

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 STOP	RAGE REQUIR	REMENTS*		
Company Name: Camber Pharmaceuticals				Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/ANI	DA/BLA (drug); PMA/510	k)(med device	e):	20	3825					Temperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab	Medical Device Class, if applicable:														
DUNS:	11-856-3719									Other Temperature Range	Requirement	Excursions p	ermitted to 1	5–30°C (59–8	36°F)
Proprietary Name (If Applicable) a		Nebivol	ol Tablets 5 mg							(write in)					
Selling Unit NDC:	31722-586-30		Unit of Use NDC:		31722-586-30		3317225863	306		Notes					
UDI			CVX Code:			MVX Code:									
Description:	Nebivolol Tablets 5 mg									Is this product to be shippe				No	
Active Ingredient(s): Nebivolol hydrochloride No															
Active Ingredient(s): Nebivoloi hydrochloride b. Contact for temperature excursion questions:															
URL for Additional Product Inform	ation:	amberpharma.	com							Name:	estions.	Soma Raju			
Address:	800 Centennial Ave, Suit					Address 2:				Number:		732-529-042	3		
City:	Piscataway State:			NJ					somaraju@heterousa.com						
Key Contact:	Customer Service						ustomerservice@camberpharma.com								
Phone Number:	1-866-827-3647				Fax:	732-562-8788				lations for product in any				No	
Product Therapeutic Classification	n: Beta-a	adrenergic bloc	king agent							Special returns requiremen	ts for this product?			No	
	ADDITIONAL F					PPODUCT	DESCRIPTIO	N INFORMATION	d Store produ	ct (unit of sale) upright?				No	
	ADDITIONAL	RODOCT INF		Direct Ch'r f	Cally	TRODUCT	BESCHIPTIO		-						
The product is?	KI -		Is the Product	Direct-Ship (Unit of Use	Jniy		20 -1			Protect product (unit of sa	ale) from light?			No	Monthe
a legend device? if yes, enter class #	No		Is the Product Orphan Drug Status	Unit UI USE		Size:	30 ct		e. Shelf life:	Initial shelf life at launch (if different).			24	Months Months
a product kit?	No		Orphan Drug Status				5 mg			initial shell life at launch	in unierenty.				WOITIN
if yes, list NDCs of			FDA Approval Status			Strength:	g				ORDER INFORM	IATION			
component parts						Dosage For	Table	et							
reverse numbered?	No					Desageron				Unit of Sale		What is the		unit?	
co-licensed?	No		Allergens Present							x Bottle		1 Bottle of 30			
latex-free?	Yes					Product Sha	ape:	gular, biconvex	-	Box/Carton		(Write-in, e.g	g. 1 Box of 1	0 Vials)	
preservative-free? correctional institution block?	Yes						Light	orange	-	Ampule Glass		Minimum or	dor quantitu		Yes
opioid?	No					Product Col	lor:	orange	-	Tube		Willing of	uer quantity	t I	Tes
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			, ,			Product Imp	print: 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							Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?	No					Vial Powder Multi			Inner/Cartor	/Pack	
										Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS					-						
Authorized Generic *If Authorized Generic, other							PHARMACY ORDER / BILL UNIT								
I. Orange Book Rating:	AB							s are not applicable	Rec. sell unit to			Rx billing ur			
II. Generic Equivalent to What Bran		ic							itee. sen unit t	o customer i		KX bining u	Each	acy.	
							(Write-in, e.g. 1	I Vial)			Gram				
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION															
Does supplier meet DSCSA definit	tion of manufacturer?		Yes	_	GLN:	0331722498975				ITEN	I AND PACKING I	NFORMATION			
Is product exempt from DSCSA?			UVI						1		_				
If yes, select exemption:					GCP:				1	Weight Lbs.		ions (US msm	'		Saleable #
Other exemption - Write in: Is product repackaged?			No		If yos was as	iginal product pur	rchased		Item/Each:	-	Depth	Width	Height	(Cube)	Pieces
Is product sold by manufacturer's	exclusive distributor?		Yes	-	direct from m		lenased		nem/Lacii.	0.06	1.52	1.52	2.54	5.87	1
Has FDA granted waiver/exception			No	-		ce manufacturer fo	or repackaged	d product	Box/Carton/Bu	ndle/					
If yes, attach documentation from	n FDA.								Inner Pack:						
									Case:	1.9	10	6.75	4.25	286.88	24
		GTIN	AND HIBCC PRODUCT I	NFORMATION					Pallet:						
Saleable Unit of Measure	Saleable	Quantity	HIBCC		CTI	N-14	Lini	t of Use GTIN-14	Pallet:						
x Item/Each		1	TIDOC			31722586306		31722586306							
Box/Carton/Bundle/Inner Pack								COST INFORMATION			WHOLESALER USE ONLY:				
X Case	2	4			203	31722586300									
Pallet					_				Regular Cost			Vendor #:			
	-						_		Invoice Cost (V	VAC) (\$)	\$7.00	Whsl. Code			
	-				-		-		As of date:	4/15/2024		Fineline Coo	1e:		
	-						-		As or date:	7/10/2024		1			
									1			1			
l.			Attach copy of SAFETY DA	ATA SHEET (SI	DS) or non haza	rd letter, PACKAGE	E INSERT. LAI	BEL AND PHOTO OF P	RODUCT PACKAG	GING and BARCODE.		•			
*Please provide any additional info	ormation on page 2.				, -, -, -, -, -, -, -, -, -, -, -, -,	See new p. 3 for				Signature:					
	1.00									-					

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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?