

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

Version 2024						Introduction Type:	New Item		x Final Version			Date:	7/17/	2024
			PRODUCT INFORMAT	ION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharmac	ceuticals, Inc.				Application:	ANDA	a. Temperature -	- Indicate the USP tempe	rature 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	ble:					<u> </u>			-					
DUNS:	11-856-3719							0	ther Temperature Range F	Requirement				
Proprietary Name (If Applicable) a		ame: Metopro	olol Succinate Extended-Rel	ease Tablets, l	JSP 200 mg				(write in)					
Selling Unit NDC:	31722-592-01		Unit of Use NDC:				722592017	Ne	otes					
UDI			CVX Code:			MVX Code:								
Description:	Metoprolol Succin	nate Extended-Release	e Tablets, USP 200 mg					Is	this product to be shipped	I to customers on ic	e?		No	
								Is	this product to be shipped	I to customers on d	ry ice?		No	
Active Ingredient(s):		Metoprolol succinate	e, USP											
UBL for Additional Brade destination									mperature excursion que	estions:	Soma Raju			
URL for Additional Product Inform Address:	800 Centennial A	www.camberpharma	<u>.com</u>		1	Address 2:			ame: umber:		732-529-042	2		
City:	Piscataway	ive, Juile 1			State:		p: 08854		roup E-mail:			eterousa.com	<u> </u>	
Key Contact:	Customer Service	e			Email:	customerservice@can			Toup E mail.		<u>oomaraja on</u>	01010404.0011	<u>.</u>	
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regula	tions for product in any	states?			No	
Product Therapeutic Classification	n:	Beta ₁ -selective (cardiosele	ective) adrenergic receptor blocking	agent	1			Si	pecial returns requirement	s for this product?			No	
Opposital rotation (equilibrium) to this product.														
	ADDIT	IONAL PRODUCT INF	ORMATION			PRODUCT DESC	CRIPTION INFORMATION	d. Store product	(unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	nly			Pi	rotect product (unit of sa	le) from light?		i	No	
a legend device?		No	Is the Product	Neither		Size:	100 ct	e. Shelf life:	, , , , , , , , , , , , , , , , , , , ,	,			24	Months
if yes, enter class #			Orphan Drug Status			Size:		In	itial shelf life at launch (i	f different):				Months
a product kit?		No				Strength:	200 mg							
if yes, list NDCs of			FDA Approval Status							ORDER INFORM	IATION			
component parts		No				Dosage Form:	Extended-release, film coated tablet		nit of Sale		What is the	NDC selling	unit?	
reverse numbered? co-licensed?		No No	Allergens Present				coated tablet	U	x Bottle		1 Bottle of 10		umr	
latex-free?		Yes					Oval, biconvex		Box/Carton			g. 1 Box of 10	(Vials)	
preservative-free?		Yes	Alcoho	I, Whey		Product Shape:			Ampule		(,		
correctional institution block?		No				Product Color:	White to off white		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Froduct Color.			Tube				'	
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Debossed with 'J' on one side and '78' on the other side separating 7 & 8 with		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	ınit dose for						score line		Vial Liquid Multi		If Yes, how		ch package t	type?
hospital scanning?			Is this product covered un Trade Agreements Act (T.		No				Vial Powder Sgl Vial Powder Multi			Each	DI-	
If Unit Dose, indicate NDC here:			Trade Agreements Act (1)	AA) r	NO			_	Other: Write In			Inner/Carton/ Case	Раск	
			FOR GENERIC DRUG PRO	DUCTE					Other. Write in			Case		
			FOR GENERIC DRUG PRO	DUCIS										
					Aı	thorized Generic *If A	Authorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB			7			tion fields are not applicable	Rec. sell unit to				nit to pharma	.01/1	
II. Generic Equivalent to What Brai		Toprol XL		1				reco. Sen unit to	oustomer :	1	IXX Dilling ui	Each	cy.	
		., .						(Write-in, e.g. 1 \	/ial)	I		Gram		
		DRUG SUPPL	Y CHAIN SECURITY ACT ([DSCSA) INFOR	RMATION			HCPCS J-Code:				Milliliter		
Does supplier meet DSCSA definit	tion of manufactu	irer?	Yes		GLN:	0331722498975			ITEM	AND PACKING IN	IFORMATION			
Is product exempt from DSCSA?			No											
If yes, select exemption:					GCP:				Weight Lbs.		ons (US msm		Volume	Saleable #
Other exemption - Write in:										Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No Yes	-	If yes, was or direct from m	riginal product purchas	ed	Item/Each:	0.33	2.2	2.2	4.74	22.94	1
Is product sold by manufacturer's Has FDA granted waiver/exception			No	+		iir r ce manufacturer for rep	packaged product	Box/Carton/Bune	dlo/					
If yes, attach documentation from		TOUUCL?	140		FIOVIUE Soul	ce manuracturer for rep	ackaged product	Inner Pack:	uie/					
yoo, attaon accamomation not								Case:						
		GTIN	N AND HIBCC PRODUCT IN	IFORMATION					8.6	13.5	9.5	5.75	737.44	24
								Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GTI	N-14	Unit of Use GTIN-14							
		Quantity				04700500047								
X Item/Each	N	1			003	31722592017			COST INFORMATION			WHOLESALE	D LISE ON	v
Box/Carton/Bundle/Inner Pack X Case	N	24			203	31722592011			COST INFORMATION		· · · · · · ·	MIOLESALE	K USE UNL	1.
Pallet	IN	24			203			Regular Cost			Vendor #:			
								Invoice Cost (W/	AC) (\$)	\$60.32	Whsl. Code	#:		
1 cinet					-			` ·						
T and							l				Fineline Cod	le:		
1 carect								As of date:	6/11/2021		Fineline Cod	ie:		
· carec								As of date:	6/11/2021		Fineline Cod	le:		
											Fineline Cod	le:		
*Please provide any additional info			Attach copy of SAFETY DA	TA SHEET (SC	S) or non haza		ERT, LABEL AND PHOTO OF Pignated Drop Ship Only.	PRODUCT PACKAGI			Fineline Cod	le:		



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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?