

## **Standard Pharmaceutical Product Information (Rx Product Only)**

	August 2014 Introduction Type: New Item							Final Version			Date:	12/8	/2020		
			PRODUCT INFORMATION					SPECIAL HANDLI	NG AND ST	ORAGE REQ	UIREMENTS	S*			
Company Name:	mpany Name: Camber Pharmaceuticals Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.							
	IDA/ANDA/BLA (drug); PMA/510(k)(med device):			212378			Temperature Range Controlled Room – between 20 and 25 C (68° – 77° f								
	826774775						Other Temperature Range Requirement								
	cable) and Established Name: Baclofen Tablets, USP 10 mg, 1000 Ct.							ite in)	quirement				1		
Selling Unit NDC:	31722-998-10	Hume. Buoloicii	Individual Unit NDC:		UPC: 331722998109			ite iii)					ı		
UDI	CVX Code:				MVX Code:			Is this product to be shipped to customers on ice?							
Description: white to off-white, round, flat tablet with bevel edge, debossed "I 114" on one side						Is this product to be shipped to customers on dry ice? No					•				
Description.	write to on-write, rou	id, nat tablet with bever ex	age, debossed 1114 on one side	e and scored on the other si	ed on the other side			is this product to be shipped to customers on dry ice?				INO	•		
Active Ingredient(s): Baclofen USP							b. Contact for temperat	ture excursion ques	tions:						
							Name:			Soma Raju					
URL for Additional Product Information: www.camberpharma.com						Number:			732-529-0423						
Address:	1031 Centennial Avenue			Address 2:			Group E-mail: somaraju@heterousa.com								
City:	Piscataway			State: NJ Zip: 08854			41								
Key Contact:	Customer Service			Fax: customerservice@camberpharma.com			c. Special regulations f					No			
Phone Number: Product Therapeutic Classifi	732-529-0430			Fax: /32-562-8788			Special i	eturns requirements t	ior triis prodi	JCL?		No	-		
Product Therapeutic Classifi	iication.						d. Store product (unit o	of colo) upright?				No			
ADDITIONA	AL PRODUCT INFORM	ATION	1	PRODI	UCT DESCRIPTION IN	FORMATION		product (unit of sale	) from light	,		No	•		
		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	1	PRODUCT DESCRIPTION INFORMATION			<b>-1</b>	product (dilit or sale	, nom ngm				Months		
Is the Product a legend device?		No	No				e. Shelf life: Initial shelf life at launch (if different):					Months			
reverse numbered?		No		Size:	Size: 1000 Ct.		Initial Sil	ion ino at launon (ii v	amorone,.			WOILLIS			
co-licensed?		No	1					0	RDER INFO	RMATION					
Is the Product		Direct-Ship Only	1	Strength: 10 mg											
Is the Product		Neither	1	Dosage Form:	Solid Oral Tablets		Unit of S				NDC selling	unit?			
			1				хх	Bottle		1 bottle of 1					
If Unit Dose, is item bar code	ed to unit dose for hosp	ital scanning?	1					Box/Carton		(Write-in, e	g. 1 Box of 1	0 Vials)			
If Unit Dose NDC, indicate N	IDC here:	INO	1	Product Shape: Round			Ampule Glass		Minimum o	rder quantity	12	Yes			
II Offit Dose NDC, indicate N	DO Here.		1					Tube		William	idei quantit	<i>,</i> :	163		
Country of Origin		USA	1	Product Color:	Product Color: White to off white			Vial Liquid Sgl							
			Product Imprint:	Product Imprint:   1114			Vial Liquid Multi If Yes, how many of which package type?					type?			
Is this product covered under the Trade Agreements Act (TAA)?			Product imprint.			Vial Powder Sql 12 Each									
			1				<u> </u>	Vial Power Multi			Inner/Cartor	/Pack			
			FOR GENERIC DRUG PRODUC	TC .				Other: Write In	1		Case				
			OR GENERIC BROS FRODOS	10					_						
		Authorized Generic *If Authorized Generic, other section							PHARMACY ORDER / BILL UNIT						
I. Orange Book Rating:	AB			Authorized	Generic 1 Autr	orized Generic, other section				ER / BILL UN		Rx billing unit to pharmacy:			
	AR			Authorized		norized Generic, other section are not applicable	Rec. sell unit to custon		WACTORD			acv.			
	AB at Brand?:	LIORESAL		Authorized			Rec. sell unit to custon				nit to pharm	асу:			
II. Generic Equivalent to Wha		LIORESAL		Authorized								асу:			
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## **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 No a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No Organic Corrosive No Oxidizer Is the product a CA Prop 65 reproductive toxicant? Inorganic 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 Hazardous Waste Identification b. Proper Shipping Name 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) No Phone: Limited Quantity REMS Program Manager Name: 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: PCPDP #: NPI#: ADD'L STORAGE INFORMATION Is the Product... Comments Controlled Substance? Nο Controlled by State(s)? No Registry: ARCOS Reportable? No Registry Program Contact Name: Phone Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code Listed Chemical (List I or II) No RETURN INSTRUCTIONS If ves. 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: contact - customerservice@camberpharma.com No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices URL/Link to returns policy: Restricted to retail pharmacy only: No Special regulations or returns requirements for this product in certain states? No Restricted to hospital, clinics, and physician offices only: No If so, which states? Other requirements? Comments? 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: a. EDI	Purchase order daily receipt cut off time by supplier Cut off time: Eastern					
b. Autofax c. Fax d. Phone only  Fax Number: Fax Number: Phone No.:	Shipping lead time of PO: Hours Days					
e. Supplier Web Site only  Minimum Order Quantity:  Supplier's Customer Service Number:  Contracted 3PL company / contact #:  Name: Phone:	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:	Overnight receipt available:					
Drop Ship service fee billed with each order:	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, 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:	Saturday Overnight receipt available:  PO Receipt Cut off time: 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:	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?					