

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

						Introduction Type:	New Item		x Final Version			Date:	8/30	/2024
			PRODUCT INFORMAT	TION					SPECIAL HAN	IDLING AND STOP	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharmace	euticals, Inc.				Application:	ANDA	a. Temperatur	re – Indicate the USP temp	erature range for t	his product.			
Application Number for NDA/ANI	DA/BLA; PMA/510	(k): 216591				NDA 505(b) Type:	NOT APPLICABLE		Temperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab	le:							T .						
	11-856-3719							_	Other Temperature Range	Requirement	After reconstitutio without significant		stored in a refrigerat	tor for 96 hours
Proprietary Name (If Applicable) and		me: Vancom	nycin Hydrochloride for Injec	ction, USP 1 g/vi	al (Single-dos				(write in)		without significan	rioss or potency.		
Selling Unit NDC:	31722-211-10		Unit of Use NDC:			UPC: 331 MVX Code:	722211109		Notes					
UDI			CVX Code:			WAY Code.		1						1
Description:	Vancomycin Hydro	ochloride for Injection,	, USP 1 g/vial (Single-dose)	Vial)					Is this product to be shippe				No	-
Active Ingredient(s):		Vancomycin hydroch	ploride LISP						Is this product to be shippe	a to customers on a	ary ice?		No	
Active ingredient(3).		vancomychi nydroch	lionde, oor					b. Contact for	temperature excursion qu	estions:				
URL for Additional Product Inform	ation:	www.camberpharma.	com						Name:		Soma Raju			
Address:	800 Centennial Av	ve, Suite 1				Address 2:		1	Number:		732-529-042	23		
City:	Piscataway	State: NJ					08854		Group E-mail: somaraju@heterousa.com					
Key Contact:	Customer Service				Email:	customerservice@can	berpharma.com							1
Phone Number:	1-866-827-3647	Tota and a set of a set of the	a south to the		Fax:	732-562-8788			ulations for product in any				No	-
Product Therapeutic Classification	c.	Tricyclic glycopeptide	e antibiotic						Special returns requiremen	ts for this product?			No	
		ONAL PRODUCT INF	ORMATION			PRODUCT DESC	RIPTION INFORMATION		uct (unit of sale) upright?				No	1
The unschool is 0	Abbillio			Direct Chip Or	alti	TROBOOT BEDO		u. Store prout		- I) (I'I(O				1
The product is? a legend device?		No	Is the Product Is the Product	Direct-Ship Or Unit Dose	пу		10 single dose vials	e. Shelf life:	Protect product (unit of s	ale) from light?			No 24	Months
if yes, enter class #		110	Orphan Drug Status	0.112 2000		Size:	10 Single Gode vidio		Initial shelf life at launch	(if different):			24	Months
a product kit?		No				Strength:	1 gm/vial							
if yes, list NDCs of			FDA Approval Status			Strength.				ORDER INFORM	IATION			
component parts		1				Dosage Form:	Sterile, lyophilized powder or cake for preparing intravenous infusions or				M			
reverse numbered?		No	Allorgona Brocont			-	iniections		Unit of Sale Bottle		1 Box of 10	NDC selling		
co-licensed? latex-free?		No Yes	Allergens Present				Single dose vial		x Box/Carton		-	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes				Product Shape:	engle dece that		Ampule		(11110 111, 0	.g. 1 Dox 01 1	, (10.0)	
correctional institution block?		No				Product Color:	White to tan		x Glass		Minimum o	rder quantity	?	Yes
opioid?		No				Froduct Color.			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	N/A		Vial Liquid Sgl					
If Unit Dose, is item bar coded to un hospital scanning?		Yes	Is this product covered u	under the					Vial Liquid Multi x Vial Powder Sgl			Each	ich package i	type?
If Unit Dose, indicate NDC here:		31722-211-33	Trade Agreements Act (1		No				Vial Powder Multi			Inner/Cartor	/Pack	
			1	,					Other: Write In			Case		
			FOR GENERIC DRUG PRO	ODUCTS								-		
											_			
					Au		uthorized Generic, other		Pł	IARMACY ORDER	/ BILL UNIT			
	AP					Sec	ion fields are not applicable	Rec. sell unit	to customer?	_	Rx billing u	nit to pharm	acy:	
II. Generic Equivalent to What Bran	ıd?:	Vancomycin Hydroch	hloride for Injection (Freseni	ius Kabi USA, LL	.C)							Each		
								(Write-in, e.g.						
					MATION							Gram		
		DRUG SUPPLY	Y CHAIN SECURITY ACT ((DSCSA) INFORI	MATION			HCPCS J-Cod	le:			Gram Milliliter		
Does supplier meet DSCSA definit	ion of manufacture			_	MATION GLN:	0331722498975			J3370	AND PACKING I	NFORMATIO	Milliliter		
Does supplier meet DSCSA definit Is product exempt from DSCSA?	ion of manufacture		Y CHAIN SECURITY ACT (_		0331722498975			J3370	AND PACKING I	NFORMATIO	Milliliter		
	ion of manufactur		Y CHAIN SECURITY ACT (0331722498975			J3370 ITEI		NFORMATIO	Milliliter	Volume	Saleable #
