

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

Version 2021						Introduction Ty	ype:	New Item		x Final V	ersion			Date:	6/23/2024	
			PRODUCT INFORMA	TION						SPE	CIAL HAN	DLING AND STOR	AGE REQUII	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					and 25 C (68	25 C (68° – 77° F)			
Application fundamental and a series of the																
DUNS:	11-856-3719									Other Temperatu	re Range R	equirement	Excursions r	ermitted to 1	5-30°C (59-8	86°F)
Proprietary Name (If Applicable) a		me: Nebiv	volol Tablets 10 mg							(write in)					(.,
Selling Unit NDC:	31722-587-90		Unit of Use NDC:		31722-587-90	UPC:	331722	587907		Notes						
UDI			CVX Code:			MVX Code:										
Description:	Nebivolol Tablets	10 ma								la thia product to	ho obinnod	to customers on ic	-2		No	1
Description.	Nebivoidi Tablets	10 mg										to customers on di			No	
Active Ingredient(s): Nebivolol hydrochloride									is this product to	be shipped	to customers on a	y 100 :		140	1	
							b. Contact fo	r temperature exc	ursion que	stions:						
URL for Additional Product Information: www.camberpharma.com						Name: Soma Raju										
Address:	800 Centennial Av	ve, Suite 1				Address 2:			·	Number:			732-529-042	3		
City:	Piscataway				State:	NJ		08854			somaraju@heterousa.com					
Key Contact:	Customer Service)			Email:	customerservice@	camber	rpharma.com								
Phone Number:	1-866-827-3647				Fax:	732-562-8788			c. Special reg	gulations for prod	uct in any	states?			No	1
Product Therapeutic Classificatio	n:	Beta-adrenergic bl	locking agent							Special returns re	equirements	s for this product?			No	
Openia indiana requirementa in the present.											1					
	ADDITI	ONAL PRODUCT IN	NFORMATION			PRODUCT D	ESCRIF	PTION INFORMATION	d. Store prod	luct (unit of sale) u	upright?				No	1
The product is?			Is the Product	Direct-Ship C	nlv					Protect product	(unit of sal	le) from light?			No	ī
a legend device?		No	Is the Product	Unit of Use			0	90 ct	e. Shelf life:	. rotoot product	(4	,g			24	Months
if yes, enter class #		110	Orphan Drug Status			Size:		00 00	0. 0	Initial shelf life a	at launch (i	f different):				Months
a product kit?		No	o.p.iai. Drug otatuo					10 mg			(.					
if yes, list NDCs of		1.14	FDA Approval Status			Strength:						ORDER INFORM	ATION			
component parts						B		Tablet								
reverse numbered?		No				Dosage Form	.			Unit of Sale			What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							x Bottle			1 Bottle of 9) Tablets		
latex-free?		Yes				Product Shap		Triangular, biconvex		Box/Ca	rton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes				Froduct Shap	Je.			Ampule	•					
correctional institution block?		No				Product Color	r. [Light peach		Glass			Minimum or	der quantity	?	Yes
opioid?		No				r roduct color	١. ا			Tube						
Cannabinoid?		No	Country of Origin	India		Product Impri		Debossed with 'J' on one side		Vial Liq						
If Unit Dose, is item bar coded to u	unit dose for					1 Toddot IIIIpii		and '10' on the other side			uid Multi				ch package	type?
hospital scanning?			Is this product covered u								wder Sgl		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (ГАА)?	No						wder Multi			Inner/Carton	/Pack	
										Other: \	Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS												
											BU	ARMACY ORDER	/ DULL LINUT			
				_	Aut			orized Generic, other fields are not applicable			PH					
I. Orange Book Rating:	AB						Section	neius are not applicable	Rec. sell unit	to customer?			Rx billing u		acy:	
II. Generic Equivalent to What Bra	ınd?:	Bystolic								4300				Each		
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION						(Write-in, e.g	. 1 Viai)				Gram Milliliter					
		DRUG SUFF	LI CHAIN SECURITI ACT	DSCSA) INFOR	IWATION									Millille		
Does supplier meet DSCSA defini	ition of manufactur	er?	Yes	_	GLN:	0331722498975					ITEM	AND PACKING IN	IFORMATIO	J		
Is product exempt from DSCSA?	ition of manaractar		No	_	OLIT.	0001122400010						7.1.1.2 1 7.1.3 1.1.1.2 1.1.1		•		
			-		000							Dimensis	ons (US msn	uto \	M = 1	0-11-1-#
If yes, select exemption: Other exemption - Write in:					GCP:					Weig	ght Lbs.	Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Is product repackaged?			No		If you was ori	ginal product purcl	hacad		Item/Each:						I .	
Is product sold by manufacturer's	exclusive distribu	itor?	Yes	_	direct from mf		iluscu		item/Lucii.		0.12	1.74	1.74	3.36	10.17	1
Has FDA granted waiver/exceptio			No	-		e manufacturer for	repack	raged product	Box/Carton/E	Bundle/						
If yes, attach documentation from								g p	Inner Pack:							
-									Case:		3.15	11.5	8	4.5	414	24
		GT	IN AND HIBCC PRODUCT I	NFORMATION						,	3.15	11.5	0	4.5	414	24
									Pallet:							
Saleable Unit of Measure	S	aleable Quantity	HIBCC		GTIN			Unit of Use GTIN-14								
X Item/Each		1			0033	1722587907		00331722587907								
Box/Carton/Bundle/Inner Pack										COST INFOR	MATION			WHOLESALI	ER USE ONL	.Y:
X Case		24			2033	1722587901										
Pallet									Regular Cost				Vendor #:			
									Invoice Cost	(WAC) (\$)		\$21.00	Whsl. Code			
									1	4/45/00	10.4		Fineline Co	de:		
	_								As of date:	4/15/20	124					
 			Attach convert CAFETY D	TA CHEET (OD	(C) or non-hor-	d letter BACKACE	INICEDT		PODLICT DACK	VCINC or 1 DVDO	ODE					
			ALIACTI CODY OF SAFETY DA	AIA SHEET (SD	ט נבי ui nun nazar	u ieller, PACKAGE I	INDEKI	I, LADEL AND PHOTO OF P	KUDUCI PACK	AGING AND BARCO	JUE.					
*Please provide any additional inf	iormation	•	.,			Coo now = 2 f == 5		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?	SDS nazdru Glassification						
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) No	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?