

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. ANDA						a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN	DA/BLA; PMA/510(k):	204787				NDA 505(b) Type:	NOT APPLICABLE		nperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applical	ble:							T						
DUNS:	11-856-3719							Oth	er Temperature Range I	Requirement				
Proprietary Name (If Applicable) a		: Lacosar	nide Tablets, USP 100 mg						(write in)					
Selling Unit NDC:	31722-813-60		Unit of Use NDC: CVX Code:		31722-813-60	UPC: 33 MVX Code:	1722813600	Not	es					
UDI			CVX Code:			WVX Code:		1						
Description:	Lacosamide Tablets,	USP 100 mg							his product to be shipped				No	_
Active Ingredient(s):	La	acosamide, USP						ls ti	his product to be shipped	d to customers on o	dry ice?		No	
Active ingreaterin(s).								b. Contact for tem	perature excursion qu	estions:				
URL for Additional Product Inform		ww.camberpharma.	<u>com</u>					Nar			Soma Raju			
Address:	800 Centennial Ave,	Suite 1				Address 2:			nber:		732-529-042			
City:	Piscataway				State: Email:		ip: 08854	Gro	oup E-mail:		somaraju@	neterousa.cor	<u>n</u>	
Key Contact: Phone Number:	Customer Service 1-866-827-3647				Fax:	customerservice@ca 732-562-8788	mberpharma.com	c Special regulati	ons for product in any	states?			*Yes	1
Product Therapeutic Classificatio		nticonvulsant			Tux.	132-302-0100			cial returns requirement				No	-
Froduct Therapeutic Classificatio	л. 	niconvulsani						Spe	cial returns requirement	is for this product?			INU	
	ADDITION	AL PRODUCT INFO	ORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store product (unit of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship O	nlv				tect product (unit of sa	ale) from light?			No	1
a legend device?	N	n	Is the Product	Unit of Use	iny in the second se		60 ct	e. Shelf life:	teet product (unit of se	ale) ironi ngitti			24	Months
if yes, enter class #		<u> </u>	Orphan Drug Status			Size:	0000		ial shelf life at launch (if different):				Months
a product kit?	No	0				Strength:	100 mg							
if yes, list NDCs of			FDA Approval Status			Strength.				ORDER INFOR	MATION			
component parts						Dosage Form:	Film coated tablet							
reverse numbered?	No		Allermone Dresent			-			t of Sale		1 Bottle of 6	NDC selling	unit?	
co-licensed? latex-free?	No		Allergens Present				Oval, biconvex		x Bottle Box/Carton			.g. 1 Box of 1	(Vials)	
preservative-free?	Ye		S	oy		Product Shape:	oval, biconvex		Ampule		(white iii, e	.g. 1 Dox 01 1	0 1013)	
correctional institution block?						Des des si Ocher	Yellow		Glass		Minimum o	rder quantity	?	Yes
opioid?	No					Product Color:			Tube					
Cannabinoid?	No	0	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					ou dot imprint	and '13' on the other side		Vial Liquid Multi			many of whi	ch package	type?
hospital scanning? If Unit Dose, indicate NDC here:			Is this product covered u Trade Agreements Act (1		No				Vial Powder Sgl		24	Each Inner/Carton	/De els	
II ONIT Dose, Indicate NDC here:			Trade Agreements Act (1	AA)?	No				Vial Powder Multi Other: Write In			Case	Pack	
			FOR GENERIC DRUG PR	ODUCTS										
			TOR GENERIO DROGT R	000010										
					Au	thorized Generic *If	Authorized Generic, other		PH	IARMACY ORDER	R / BILL UNIT			
I. Orange Book Rating:	AB					se	ction fields are not applicable	Rec. sell unit to customer?			Rx billing unit to pharmacy: Each			
II. Generic Equivalent to What Bra	and?: Vi	mpat												
								(Write-in, e.g. 1 Vi	al)			Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (DSCSA) INFOR	MATION			HCPCS J-Code:				Milliliter		
Does supplier meet DSCSA defini	ition of manufactura-2		Yes	_	GLN:	0843368117603			ITEA	AND PACKING I	NEORMATIO	N		
Is product exempt from DSCSA?			No	-	GLN.	0043300117003			1124	ANDTACKINGT		N		
If yes, select exemption:					GCP:			1		Dimono	ions (US msr	nte)	Volume	Saleable #
If yes, select exemption: Other exemption - Write in:					GUP:			1	Weight Lbs.	Dimens	Width	nts.) Height	Volume (Cube)	Saleable # Pieces
Is product repackaged?			No		If yes, was or	riginal product purcha	sed	Item/Each:					. /	
Is product sold by manufacturer's	s exclusive distributor	?	Yes		direct from m				0.08	1.6	1.6	3	7.68	1
Has FDA granted waiver/exception	on/exemption for produ		No		Provide sour	ce manufacturer for re	packaged product	Box/Carton/Bundl	e/					
If yes, attach documentation from	m FDA.							Inner Pack:						
		CTIN	AND HIBCC PRODUCT I					Case:	2.4	10	7	4	280	24
		GTIN	AND HIBCC PRODUCT I	NFORMATION				Pallet:						
Saleable Unit of Measure	RFID tag(Y/N) Sa	aleable	HIBCC		GTI	N-14	Unit of Use GTIN-14	r anet.						
		uantity	11000		0.1					1				
x Item/Each	N	1			003	31722813600	00331722813600							
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESAL	ER USE ONL	_Y:
X Case	N	24			203	31722813604					_			
Pallet								Regular Cost			Vendor #:			
								Invoice Cost (WA	2) (\$)	\$11.97	Whsl. Code			
								11	-		Fineline Co	ue.		
								As of date:	12/1/2024					
								As of date:	12/1/2024					
								As of date:	12/1/2024					
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza	rd letter, PACKAGE INS	SERT, LABEL AND PHOTO OF I							
*Please provide any additional inf	formation on page 2.		Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza		SERT, LABEL AND PHOTO OF I signated Drop Ship Only.	PRODUCT PACKAGIN						

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	SDS Hazard Classification 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



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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?	