

Version 2021						Introduction	Туре:	New Item	]	Final	Version			Date:	04.04	.2023	
PRODUCT INFORMATION						SPECIAL HANDLING AND STOR				AGE REQUIR	REMENTS*						
Company Name: Eugia US LLC (f/k/a AuroMedics Pharma LLC)					Applica	tion:	ANDA	a. Temperature – Indicate the USP temperature range f			erature range for t	r this product.					
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 217401										Temperature R		Controlled Room -		and 25 C (68	8° – 77° F)		
Medical Device Class, if applicable:																	
DUNS:	968961354									Other Tempera	iture Range I	Requirement					
Proprietary Name (If Applicable) a		me: Vanco	mycin Hydrochloride for Inje	ction, USP 1.25						(write in)							
Selling Unit NDC:	55150-0471-10		Unit of Use NDC:		55150-0471-0		355150	0471102		Notes							
UDI			CVX Code:			MVX Code:											
Description:	Vancomycin Hydrod	chloride for Injection	, USP 1.25 g/vial(10's)									to customers on id			No		
Active Ingredient(s): Vancomycin Hydrochloride Is this product to be shipped to customers on dry ice? No																	
Active ingredient(s):		vancomycin nyurod	nionde						b. Contact for	temperature ex	cursion au	estions:					
URL for Additional Product Inform	mation:	eugiaus.com							b. contact for	Name:	koursion qu	conona.	Kevin Cagne	etti			
Address:	279 Princeton-High	tstown Road				Address 2:				Number:			732.839.940	0 ex 8009			
City:	East Windsor				State:	NJ	Zip:	08520		Group E-mail:			kcagnetti@	EugiaUS.c	<u>om</u>		
Key Contact:					Email:												
Phone Number:	888-238-7880				Fax:	732-355-9449			c. Special regulations for product in any states? No								
Product Therapeutic Classificatio	on:	Anti bacterial								Special returns	requirement	s for this product?			No		
		NAL PRODUCT INI				PRODUCT	DESCRU	PTION INFORMATION	d Store produ	ct (unit of sale	) unright?				No		
The product is 2				Direct-Ship 0	Dely		BEGGI	- How IM ONWATION	a. Store produ	-		ala) from Hat 10			No		
The product is? a legend device?	Γ	No	Is the Product Is the Product	Neither	Jniy		ſ	10 x 30 mL Single Dose V	e. Shelf life:	Protect produc	ct (unit of sa	ale) from light?			24	Months	
if yes, enter class #			Orphan Drug Status			Size:		TO X SUTTLE SITISTE DUSE V	e. onen me:	Initial shelf life	e at launch (	if different):			24	Months	
a product kit?		No				0		1.25 g/vial			(						
if yes, list NDCs of			FDA Approval Status			Strength:		Ū				ORDER INFORM	ATION				
component parts						Dosage For	m:	Powder									
reverse numbered?		No								Unit of Sale			What is the		unit?		
co-licensed?		No	Allergens Present				ſ			Bottle			1 box of 10 v		0 \ ( - 1 - )		
latex-free? preservative-free?	-	Yes Yes				Product Sha	ape:			x Box/C			(Write-in, e.	g. 1 Box of 1	u viais)		
correctional institution block?		No								Glass			Minimum or	der quantity	1?	Yes	
opioid?		No				Product Col	lor:			Tube							
Cannabinoid?		No	Country of Origin	India		Product Imp	orint.			Vial L	iquid Sgl						
If Unit Dose, is item bar coded to u	unit dose for					i roudet imp	print.				iquid Multi				ch package	type?	
