharmacy: 25 Vials x Each							
ii. Generio Equivalent to What Bi	and					(Write-in, e.g. 1				Gram			
	DRUG SUP	PLY CHAIN SECURITY ACT (DSCSA) INFOR	RMATION						x	Milliliter			
Does supplier meet DSCSA defin	ition of monufactures?	Yes GL	N.			1	ITEM	AND PACKING IN	NEODMATIO	NI .			
Is product exempt from DSCSA?		No GL	.N:				IIEW	AND FACKING II	VECKIMATIO	N			
If yes, select exemption:						1		Dimensi	ons (US msn	nts.)	Volume		
Other exemption - Write in:							Weight Lbs.	Depth	Width	Height	(Cube)	# Pieces:	
Is product repackaged?				nal product purchased		Item/Each:	0.49	3.54	3.54	1.97	24.687252	25	
Is product sold by manufacturer'			ect from mfr?			D/O//D							
Has FDA granted waiver/exception	on/exemption for product?	No If y	es, attach doo	cumentation from FDA.		Box/Carton/Bur Inner Pack:	ndle/				0		
	G	TIN AND HIBCC PRODUCT INFORMATION				Case:	40.00	40.0	0.00	40.04	4004 0705	0.4	
							13.98	12.2	8.66	10.24	1081.8765	24	
Saleable Unit of Measure	Quantity	HIBCC	GTIN-		Unit of Use GTIN-14	Pallet:	1151.05	48	40	56.18	107865.6	1920	
X Item/Each Box/Carton/Bundle/Inner Pack	25		00355	150364251									
Case Case	24 50355150364256						COST INFORMATION WHOLESALER USE ONLY:				Y:		
Pallet	1920			150364250									
						Regular Cost			Vendor #:	_			
						Invoice Cost (W	VAC) (\$)	\$85.00	Whsl. Code				
	-					As of date:	5/17/2021		Fineline Co	ue:			
		Attach copy of SAFETY DATA SHEET (SD	S) or non haza	ard letter, PACKAGE INSE	RT, LABEL AND PHOTO OF	PRODUCT PACKAG	GING and BARCODE.						
*Please provide any additional in	formation on page 2.			See new p. 3 for Desig	nated Drop Ship Only.	8	Signature:			Aravinda	Kumar A.		



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For Designated Drop Ship Only Products, Please Use Page 3

MATE	RIAL HAZARD CLASSIFICATION and TRANSPORTATION				
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen?	No SDS Hazard Classification No Organic Corrosive				
Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning?	No Inorganic Oxidizer Steroid/Androgen Contact Hazard				
c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP?	No Aerosol Class; Identify NFPA Storage Level: No Is the product a NIOSH hazardous drug? No If yes, indicate which:				
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group	No Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics				
e. Inhalation Hazard? Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)	No No REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? No				
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group	If Yes, is it managed with a pharmacy registry? Website URL:				
e. Inhalation Hazard? Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	No Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)				
Is this a reportable quantity? RQ Threshold: Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4)	REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: No Phone: DEA #: PCPDP#: NPI #:				
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Registry: Registry Program Contact Name: Phone:				
ADD'L STORAGE INFORMATION Is the Product	Comments RETURN INSTRUCTIONS				
Controlled Substance? Controlled by State(s)? ARCOS Reportable? Schedule No. CLASS OF TRADE RESTRICTION: Controlled Substance Code Listed Chemical (List I or II) If yes, indicate which: Is it a scheduled listed chemical product?:	No Contact tel. # if product received damaged: No Is product returnable for credit: URL/Link to returns policy: Yes				
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:	http://auromedics.com/policies/return-policy/ Special regulations or returns requirements for this product in certain states?				
Restricted from US territories? (explain in comments) Comments:	No product in Certain states? No If so, which states? Other requirements? Comments?				
MISC	ELLANEOUS 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:	Purchase order daily receipt cut off time by supplier					
a. EDI	Cut off time:					
b. Autofax Fax Number:						
c. Fax Number:	Shipping lead time of PO: Hours Days					
d. Phone only Phone No.:						
e. Supplier Web Site only Site Address:	Ships same day for next day receipt:					
Minimum Order Quantity:	Ships for second day receipt:					
Supplier's Customer Service Number:	Ships regular ground for 3-10 days receipt:					
Contracted 3PL company / contact #: Name:						
Phone:						
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:	Days of week overnight is available: Monday					
Comments:	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	Saturday Overnight receipt available:					
Restricted to retail pharmacy only:	PO Receipt Cut off time:					
Restricted to hospital, clinics, and physician offices only:	Phone: Phone #:					
Restricted from US territories? (explain in comments)	Order receipt method: Fax: Fax: Fax#:					
Comments:	EDI:					
	Overnight Fees apply:					
	Other fees apply:					
Other Data Information Required to Process PO:	Return Instructions					
Patient Procedure Date:	Contact # if product is received damaged:					
Physician Name:	Is product returnable for credit:					
Physician/Clinic Phone #	URL/Link to returns policy:					
Physician State License #						
Physician/Clinic DEA #:	Special regulations or returns requirements for this product in certain states?					
Physician/Clinic Specialty:	If so, which states? Other requirements? Comments?					
Miscellaneous Notes:						
	ADDITIONAL INFORMATION					
	Is product order for scheduled patient procedure?					
	Is product order for restocking purposes?					
	15 product order for restocking purposes:					