

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

Version 2024						Introduction Type	e: New Item	x	Final Version			Date:	2/25	/2025
			PRODUCT INFORMA	TION					SPECIAL HAN	IDLING AND STOP	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN	NDA/BLA; PMA/510	(k): 204787				NDA 505(b) Type:	NOT APPLICABLE		rature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applical	able:													
DUNS:	11-856-3719								Temperature Range	Requirement				
Proprietary Name (If Applicable) a		ame: Lacosa	mide Tablets, USP 150 mg						vrite in)					
Selling Unit NDC:	31722-814-60		Unit of Use NDC:		31722-814-60	UPC: 33 MVX Code:	1722814607	Notes						
UDI			CVX Code:			WVX Code:								1
Description:	Lacosamide Table	ets, USP 150 mg							product to be shippe				No	_
Active Ingredient(s):		Lacosamide, USP						Is this p	product to be shippe	d to customers on o	dry ice?		No	
Active ingredient(s).		Lacosamue, USP						b. Contact for temper	ature excursion qu	estions.				
URL for Additional Product Inform	mation:	www.camberpharma	.com					Name:			Soma Raju			
Address:	800 Centennial Av					Address 2:		Numbe	er:		732-529-042	23		
City:	Piscataway				State:	NJ Z	ip: 08854	Group	E-mail:		somaraju@I	neterousa.cor	<u>n</u>	
Key Contact:	Customer Service	•			Email:	customerservice@ca	mberpharma.com							-
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regulations					*Yes	-
Product Therapeutic Classificatio	on:	Anticonvulsant						Special	l returns requiremen	ts for this product?			No	
		ONAL PRODUCT INF				PRODUCT DES	CRIPTION INFORMATION	d Store meduat ()	of colo) unside to C				Nie	1
	ADDITI	ONAL PRODUCT INF		Discus City -		PRODUCT DES	CKIPTION INFORMATION	d. Store product (unit					No	
The product is?		Ne	Is the Product	Direct-Ship On	niy		60 ct		t product (unit of sa	ale) from light?			No	Mortha
a legend device? if yes, enter class #		No	Is the Product Orphan Drug Status	Unit of Use		Size:	00 Cl	e. Shelf life:	shelf life at launch (	(if different):			24	Months Months
a product kit?		No	Siphan Brug Status				150 mg		a launch	anner enty.				montina
if yes, list NDCs of			FDA Approval Status			Strength:					MATION			
component parts						Dosage Form:	Film coated tablet							
reverse numbered?		No				Dosage Form.		Unit of				NDC selling	unit?	
co-licensed?		No	Allergens Present				Quel bisson	x			1 Bottle of 6		0 1 ( - 1 - 1	
latex-free? preservative-free?		Yes	s	юу		Product Shape:	Oval, biconvex		Box/Carton Ampule		(Write-in, e	g. 1 Box of 1	0 Vials)	
correctional institution block?		No					Salmon		Glass		Minimum o	der quantity	2	Yes
opioid?		No				Product Color:	Gainon		Tube		Willing of the second s	aci quantity	•	103
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Debossed with 'J' on one side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for			1		Froduct Imprint.	and '14' on the other side		Vial Liquid Multi			many of whi	ch package	type?
hospital scanning?			Is this product covered u						Vial Powder Sgl		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (	IAA)?	No				Vial Powder Multi			Inner/Cartor	/Pack	
			FOR GENERIC DRUG PR						Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCIS										
				Γ	Au	thorized Generic *If	Authorized Generic, other		Pł	HARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						ction fields are not applicable	Rec. sell unit to customer?			Rx billing unit to pharmacy: Each			
II. Generic Equivalent to What Bra		Vimpat												
		·						(Write-in, e.g. 1 Vial)		_		Gram		
		DRUG SUPPL	Y CHAIN SECURITY ACT (	DSCSA) INFORM	MATION			HCPCS J-Code:		_		Milliliter		
			N						1751					
Does supplier meet DSCSA defini Is product exempt from DSCSA?		rer r	Yes No	- '	GLN:	0843368117603			IIEM	I AND PACKING I	NFORMATIO			
			110							<b>D</b>				
If yes, select exemption:					GCP:			1	Weight Lbs.		ions (US msr		Volume (Cube)	Saleable # Pieces
Other exemption - Write in: Is product repackaged?			No		If yes was or	iginal product purcha	sed	Item/Each:		Depth	Width	Height		
Is product sold by manufacturer's	s exclusive distribu	itor?	Yes		direct from m				0.1	1.6	1.6	3	7.68	1
Has FDA granted waiver/exception			No			 ce manufacturer for re	packaged product	Box/Carton/Bundle/						
If yes, attach documentation from		·		-				Inner Pack:						
								Case:	2.84	10	7	4	280	24
		GTIN	I AND HIBCC PRODUCT II	NFORMATION				Balleti						
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GTI	N-14	Unit of Use GTIN-14	Pallet:						
	111112 tag(1/N)	Quantity	1000		GII		Unit 01 038 GTIN-14							
X Item/Each	N	1			003	31722814607	00331722814607							
Box/Carton/Bundle/Inner Pack								COST INFORMATION			WHOLESALER USE ONLY:			
	N	24			203	31722814601								
X Case								Regular Cost			Vendor #:			
X Case Pallet								Invoice Cost (WAC) (\$	\$)	\$17.05	Whsl. Code	#:		
								As of date:	12/1/2024		Fineline Co			
								As of date:	12/1/2024					
								As of date:	12/1/2024					
			Attach copy of SAFETY DA	TA SHEET (SDS	6) or non haza	rd letter, PACKAGE INS	SERT, LABEL AND PHOTO OF I							
	formation on page		Attach copy of SAFETY DA	TA SHEET (SDS	6) or non haza		SERT, LABEL AND PHOTO OF I signated Drop Ship Only.		nd BARCODE.					