hospital scanning?			Is this product covered u								owder Sql			Each			
If Unit Dose, indicate NDC here: Trade Agreements Act (TAA)? No									ower Multi Write In			Inner/Carton Case	/Pack				
			FOR GENERIC DRUG PRO						1	Other	. write in			Case			
			TOR GENERIC DROGT R	550013													
					Au	thorized Generic	*If Auth	horized Generic, other			PH	ARMACY ORDER	/ BILL UNIT				
I. Orange Book Rating:	AP							n fields are not applicable	Rec. sell unit t	o customer?			Rx billing ur	nit to pharm	acv:		
II. Generic Equivalent to What Brand?: VANCOMYCIN HYDROCHLORIDE								1 vial		1	x Each						
								(Write-in, e.g.	1 Vial)		4		Gram				
		DRUG SUPPL	Y CHAIN SECURITY ACT (I	DSCSA) INFOR	MATION									Milliliter			
Development in a set DOOOA definit		0	Vee	_	<b>0</b> 1 N						ITEM	AND PACKING IN	FORMATION	1			
Does supplier meet DSCSA defini Is product exempt from DSCSA?	ition of manufacture	er ?	Yes	_	GLN:							AND PACKING IN	FURMATION				
If yes, select exemption:	L			_	GCP:							Dimoral	ons (US msm	te )	Volume	Saleable #	
If yes, select exemption: Other exemption - Write in:	-				GCP:				1	We	eight Lbs.	Dimensio	Width	its.) Height	Volume (Cube)	Saleable # Pieces	
Is product repackaged?	-		No		If yes, was or	iginal product			Item/Each:								
Is product sold by manufacturer's	s exclusive distribut	tor?	No	-		irect from mfr?					0.7494	6.5	2.68	3.15	54.873	10	
Has FDA granted waiver/exception					Provide sour	ce manufacturer f	for repac	ckaged product	Box/Carton/Bu	undle/							
If yes, attach documentation from	m FDA.								Inner Pack:								
		CTI	AND HIBCC PRODUCT IN	FORMATION					Case:		8.969	14.763	7.677	7.874	892.404	100	
		GTIN		FORMATION					Pallet:								
Saleable Unit of Measure	Sa	leable Quantity	HIBCC		GTI	N-14		Unit of Use GTIN-14	r anet.		840.26	48	40	52.24	100300.80	9000.00	
X Item/Each		10				55150471102			1			1	11				
Box/Carton/Bundle/Inner Pack	1									COST INFO	ORMATION		V	VHOLESALI	ER USE ONL	Y:	
Case		100				55150471107											
Pallet	- I	9000			703	55150471101			Regular Cost				Vendor #:	и.			
							Invoice Cost (WAC) (\$) \$201.00			Whsl. Code #: Fineline Code:							
								As of date: 8/3/2023									
	1								, to or date.	5.0720							
U									[]								
			Attach copy of SAFETY DAT	TA SHEET (SD	S) or non hazar	d letter, PACKAGE	INSERT	T, LABEL AND PHOTO OF F	PRODUCT PACKA	GING and BAR	CODE.						
*Please provide any additional inf	formation on page 2	2.				See new p. 3 for	r Design	nated Drop Ship Only.		Signature:			C	0.Venkata Su	render Reddy	/	

Version 2021 For Designat	ed Drop Ship Only Products, Please Use Page 3
MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? No Does the product label bear a CA Prop 65 warning? C. Contact Hazard? No	SDS Hazard Classification         Organic       Corrosive         Inorganic       Oxidizer         Steroid/Androgen       Contact Hazard         Does the product have an Aerosol class? If yes,       No
d. Does this product require special clean-up instructions?     No       (If yes, attach SDS with special instructions.)	identify NFPA Storage Level:         NFPA Storage Level:         Is the product a NIOSH hazardous drug?         If yes, indicate which:
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMS or REGISTRY RESTRICTIONS
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? No	Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? Website URL:
Is the product restricted for air shipment? If so, indicate restriction:           No           Passenger           Cargo           Passenger & Cargo	Med Guide Required     No       Limited Distribution Requirement     No       Comments / Details: (For example, iPledge program?)     No
Is this a reportable quantity? No RQ Threshold: Is this a marine pollutant? No 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) Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	REMS:     No       REMS Program Manager Name:     No       Supplier Manages REMS registry exclusively:     No       Wholesale distributor support:     No       Provider Name:     DEA #:       Site Enrollment Number assigned     NCPDP#:       by Supplier:     NPI #:
SP#	Registry: No
ADD'L STORAGE INFORMATION Is the Product	Registry Program Contact Name:     Phone:       Comments
Controlled Substance?         No         Controlled Substance Code           Controlled by State(s)?         No         Listed Chemical (List I or II)         No           ARCOS Reportable?         No         If yes, indicate which:         No           Schedule No.         Is it a scheduled listed chemical product?:         No	RETURN INSTRUCTIONS         Contact tel. # if product received damaged:         Is product returnable for credit:       Yes         URL/Link to returns policy:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	https://eugiaus.com/policies/return-policy/
NO restriction: Select YE's i sold to retail pharmacy, hospitals, clinics and physician offices     Yes       Restricted to retail pharmacy only:     No       Restricted to hospital, clinics, and physician offices only:     No       Restricted from US territories? (explain in comments)     No       Comments:     No	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?
