

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014 Introduction Type: New Item									Final Version			Date:				
PRODUCT INFORMATION									SPECIAL HANDLING AND STORAGE REQUIREMENTS*							
Company Name: Camber Pharmaceuticals Application: ANDA								a. Temperature – Indicate the USP temperature range for this product.								
				205541	205541				Temperature Range Controlled Room – between 20 and 25 C (68° – 7						C (68° - 77° F	
DUNS:	826774775								•	·						
	roprietary Name (If Applicable) and Established Name: Metoprolol Succinate Extended-release Tablet						USP, 100mg 100ct				Other Temperature Range Requirement (write in)					
Selling Unit NDC:	. tunio	Individual Unit NDC:	, 10001	UPC:			1									
Selling Unit NDC: 31722-591-01 Individual Unit NDC: UDI CVX Code:				l e	MVX Code:				Is this product to be shipped to customers on ice?							
Description: White to off-white, oral solid ER tablet, round shape, bevel concave punches embossed with 'J' on lower punch and '77' on upper punch separating 7 & 7 by a										Is this product to be shipped to customers on dry ice? No						
score line with corresponding dies												140	•			
Active Ingredient(s): Metoprolol								b. Contact for temperature excursion questions:								
								Name:	Soma Raju							
URL for Additional Product Information: www.camberpharma.com			com						Number	732-529-0423						
Address:	1031 Centennial Avenue				Address 2:			Group E-mail: somaraju@heterousa.com								
City:	Piscataway Customer Sension				State: N.J Zip: 08854					0			NI-			
Key Contact: Phone Number:	Customer Service 732-529-0430							c. Special regulations for product in any states? Special returns requirements for this product? No						•		
				I un.	732-302-0788											
Product Therapeutic Classification: d. Store product (unit of sale) upright? No																
ADDITIONA	Protect product (unit of sale) from light?															
					PRODUCT DESCRIPTION INFORMATION											
Is the Product a legend device?		No											Months Months			
reverse numbered?			No			Size: 100			minual Shell life at lautich (il unierent):							
co-licensed?			No			Olevanith 400 mm			ORDER INFORMATION							
Is the Product		Direct-Ship Only	Strength:	Strength: 100mg												
Is the Product			Neither			Dosage Form: Oral Solid - ER Tablet			Unit of S	What is the NDC selling unit?						
				orar cond Erv rapid					Bottle 1 bottle of 100 tablets Box/Carton (Write-in, e.g. 1 Box of 10 Vials)							
If Unit Dose, is item bar coded to unit dose for hospital scanning?										Box/Carton		(Write-in, e.	.g. 1 Box of 1	0 Vials)		
N6				Product S	Product Shape: Round				<u> </u>	Ampule Glass		Minimum o	rder quantity	12	Yes	
If Unit Dose NDC, indicate NDC here:					Draduct Calary					Tube		Williamo	i uei quaimi	, .	163	
Country of Origin India Product Color: White to off-white										Vial Liquid Sgl						
Is this product covered under the Trade Agreements Act (TAA)?				Product I	Product Imprint: J' on lower punch and '77' on upper punch sepa			Vial Liquid Multi If Yes, how many of which package type?								
Is this product covered under the Trade Agreements Act (TAA)? No			i roddol ii	o on lower parion and 77 on apper parion sepa			Vial Powder Sql 24 Each									
				<u> </u>			<u> </u>	Vial Power Multi			Inner/Cartor	/Pack				
FOR GENERIC DRUG PRODUCTS										Other: Write In	1		Case			
			TOR CERENIO DROCT R	350010						<u></u>						
					uthorized Ge	eneric *If A	Authorized	Generic, other section	PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating: AB			<u> </u>	fields are not applicable				Rec. sell unit to customer?			Rx billing unit to pharmacy:					
II. Generic Equivalent to What Brand?: TOPROL-XL								1			Each					
									(Write-in, e.g. 1 Vial)		_		Gram			
		DRUG SUP	PLY CHAIN SECURITY ACT (DSCSA) INFORMATION									Milliliter			
		_	V		000047	700000000				ITEM AN	ND BAOKING	MEODMAT	ION			
Does supplier meet DSCSA		turer?	Yes No	GLN:	003317	722000000				IIEM AN	ND PACKING	INFORMAT	ION			
Is product exempt from DSC If yes, select exemption:	SA r		INU								Dimer	nsions (US m	ismts)	Volume		
Other exemption - Write in:										Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:	
Is product repackaged?			No	If Yes, was or	iginal produc	ct purchased di	lirect		Item:	0.15		3.2	1.9		1	
Is product sold by manufactor			No	from mfr?			_			0.15		3.2	1.9			
Has FDA granted waiver/exc	eption/exemption for	product?	No	If yes, attach	documentati	ion from FDA.			Box/Carton/Bundle/					ı '		
			GTIN PRODUCT INFORM	ATION					Inner Pack:					·		
			GTIN PRODUCT INFORM	Saleabl					Case:	4.95	11.3	4.5	8	ı '	24	
			Level	e Unit		Ous	antity G	STIN-14	Pallet:							
Serialized?	Yes	Х	Item	X X 21)			0331722591010	III and .					ı '		
If not, when?		1	Box/Carton/Bundle/Inner Pack	21		Linear			UPC:	Case:						
Items aggregated?	Yes	X	Case	X 21		_	24 2	0331722591014		Carton:						
	Pallet 2D Linear															
						Linear			COST	INFORMATION			WHOLESAL	ER USE ONL	.Y:	
			-	21		Linear	<u> </u>		Regular Cost			Vendor #:				
				21		Linear	— H		Invoice Cost (WAC) (\$)		\$37.91	Whsl. Code	#:			
]]		<u> </u>			<u> </u>				Federal Excise Tax Pe		Ψ07.01	Fineline Co				
									As of date:							
			Attach copy of SAFETY DAT	A SHEET (SDS) or non	hazard letter,	PACKAGE INSI	ERT, LABE	L AND PHOTO OF PR	ODUCT PACKAGING and E	BARCODE.						
*Please provide any addition	al information on nac	10.2			See ne	w n 3 for Desig	anated Dro	on Shin Only	Signatur	ro-						



