

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

Version 2021						Introduction T	уре:	New Item		x Final Ve	ersion			Date:	6/23	3/2024
			PRODUCT INFORMA	TION						SPE	CIAL HAND	LING AND STOR	AGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.										
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 203825							Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)									
Medical Device Class, if applicable:																
DUNS:	11-856-3719								l l	Other Temperatu	re Range Re	equirement	Excursions r	permitted to 1	5-30°C (59-	-86°F)
Proprietary Name (If Applicable) a		ame: Nebiv	olol Tablets 2.5 mg						ī I	(write in)	ro rango ra	oquironioni	- Literature	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	0 00 0 00	.,
Selling Unit NDC:	31722-585-30		Unit of Use NDC:		31722-585-30	UPC:	33172	2585309		Notes						
UDI			CVX Code:			MVX Code:	00112									
Description:	Nebivolol Tablets	s 2.5 mg													No	-
Active Ingredient(s): Nebivolol hydrochloride									Is this product to	be snipped	to customers on a	ry ice?		No		
Active ingredient(s):		Nebivoloi riyarochi	onde						h Contact fo	or temperature exc	urcion aug	etions:				
URL for Additional Product Information: www.camberpharma.com						b. Contact ic	Name:	ursion que	stions:	Soma Raju						
Address:	800 Centennial A		ia.com			Address 2:			1	Number:			732-529-042	3		
City:	Piscataway				NJ		08854		Group E-mail:				neterousa.cor	n		
Key Contact:	Customer Service	e.	Email: customerservice@caml				acambe			Group E maii.	<u>somaraja e r</u>	marajo metorododisem				
Phone Number:	1-866-827-3647				732-562-8788			c Special re	gulations for produ	uct in any s	tates?			No	1	
Product Therapeutic Classification		Reta-adrenergic bl	ocking agent						or openiar re		-				No	1
Product Therapeutic Classification: Beta-adrenergic blocking agent No																
	ADDIT	IONAL PRODUCT IN	NFORMATION			PRODUCTO	DESCRI	PTION INFORMATION	d. Store product (unit of sale) upright?							1
The modern to 2				Direct-Ship C	Only	11.050012	-100111		a. otore proc							1
The product is?			Is the Product		only					Protect product	(unit of sale	e) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:		30 ct	e. Shelf life:						24	Months
if yes, enter class #			Orphan Drug Status					0.5		Initial shelf life a	it launch (if	different):				Months
a product kit?		No	ED 4 4 101-1			Strength:		2.5 mg				ORDER INFORM	ATION			
if yes, list NDCs of			FDA Approval Status					T-1-1-1				ORDER INFORM	IATION			
component parts reverse numbered?		lat.				Dosage Form	n:	Tablet		Unit of Sale			What is the	NDC colling	unit?	
co-licensed?		No No	Allergens Present							x Bottle			1 Bottle of 3		unit:	
latex-free?		Yes	Allergens Present					Triangular, biconvex		Box/Ca	rton			g. 1 Box of 1	O Viole)	
preservative-free?		Yes				Product Shap	pe:	mangular, biconvex		Ampule			(vviite-iii, e.	g. 1 box 01 1	U Viais)	
correctional institution block?		No						White to off-white		Glass			Minimum o	dor quantity	2	Yes
opioid?		No				Product Colo	or:	Write to oil-write		Tube			William Ci	uer quantity		163
Cannabinoid?		No	Country of Origin	India				Debossed with 'J' on one side		Vial Liq	uid Sal					
If Unit Dose, is item bar coded to	unit dose for	140	country or origin	maia		Product Impr	rint:	and '8' on the other side			uid Multi		If Yes, how	many of whi	ch package	type?
hospital scanning?	unit dosc for		Is this product covered u	inder the							wder Sql			Each	on paonago	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
If Unit Dose, indicate NDC here:			Trade Agreements Act (No						wder Multi			Inner/Cartor	/Pack	
iii omit Bood, maioato 1420 nore.										Other: V				Case		
			FOR GENERIC DRUG PR	ODUCTS										1		
					Aut	horized Generic	*If Auth	horized Generic, other	PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating:	AB						section	n fields are not applicable	Rec. sell uni	t to customer?			Rx billing u	nit to nharm	acv.	
II. Generic Equivalent to What Bra		Bystolic											TOX Dilling to	Each	,.	
ii. Generio Equivalent to What Brand.						(Write-in, e.g. 1 Vial) Gram										
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION						• • • • • • •	, .,				Milliliter					
Does supplier meet DSCSA defini	ition of manufactu	rer?	Yes		GLN:	0331722498975					ITEM	AND PACKING IN	IFORMATIO	V		
Is product exempt from DSCSA?			No													
If ves. select exemption:					GCP:							Dimension	ons (US msn	nts.)	Volume	Saleable #
Other exemption - Write in:					•				' [Weig	ght Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was ori	iginal product purc	chased		Item/Each:		0.06	1.52	1.52		5.87	
Is product sold by manufacturer's	exclusive distrib	utor?	Yes		direct from mi						0.00	1.52	1.52	2.54	5.87	1
Has FDA granted waiver/exceptio	n/exemption for p	roduct?	No	\Box	Provide source	e manufacturer for	r repac	kaged product	Box/Carton/I	Bundle/						
If yes, attach documentation fro	m FDA.								Inner Pack:							
									Case:		1.75	10	6.75	4.25	286.88	24
		GT	IN AND HIBCC PRODUCT I	NFORMATION							0		00	20	200.00	
II									Pallet:							
Saleable Unit of Measure	\$	Saleable Quantity	HIBCC		GTIN			Unit of Use GTIN-14								
X Item/Each		1			0033	31722585309		331722585309		COSTANGOS	MATION			WILOL EQ	ER USE ONL	V
Box/Carton/Bundle/Inner Pack		0.1			-		-			COST INFOR	MATION			WHOLESAL	ER USE ONL	.Y:
X Case		24			2033	31722585303	-		Demi-ter C				Vand #			
Pallet									Regular Cos				Vendor #:	ш.		
	_								Invoice Cost	(VVAC) (\$)	-	\$7.00	Whsl. Code			
	-						-		As of date:	4/15/20	24		Fineline Co	ue.		
	-								As of date:	4/15/20			1			
ļ '			Attach copy of SAFETY D	ATA SHEET (SE	S) or non hazar	d letter PACKAGE	INSEP	T, LABEL AND PHOTO OF P	BUDITICE BYCK	AGING and RAPCO	DDE					
*Please provide any additional inf	formation on page	2.	,	011221 (02	, or non nazar			ated Drop Ship Only.		Signature:						



