

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

Version 2021						Introduction	Туре:	Post Launch Change] [1 Final Version			Date:	3/8/2	2023	
			PRODUCT INFORMA	TION						SPECIAL HA	NDLING AND STO	RAGE REQUII	REMENTS*	*		
Company Name: Camber Pharmaceuticals, Inc. Application:					ANDA	a. Temperature – Indicate the USP temperature range for this product.										
Application Number for NDA/ANI			evice):	210	6591					Temperature Range	Controlled Room		and 25 C (68	° – 77° F)		
Medical Device Class, if applicab									1		L					
DUNS:	11-856-3719								-	Other Temperature Range	Requirement					
Proprietary Name (If Applicable) a		ne: Var	ncomycin HCI for Injection, USF	1gm/vial 10 x 3					I	(write in)						
Selling Unit NDC:	31722-211-10		Unit of Use NDC:		31722-211-10		33172221	1109	. '	Notes						
UDI			CVX Code:			MVX Code:										
Description:	Vancomycin HCI for	r Injection, USP	1gm vial-							Is this product to be shipped				No		
Is this product to be shipped to customers on dry ice? No																
Active Ingredient(s): Vancomycin HCI b. Contact for temperature excursion questions:																
URL for Additional Product Information: www.camberpharma.com								Name: Soma Raju								
Address:			ntennial Ave, Suite 1			Address 2:			÷	Number:		732-529-042	23			
City:	Piscataway State:				NJ	Zip: 08	8854	Group E-mail:			somaraju@heterousa.com					
Key Contact:	Customer Service				Email:	customerservice	customerservice@camberpharma.com									
Phone Number:	1-866-827-3647	-866-827-3647 Fax:			Fax:	732-562-8788			c. Special regu	lations for product in an	y states?			No		
Product Therapeutic Classification	n: (Glycopeptide An	itibiotic						:	Special returns requirement	nts for this product?			No		
									-						1	
	ADDITIO	NAL PRODUCT	INFORMATION			PRODUCT	DESCRIPTI	ON INFORMATION		ct (unit of sale) upright?				No		
The product is?	-		Is the Product	Direct-Ship C	Dnly	1				Protect product (unit of s	sale) from light?			No		
a legend device?	1	No	Is the Product	Unit of Use		Size:		mL (x10 vials per	e. Shelf life:					24	Months	
if yes, enter class #		Nia	Orphan Drug Status			1		ton)	'	Initial shelf life at launch	(If different):				Months	
a product kit? if yes, list NDCs of	۲ ا	No	FDA Approval Status			Strength:	igr	m/vial			ORDER INFORI					
component parts							Inie	ection - (Intravenous)			011021111110111					
reverse numbered?	1	No				Dosage For	m:	(Unit of Sale		What is the	NDC selling	unit?		
co-licensed?		No	Allergens Present							Bottle		1 box of 10	vials			
latex-free?		Yes				Product Sha	Lyc	ophized Powder Cake		1 Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)		
preservative-free?		Yes				i roudot one			_	Ampule						
correctional institution block?		No				Product Col	lor:	nite to tan	_	Glass		Minimum o	rder quantity	?	Yes	
opioid? Cannabinoid?		No No	Country of Origin	India			N/A	\	-	Tube Vial Liquid Sql						
If Unit Dose, is item bar coded to u		NO	Country of Origin	Inula		Product Imp	orint:	1	-	Vial Liquid Sgi Vial Liquid Multi		If Yes how	many of whi	ch package i	type?	
hospital scanning?		No	Is this product covered u	nder the					-	Vial Powder Sql			Each	on puonago	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
If Unit Dose, indicate NDC here:			Trade Agreements Act (1		No					Vial Power Multi			Inner/Cartor	/Pack		
	lan in the second se									Other: Write In		1	Case			
			FOR GENERIC DRUG PR	ODUCTS												
	-				Au	thorized Generic		zed Generic, other Ids are not applicable			HARMACY ORDER					
I. Orange Book Rating:							Section ne	ius are not applicable	Rec. sell unit to	o customer?		Rx billing u	nit to pharm	acy:		
II. Generic Equivalent to What Brand?:							(Write-in, e.g. 1 Vial) Each									
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION Gram																
Does supplier meet DSCSA definit	tion of manufacturer	r?	Yes		GLN:	0331722000000				ITE	M AND PACKING I	NFORMATIO	N			
Is product exempt from DSCSA?			No]							
If yes, select exemption:					GCP:]]	Weight Lbs.	Dimens	ions (US msn	nts.)	Volume	Saleable #	
Other exemption - Write in:							-			weight LDS.	Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?	avaluaina distrit		No	_		iginal product pur	rchased		Item/Each:	0.65	6.37	2.5	3.56	56.693	1	
Is product sold by manufacturer's Has FDA granted waiver/exceptior			Yes	_	direct from m	rr? ce manufacturer fo	or ropockog	ad product	Box/Carton/Bu	ndlo/						
If yes, attach documentation from			110		Flovide soul		операскау		Inner Pack:							
									Case:	14.4	13.25	13	8	1378	20	
		0	GTIN AND HIBCC PRODUCT II	NFORMATION						14.4	13.25	13	0	1376	20	
									Pallet:							
Saleable Unit of Measure	Sal	leable Quantity	HIBCC			N-14		nit of Use GTIN-14								
X Item/Each Box/Carton/Bundle/Inner Pack	_	1		00331722211109 00331722211109												
Box/Carton/Bundle/Inner Pack	-	20			20331722211103					COST INFORMATION			WHOLESALER USE ONLY:			
Pallet	-	20							Regular Cost			Vendor #:				
									Invoice Cost (V	VAC) (\$)	\$30.00	Whsl. Code	#:			
]								II È			Fineline Co				
									As of date:							
μ												1				
*PI			Attach copy of SAFETY DA	ATA SHEET (SD	0S) or non haza											
*Please provide any additional info	ormation on page 2.					See new p. 3 for	r Designate	d Drop Ship Only.	:	Signature:						

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

Version 2021 For Design	nated Drop Ship Only Products, Please Use Page 3
MATERIAL H	IAZARD 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? No Is the product a CA Prop 65 reproductive toxicant? No Does the product label bear a CA Prop 65 warning? 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 Is this product regulated for shipment by DOT? No	x Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No Is the product a NIOSH hazardous drug? No
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	If yes, indicate which: Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? No	REMS or REGISTRY RESTRICTIONS 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 Is this a reportable quantity?	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?) REMS: No
RQ Threshold: No 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	REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: Provider Name: Provider Name: DEA #: Site Enrollment Number assigned NCPDP#: by Supplier: NPI #:
Special Provision (listed in Column 7 of 49 CFR 172.101); 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 by State(s)? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: If yes, indicate which:	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 Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No Comments: Ves	contact - customerservice@camberpharma.com Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?
MISCELLAN	EOUS NOTES and/or Image of Product Barcode:



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Version 2021 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: Image: Comparison of the co
Class of Trade Restriction:	PO Receipt Cut off time:
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:	Saturday Overnight receipt available: PO Receipt Cut off time: Order receipt method: Phone: Fax: 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: 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?