

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

Version 2021						Introduction	Туре:	New Item	[x Final Version			Date:	6/23/2024			
			PRODUCT INFORMA	TION						SPECIAL HAN	IDLING AND STO	RAGE REQUI	REMENTS*	*			
Company Name: Camber Pharmaceuticals Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.											
	lumber for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 203825 Temperature Range Controlled Room - between 20 and 25 C							and 25 C (68	° – 77° F)								
Medical Device Class, if applicable:																	
DUNS:	11-856-3719									Other Temperature Range	Requirement	Excursions	permitted to 1	5–30°C (59–8	86°F)		
Proprietary Name (If Applicable) and		ame: Nebi	ivolol Tablets 5 mg							(write in)							
Selling Unit NDC:	31722-586-90		Unit of Use NDC:		31722-586-90		3317225869	00		Notes							
UDI			CVX Code:			MVX Code:											
Description:	Nebivolol Tablets	s 5 mg								Is this product to be shippe				No]		
Is this product to be shipped to customers on dry ice? No							_										
Active Ingredient(s): Nebivolol hydrochloride b. Contact for temperature excursion questions:																	
URL for Additional Product Inform	ation:	www.camberphar	ma.com							Name:	estions:	Soma Raju					
Address:	800 Centennial A					Address 2:				732-529-0423							
City:	Piscataway				State:	NJ	NJ 08854			Group E-mail:				somaraju@heterousa.com			
Key Contact:	Customer Service	е			Email:		customerservice@camberpharma.com										
Phone Number:		-866-827-3647 Fax:			Fax:	732-562-8788			c. Special regu	No							
Product Therapeutic Classification	า:	Beta-adrenergic b	blocking agent						Special returns requirements for this product?				No				
						DRODUAT	DECODUCTO			at fourth a first hard hard hard hard hard hard hard hard					1		
	ADDITI	IONAL PRODUCT I				PRODUCT	DESCRIPTIO	N INFORMATION	-	ct (unit of sale) upright?				No	1		
The product is?			Is the Product	Direct-Ship C	Uniy		0.7			Protect product (unit of s	ale) from light?			No			
a legend device?		No	Is the Product	Unit of Use		Size:	90 ct		e. Shelf life:	Initial chalf life at laws -	if different's			24	Months		
if yes, enter class # a product kit?		No	Orphan Drug Status			1	5 mg			Initial shelf life at launch	ir ainterent):				Months		
if yes, list NDCs of		NO	FDA Approval Status			Strength:	5 mg				ORDER INFORI	MATION					
component parts						Dosage For	m. Table	ət									
reverse numbered?		No				Dosage For				Unit of Sale			NDC selling	unit?			
co-licensed?		No	Allergens Present							x Bottle		1 Bottle of 9					
latex-free?		Yes				Product Sha	ape: Trian	gular, biconvex		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)			
preservative-free?		Yes					Linht			Ampule Glass		Minimum		•	Yes		
correctional institution block? opioid?		No No				Product Co	lor:	orange		Tube		winimum o	rder quantity	ſ	res		
Cannabinoid?		No	Country of Origin	India			. Debos	ssed with 'J' on one side		Vial Liquid Sgl							
If Unit Dose, is item bar coded to u	nit dose for		,			Product Imp	orint: and '9	on the other side		Vial Liquid Multi		If Yes, how	many of whi	ch package t	type?		
hospital scanning?			Is this product covered u	inder the						Vial Powder Sgl		24	Each				
If Unit Dose, indicate NDC here:			Trade Agreements Act (FAA)?	No					Vial Powder Multi			Inner/Carton	/Pack			
										Other: Write In			Case				
			FOR GENERIC DRUG PR	ODUCTS													
					Δυ	thorized Generic	*If Authorize	d Generic, other		PI	ARMACY ORDER						
L Orenne Back Beting	AB			-		anonzed Generic		s are not applicable	Rec. sell unit t				nit to pharma				
I. Orange Book Rating: II. Generic Equivalent to What Brar		Bystolic							Nec. sen unit t	o customer :		RX billing u	Each	acy:			
II. Generic Equivalent to what Brand ?: bystolic							(Write-in, e.g. 1 Vial) Gram										
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION								,			Milliliter						
Does supplier meet DSCSA definit	tion of manufactu	rer?	Yes	_	GLN:	0331722498975				ITEI	I AND PACKING I	NFORMATIO	N				
Is product exempt from DSCSA?		L	No														
If yes, select exemption:					GCP:					Weight Lbs.		ions (US msn		Volume	Saleable #		
Other exemption - Write in: Is product repackaged?			No		If you was as	riginal product pu	rehead		Item/Each:	-	Depth	Width	Height	(Cube)	Pieces		
Is product sold by manufacturer's	exclusive distribu	utor?	Yes	-	direct from m		chased		item/Each:	0.11	1.74	1.74	3.36	10.17	1		
Has FDA granted waiver/exception			No	-		ce manufacturer f	or repackaged	d product	Box/Carton/Bu	ndle/							
If yes, attach documentation from		L							Inner Pack:								
									Case:	3.15	11.5	8	4.5	414	24		
		G	TIN AND HIBCC PRODUCT I	NFORMATION								-					
Saleable Unit of Measure					0.71		11-1	OTIN 44	Pallet:								
X Item/Each	2	Saleable Quantity	HIBCC			N-14 31722586900		t of Use GTIN-14 31722586900									
Box/Carton/Bundle/Inner Pack		· · · ·				01722000000		01122000000		COST INFORMATION			WHOLESALI	ER USE ONL	.Y:		
X Case		24			203	31722586904						1					
Pallet	_								Regular Cost			Vendor #:					
							_		Invoice Cost (VAC) (\$)	\$21.00	Whsl. Code					
	-						-		An of data	4/15/2024		Fineline Co	de:				
	-				-		-		As of date:	4/15/2024		-					
	1																
<u> </u> +			Attach copy of SAFETY DA	TA SHEET (SP)S) or non haza	rd letter, PACKAG	E INSERT, I AI	BEL AND PHOTO OF F	RODUCT PACKA	GING and BARCODF							
*Please provide any additional info	ormation on page	2.			, oon naza	See new p. 3 fo				Signature:							

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

Version 2021 For Designated 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? 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? (if yes, answer a-e below and provide SDS) a. UN/Identification Number 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, indicate which: Image: Storage Level:						
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Code:						
(if yes, answer a-e below and provide SDS)	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: No 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) Special Permit; DOT-SP	REMS: No 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 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 Controlled by State(s)? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which:	RETURN INSTRUCTIONS Contact tel. # if product received damaged: 732-529-0430 Is product returnable for credit: Yes						
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	contact email: customerservice@camberpharma.com						
Restricted to retail pharmacy only: No Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No	Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?						
Comments:							
	EOUS NOTES and/or Image of Product Barcode:						



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

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?