MISCELLANE	OUS NOTES and/or Image of Product Barcode:



Version 2021 FOR DESIGN/	TED 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 Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	ber:     Shipping lead time of PO:     Hours     Days       o.:
Expedited Freight Charges or Other Designation	ted 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 Restrictio No restriction: Select YES if sold to retail pharmacy, hospitals, clini Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	
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?



Version 2021						Introduction	Type:	New Item	]	F	inal Version			Date:	04.04	.2023
			PRODUCT INFORMAT	TION							SPECIAL HAND	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Eugia US LLC (f/	k/a AuroMedics Pharm	na LLC)			Applica	ation:	ANDA	a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/AN	lication Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 217401								Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)							
Medical Device Class, if applicable:																
DUNS:	968961354										perature Range F	Requirement				
Proprietary Name (If Applicable) a		lame:								(write	e in)					
Selling Unit NDC: UDI	55150-0472-10		Unit of Use NDC: CVX Code:		55150-0472-0	1 UPC: MVX Code:	35515	0472109		Notes						
						WVX Code.										
Description:	Vancomycin Hyd	rochloride for Injection	, USP 1.5 g/vial(10's)									to customers on i			No No	
Active Ingredient(s): Vancomycin Hydrochloride No																
									b. Contact fo	r temperatu	re excursion que	estions:				
URL for Additional Product Inform		eugiaus.com							]	Name:			Kevin Cagne			
Address:	279 Princeton-Hi	ghtstown Road				Address 2:				Number:			732.839.940			
City:	East Windsor				State: Email:	NJ	Zip:	08520	Group E-mail:				kcagnetti@EugiaUS.com			
Key Contact: Phone Number:	888-238-7880				Fax:	732-355-9449			c. Special regulations for product in any states? No						No	
Product Therapeutic Classification		Anti bacterial				102 000 0110			o. opeoidi reg	-		s for this product?	No			
		/ Introduction da								opeoidi ret	unis requirement	s for this product:			110	
	ADDITI	IONAL PRODUCT INF				PRODUCT	DESCRI	IPTION INFORMATION	d. Store prod	luct (unit of	sale) upright?				No	
The product is?			Is the Product	Direct-Ship	Only				11	Protect pr	oduct (unit of sa	ale) from light?			No	
a legend device?		No	Is the Product	Neither		Size:		10 x 30 mL Single Dose V	e. Shelf life:						24	Months
if yes, enter class #			Orphan Drug Status			5120.				Initial she	lf life at launch (	if different):				Months
a product kit?		No				Strength:		1.5 g/vial								
if yes, list NDCs of component parts			FDA Approval Status					Powder				ORDER INFORM	ATION			
reverse numbered?		No				Dosage For	rm:	Powder		Unit of Sa	ام		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present				1				Bottle		1 box of 10			
latex-free?		Yes				Product Sha				X E	Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes				FIGURE SI	ape.				mpule					
correctional institution block?		No				Product Co	lor:				Blass		Minimum o	der quantity	?	Yes
opioid? Cannabinoid?		No	Country of Origin	India							ube /ial Liquid Sgl					
If Unit Dose, is item bar coded to u	init dose for	No	Country of Origin	Inula		Product Im	print:				ial Liquid Sgl		If Yes how	many of whi	ch package	type?
hospital scanning?	unit dose for		Is this product covered u	nder the							ial Powder Sol			Each	en package	type:
If Unit Dose, indicate NDC here:			Trade Agreements Act (		No					V	ial Power Multi			Inner/Carton	/Pack	
							Other: Write In		1	Case						
			FOR GENERIC DRUG PR	ODUCTS									]			
						the size of Quantum is	+16 A	having a Quancia subar			BU	ARMACY ORDER				
	10				Au	thorized Generic		horized Generic, other n fields are not applicable	Dec. editori			ARIMACTORDER				
I. Orange Book Rating: AP II. Generic Equivalent to What Brand?: VANCOMYCIN HYDROCHLORIDE						0001101		Rec. sell unit	to custome	r /	1	Rx billing u x	n <b>it to pharm</b> Each	acy:		
								(Write-in e a					Gram			
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION     (Write-in, e.g. 1 Vial)     Gram																
				_												
Does supplier meet DSCSA defin	ition of manufactu	urer?	Yes	_	GLN:						ITEM	AND PACKING IN	IFORMATION			
Is product exempt from DSCSA?												<b></b> .				
