

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

Version 2024						Introduction Type	: New Item		x Final Version			Date:	7/16/	2024
			PRODUCT INFORMATI	ION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharmac	ceuticals, Inc.				Application:	ANDA	a. Temperature	- Indicate the USP temper	erature range for th	nis product.			
Application Number for NDA/ANI	DA/BLA; PMA/510	O(k): 205541				NDA 505(b) Type:	NOT APPLICABLE		emperature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab	le:								-					
DUNS:	11-856-3719							C	Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) a		ame: Metopro	olol Succinate Extended-Rele	ease Tablets, L	ISP 100 mg				(write in)					
Selling Unit NDC:	31722-591-10		Unit of Use NDC:				1722591102	N	lotes					
UDI			CVX Code:			MVX Code:								
Description:	Metoprolol Succir	nate Extended-Release	Tablets, USP 100 mg					Is	s this product to be shipped	d to customers on ic	e?		No	
								Is	s this product to be shipped	d to customers on d	ry ice?		No	
Active Ingredient(s):		Metoprolol succinate	, USP						_					
URL for Additional Product Inform									emperature excursion que	estions:	Soma Raju			
Address:	nformation: www.camberpharma.com 800 Centennial Ave, Suite 1				Address 2:			lame: lumber:		732-529-042	3			
City:	Piscataway	ve, Juile 1			State:		p: 08854		Group E-mail:			eterousa.con)	
Key Contact:	Customer Service	9			Email:	customerservice@car			oup 2 maii				-	
Phone Number:	1-866-827-3647				Fax:	732-562-8788						No		
Product Therapeutic Classification	1:	Beta ₁ -selective (cardiosele	ective) adrenergic receptor blocking a	agent				s	Special returns requirement	s for this product?			No	
Special fouring requirements for units product.														
ADD	ITIONAL PRODU	CT INFORMATION				PRODUCT DESC	CRIPTION INFORMATION	d. Store produc	t (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship O	nly			l P	Protect product (unit of sa	ale) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	1000 ct	e. Shelf life:		, , ,			24	Months
if yes, enter class #			Orphan Drug Status			Size:		lı lı	nitial shelf life at launch (if different):				Months
a product kit?		No				Strength:	100 mg							
if yes, list NDCs of			FDA Approval Status							ORDER INFORM	IATION			
component parts		1				Dosage Form:	Extended-release, film coated tablet		Init of Sale		What is the	NDCIII		
reverse numbered? co-licensed?		No No	Allergens Present				coated tablet	1	x Bottle		1 Bottle of 10		umr	
latex-free?		Yes					Round, biconvex	-	Box/Carton			g. 1 Box of 10	(Vials)	
preservative-free?		Yes	Alcohol	, Whey		Product Shape:	rtouria, biodrivox		Ampule		(**************************************	g. 1 Box 01 11	· · iaio)	
correctional institution block?		No				Product Color:	White to off white		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Color:			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Debossed with 'J' on one side and '77' on the other side separating 7 & 7		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for					i roddot iii.piiiiti	with score line		Vial Liquid Multi		If Yes, how		ch package t	type?
hospital scanning?			Is this product covered un						Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (TA	AA)?	No			_	Vial Powder Multi Other: Write In			Inner/Carton Case	Pack	
			FOR GENERIC DRUG PRO	DUCTO				_	Other, write in			Case		
			FOR GENERIC DRUG PRO	DUCIS										
					Διι	thorized Generic *If /	Authorized Generic, other		PH	IARMACY ORDER	/ BILL UNIT			
I Oranga Baak Batings	AB			Т	7.0		ction fields are not applicable	Rec. sell unit to						
I. Orange Book Rating: II. Generic Equivalent to What Brai		Toprol XL						Rec. sell utilit to	customerr	1	Rx billing ur	Each	cy:	
ii. Generic Equivalent to What Brai	iu:.	TOPIOLAL						(Write-in, e.g. 1	Vial)			Gram		
		DRUG SUPPLY	Y CHAIN SECURITY ACT (D	SCSA) INFOR	MATION			HCPCS J-Code:				Milliliter		
Does supplier meet DSCSA definit	ion of manufactu	rer?	Yes		GLN:	0331722498975			ITEM AND I	PACKING INFORM	ATION			
Is product exempt from DSCSA?			No											
If yes, select exemption:					GCP:				Weight Lbs.	Dimensi	ons (US msm	ıts.)	Volume	Saleable #
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			riginal product purchas	ed	Item/Each:	1.35	3.5	3.5	7	85.75	1
Is product sold by manufacturer's			Yes No	-	direct from m			- 10 . 15						
Has FDA granted waiver/exception If yes, attach documentation from		roduct?	INU		Provide sour	ce manufacturer for rep	backaged product	Box/Carton/Bur Inner Pack:	ndle/					
ii yes, attacii documentation iron	II FDA.							Case:						
		GTIN	AND HIBCC PRODUCT IN	FORMATION				Gusc.	17.85	14.5	11	7.75	1236.13	12
								Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GTI	N-14	Unit of Use GTIN-14							
		Quantity			_									
x Item/Each	N	1			003	31722591102			OCCUPATION OF THE PROPERTY OF			MIOI EGA	D HOE eve	v -
Box/Carton/Bundle/Inner Pack	N	10			000	24722504406			COST INFORMATION			WHOLESALE	R USE ONL	Υ:
X Case	N	12			203	31722591106		Regular Cost			Vendor #:			
1 Elliot								Invoice Cost (W	(AC) (\$)	\$379.10	Whsl. Code	#:		
									- , \+/	ψ070.10	Fineline Cod			
								As of date:	6/11/2021]			
]			
I I								11						
*Please provide any additional info			Attach copy of SAFETY DAT	TA SHEET (SD	S) or non haza		ERT, LABEL AND PHOTO OF P ignated Drop Ship Only.		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?	CDO TRACATO ORGANICATION						
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?						