

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

Version 2024						Introduction T	Туре:	New Item		x Final Version			Date:	2/25	/2025
			PRODUCT INFORMA	TION						SPECIAL HAN	IDLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Camber Pharmac					Applicat		ANDA	a. Temperature –	Indicate the USP temp					
Application Number for NDA/AN		O(k): 204787	·			NDA 505(b) Type:	: N	IOT APPLICABLE	Ten	nperature Range	Controlled Room -	- between 20	and 25 C (68	5° − 77° F)	
Medical Device Class, if applicable:															
DUNS: Proprietary Name (If Applicable) a	11-856-3719	ame: Locaca	mide Tablets, USP 50 mg						Oth	er Temperature Range (write in)	kequirement				
Selling Unit NDC:	31722-812-60	ame: Lacosa	Unit of Use NDC:		31722-812-60	UPC:	3317228	12603	Not						
UDI			CVX Code:			MVX Code:	0011220	.2000	1100	00					
Description: Lacosamide Tablets, USP 50 mg Is this product to be shipped to customers on ice?									No	1					
2 coonpact		,g								nis product to be shippe				No	1
Active Ingredient(s):		Lacosamide, USP													-
URL for Additional Product Information: www.camberpharma.com							perature excursion qu	estions:	Soma Raju						
Address:	800 Centennial A		.com		1	Address 2:			Nar	ne: nber:		732-529-042	13		
City:	Piscataway	tve, oute 1			State:	NJ	Zip:	08854		oup E-mail:			eterousa.cor	m	
Key Contact:	Customer Service	e	Email: customerservice@camberpharma.com												
Phone Number:	1-866-827-3647				Fax:	732-562-8788			c. Special regulati	ons for product in any	states?			*Yes	
Product Therapeutic Classification	n:	Anticonvulsant							Spe	ecial returns requiremen	ts for this product?			No	
	ADDIT	IONAL PRODUCT INF	CORMATION			PRODUCT	DESCRIPT	TION INFORMATION						NI:	1
	ADDITI	IONAL PRODUCT INF		D: . 01: 4		PRODUCTL	DESCRIPT	ION INFORMATION	1 1	unit of sale) upright?				No	
The product is?			Is the Product	Unit of Use	Only		00	\		tect product (unit of s	ale) from light?			No	
a legend device? if yes, enter class #		No	Is the Product Orphan Drug Status	Unit of Use		Size:	60) ct	e. Shelf life:	ial shelf life at launch	if different):			24	Months Months
a product kit?		No	Orphan Drug Status				50) mg		iai sileli ille at laulicii i	ii diilerentj.				WOILLIS
if yes, list NDCs of			FDA Approval Status			Strength:					ORDER INFORM	IATION			
component parts						Dosage Forn	m: Fil	Im coated tablet							
reverse numbered?		No	All B							t of Sale		What is the		unit?	
co-licensed? latex-free?		No Yes	Allergens Present				0	val. biconvex		Bottle Box/Carton		1 Bottle of 6	g. 1 Box of 1	0 Viale)	
preservative-free?		Yes	S	oy		Product Shap	ipe:	vai, biconvex		Ampule		(vviite iii, e.	g. 1 Dox 01 1	o viaio)	
correctional institution block?		No				Product Cold	or: Pi	nk		Glass		Minimum or	der quantity	/?	Yes
opioid?		No				Froduct Cold				Tube					
Cannabinoid?		No	Country of Origin	India		Product Impr		bossed with 'J' on one side d '12' on the other side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to unhospital scanning?	init dose for		Is this product covered u	ndor the						Vial Liquid Multi Vial Powder Sql			many of whi	ich package	type?
If Unit Dose, indicate NDC here:			Trade Agreements Act (1		No					Vial Powder Multi		24	Inner/Carton	1/Pack	
•										Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS											
						the article of Occasion	*16 A	dent Orange allega		DI	HARMACY ORDER	/ DILL LIMIT			
l	AD			_	Au	thorized Generic		rized Generic, other elds are not applicable	December 11 contracts		TARMACT ORDER				
I. Orange Book Rating: II. Generic Equivalent to What Bra	AB	Vimpat					0000001111	orao aro not apprioabro	Rec. sell unit to cu	ustomer?		Rx billing u	nit to pharma Each	acy:	
ii. Generic Equivalent to What Bra	iiu:.	vimpat							(Write-in, e.g. 1 Vi	al)			Gram		
		DRUG SUPPL	Y CHAIN SECURITY ACT (DSCSA) INFO	RMATION				HCPCS J-Code:	<u>'</u>	_		Milliliter		
Does supplier meet DSCSA defini	of		Yes	_	GLN:	0843368117603				ITC	AND PACKING IN	JEORMATION	1		
Is product exempt from DSCSA?	tion of manufactu	ilei r	No	_	GLN.	0043300117003				1151	I AND I ACKING II	II OKWATIOI	•		
If yes, select exemption:					GCP:						Dimensi	ons (US msm	nts)	Volume	Saleable #
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			iginal product purd	chased		Item/Each:	0.06	1.5	1.5	3	6.75	1
Is product sold by manufacturer's			Yes	_	direct from m							1.0		0.70	
Has FDA granted waiver/exception If yes, attach documentation from		roduct?	No		Provide source	ce manufacturer fo	or repacka	ged product	Box/Carton/Bundl Inner Pack:	e/					
ii yes, attacii documentation noi	III DA.								Case:						
		GTIN	N AND HIBCC PRODUCT II	NFORMATION						1.96	9.5	6.5	4	247	24
									Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC		GTI	N-14	·	Unit of Use GTIN-14							
X Item/Each	N	Quantity			003	31722812603		00331722812603							
Box/Carton/Bundle/Inner Pack					1					COST INFORMATION			WHOLESALI	ER USE ONL	_Y:
X Case	N	24			203	31722812607									
Pallet									Regular Cost			Vendor #:			
									Invoice Cost (WAC	J) (\$)	\$6.38	Whsl. Code Fineline Code			
									As of date:	12/1/2024		I Wellie Co	uc.		
												1			
			_												
1			Attach copy of SAFETY DA	TA SHEET (SI	S) or non haza										
*Please provide any additional inf	ormation on page	2.				See new p. 3 for	r Designate	ed Drop Ship Only.	Sig	nature:					