## **HDA** Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2024 For Design	nated Drop Ship Only Products, Please Use Page 3
MATERIAL H	IAZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No Is the product a CA Prop 65 reproductive toxicant? No Does the product label bear a CA Prop 65 warning? C. Contact Hazard? d. Does this product require special clean-up instructions? No	X       Organic       Corrosive         Inorganic       Oxidizer         Steroid/Androgen       Contact Hazard         Does the product have an Aerosol class? If yes, identify NFPA Storage Level:       No
(If yes, attach SDS with special instructions.)         e. Does the product contain DEHP?         No         Is this product regulated for shipment by DOT?         (if yes, answer a-e below and provide SDS)         a. UN/Identification Number	NFPA Storage Level:
b. Proper Shipping Name Toxic solids, Organic, n.o.s (Lacosamide) c. DOT Hazard Class Not Regulated d. Packing Group III e. Inhalation Hazard? No	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics
Is this product regulated for shipment by IATA? Yes (if yes, answer a-e below and provide SDS) a. UN/Identification Number UN2811 b. Proper Shipping Name Toxic solid, organic. n.o.s. (Lacosamide) C. DOT Hazard Class d. Packing Group e. Inhalation Hazard? No	REMS or REGISTRY RESTRICTIONS         Is there a REMS on this product?       No         If Yes, is it managed with a pharmacy registry?       Website URL:
Is the product restricted for air shipment? If so, indicate restriction:          No         Passenger         Cargo         Passenger & Cargo         Is this a reportable quantity?	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)  REMS: 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) Special Permit; DOT-SP Special Permit; DOT-SP Special Permit; DOT-SP	REMS Program Manager Name:     NO       Supplier Manages REMS registry exclusively:     Phone:       Wholesale distributor support:     DEA #:       Provider Name:     DEA #:       Site Enrollment Number assigned     NCPDP#:       by Supplier:     NPI #:
SP#	Registry: No
ADD'L STORAGE INFORMATION Is the Product	Registry Program Contact Name:     Phone:       Comments
Controlled Substance?         Yes         Controlled Substance Code         2746           Controlled by State(s)?         Yes         Listed Chemical (List I or II)         No           ARCOS Reportable?         Yes         If yes, indicate which:         Is it a scheduled listed chemical product?:         No	RETURN INSTRUCTIONS       Contact tel. # if product received damaged:     1-866-827-3647       Is product returnable for credit:     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       Restricted to retail pharmacy only:     No       Restricted to hospital, clinics, and physician offices only:     No       Restricted from US territories? (explain in comments)     No	contact - customerservice@camberpharma.com         Special regulations or returns requirements for this product in certain states?         No         If so, which states? Other requirements? Comments?
MISCELLAN	IEOUS NOTES and/or Image of Product Barcode:
*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Pa	rt 1301.72.

Release DATE



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

Version 2024	FOR DESIGNATED DROP SHIP PRODUCT ONLY - if r	ot a designated drop ship, do not complete.	
Order Method for Des	signated Drop Ship Product	Standard Order Receipt and Processing	
Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name Phone Expedited Freight Charges o		Purchase order daily receipt cut off time by supplier         Cut off time:         Shipping lead time of PO:         Hours         Da         Ships same day for next day receipt:         Ships for second day receipt:         Ships regular ground for 3-10 days receipt:         Overnight and Priority Overnight PO Processing	ays
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:		Days of week overnight is available: Monday	
Comments:	s only:	Days of week overnight is available:       Tuesday         Tuesday       Wednessi         Priority Overnight receipt available:       Friday         PO Receipt Cut off time:       PO Receipt Cut off time:         Order receipt method:       Phone:         Fax:       EDI:         Overnight Fees apply:       Policity	/ day
Other Data Informati	ion 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?	
Miscell	aneous Notes:		
		ADDITIONAL INFORMATION	
		Is product order for scheduled patient procedure? Is product order for restocking purposes?	