If yes, select exemption:					GCP:				1		Weight Lbs.		ons (US msn Width	,	Volume (Cube)	Saleable # Pieces
Other exemption - Write in: Is product repackaged?			No		If yes was or	iginal product			Item/Each:			Depth	Width	Height	· /	
Is product sold by manufacturer's	s exclusive distrib	outor?	No	-		rect from mfr?			nem/Laon.		0.782	6.5	2.68	3.15	54.873	10
Has FDA granted waiver/exception	n/exemption for p					ce manufacturer	for repa	ckaged product	Box/Carton/E	Bundle/						
If yes, attach documentation fro	m FDA.								Inner Pack:							
		CTIN	AND HIBCC PRODUCT IN	FORMATION					Case:		9.295	14.763	7.677	7.874	892.404	100
		GTIN		FURMATION					Pallet:							
Saleable Unit of Measure	5	Saleable Quantity	HIBCC		GTI	N-14		Unit of Use GTIN-14	r anet.		869.60	48	40	52.24	100300.80	9000.00
X Item/Each		10				55150472109										
Box/Carton/Bundle/Inner Pack										COSTI	NFORMATION		\\	VHOLESALI	ER USE ONL	.Y:
Case		100				55150472104	_									
Pallet		9000			703	55150472108			Regular Cost				Vendor #:	м.		
						Invoice Cost (WAC) (\$) \$241.20			Whsl. Code #: Fineline Code:							
								As of date:								
	1															
							_		]]							
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non hazar			T, LABEL AND PHOTO OF	PRODUCT PACK							
*Please provide any additional int	formation on page	e 2.				See new p. 3 fo	or Desigr	nated Drop Ship Only.		Signature	:		[	0.Venkata Su	render Reddy	ý

Version 2021 For Designat	ed Drop Ship Only Products, Please Use Page 3
MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? No Does the product label bear a CA Prop 65 warning? C. Contact Hazard? No	SDS Hazard Classification         Organic       Corrosive         Inorganic       Oxidizer         Steroid/Androgen       Contact Hazard         Does the product have an Aerosol class? If yes,       No
d. Does this product require special clean-up instructions?     No       (If yes, attach SDS with special instructions.)	identify NFPA Storage Level:         NFPA Storage Level:         Is the product a NIOSH hazardous drug?         If yes, indicate which:
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMS or REGISTRY RESTRICTIONS
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? No	Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? Website URL:
Is the product restricted for air shipment? If so, indicate restriction:           No           Passenger           Cargo           Passenger & Cargo	Med Guide Required     No       Limited Distribution Requirement     No       Comments / Details: (For example, iPledge program?)     No
Is this a reportable quantity? No RQ Threshold: Is this a marine pollutant? No 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) Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	REMS:     No       REMS Program Manager Name:     No       Supplier Manages REMS registry exclusively:     No       Wholesale distributor support:     No       Provider Name:     DEA #:       Site Enrollment Number assigned     NCPDP#:       by Supplier:     NPI #:
SP#	Registry: No
ADD'L STORAGE INFORMATION Is the Product	Registry Program Contact Name:     Phone:       Comments
Controlled Substance?         No         Controlled Substance Code           Controlled by State(s)?         No         Listed Chemical (List I or II)         No           ARCOS Reportable?         No         If yes, indicate which:         No           Schedule No.         Is it a scheduled listed chemical product?:         No	RETURN INSTRUCTIONS         Contact tel. # if product received damaged:         Is product returnable for credit:       Yes         URL/Link to returns policy:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	https://eugiaus.com/policies/return-policy/
NO restriction: Select YE's i sold to retail pharmacy, hospitals, clinics and physician offices     Yes       Restricted to retail pharmacy only:     No       Restricted to hospital, clinics, and physician offices only:     No       Restricted from US territories? (explain in comments)     No       Comments:     No	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?
MISCELLANE	OUS NOTES and/or Image of Product Barcode:



Version 2021 FOR DESIGN/	TED 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 Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	ber:     Shipping lead time of PO:     Hours     Days       o.:
Expedited Freight Charges or Other Designation	ted 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 Restrictio No restriction: Select YES if sold to retail pharmacy, hospitals, clini Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	
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?