

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

Version 2024								Туре:	New Item		x Final Version			Date:	7/1/	2025	
PRODUCT INFORMATION										SPECIAL HANDLING AND STORAGE REQUIREMENTS*							
Company Name: Camber Pharmaceuticals, Inc.								Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/AN	DA/BLA; PMA/510)(k):	216591				NDA 505(b) Type: NOT APPLICABLE			Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)							
Medical Device Class, if applicat	ble:																
DUNS:	11-856-3719									Other Temperature Range Requirement			After reconstitution, this vial may be stored in a refrigerator for 96 hours without significant loss of potency.				
Proprietary Name (If Applicable) a											(write in)			will but significant loss of potency.			
Selling Unit NDC:	31722-211-10	722-211-10 Unit of Use NDC:					UPC:	UPC: 331722211109 MVX Code:			Notes						
UDI							MVX Code:	MVX Code.								-	
Description:	Vancomycin Hydr	ochloride for I	njection, USP 1 g/via	al (Single-dose	Vials)					Is this product to be shippe				No No			
Active Ingredient(s): Vancomycin hydrochloride, USP																	
URL for Additional Product Information: www.camberpharma.com										b. Contact fo	r temperature excursion q Name:	uestions:	Soma Raju				
Address:		ennial Ave, Suite 1					Address 2:			Number: 73				23			
City:	Piscataway						te: NJ Zip: 08854			Group E-mail:				neterousa.cor	n		
Key Contact:	Customer Service	9				Email:	customerservice@camberpharma.com				•						
Phone Number:	1-866-827-3647						Fax: 732-562-8788			c. Special regulations for product in any states?				No			
Product Therapeutic Classification	n:	Tricyclic glyd	copeptide antibiotic								Special returns requirement	nts for this product?			No		
																7	
ADDITIONAL PRODUCT INFORMATION							PRODUCT DESCRIPTION INFORMATION				d. Store product (unit of sale) upright?				No		
The product is?				Is the Product Direct-Ship						Protect product (unit of sale) from light?					No		
a legend device?		No	Is the Pro		Unit Dose		Size:	10	0 single-dose vials	e. Shelf life:	ladelad abatelite at lassach	(16 -1166)			18	Months	
if yes, enter class # a product kit?		No			Orphan Drug Status			1 gm/vial			initiai sneir lire at launch	shelf life at launch (if different):				Months	
if yes, list NDCs of		FDA Approval Status					Strength:		gili/viai		IATION						
component parts	- Darright Guide						D F	Ste	erile, lyophilized powder or cake for								
reverse numbered?	No						Dosage Forn		eparing intravenous infusions or ections		Unit of Sale		NDC selling	unit?	.?		
co-licensed?		No	Allergen	s Present							Bottle		1 Box of 10				
latex-free?		Yes					Product Sha	ipe:	owder in single-dose vial	x Box/Carton (Write-in, e.g. 1 Box of 10 Vials)					0 Vials)		
preservative-free? correctional institution block?	Yes No						White to tan			Ampule x Glass		Minimum order quantity? Yes			Yes		
opioid?		No					Product Cole	or:	mile to tan		Tube		Williamo	ruer quantity	r	162	
Cannabinoid?		No Country of Origin India				Braduat Imprint			/A	Vial Liquid Sgl							
If Unit Dose, is item bar coded to u	is item bar coded to unit dose for					Product Imprint:					Vial Liquid Multi		If Yes, how many of which package type?				
hospital scanning?										x Vial Powder Sgl 1 Each							
If Unit Dose, indicate NDC here: 31722-211-33 Trade Agreements Act (TAA)?						No				Vial Powder Multi Inner/Carton/Pack							
FOR GENERIC DRUG PRODUCTS											Other: Write In			Case			
			FOR GENE	RIC DRUG PR	RODUCTS												
						Δ.	thorized Generic	*If Author	rized Ceneric other		Р	HARMACY ORDER	/ BILL UNIT				
I. Orange Book Rating: AP							Authorized Generic *If Authorized Generic, other section fields are not applicable			Rec. sell unit to customer? Rx billing unit to pharmacy:							
I. Orange Book Rating: II. Generic Equivalent to What Brand?: Vancomycin Hydrochloride for Injection (Fresenius Kabi USA, L					LC)				ixec. sen unit	Each							
ii. Generic Equivalent to What Brands.						·			(Write-in, e.g. 1 Vial)				Gram				
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION										HCPCS J-Co				Milliliter			
											J3373						
Does supplier meet DSCSA definition of manufacturer? Yes GLN:							GLN: 0331722498975				ITEM AND PACKING INFORMATION						
Is product exempt from DSCSA? No																	
If yes, select exemption:						GCP:					Weight Lbs.		ions (US msr		Volume	Saleable #	
Other exemption - Write in: Is product repackaged?			No			If you was -	riginal product pur	chaecd		Item/Each:	-	Depth	Width	Height	(Cube)	Pieces	
Is product repackaged? Is product sold by manufacturer's	avelusiva distribu	ıtor?	Ye	<u> </u>	-	direct from n		Ciiaseu		itelli/Eacil.	0.65	6.37	2.5	3.56	56.69	1	
Has FDA granted waiver/exception/exemption for product?						Provide source manufacturer for repackaged product			ged product	Box/Carton/E	Bundle/						
If yes, attach documentation from	m FDA.									Inner Pack:							
										Case:	14.4	13.25	13	8	1378	20	
			GTIN AND HIBC	C PRODUCT I	NFORMATION						1	11		-			
Saleable Unit of Measure	DEID tog(V/N)	Calcabla	HIBCC			CTI	N-14		Unit of Use GTIN-14	Pallet:							
Jaieable Offic of Measure	RFID tag(Y/N)	Quantity	півсс			GII	14-14	,	OTHE OF USE GTHV-14								
x Item/Each																	
Box/Carton/Bundle/Inner Pack										WHOLESALER USE ONLY:							
X Case N 20				203	20331722211103												
Pallet							Regular Cost			Vendor #:							
								Invoice Cost (WAC) (\$) \$30.00			Whsl. Code #: Fineline Code:						
								_		As of date:	12/1/2022		rineline Co	ue:			
										As or date.	12/1/2022		1				
			Attach copy	of SAFETY DA	ATA SHEET (SD	S) or non haza	rd letter, PACKAGE	INSERT,	LABEL AND PHOTO OF P	RODUCT PACK	AGING and BARCODE.						
	ormation on page		1,		•				ed Dron Shin Only								