

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

Version 2021						Introduction Type:	Post Launch Change		x Final Version			Date:	6/23	3/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STO	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharmac	euticals, Inc.				Application:	ANDA	a. Temperatur	re - Indicate the USP tempe	erature range for t	his product.			
Application Number for NDA/AN	NDA/BLA (drug); PN	/IA/510(k)(med devi	ce):	21:	2378			1	Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applica			·					Ť l	· -					
DUNS:	11-856-3719								Other Temperature Range I	Requirement				
Proprietary Name (If Applicable)	and Established Na	me: Baclot	en Tablets, USP 20 mg					I	(write in)					
Selling Unit NDC:	31722-999-01		Unit of Use NDC:				22999014		Notes					
UDI			CVX Code:			MVX Code:		1						
Description:	Baclofen Tablets,	USP 20 mg						Ţ	Is this product to be shipped	to customers on	ce?		No	1
									Is this product to be shipped				No	1
Active Ingredient(s):		Baclofen, USP						I						
								b. Contact for	temperature excursion qu	estions:				
URL for Additional Product Inform		www.camberpharm	a.com					1	Name:		Soma Raju			
Address:	800 Centennial Av	/e, Suite 1			State:	Address 2: NJ Zip:	00054	-	Number:		732-529-042			
City: Key Contact:	Piscataway Customer Service				Email:	customerservice@camb	08854	-	Group E-mail:		<u>somaraju@r</u>	neterousa.cor	<u>n</u>	
Phone Number:	1-866-827-3647	<u> </u>			Fax:	732-562-8788	Derphamia.com	c Special reg	ulations for product in any	states?			No	1
Product Therapeutic Classification		Muscle relaxant an	d antisnastic		I ux.	732 302 0700		c. Special reg	Special returns requirement				No	-
Troduct Therapeutic Glassification	on.	Wascie Telaxant an	и иниорионе						opecial returns requirement	s for this product:			140]
	ADDITI	ONAL PRODUCT IN	FORMATION			PRODUCT DESC	RIPTION INFORMATION	d Store produ	uct (unit of sale) upright?				No	1
	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	51.7.E 1 1.05 5 5 1 11.		Direct-Ship C	Sml	1 1105001 52001		u. otore produ						1
The product is? a legend device?		No	Is the Product Is the Product	Neither	riiy		100 ct	e. Shelf life:	Protect product (unit of sa	ile) from light?			No 24	Mantha
if yes, enter class #		INO	Orphan Drug Status	rveitriei		Size:	100 Ct	e. Shell life:	Initial shelf life at launch (if different).			24	Months Months
a product kit?		No	Orphan Drug Status				20 mg		ililiai Sileii ille at iaulicii (ii dillerelli).				WOILLIS
if yes, list NDCs of		140	FDA Approval Status			Strength:	25g			ORDER INFORI	MATION			
component parts						B	Tablet							
reverse numbered?		No				Dosage Form:			Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 1	00 Tablets		
latex-free?		Yes	Dairy	Lactose		Product Shape:	Round, flat, bevel edged		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	Duny,	Luciosc		i roddot onape.			Ampule					
correctional institution block?	•	No				Product Color:	White to off-white		Glass		Minimum o	der quantity	/?	Yes
opioid?		No					D 1 1 11 11 11 11 11 11 11 11 11 11 11 1		Tube					
Cannabinoid?		No	Country of Origin	USA		Product Imprint:	Debossed with 'I 115' on one side and scored on the other side		Vial Liquid Sgl		W. V 1			
If Unit Dose, is item bar coded to hospital scanning?	unit dose for		Is this product covered of						Vial Liquid Multi Vial Powder Sql			many of whi	ich package	type?
If Unit Dose, indicate NDC here:			Trade Agreements Act (Yes				Vial Powder Sgi Vial Powder Multi		24	Inner/Cartor	/Pook	
II Offit Dose, indicate NDC fiere.			Trade Agreements Act (174):	Tes				Other: Write In			Case	I/FdUK	
			FOR GENERIC DRUG PR	ODUCTS				1	Guion Willoui			ouse		
			TOR GENERIO BROSTI	000010										
					Au	thorized Generic *If Au	uthorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I Oranga Book Batings	AB						on fields are not applicable	Rec. sell unit			Rx billing u	nit to phorm	201/1	
I. Orange Book Rating: II. Generic Equivalent to What Bra		Lioresal						itee. sen unit	to customer i	1	KX billing u	Each	acy.	
ii. Generic Equivalent to What Bra	anu:.	Liorcoai						(Write-in, e.g.	1 Vial)	1		Gram		
		DRUG SUPPI	Y CHAIN SECURITY ACT	(DSCSA) INFOR	RMATION			(, . 5				Milliliter		
				•										
Does supplier meet DSCSA defin	nition of manufactur	er?	Yes		GLN:	0331722498975			ITEN	I AND PACKING I	NFORMATIO	V		
Is product exempt from DSCSA?	•		No											
If yes, select exemption:					GCP:			1		Dimens	ions (US msn	nts.)	Volume	Saleable #
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was or	riginal product purchase	d	Item/Each:	0.15	2.10	2.10	3.90	17.20	1
Is product sold by manufacturer's			Yes	_	direct from m					2.10	2.10	0.00	17.20	
Has FDA granted waiver/exception		oduct?	No		Provide sour	ce manufacturer for repa	ckaged product	Box/Carton/B	undle/					
If yes, attach documentation fro	om FDA.							Inner Pack:						
		CT	N AND HIBCC PRODUCT I	NEORMATION				Case:	4.00	13.25	8.75	4.50	521.72	24
		GII	N AND HIBCC PRODUCT I	NIORMATION				Pallet:						
Saleable Unit of Measure	9	aleable Quantity	HIBCC		GTI	N-14	Unit of Use GTIN-14	railet.						
	3	1	TIBOO			31722999014	JIII OI OSE GTIN-14							
X Item/Each									COST INFORMATION			WHOLESAL	ER USE ONL	_Y:
					103	31722999011								
X Item/Each Box/Carton/Bundle/Inner Pack X Case		24						1.1						
Box/Carton/Bundle/Inner Pack		24						Regular Cost			Vendor #:			
Box/Carton/Bundle/Inner Pack X Case		24						Regular Cost Invoice Cost ((WAC) (\$)	\$8.00	Vendor #: Whsl. Code	#:		
Box/Carton/Bundle/Inner Pack X Case		24						Invoice Cost (\$8.00				
Box/Carton/Bundle/Inner Pack X Case		24							(WAC) (\$) 7/1/2021	\$8.00	Whsl. Code			
Box/Carton/Bundle/Inner Pack X Case		24						Invoice Cost (\$8.00	Whsl. Code			
Box/Carton/Bundle/Inner Pack X Case		24						Invoice Cost (7/1/2021	\$8.00	Whsl. Code			
Box/Carton/Bundle/Inner Pack X Case			Attach copy of SAFETY D.	ATA SHEET (SC	DS) or non haza	ord letter, PACKAGE INSE See new p. 3 for Desig	RT, LABEL AND PHOTO OF F	Invoice Cost (7/1/2021	\$8.00	Whsl. Code			



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic? No	SDS Hazard Classification					
b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? No Does the product label bear a CA Prop 65 warning? No	x Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard					
c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP?	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:					
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name	Is the product a NIOSH hazardous drug? If yes, indicate which:					
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification					
e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	EPA Hazardous Waste Code: Waste Characteristics					
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMS or REGISTRY RESTRICTIONS					
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:					
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)					
Is this a reportable quantity? No RQ Threshold: Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit? No (if yes, identify method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4)	REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: No Phone: DEA #: NCPDP#: NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments					
ADD'L STORAGE INFORMATION	Registry: Registry Program Contact Name: Comments No Phone:					
Is the Product						
Controlled Substance Code Controlled by State(s)? ARCOS Reportable? Schedule No. No Controlled Substance Code Listed Chemical (List I or II) No If yes, indicate which: Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION:	RETURN INSTRUCTIONS Contact tel. # if product received damaged: I-866-827-3647 Is product returnable for credit: Yes					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	URL/Link to returns policy: contact - customerservice@camberpharma.com					
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: No	Special regulations or returns requirements for this product in certain states?					
Restricted from US territories? (explain in comments) No Comments:	If so, which states? Other requirements? 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 fo	r 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:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity:	Fax Number: Fax Number: Phone No.: Site Address:	Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt:
F	Name: Phone:	Ships regular ground for 3-10 days receipt:
Expedited Freight Charg	ges 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 only: Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician of Restricted from US territories? (explain in conficulty) Comments:	offices only:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Infor	rmation 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?
Mis	scellaneous Notes:	
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure? Is product order for restocking purposes?