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For Designated Drop Ship Only Products, Please Use Page 3

	MATERIAL HAZ	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?	No	x Organic	Corrosive					
Is the product a CA Prop 65 reproductive toxicant?	No	Inorganic	Oxidizer					
Does the product label bear a CA Prop 65 warning?	No	Steroid/Androgen	Contact Hazard					
bood the product laber boar a over rop of warning.	140	Grorous vital oggin	- Contact Hazara					
c. Contact Hazard?	No	Does the product have an Aerosol class? If yes,	No					
d. Does this product require special clean-up instructions?	No	identify NFPA Storage Level:						
(If yes, attach SDS with special instructions.)	INU	NFPA Storage Level:						
e. Does the product contain DEHP?	No	141 1 A Glorage Level.						
·								
Is this product regulated for shipment by DOT?	Yes	Is the product a NIOSH hazardous drug?	No					
(if yes, answer a-e below and provide SDS)		If yes, indicate which:						
a. UN/Identification Number UN2811								
b. Proper Shipping Name Toxic solids, Organic, n.o.s (Lacosamide)								
c. DOT Hazard Class Not Regulated		Hazardous Waste Identification						
d. Packing Group								
e. Inhalation Hazard?	No	EPA Hazardous Waste Code:	Waste Characteristics					
Is this product regulated for shipment by IATA?	Yes							
(if yes, answer a-e below and provide SDS)		REMS o	r REGISTRY RESTRICTIONS					
a. UN/Identification Number UN2811								
b. Proper Shipping Name Toxic solid, organic. n.o.s. (Lacosamide)		Is there a REMS on this product?	No					
c. DOT Hazard Class Not Regulated		If Yes, is it managed with a pharmacy registry?						
d. Packing Group		Website URL:						
e. Inhalation Hazard?	No							
Is the product restricted for air shipment? If so, indicate restriction:	No	Med Guide Required	No					
Passenger	140	Limited Distribution Requirement	TVO					
Cargo		Comments / Details: (For example, iPledge program?)						
Passenger & Cargo		Comments / Details. (For example, iFledge program?)						
Is this a reportable quantity? No		REMS:	No					
RQ Threshold:		REMS Program Manager Name:	Phone:					
Is this a marine pollutant? No		Supplier Manages REMS registry exclusively:						
Is this product shipped utilizing an authorized DOT exception or Special Permit?		Wholesale distributor support:						
No (if yes, identify method below)		Provider Name:	DEA #:					
Limited Quantity		Site Enrollment Number assigned	NCPDP#:					
Consumer Commodity, ORM-D		by Supplier:	NPI #:					
Small Quantity (49 CFR 173.4)								
Special Permit; DOT-SP		Comments						
Special Provision (listed in Column 7 of 49 CFR 172.101);								
SP#		Registry:	No					
		Registry Program Contact Name:	Phone:					
ADD'L STORAGE INFORMATION		Comments						
Is the Product								
Controlled Substance? Yes Controlled Substance Code 2746		R	ETURN INSTRUCTIONS					
Controlled by State(s)? Yes Listed Chemical (List I or II)	No							
ARCOS Reportable? Yes If yes, indicate which:		Contact tel. # if product received damaged:	1-866-827-3647					
Schedule No. 5 Is it a scheduled listed chemical product	: No	Is product returnable for credit:	Yes					
CLASS OF TRADE RESTRICTION:		URL/Link to returns policy:	1.77					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes	contact - customerse	ervice@camberpharma.com					
Restricted to retail pharmacy only:	No	Special regulations or returns requirements for this						
Restricted to hospital, clinics, and physician offices only:	No	product in certain states?	No					
Restricted from US territories? (explain in comments)	No	If so, which states? Other requirements? Comments?	110					
, , ,	INU	11 30, Willon States: Other requirements: Comments?						
Comments:								
	MISCELLANE	OUS NOTES and/or Image of Product Barcode:						
*Storage of this product must abide by the federally mandated DEA requirements outline								
Otorage of this product must ablue by the rederany mandated DEA requirements outline	u iii Z i OFK Fall	1001.72.						



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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 b. Autofax Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time:					
c. Fax d. Phone only 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/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?					