

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

Version 2024						Introduction Ty	pe: New Item		x Final Version			Date:	7/16/	6/2024	
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*			
Company Name: Camber Pharmaceuticals, Inc.						Application	on: ANDA	DA a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/AN	NDA/BLA; PMA/510	O(k): 20	5541			NDA 505(b) Type:	NOT APPLICABLE		emperature Range	Controlled Room		and 25 C (68	3° – 77° F)		
Medical Device Class, if applica	ıble:														
DUNS:	11-856-3719								Other Temperature Range	Requirement					
Proprietary Name (If Applicable) a		ame: M	etoprolol Succinate Extended-Re	lease Tablets,	USP 50 mg				(write in)						
Selling Unit NDC:	31722-590-10		Unit of Use NDC:				331722590105	_ N	lotes						
UDI			CVX Code:			MVX Code:									
Description:	Metoprolol Succir	nate Extended-Re	lease Tablets, USP 50 mg						s this product to be shippe				No		
Active Ingredient(s): Metoprolol succinate, USP Is this product to be shipped to customers on dry ice?											No				
									b. Contact for temperature excursion questions:						
URL for Additional Product Inform		www.camberph	arma.com		_	Address 2:		→	lame:		Soma Raju	•			
Address:	800 Centennial A Piscataway	ve, Suite 1			State:	NJ	7: 00054		lumber:		732-529-042	23 heterousa.cor			
City: Key Contact:	Customer Service	2			Email:	-	Zip: 08854 camberpharma.com		Group E-mail:		Somarajuei	neterousa.com	ш		
Phone Number:	1-866-827-3647				Fax:	732-562-8788	<u>camberpharma.com</u>	c. Special regulations for product in any states?				No	1		
Product Therapeutic Classification		Beta,-selective (car	dioselective) adrenergic receptor blocking	agent							requirements for this product?				
			, , ,		_										
AD	DITIONAL PRODU	CT INFORMATIO)N			PRODUCT DI	ESCRIPTION INFORMATION	d. Store produc	t (unit of sale) upright?		No			1	
The product is?			Is the Product	Direct-Ship (Only			-1	rotect product (unit of sa	ale) from light?			No	ī	
a legend device?		No	Is the Product	Neither	,	Si	1000 ct	e. Shelf life:		., g			24	Months	
if yes, enter class #			Orphan Drug Status			Size:			nitial shelf life at launch (if different):				Months	
a product kit?		No				Strength:	50 mg							_	
if yes, list NDCs of			FDA Approval Status			ou chigan.				ORDER INFORM	MATION				
component parts		Ta a				Dosage Form:	Extended-release, film	.			Maria - 1 - 1 - 1 - 1	NDO III			
reverse numbered? co-licensed?		No	Allamana Duagant			_	coated tablet		Init of Sale x Bottle		1 Bottle of 1	NDC selling	unit?		
latex-free?		No Yes	Allergens Present				Round, biconvex	ı	x Bottle Box/Carton			g. 1 Box of 1	0 Viale)		
preservative-free?		Yes	Alcoho	ol, Whey		Product Shap	e:		Ampule		(**************************************	.g. 1 D0x 01 1	o viais)		
correctional institution block?		No	L				White to off white		Glass		Minimum o	rder quantity	/?	Yes	
opioid?		No				Product Color	:		Tube						
Cannabinoid?		No	Country of Origin	India		Product Impri	nt: Debossed with 'J' on one side and '76' on the other side separating 7 & 6 with		Vial Liquid Sgl						
If Unit Dose, is item bar coded to	unit dose for					r roduct impri	score line		Vial Liquid Multi				ich package t	type?	
hospital scanning?			Is this product covered u						Vial Powder Sgl		12	Each			
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	AA)?	No				Vial Powder Multi			Inner/Carton	n/Pack		
									Other: Write In			Case			
			FOR GENERIC DRUG PR	ODUCIS											
					Au	uthorized Generic	*If Authorized Generic, other		Ph	IARMACY ORDER	/ BILL UNIT				
I. Orange Book Rating:	AB						section fields are not applicable	Rec. sell unit to	customer?		Rx billing u	nit to pharm	acv:		
II. Generic Equivalent to What Brand?: Toprol XL				Each			,								
							(Write-in, e.g. 1	Vial)	_		Gram				
		DRUG SU	PPLY CHAIN SECURITY ACT (DSCSA) INFO	RMATION			HCPCS J-Code:				Milliliter			
Does supplier meet DSCSA defini	ition of manufactur	ror?	Yes	_	GLN:	0331722498975			ITEM AND	PACKING INFORM	IATION -				
Is product exempt from DSCSA?		iei i	No Yes	-	GLN:	0331722496975			TIEM AND	FACKING INFORM	ATION				
i i			***		GCP:					Dimensi	ons (US msr	mto \	Value -	Calaabla "	
If yes, select exemption: Other exemption - Write in:					GCP:			_	Weight Lbs.	Depth	Width	Height	Volume (Cube)	Saleable # Pieces	
Is product repackaged?			No		If yes, was o	riginal product purch	nased	Item/Each:							
Is product sold by manufacturer's	s exclusive distrib	utor?	Yes	-	direct from n				0.71	3	3	4.85	43.65	1	
Has FDA granted waiver/exceptio	on/exemption for p		No	7		ce manufacturer for	repackaged product	Box/Carton/Bur	idle/						
If yes, attach documentation fro	m FDA.	-						Inner Pack:							
								Case:	9.85	12.5	10.5	6.75	885.94	12	
			GTIN AND HIBCC PRODUCT IF	NFORMATION				Pallet:							
Saleable Unit of Measure	RFID tag(Y/N)	Calcabla	HIBCC		CTI	IN-14	Unit of Use GTIN-14	Pallet:							
Saleable Offit of Measure	KFID (ag(1/N)	Quantity	ПВСС		GII	IIN-14	Offit of Ose G1114-14								
x Item/Each	N	1 1			003	331722590105		111							
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESAL	ER USE ONL	LY:	
X Case	N	12			203	331722590109									
Pallet								Regular Cost			Vendor #:				
								Invoice Cost (W	AC) (\$)	\$252.30	Whsl. Code				
								An of data:	6/11/2021		Fineline Co	de:			
								As of date:	0/11/2021		1				
			Attach copy of SAFETY DA	TA SHEET (SI	OS) or non haza	ard letter, PACKAGE I	NSERT, LABEL AND PHOTO OF	PRODUCT PACKAG	ING and BARCODE.						



