



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

Version 2024

Introduction Type: New Item

☒ Final Version

Date: 7/1/2025

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Camber Pharmaceuticals, Inc.				Application: ANDA			
Application Number for NDA/ANDA/BLA; PMA/510(k): 216591				NDA 505(b) Type: NOT APPLICABLE			
Medical Device Class, if applicable:							
DUNS: 11-856-3719							
Proprietary Name (If Applicable) and Established Name: Vancomycin Hydrochloride for Injection, USP 1 g/vial (Single-dose Vials)							
Selling Unit NDC: 31722-211-10				Unit of Use NDC:			
UDI				UPC: 331722211109			
CVX Code:				MVX Code:			
Description: Vancomycin Hydrochloride for Injection, USP 1 g/vial (Single-dose Vials)							
Active Ingredient(s): Vancomycin hydrochloride, USP							
URL for Additional Product Information: www.camberpharma.com							
Address: 800 Centennial Ave, Suite 1				Address 2:			
City: Piscataway				State: NJ Zip: 08854			
Key Contact: Customer Service				Email: customerservice@camberpharma.com			
Phone Number: 1-866-827-3647				Fax: 732-562-8788			
Product Therapeutic Classification: Tricyclic glycopeptide antibiotic							
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is?		Is the Product...		Size:		10 single-dose vials	
a legend device?		Is the Product...		Strength:		1 gm/vial	
if yes, enter class #		Orphan Drug Status		Dosage Form:		Sterile, lyophilized powder or cake for preparing intravenous infusions or injections.	
a product kit?				Product Shape:		Powder in single-dose vial	
if yes, list NDCs of component parts		FDA Approval Status		Product Color:		White to tan	
reverse numbered?				Product Imprint:		N/A	
co-licensed?		Allergens Present					
latex-free?							
preservative-free?		Country of Origin		India			
correctional institution block?							
opioid?							
Cannabinoid?							
If Unit Dose, is item bar coded to unit dose for hospital scanning?		Is this product covered under the Trade Agreements Act (TAA)?		No			
If Unit Dose, indicate NDC here:				31722-211-33			
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: AP				<input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: Vancomycin Hydrochloride for Injection (Fresenius Kabi USA, LLC)							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer?				GLN: 0331722498975			
Is product exempt from DSCSA?							
If yes, select exemption:				GCP:			
Other exemption - Write in:							
Is product repackaged?				If yes, was original product purchased direct from mfr?			
Is product sold by manufacturer's exclusive distributor?				Provide source manufacturer for repackaged product			
Has FDA granted waiver/exception/exemption for product?							
If yes, attach documentation from FDA.							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure		RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14	
<input checked="" type="checkbox"/> Item/Each		N	1		00331722211109		
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack		N	20		20331722211103		
<input checked="" type="checkbox"/> Case							
<input checked="" type="checkbox"/> Pallet							
ITEM AND PACKING INFORMATION							
	Weight Lbs.	Dimensions (US msmts.)	Volume (Cube)	Saleable # Pieces			
		Depth	Width	Height			
Item/Each:	0.65	6.37	2.5	3.56	56.69	1	
Box/ Carton/ Bundle/ Inner Pack:							
Case:	14.4	13.25	13	8	1378	20	
Pallet:							
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost				Vendor #:			
Invoice Cost (WAC) (\$)				Whsl. Code #:			
As of date: 12/1/2022				Fineline Code:			

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING AND BARCODE.

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature: