

Standard Pharmaceutical Product Information (Rx Product Only)

	© August 2014 Introduction Type: New Item							Final Version			Date:	12/15	/2020		
			PRODUCT INFORMATION	N					SPECIAL HANDLI	ING AND ST	ORAGE REQ	UIREMENTS	*		
Company Name:	Combon Dhamasauti	eele			Annli	ootion:	ANDA	- T lastic							
Company Name: Camber Pharmaceuticals Application Number for NDA(ANDA/ELA/Church; DMA/ELA/Church; DMA/ELA/Chur				1040070				a. Temperature – Indicate the USP temperature range for this product. Temperature Range Controlled Room – between 20 and 25 C (68° – 77° f							
					212378										
DUNS: 82	826774775								Other Temperature Range Requirement						
Proprietary Name (If Applicable	le) and Established	Name: Baclofen	Tablets, USP 10 mg, 100Ct.					(wri	ite in)						
Selling Unit NDC: 3°	31722-998-01		Individual Unit NDC:		UPC:	33172299801	17								
UDI			CVX Code:		MVX Code:			Is this pro	oduct to be shipped t	to customers	on ice?		No		
Description: white to off-white, round, flat tablet with bevel edge, debossed "I 114" on one side an					and scored on the other side			Is this product to be shipped to customers on dry ice? No							
Description.	write to on-write, rou	nu, nat tablet with bever et	uge, debossed 1 114 off offers	side and scored on the o	ulei side.			is tills pit	oduct to be shipped t	to customers	on dry ice:		110		
Active Ingredient(s):		Baclofen, USP						b. Contact for temperat	turo overureion auge	tione:					
Active Ingredient(s): Baclofen, USP							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								
	Piscataway			State:	State: NJ Zip: 08854			Oloup L	-man.		30maraja@i	101010434.00			
	Piscataway Customer Service				Email: customerservice@camberpharma.com				for product in any st	tatos?			No		
	732-529-0430				Fax: 732-562-8788				eturns requirements		ict?	•	No		
Product Therapeutic Classifica					1 dx. //32-002-0700			- Openan	otarrio roquirorriorito	ioi ano prode		•			
Froduct Therapeutic Classifica	auon.								. f1-1				N1.		
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ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION				product (unit of sale	e) irom light?			No			
Is the Product								e. Shelf life:					24	Months	
a legend device?		No		Size:	Size: 100			Initial shelf life at launch (if different):			Months		Months		
reverse numbered?		No		GIZC.	100										
co-licensed?		No		Strength:	10 mg				0	RDER INFO	RMATION				
Is the Product		Direct-Ship Only		ou ongun	10 mg										
Is the Product		Neither		Dosage Forn	n: Solid Oral 1	Γablets		Unit of S			What is the		unit?		
				2 cougo : c		. 45.010		х	Bottle		1 bottle of 2				
If Unit Dose, is item bar coded to	to unit dose for hose	nital scanning?							Box/Carton		(Write-in, e	g. 1 Box of 1	0 Vials)		
		No No		Product Sha	pe: Round				Ampule						
If Unit Dose NDC, indicate NDC	C here:				Flound Shape.			Glass Minimum order quantity? Ye			Yes				
				Product Cold	Product Color: White to off white				Tube						
Country of Origin USA					Write to on write			Vial Liquid Sgl							
Is this product covered under the Trade Agreements Act (TAA)?				Product Imprint: I 114			Vial Liquid Multi If Yes, how many of which package type?								
Is this product covered under th	he Trade Agreement	s Act (TAA)?		Product Impi	rint: 114								ich package t	ype?	
Is this product covered under the	he Trade Agreement	s Act (TAA)?		Product Impi	rint: I 114				Vial Powder Sql			Each		ype?	
Is this product covered under the	he Trade Agreement	s Act (TAA)?		Product Impi	rint: I 114				Vial Powder Sql Vial Power Multi			Each Inner/Carton		ype?	
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Is this product covered under the	he Trade Agreement		FOR GENERIC DRUG PRODU		rint: 1114				Vial Powder Sql Vial Power Multi]		Each Inner/Carton		ype?	
Is this product covered under th	he Trade Agreement		FOR GENERIC DRUG PRODU	JCTS					Vial Powder Sql Vial Power Multi Other: Write In		24	Each Inner/Carton Case		ype?	
Is this product covered under th	he Trade Agreement		FOR GENERIC DRUG PRODU	JCTS	norized Generic		Generic, other section		Vial Powder Sql Vial Power Multi Other: Write In	MACY ORDE		Each Inner/Carton Case		ype?	
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I. Orange Book Rating: II. Generic Equivalent to What is Does supplier meet DSCSA del Is product exempt from DSCSA If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacture Has FDA granted waiver/excep	AB Brand?: efinition of manufact A? er's exclusive distription/exemption for	butor? X X X	Yes No No No No Sal Level Lem Bow/Cartor/Bundle/Inner Pack Case	If Yes, was origing from mfr? If yes, attach does to the second of the s	norized Generic 0331722000000 mal product purchase cumentation from FD. Linear	A. Quantity 1 24	GTIN-14 00331722998017	Item: Box/Carton/Bundle/ Inner Pack: Case: Pallet: UPC: Regular Cost (WAC) (\$) Federal Excise Tax Per As of date:	Vial Powder Sql Vial Power Multi Other: Write In PHARI ner? ITEM AN Weight Lbs. 0.2 2.4 Case: Carton: INFORMATION	Dimet Depth	R/BILL UN Rx billing u Billing u Billing u Billing u Billing u Color	Each Inner/Carton Case T nit to pharm Each Gram Milliliter ON Issmts.) Width 1.5 7	Volume (Cube)	# Pieces: 1 24 220	



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. 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?					