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): SDS Hazard Classification a. Cvtotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No X Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? Inorganic Oxidizer No Does the product label bear a CA Prop 65 warning? No Steroid/Androgen Contact Hazard c. Contact Hazard? No Aerosol Class; Identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) Is the product a NIOSH hazardous drug? e. Does the product contain DEHP? No If yes, indicate which: Is this product regulated for shipment by DOT or IATA? No (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name **Hazardous Waste Identification** c. DOT Hazard Class EPA Hazardous Waste Code: d. Packing Group e. Inhalation Hazard? No REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: Passenger Is there a REMS on this product? No Cargo If Yes, is it managed with a pharmacy registry? Passenger & Cargo Website URL: Is this a reportable quantity? RQ Threshold: Comments / Details: (For example, iPledge program?) Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) REMS: Limited Quantity REMS Program Manager Name: Phone: Consumer Commodity, ORM-D Supplier Manages REMS registry exclusively: Small Quantity (49 CFR 173.4) Wholesale distributor support: Special Permit; DOT-SP Provider Name: Special Provision (listed in Column 7 of 49 CFR 172.101); Site Enrollment Number assigned DEA #: by Supplier: SP# PCPDP #: NPI#: ADD'L STORAGE INFORMATION Is the Product... Comments Controlled Substance? No Controlled by State(s)? No Registry: No ARCOS Reportable? Registry Program Contact Name: Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code **RETURN INSTRUCTIONS** Listed Chemical (List I or II) No If yes, indicate which: 732-529-0430 Is it a scheduled listed chemical product?: No Contact tel. # if product received damaged: **CLASS OF TRADE RESTRICTION:** Is product returnable for credit: Yes URL/Link to returns policy: contact - customerservice@camberpharma.com No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: No Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments? Restricted to hospital, clinics, and physician offices only: Nο Restricted from US territories? (explain in comments) No Comments: MISCELLANEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Page 3)

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:	Purchase order daily receipt cut off time by supplier					
a. EDI	Cut off time:					
b. Autofax Fax Number:						
c. Fax Fax Number:	Shipping lead time of PO: Hours Days					
d. Phone only						
e. Supplier Web Site only Site Address:	Ships same day for next day receipt:					
Minimum Order Quantity:	Ships for second day receipt:					
Supplier's Customer Service Number:	Ships regular ground for 3-10 days receipt:					
Contracted 3PL company / contact #: Name:						
Phone:						
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing					
Expedited freight fees billed with each order:	Overnight receipt available:					
Drop Ship service fee billed with each order:	PO Receipt cut off time: Eastern					
Drop Ship miscellaneous fees billed:	Days of week overnight is available:					
Comments:	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, clinics and physician offices	Saturday Overnight receipt available:					
Restricted to retail pharmacy only:	PO Receipt Cut off time:					
Restricted to hospital, clinics, and physician offices only:	Order receipt method: Phone: Phone #:					
Restricted from US territories? (explain in comments)	Fax: Fax #:					
Comments:	EDI:					
	Overnight Fees apply:					
	Other fees apply:					
Other Data Information Required to Process PO:	Return Instructions					
Patient Procedure Date:	Contact # if product is received damaged:					
Physician Name:	Is product returnable for credit:					
Physician/Clinic Phone #	URL/Link to returns policy:					
Physician State License #	Special regulations or returns requirements for this product in certain states?					
Physician/Clinic DEA #:	If so, which states? Other requirements? Comments?					
Physician/Clinic Specialty:						
Miscellaneous Notes:						
	ADDITIONAL INFORMATION					
	Is product order for scheduled patient procedure?					
	Is product order for restocking purposes?					