Is product exempt from DSCSA?	ion of manufactur		Y CHAIN SECURITY ACT (Yes No		GLN: GCP:			HCPCS J-Cod	J3370			Milliliter	Volume (Cube)	Saleable # Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?			Y CHAIN SECURITY ACT (Yes No		GLN: GCP: If yes, was o	riginal product purchase	ed		J3370 ITEI	Dimensi	ions (US msr	Milliliter		
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	exclusive distribut	rer?	Y CHAIN SECURITY ACT (Yes No No Yes		GLN: GCP: If yes, was of direct from n	riginal product purchase		HCPCS J-Cod	le: 	Dimens Depth	ions (US msr Width	Milliliter N nts.) Height	(Cube)	Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior	exclusive distribut	rer?	Y CHAIN SECURITY ACT (Yes No		GLN: GCP: If yes, was of direct from n	riginal product purchase		HCPCS J-Cod	le: 	Dimens Depth	ions (US msr Width	Milliliter N nts.) Height	(Cube)	Pieces
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Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation from Saleable Unit of Measure X Item/Each BovCarton/Bundle/Inner Pack Case	exclusive distribut vexemption for pro n FDA. RFID tag(Y/N) N	rer?	Y CHAIN SECURITY ACT (Yes No No Yes No No No		GLN: GCP: If yes, was of direct from n Provide sour GTI	riginal product purchase nfr? rce manufacturer for rep IN-14 331722211109	ackaged product	HCPCS J-Cod Item/Each: Box/Carton/Bi Inner Pack: Case: Pallet:	le: J3370 ITE Weight Lbs. 0.65 undle/ 14.4 COST INFORMATION	Dimensi Depth 6.37 13.25	Vendor #:	Milliliter N Height 3.56 8 WHOLESAL #:	(Cube) 56.69	Pieces 1
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Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2024 For Designa	ted Drop Ship Only Products, Please Use Page 3				
MATERIAL HA	ZARD 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? Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? No	x Organic Corrosive 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? Is this product regulated for shipment by DOT? No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No NFPA Storage Level: Image: Storage Level: Is the product a NIOSH hazardous drug? No				
(if yes, answer a-e below and provide SDS) a. UN/dentification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group	If yes, indicate which: Hazardous Waste Identification				
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics				
Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) (if Unit for the North Context of the Nor	REMS or REGISTRY RESTRICTIONS				
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	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: Passenger Cargo Passenger & Cargo	Med Guide Required No Limited Distribution Requirement Comments / Details: (For example, iPledge program?)				
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? No (if yes, identify method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4)	REMS: No REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: DEA #: Provider Name: NCPDP#: Site Enrollment Number assigned NPI #:				
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments				
SP#ADD'L STORAGE INFORMATION	Registry: No Registry Program Contact Name: Phone: Comments				
Is the Product Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS				
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: If Schedule No. Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: 1-866-827-3647 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 Restricted to retail pharmacy only: No	contact - customerservice@camberpharma.com Special regulations or returns requirements for this				
No No Restricted from US territories? (explain in comments) No	Special regulations of returns requirements for this product in certain states? If so, which states? Other requirements? Comments?				
Comments:					
MISCELLANE	OUS NOTES and/or Image of Product Barcode:				



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

Version 2024 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 Fax Number: c. Fax Fax Number: d. Phone only Phone No.: e. Supplier Web Site only Site Address: Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name:	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:
Phone:	Overnight and Drivity Overnight DO Broossing
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: PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: PO Receipt Cut off time: Phone: Order receipt method: Phone: Fax: EDI: EDI: Covernight Fees apply: Other fees apply: Image: Covernight Fees apply:
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?
Miscellaneous Notes:	
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure?