

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

Version 2021						Introduction 1	Туре:	New Item		x Fi	inal Version			Date:	7/22/	2024	
			PRODUCT INFORMA	TION							SPECIAL HAN	DLING AND STOR	AGE REQUIR	REMENTS*			
Company Name: Camber Pharmaceuticals, Inc. ANDA Application: ANDA						ANDA	a. Temperature – Indicate the USP temperature range for this product.										
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 216335 Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)																	
Medical Device Class, if applicable:																	
	11-856-3719										perature Range F	Requirement			ween 15°C to	30°C (59°F	
Proprietary Name (If Applicable) an		Lacosa	amide Injection, USP 200 mg	g/20 mL (10 mg/	/mL) Single-Dos					(write	in)		to 86°F). Do	not freeze.			
Selling Unit NDC: UDI	31722-203-31		Unit of Use NDC: CVX Code:			UPC: MVX Code:	331722203	319		Notes							
	l	100 000				WYX Couc.				In the second					N		
Description: Lacosamide Injection, USP 200 mg/20 mL (10 mg/mL) Single-Dose Vials Is this product to be shipped to customers on ice? No Is this product to be shipped to customers on dry ice? No																	
Active Ingredient(s): Lacosamide, USP																	
b. Contact for temperature excursion questions:																	
URL for Additional Product Information		v.camberpharma	a.com							Name:			Soma Raju 732-529-042				
Address:	00 Centennial Ave, Suite 1			Address 2:	Address 2: Zip: 08854			Number: Group E-mail:									
City: Key Contact:	Customer Service	(ooddand)							Group E-mail:				somaraju@n	omaraju@heterousa.com			
	1-866-827-3647					customerservice@camberpharma.com 732-562-8788			c. Special regulations for product in any states?				*Yes				
Product Therapeutic Classification	: Anti	convulsant								Special returns requirements for this product? No							
	ADDITIONAL	PRODUCT IN	FORMATION			PRODUCT	DESCRIPTIC	IN INFORMATION	d. Store prod	uct (unit of s	sale) upright?				No		
The product is?			Is the Product	Direct-Ship C	Only		_			Protect pro	oduct (unit of sa	le) from light?			No		
a legend device?	No		Is the Product	Unit Dose		Size:		20 mL single-dose	e. Shelf life:						24	Months	
if yes, enter class #			Orphan Drug Status				vials			Initial shelt	f life at launch (i	f different):				Months	
a product kit? if yes, list NDCs of	No		FDA Approval Status			Strength:	200 mg/r	mg/20 mL (10				ORDER INFORM					
component parts			T DA Approvar Status				Stori	le solution for				ONDER IN ON	ATION				
reverse numbered?	No					Dosage Form	m: infus			Unit of Sal	e		What is the	NDC selling	unit?		
co-licensed?	No		Allergens Present								ottle		1 Carton of 1				
latex-free?	Yes					Product Sha	ape: N/A				ox/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)		
preservative-free?	Yes						Clas	r estadana			mpule		Minimum au		.	Vee	
correctional institution block? opioid?	No					Product Col	or:	r, colorless			lass ube		Minimum or	der quantity	r	Yes	
Cannabinoid?	No		Country of Origin	India		Buckey	N/A				ial Liquid Sgl						
If Unit Dose, is item bar coded to ur			, ,			Product Imp	orint:				ial Liquid Multi		If Yes, how	many of whi	ch package t	type?	
hospital scanning?	Yes		Is this product covered u								ial Powder Sgl			Each			
If Unit Dose, indicate NDC here:	317	22-203-20	Trade Agreements Act (FAA)?	No						ial Powder Multi			Inner/Cartor	/Pack		
			FOR GENERIC DRUG PR	ODUCTO						0	ther: Write In			Case			
			FOR GENERIC DRUG PR	ODUCIS					_								
					Au	thorized Generic	*If Authorize	ed Generic, other	PHARMACY ORDER / BILL UNIT								
I. Orange Book Rating:	section fields are not applicable							ls are not applicable	Rec. sell unit to customer? Rx billing unit to pharmacy:								
II. Generic Equivalent to What Brand?: Vimpat							Each										
									(Write-in, e.g.	1 Vial)				Gram			
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION																	
Does supplier meet DSCSA definit	ion of manufacturer?		Yes	_	GLN:	0860000397957					ITEM	AND PACKING I	NFORMATION	١			
Is product exempt from DSCSA?		1	No														
If yes, select exemption:					GCP:						Weight Lbs.	Dimensi	ons (US msm	nts.)	Volume	Saleable #	
Other exemption - Write in:											weight LDS.	Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?		1	No	_		riginal product pur	chased		Item/Each:		0.66	6.32	2.53	2.77	44.29	1	
Is product sold by manufacturer's Has FDA granted waiver/exception		+2	Yes	-	direct from m Provide source	nfr? ce manufacturer fo	or renackaco	d product	Box/Carton/B	undle/							
If yes, attach documentation from		··			. Tortae soul		. repairinge	- p. 00001	Inner Pack:								
									Case:		13.66	13.04	8.3	5.93	641.82	20	
		GTI	N AND HIBCC PRODUCT II	NFORMATION							13.00	13.04	0.5	5.55	041.02	20	
Saleable Unit of Measure	Calaak	le Quantity	LURCO		CTI	N-14	L las		Pallet:								
X Item/Each	Salead	1	HIBCC			N-14 31722203319	Un	it of Use GTIN-14	L								
Box/Carton/Bundle/Inner Pack	Box/Cartor/Bundle/Inner Pack							COST INFORMATION				WHOLESALER USE ONLY:					
X Case		20			203	31722203313											
Pallet							_		Regular Cost				Vendor #:				
							-		Invoice Cost	(WAC) (\$)		\$400.00	Whsl. Code				
					_		-		As of date:	1	1/21/2022		Fineline Coo	je:			
							-		no or uald.				1				
							-										
			Attach copy of SAFETY DA	ATA SHEET (SD	S) or non haza				RODUCT PACKA	GING and E	ARCODE.						
*Please provide any additional info	ormation on page 2.					See new p. 3 for	r Designated	Drop Ship Only.		Signature:							

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

Version 2021 For Designation	ated Drop Ship Only Products, Please Use Page 3						
MATERIAL H/	AZARD 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 b. Proper Shipping Name	NFPA Storage Level: Is the product a NIOSH hazardous drug? If yes, indicate which:						
c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics						
Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? Is the product restricted for air shipment? If so, indicate restriction: No Passenger Cargo Passenger & Cargo Is this a reportable quantity? No RQ Threshold: Is this product shipped utilizing an authorized DOT exception or Special Permit? No (if yes, identify method below)	REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? No Website URL: No Med Guide Required No Limited Distribution Requirement No Comments / Details: (For example, iPledge program?) No REMS: No REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: DEA #:						
Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4) Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Site Enrollment Number assigned by Supplier: NCPDP#: NPI #: Comments						
Is the Product							
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: Isted Chemical product?: No Schedule No. 5 Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	RETURN INSTRUCTIONS Contact tel. # if product received damaged: 1-866-827-3647 Is product returnable for credit: Yes URL/Link to returns policy: contact - customerservice@camberpharma.com						
Restricted to retail pharmacy only: No Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No Comments:	Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?						
MISCELLANI *Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Par	t 1301.72.						



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Version 2021 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 c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	Purchase order daily receipt cut off time by supplier Cut off time: 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 Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available: Image: Comparison of the co
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: Order receipt method: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?