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION							
Is this product (check all that apply): a. Cytotoxic? No	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	SDO TRACTIC CIRCUSTICATION						
Is the product a CA Prop 65 carcinogen?	x Organic Corrosive						
Is the product a CA Prop 65 reproductive toxicant?	Inorganic Oxidizer						
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard						
c. Contact Hazard?	Does the product have an Aerosol class? If yes, No						
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:						
(If yes, attach SDS with special instructions.)	NFPA Storage Level:						
e. Does the product contain DEHP?							
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug? No						
(if yes, answer a-e below and provide SDS)	If yes, indicate which:						
a. UN/Identification Number							
b. Proper Shipping Name							
c. DOT Hazard Class	Hazardous Waste Identification						
d. Packing Group							
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics						
Is this product regulated for shipment by IATA?							
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS						
a. UN/Identification Number							
b. Proper Shipping Name	Is there a REMS on this product?						
c. DOT Hazard Class	If Yes, is it managed with a pharmacy registry?						
d. Packing Group	Website URL:						
e. Inhalation Hazard?							
Is the product restricted for air shipment? If so, indicate restriction:	Med Guide Required No						
Passenger	Limited Distribution Requirement						
Cargo	Comments / Details: (For example, iPledge program?)						
Passenger & Cargo							
Is this a reportable quantity? No	REMS: No						
RQ Threshold:	REMS Program Manager Name: Phone:						
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:						
Is this product shipped utilizing an authorized DOT exception or Special Permit? No (if yes, identify method below)	Wholesale distributor support:						
No (if yes, identify method below) Limited Quantity	Provider Name: Site Enrollment Number assigned DEA #: NCPDP#:						
Consumer Commodity, ORM-D	by Supplier: NPI #:						
Small Quantity (49 CFR 173.4)	Бу Сарриет.						
Special Permit; DOT-SP	Comments						
Special Provision (listed in Column 7 of 49 CFR 172.101);							
SP#	Registry: No						
	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	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:	Contact tel. # if product received damaged: 732-529-0430						
Schedule No. Is it a scheduled listed chemical product?: No	Is product returnable for credit:						
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:	Special regulations or returns requirements for this						
Restricted to hospital, clinics, and physician offices only: No	product in certain states?						
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?						
Comments:							
- Commonted							
_ MICCELL AND	US NOTES and/or Image of Product Barcode:						
MISCELLANEO	03 NOTES and/or image of Product Barcoue.						



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FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop S	nip Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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 Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order:		Overnight receipt available: PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:		Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
		Priority Overnight receipt available:
Class of Trade Restriction		PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		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? Is product order for restocking purposes?