

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 INFORMA	TION							SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.										
Application Number for NDA/AN			evice):	20	4787							Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applical	ble:															
DUNS:	82-677-4775										mperature Range F	Requirement				
Proprietary Name (If Applicable) a		ame: La	cosamide Tablets 50mg 60ct								te in)					
Selling Unit NDC: UDI	31722-812-60		Unit of Use NDC: CVX Code:			UPC: MVX Code:	331722	2812603	-	Notes						
-						WVX Code.			1							
Description:	Oral Solid - Table	t, oval shaped, pii	nk, Upper: '12' Lower: 'J'								oduct to be shipped				No No	-
Active Ingredient(s):		Lacosamide							+	is this pro	oduct to be shipped	i to customers on t	ily ice?		INO	
Active ingredient(s).								b. Contact fo	r temperat	ure excursion que	estions:					
URL for Additional Product Inform										Name:	•		Soma Raju			
Address:	1031 Centennial Ave (and) 800 Centennial Ave, Suite 1				Address 2:				Number:			732-529-042				
City:	Piscataway					NJ		08854	Group E-mail: somaraju@het				heterous	i.com		
Key Contact: Phone Number:				Email: Fax:	customerservice@camberpharma.com 732-562-8788			a Cassiel se						No	1	
Product Therapeutic Classification					гах.	732-302-6766			c. Special reg	-	or product in any eturns requirement				No	-
Froduct Therapeutic Classificatio	11.									Special II	eturns requirement	s for this product?			INU	
	ADDIT	IONAL PRODUCT	INFORMATION			PRODUCT	DESCRI	PTION INFORMATION	d. Store prod	duct (unit o	f sale) upright?				No	1
The product is?			Is the Product	Direct-Ship C	Only					•	product (unit of sa	le) from light?			No	i
a legend device?		No	Is the Product	Neither	Jy			60ct	e. Shelf life:	riotect	noduct (dilit or sa	ie) iroin light:			24	Months
if yes, enter class #		1110	Orphan Drug Status			Size:				Initial sh	elf life at launch (i	if different):				Months
a product kit?		No	, ,			Strength:		50mg			•					4
if yes, list NDCs of			FDA Approval Status			Su engui.						ORDER INFORM	IATION			
component parts reverse numbered?		ls.				Dosage Forn	m:	Oral Solid - Tablet		11-21-40	-1-		What is the	NDC aallina		
co-licensed?		No No	Allergens Present				l.			Unit of S	Bottle		1 bottle of 60		unit?	
latex-free?		Yes	Allergens Fresent					Oval			Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		Yes				Product Sha	ipe:				Ampule		(9	,	
correctional institution block?						Product Cole	or.	Pink			Glass		Minimum or	der quantity	?	Yes
opioid?		No				r roduct con					Tube					
Cannabinoid?		No	Country of Origin	India		Product Imp	rint:	Upper: '12' 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			I.				Vial Liquid Multi Vial Powder Sql		If Yes, how	many of who	ch package	type?
If Unit Dose, indicate NDC here:			Trade Agreements Act (No						Vial Power Multi		24	Inner/Cartor	/Pack	
II OTHE BOSE, INGICATE TABOTICIE.			Trade / igreemente / tet (140						Other: Write In			Case	i dok	
			FOR GENERIC DRUG PR	ODUCTS												
													-			
					Au	uthorized Generic		horized Generic, other				ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating: AB				section fields are not applicable			Rec. sell unit to customer?				Rx billing unit to pharmacy:					
II. Generic Equivalent to What Bra	ınd?:	Vimpat							OME In the second	4 1 (- 1)				Each Gram		
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMAT				RMATION				(Write-in, e.g. 1 Vial) Gram								
		D.(00 00)	TET SHAM SESSION AST	DOGGA) IIII GI	tili ATTON									Willinger		
Does supplier meet DSCSA defini	ition of manufactu	rer?	Yes		GLN:	0331722000000					ITEM	I AND PACKING II	NFORMATIO	N		
Is product exempt from DSCSA?			No													
If yes, select exemption:					GCP:						Weight Lbs.	Dimensi	ons (US msn	nts.)	Volume	Saleable #
Other exemption - Write in:											Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No	_		riginal product			Item/Each:		0.07		1.531	2.375	0	1
Is product sold by manufacturer's Has FDA granted waiver/exception			No No	+		irect from mfr? ce manufacturer fo	or renaci	kaged product	Box/Carton/E	Rundle/						
If yes, attach documentation from		- Coduct:	140		r rovide sour	ce manufacturer re	Ji repaci	kageu product	Inner Pack:	Juliule/					0	
, , , , , , , , , , , , , , , , , , , ,									Case:		1.96	9.75	6.5	4	0	24
		-	GTIN AND HIBCC PRODUCT II	NFORMATION							1.90	9.75	0.5	4	U	24
									Pallet:						0	
Saleable Unit of Measure	\$	Saleable Quantity	HIBCC			IN-14 331722812603		Unit of Use GTIN-14								
X Item/Each Box/Carton/Bundle/Inner Pack		1			003	031722012003				cos	INFORMATION			WHOLESAL	ER USE ONL	Y:
X Case		24			203	331722812607				000						•••
Pallet									Regular				Vendor #:			
									Invoice Cost	(WAC) (\$)		\$25.86	Whsl. Code			
													Fineline Co	de:		
	-								As of date:				ł			
!			Attach conv of SAFETY DA	TA SHEET (SE	OS) or non haza	ard letter PACKAGE	INSER	T, LABEL AND PHOTO OF F	PRODUCT PACK	AGING and	BARCODE					
*Please provide any additional inf		2	, maon copy of OAI ETT DA	(31	of non naza			ated Dron Shin Only	JDGGTTAGK	Signatur	a.					



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For Designated Drop Ship Only Products, Please Use Page 3

MA	TERIAL HAZ	ARD 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	EPA Hazardous Waste Code:		Waste Characteristics		
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)	No	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	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		rvice@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 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?				