

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

Version 2021						Introduction 7	Туре:	New Item		x	Final Version			Date:	3/17	/2022
PRODUCT INFORMATION										SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*			
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.										
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 204787 Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)																
Medical Device Class, if applical	ble:															
DUNS:	82-677-4775										nperature Range F	Requirement				
Proprietary Name (If Applicable) a		ame: Lac	cosamide Tablets 100mg 60ct							(writ	e in)					
Selling Unit NDC: UDI	31722-813-60		Unit of Use NDC: CVX Code:			UPC: MVX Code:	33172	2813600		Notes						
-						INIVA Code.			l I				_			1
Description: Oral Solid - Tablet, oval shaped, yellow, Upper: '13' Lower: 'J'											to customers on i			No No	-	
Active Ingredient(s):		Lacosamide								is this pro	duct to be snipped	I to customers on o	ily ice?		INO	
Active ingredient(s).		Lacosamiac							b. Contact fo	r temperati	re excursion que	estions:				
URL for Additional Product Inform	nation:									Name:			Soma Raju			
Address:		Ave (and) 800 Cer	ntennial Ave, Suite 1			Address 2:				Number:			732-529-042			
City:				State:	NJ Zip: 08854			Group E-mail:			somaraju@heterousa.com					
Key Contact: Phone Number:	Customer Service 1-866-827-3647			Email: Fax:		customerservice@camberpharma.com 732-562-8788			c. Special regulations for product in any states?				No			
Product Therapeutic Classification					гах.	132-302-0100			c. Special reg	_	turns requirement		No			
Froduct Therapeutic Classificatio	11.									Special re	turns requirement	s for this product?			INU	
	ADDIT	IONAL PRODUCT	INFORMATION			PRODUCT	DESCR	IPTION INFORMATION	d. Store prod	luct (unit of	sale) upright?				No	1
The product is?			Is the Product	Direct-Ship C	Only				ui otoro prod		roduct (unit of sa	la) from light?			No	
a legend device?		No	Is the Product	Neither	Jy			60ct	e. Shelf life:	r rotect p	roduct (unit or sa	ie) iroin light:			24	Months
if yes, enter class #		1110	Orphan Drug Status			Size:		0001	or onon mo.	Initial she	elf life at launch (i	f different):				Months
a product kit?		No				Strength:		100mg			,					-
if yes, list NDCs of			FDA Approval Status			Su engui.						ORDER INFORM	MATION			
component parts		1.1				Dosage Forn	m:	Oral Solid - Tablet		11-21-40			\A/la =4 != 4la =	NDC selling		
reverse numbered? co-licensed?		No No	Allergens Present							Unit of Sa	Bottle		1 bottle of 6		unit?	
latex-free?		Yes	Allergens r resent					Oval			Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		Yes				Product Sha	ape:				Ampule		(g		
correctional institution block?						Product Cole	or:	Yellow			Glass		Minimum o	rder quantity	ı?	Yes
opioid?		No				r roduct con	01.				Tube					
Cannabinoid?		No	Country of Origin	India		Product Imp	rint:	Upper: '13' Lower: 'J'			Vial Liquid Sgl					
If Unit Dose, is item bar coded to unhospital scanning?	unit dose for		Is this product covered u	ndor the							Vial Liquid Multi Vial Powder Sql			many of wh	ich package	type?
If Unit Dose, indicate NDC here:			Trade Agreements Act (1		No						Vial Power Multi		24	Inner/Cartor	/Pack	
II OTHE BOSE, INGICATE TABOTICIE.			Trade rigidements rick (140						Other: Write In			Case	in don	
			FOR GENERIC DRUG PR	ODUCTS												
					Au	thorized Generic		horized Generic, other				ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB					section fields are not applicable			Rec. sell unit	to custom	er?		Rx billing u	nit to pharm	асу:	
II. Generic Equivalent to What Bra	ınd?:	Vimpat								4 1 0 0				Each		
DRUG CURRI V CHAIN SECURITY ACT (DCCCA) INFORMATIO				PMATION	(Write-in, e.g. 1 Vial)			Gram Milliliter								
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION													Ivillilitei			
Does supplier meet DSCSA defini	ition of manufactu	rer?	Yes		GLN:	0331722000000					ITEM	AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?		·	No													
If yes, select exemption:					GCP:						Mainhal ha	Dimensi	ons (US msr	nts.)	Volume	Saleable #
Other exemption - Write in:											Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No	_		riginal product			Item/Each:		0.1		1.6	2.98	0	1
Is product sold by manufacturer's Has FDA granted waiver/exception			No No	-		irect from mfr? ce manufacturer fo	or ronce	kagad product	Box/Carton/E	Pundlo/						
If yes, attach documentation from		Toduct?	INO		Frovide Sour	ce manuracturer ro	лтерас	kageu product	Inner Pack:	outiule/					0	
ii yoo, attaon accamentation not									Case:		2.4	10	6.75	4.25	0	24
			GTIN AND HIBCC PRODUCT II	NFORMATION							2.4	10	6.75	4.25	0	24
									Pallet:						0	
Saleable Unit of Measure	5	Saleable Quantity	HIBCC			N-14	_	Unit of Use GTIN-14								
X Item/Each Box/Carton/Bundle/Inner Pack		1			003	31722813600	-			COST	INFORMATION			WHO! ESAL	ER USE ONL	٧٠
X Case		24			203	31722813604	-			0031	INI OKWATION			WIIOLLSAL	LK USL UNI	-1.
Pallet						01122010001			Regular				Vendor #:			
									Invoice Cost	(WAC) (\$)		\$40.43	Whsl. Code			
													Fineline Co	de:		
									As of date:				-			
1			Attach conv of SAFETY DA	TA SHEET (ST	OS) or non bozo	ard letter BACKACE	INISED	T, LABEL AND PHOTO OF F	DOUICT DACK	VCING and	BARCODE					
*Please provide any additional inf		•	Allacii copy oi SAFETT DE	II OHEET (SL	o non naza			ated Drop Ship Only	NODOGI FACK	Cianatius	DI INCODE.					



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD 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? Does the product label bear a CA Prop 65 warning? 	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?	No No	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	No	Is the product a NIOSH hazardous drug? If yes, indicate which:	No				
c. DOT Hazard Class d. Packing Group		Hazardous Waste Identification					
e. Inhalation Hazard?	No No	EPA Hazardous Waste Code:	Waste Characteristics				
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)	REMS o	r REGISTRY RESTRICTIONS					
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	No	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:	No				
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	No	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)					
Is this a reportable quantity? RQ Threshold: Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit? (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);		Comments					
SP#		Registry: Registry Program Contact Name:	No	Phone:			
ADD'L STORAGE INFORMATION		Comments		There.			
Is the Product Controlled Substance? Controlled Substance Code Controlled by State(s)? Listed Chemical (List I or II)	No	RI	ETURN INSTRUCTIONS				
ARCOS Reportable? Schedule No. If yes, indicate which: Is it a scheduled listed chemical product?:	No	Contact tel. # if product received damaged: Is product returnable for credit:	1-866-827-3647 Yes				
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: Restricted to hospital, clinics, and physician offices only: Restricted to hospital, clinics, and physician offices only:	No No	Special regulations or returns requirements for this product in certain states?					
Restricted from US territories? (explain in comments) Comments:	No	If so, which states? Other requirements? Comments?					
MI	SCELLANEO	DUS NOTES and/or Image of Product Barcode:					
		<u> </u>					



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FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop S	nip 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: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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 Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order:		Overnight receipt available: 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, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess 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?