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZ	ZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply):							
a. Cytotoxic?	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?							
Is the product a CA Prop 65 carcinogen?	x Organic Corrosive						
Is the product a CA Prop 65 cereinogen: No No	Inorganic Oxidizer						
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard						
Does the product label bear a CA F10p 63 warning:	Steroid/Androgen						
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?	N 1 A diologic Level.						
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug?						
(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?	Wholesale distributor support:						
No (if yes, identify method below)	Provider Name: DEA #:						
Limited Quantity	Site Enrollment Number assigned NCPDP#:						
Consumer Commodity, ORM-D	by Supplier: NPI #:						
Small Quantity (49 CFR 173.4)	2) 24 (1)						
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	Registry Frogram Contact Name. From:						
Is the Product	RETURN INSTRUCTIONS						
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS						
Controlled by State(s)? No Listed Chemical (List I or II) No	Contact tel. # if product received damaged: 1-866-827-3647						
ARCOS Reportable? Schedule No. If yes, indicate which: Is it a scheduled listed chemical product?: No	1						
	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 - customerservice@camberpharma.com						
Restricted to retail pharmacy only:	Special regulations or returns requirements for this						
Restricted to hospital, clinics, and physician offices only: No	110						
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?						
Comments:							
MISCELLANE(DUS NOTES and/or Image of Product Barcode:						



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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: PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday					
	Priority Overnight receipt available:					
Class of Trade Restriction: 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:	PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:					
Other Data Information Required to Process PO:	Return Instructions					
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty: Miscellaneous Notes:	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?					
	ADDITIONAL INFORMATION					
	Is product order for scheduled patient procedure? Is product order for restocking purposes?					