

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

						Introduction Type:	New Item	X	Final Version			Date:	2/25/	
			PRODUCT INFORMAT	ION					SPECIAL HAND	LING AND STOR	AGE REQUIF	EMENTS*		
Company Name:	Camber Pharmac	euticals, Inc.				Application:	ANDA	a. Temperature – Indica	ate the USP temper	ature range for th	is product			
Application Number for NDA/AND		,				NDA 505(b) Type:	NOT APPLICABLE			Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab						,,,,,		T I				`		
DUNS:	11-856-3719							Other Te	emperature Range Re	equirement	Excursions r	ermitted bety	veen 15°C to	30°C (59°F
Proprietary Name (If Applicable) ar	nd Established Na	me: Lacosan	nide Oral Solution, USP 10	mg/mL					ite in)		to 86°F)			
	31722-627-26		Unit of Use NDC:	<u> </u>	31722-627-26	UPC: 331	722627269	Notes	,		Do not freez	)		
UDI			CVX Code:			MVX Code:		†						
Description:	Lacosamide Oral	Solution, USP 10 mg/m	nl					le this no	oduct to be shipped	to customers on ic	a?		No	
Description.	Lacosamiac Orai	colution, cor 10 mg/m							oduct to be shipped				No	
Active Ingredient(s):		Lacosamide, USP						1			,			
3 (.,		,,						b. Contact for temperat	ture excursion ques	stions:				
URL for Additional Product Informa	ation:	www.camberpharma.c	com					Name:	•		Soma Raju			
Address:	800 Centennial A	e, Suite 1				Address 2:		Number:	:		732-529-042			
City:	Piscataway				State:		o: 08854	Group E	-mail:		somaraju@h	eterousa.con	<u>1</u>	
Key Contact:	Customer Service					customerservice@can	nberpharma.com							
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regulations f					*Yes	
Product Therapeutic Classification	1:	Anticonvulsant						Special r	returns requirements	for this product?			No	
	ADDITI	ONAL PRODUCT INFO	ORMATION			PRODUCT DESC	CRIPTION INFORMATION	d. Store product (unit of	of sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	only				product (unit of sale	e) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	200 mL	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			0.20.		Initial sh	nelf life at launch (if	different):				Months
a product kit?		No			Strength:	10 mg/mL								
if yes, list NDCs of			FDA Approval Status			_				ORDER INFORM	ATION			
component parts reverse numbered?		lat.				Dosage Form:	Clear, oral solution	Unit of S	Sala.		What is the	NDC colling	unit?	
co-licensed?		No No	Allergens Present						Bottle		1 Bottle of 2			
latex-free?		Yes	Gluten, Whey, Soy, C	orn Alcohol	Δnimal		N/A		Box/Carton			a. 1 Box of 10		
preservative-free?		No	Products, Si		Aillilai	Product Shape:	IWA		Ampule		(vviite-iii, e.	g. 1 DOX 01 10	, viais)	
correctional institution block?		No	1100000,0	agai, mioat			Colorless to yellow or		Glass		Minimum or	der quantity	2	Yes
opioid?		No				Product Color:	yellow-brown		Tube			aci qualitity	•	103
Cannabinoid?		No	Country of Origin	India			N/A		Vial Liquid Sgl					
If Unit Dose, is item bar coded to un	nit dose for		,g			Product Imprint:			Vial Liquid Multi		If Yes. how	many of whi	ch package t	vpe?
hospital scanning?			Is this product covered ur	nder the					Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (Ta	AA)?	No				Vial Powder Multi			Inner/Carton	/Pack	
					INU				Viai i Owdei ividiti					
			3	, , , ,	140				Other: Write In			Case	. don	
			FOR GENERIC DRUG PRO		NO								don	
					NO				Other: Write In				400	
							authorized Generic, other		Other: Write In	ARMACY ORDER			. doi:	
I. Orange Book Rating:	АВ						Authorized Generic, other tion fields are not applicable		Other: Write In	ARMACY ORDER		Case		
I. Orange Book Rating: II. Generic Equivalent to What Brar		Vimpat							Other: Write In	ARMACY ORDER A	BILL UNIT	Case		
		Vimpat	FOR GENERIC DRUG PRC	DDUCTS	Au			Rec. sell unit to custon (Write-in, e.g. 1 Vial)	Other: Write In	ARMACY ORDER	BILL UNIT	Case  nit to pharma Each Gram		
		Vimpat		DDUCTS	Au			Rec. sell unit to custon	Other: Write In	ARMACY ORDER	BILL UNIT	Case  nit to pharma Each		
II. Generic Equivalent to What Brar	nd?:	Vimpat  DRUG SUPPLY	FOR GENERIC DRUG PRO	DDUCTS	Au	sec		Rec. sell unit to custon (Write-in, e.g. 1 Vial)	Other: Write In  PHA  mer?		/ BILL UNIT Rx billing u	case  iit to pharma Each Gram Milliliter		
II. Generic Equivalent to What Bran	nd?:	Vimpat  DRUG SUPPLY	FOR GENERIC DRUG PRO CHAIN SECURITY ACT (E	DDUCTS	Au			Rec. sell unit to custon (Write-in, e.g. 1 Vial)	Other: Write In  PHA  mer?	ARMACY ORDER	/ BILL UNIT Rx billing u	case  iit to pharma Each Gram Milliliter		
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II. Generic Equivalent to What Brar  Does supplier meet DSCSA definit Is product exempt from DSCSA?  If yes, select exemption:	nd?:	Vimpat  DRUG SUPPLY	FOR GENERIC DRUG PRO CHAIN SECURITY ACT (E	DDUCTS	Au	sec		Rec. sell unit to custon (Write-in, e.g. 1 Vial)	Other: Write In  PHA mer?	AND PACKING IN	/ BILL UNIT Rx billing un FORMATION	Case  iit to pharma Each Gram Milliliter	ecy:	Saleable #
II. Generic Equivalent to What Brar  Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	nd?:	Vimpat  DRUG SUPPLY	FOR GENERIC DRUG PRO CHAIN SECURITY ACT (E Yes No	DDUCTS	Au  RMATION  GLN:  GCP:	0843368117603	tion fields are not applicable	Rec. sell unit to custon (Write-in, e.g. 1 Vial) HCPCS J-Code:	Other: Write In PHA	AND PACKING IN	BILL UNIT Rx billing ui	Case  iit to pharma Each Gram Milliliter	асу:	Saleable # Pieces
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## **Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)**

#### Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

M	ATERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION				
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	No		OS Hazard Classification			
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:	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	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?		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?		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	No	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)	No			
Is this a reportable quantity? 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)		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); SP#		Comments  Registry:	No			
		Registry Program Contact Name:	140	Phone:		
ADD'L STORAGE INFORMATION		Comments				
Is the Product  Controlled Substance?  Controlled by State(s)?  ARCOS Reportable?  Schedule No.  Yes  Controlled Substance Code  Itsed Chemical (List I or II)  If yes, indicate which:  Is it a scheduled listed chemical product?:	No 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  Restricted to retail pharmacy only:  Restricted to hospital, clinics, and physician offices only:	Yes No	Special regulations or returns requirements for this product in certain states?	ervice@camberpharma.com			
Restricted from US territories? (explain in comments)  Comments:	No	If so, which states? Other requirements? Comments?				
	MISCELLANEC	DUS NOTES and/or Image of Product Barcode:				
*Storage of this product must abide by the federally mandated DEA requirements outlined in		-				



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

#### Version 2024

### 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?				