

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

Version 2021						Introduction T	уре:	New Item		x Final Version			Date:	6/23/2024	
			PRODUCT INFORMA	ΓΙΟΝ						SPECIAL HA	NDLING AND STOR	RAGE REQUIF	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			3825				Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)								
Medical Device Class, if applicable:															
DUNS:	11-856-3719									Other Temperature Range	Requirement	Excursions p	ermitted to 1	5-30°C (59-	86°F)
Proprietary Name (If Applicable) as	nd Established Na	ame: Net	pivolol Tablets 10 mg							(write in)	•				
Selling Unit NDC:	31722-587-30		Unit of Use NDC:		31722-587-30		3317225	87303		Notes					
UDI			CVX Code:			MVX Code:									
Description: Nebivolol Tablets 10 mg Is this product to be shipped to customers on ice? No									1						
									Is this product to be shipp				No		
Active Ingredient(s): Nebivolol hydrochloride													_		
								b. Contact for temperature excursion questions:							
URL for Additional Product Inform		www.camberpha	rma.com							Name:		Soma Raju			
Address:	800 Centennial Av	ve, Suite 1				Address 2:				Number:		732-529-042			
City:	Piscataway					NJ 08854				Group E-mail:		somaraju@h	eterousa.cor	<u>n</u>	
Key Contact:	1-866-827-3647				customerservice@camberpharma.com 732-562-8788			c. Special regulations for product in any states?				1			
Phone Number:		Data adamenta	Electron and a		Fax:	132-302-0100			c. Special reg	•	-			No	-
Product Therapeutic Classification	1:	Beta-adrenergic	blocking agent							Special returns requireme	nts for this product?			No	
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION d. Store product (unit of sale) upright?															
	ADDITI	ONAL PRODUCT				PRODUCT D	JESCRIPI	ION INFORMATION	d. Store prod	uct (unit of sale) upright?				No	_
The product is?			Is the Product	Direct-Ship C	Only					Protect product (unit of	sale) 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							Initial shelf life at launch	(if different):				Months
a product kit?		No	FDA Ammanual Status			Strength:	10	) mg			ORDER INFOR	AATION			
if yes, list NDCs of component parts			FDA Approval Status				To	ablet			OKDEK INFORI	MATION			
reverse numbered?		No				Dosage Form	n: '°	abiet		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							x Bottle		1 Bottle of 30			
latex-free?		Yes	J				Tr	iangular, biconvex		Box/Carton		(Write-in, e.		0 Vials)	
preservative-free?		Yes				Product Shap	pe:	3,		Ampule		, , , ,		,	
correctional institution block?		No				Product Colo	Lie	ght peach		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Froduct Colo	,ı.			Tube					
Cannabinoid?		No	Country of Origin	India		Product Impr		ebossed with 'J' on one side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for					. roudet impr	an	d '10' on the other side		Vial Liquid Multi		If Yes, how		ch package	type?
hospital scanning?			Is this product covered u							Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	AA)?	No					Vial Powder Mul Other: Write In	ti		Inner/Carton	/Pack	
										Other: write in			Case		
			FOR GENERIC DRUG PR	DDUCIS											
					Auth	norized Generic	*If Author	rized Generic, other		P	PHARMACY ORDER	/ BILL LINIT			
	4.0			_	Add	ionzed Generic		elds are not applicable	Rec. sell unit		TIARIMAGT GROEN		to a l		
	AB	Duntalia							Rec. Sell unit	to customer?		Rx billing ur		acy:	
II. Generic Equivalent to What Brand?:  Bystolic									Each Gram						
		DRUG SUF	PLY CHAIN SECURITY ACT (	DSCSA) INFO	RMATION				(vviite-iii, e.g.	i viai)			Milliliter		
													· · · · · · · · · · · · · · · · · · ·		
Does supplier meet DSCSA definit	ion of manufactur	rer?	Yes	7	GLN:	0331722498975				ITE	M AND PACKING I	NFORMATION	١		
Is product exempt from DSCSA?			No	7											
If ves. select exemption:			<u> </u>		GCP:						Dimens	ions (US msm	its.)	Volume	Saleable #
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was orig	ginal product purc	hased		Item/Each:	0.07	1.52	1.52	2.54	5.87	1
Is product sold by manufacturer's	exclusive distribu	itor?	Yes		direct from mf	r?	_			0.07	1.52	1.52	2.54	5.67	1
Has FDA granted waiver/exception		roduct?	No		Provide source	e manufacturer for	r repacka	ged product	Box/Carton/B	undle/					
If yes, attach documentation fron	n FDA.								Inner Pack:						
									Case:	1.95	10	6.75	4.25	286.88	24
		(	STIN AND HIBCC PRODUCT I	NFORMATION											
Saleable Unit of Measure		Saleable Quantity	HIBCC		GTIN	4.4		Unit of Use GTIN-14	Pallet:						
x Item/Each	5	1	ПВСС			1722587303		00331722587303							
Box/Carton/Bundle/Inner Pack					0033					COST INFORMATION			WHOLESAL	ER USE ONL	Y:
X Case		24			2033	1722587307					•				
Pallet					1		1		Regular Cost			Vendor #:			
	1						1		Invoice Cost	(WAC) (\$)	\$7.00	Whsl. Code	#:		
												Fineline Cod			
									As of date:	4/15/2024					
<u> </u>									1			<u> </u>			
l		_	Attach copy of SAFETY DA	TA SHEET (SE	OS) or non hazard				RODUCT PACKA						
*Please provide any additional info	ormation on page	2.				See new p. 3 for l	Designate	ed 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 Hazard Classification						
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?