



Date: 2/25/2025

PRODUCT INFORMATION						SPECIAL HANDLING AND STORAGE REQUIREMENTS*					
Company Name: Camber Pharmaceuticals, Inc.						Application: ANDA					
Application Number for NDA/ANDA/BLA; PMA/510(k): 204787			NDA 505(b) Type: NOT APPLICABLE								
Medical Device Class, if applicable:											
DUNS: 11-856-3719											
Proprietary Name (If Applicable) and Established Name: Lacosamide Tablets, USP 200 mg											
Selling Unit NDC: 31722-815-60		Unit of Use NDC: 31722-815-60		UPC: 331722815604							
UDI		CVX Code:		VMX Code:							
Description: Lacosamide Tablets, USP 200 mg											
Active Ingredient(s): Lacosamide, USP											
URL for Additional Product Information: www.camberpharma.com											
Address: 800 Centennial Ave, Suite 1			State: NJ			Address 2:			Zip: 08854		
City: Piscataway			Email: customerservice@camberpharma.com								
Key Contact: Customer Service			Fax: 732-562-8788								
Phone Number: 1-866-827-3647											
Product Therapeutic Classification: Anticonvulsant											
ADDITIONAL PRODUCT INFORMATION						PRODUCT DESCRIPTION INFORMATION					
The product is?		Is the Product...		Direct-Ship Only		Size:		60 ct			
a legend device?		Is the Product...		Unit of Use		Strength:		200 mg			
if yes, enter class #		Orphan Drug Status				Dosage Form:		Film coated tablet			
a product kit?						Product Shape:		Oval, biconvex			
if yes, list NDCs of component parts reverse numbered?		FDA Approval Status				Product Color:		Blue			
co-licensed?				Allergens Present		Product Imprint:		Debossed with 'J' on one side and '15' on the other side			
latex-free?				Soy							
preservative-free?				Country of Origin		India					
correctional institution block?				Is this product covered under the Trade Agreements Act (TAA)?		No					
opioid?											
Cannabinoid?											
If Unit Dose, is item bar coded to unit dose for hospital scanning?											
If Unit Dose, indicate NDC here:											
FOR GENERIC DRUG PRODUCTS											
I. Orange Book Rating: AB						<input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable					
II. Generic Equivalent to What Brand?: Vimpat											
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION											
Does supplier meet DSCSA definition of manufacturer?						Yes					
Is product exempt from DSCSA?						No					
If yes, select exemption:											
Other exemption - Write in:											
Is product repackaged?						No					
Is product sold by manufacturer's exclusive distributor?						Yes					
Has FDA granted waiver/exception/exemption for product?						No					
If yes, attach documentation from FDA.											
GLN: 0843368117603											
GCP:											
If yes, was original product purchased direct from mfr?						Provide source manufacturer for repackaged product					
GTIN AND HIBCC PRODUCT INFORMATION											
Saleable Unit of Measure		RFID tag(Y/N)		Saleable Quantity		HIBCC		GTIN-14		Unit of Use GTIN-14	
x	Item/Each	N		1				00331722815604		00331722815604	
x	Box/Carton/Bundle/Inner Pack	N		24				20331722815608			
x	Case	N									
x	Pallet	N									
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.											
*Please provide any additional information on page 2.											
See new p. 3 for Designated Drop Ship Only.											
Signature:											

a. Temperature – Indicate the USP temperature range for this product.											
Temperature Range						Controlled Room – between 20 and 25 C (68° – 77° F)					
Other Temperature Range Requirement						(write in)					
Notes											
Is this product to be shipped to customers on ice?						No					
Is this product to be shipped to customers on dry ice?						No					
b. Contact for temperature excursion questions:											
Name:						Soma Raju					
Number:						732-529-0423					
Group E-mail:						somaraju@heterousa.com					
c. Special regulations for product in any states?											
Special returns requirements for this product?						*Yes					
						No					
d. Store product (unit of sale) upright?											
Protect product (unit of sale) from light?						No					
						No					
e. Shelf life:						24					
Initial shelf life at launch (if different):						Months					
						Months					
ORDER INFORMATION											
Unit of Sale						What is the NDC selling unit?					
x Bottle						1 Bottle of 60 Tablets					
Box/Carton						(Write-in, e.g. 1 Box of 10 Vials)					
Ampule											
Glass											
Tube											
Vial Liquid Sgl											
Vial Liquid Multi											
Vial Powder Sgl											
Vial Powder Multi											
Other: Write In											
PHARMACY ORDER / BILL UNIT											
Rec. sell unit to customer?						Rx billing unit to pharmacy:					
						Each					
(Write-in, e.g. 1 Vial)						Gram					
HPCPS J-Code:						Milliliter					
ITEM AND PACKING INFORMATION											
		Weight Lbs.		Dimensions (US msmts.)		Volume (Cube)		Saleable # Pieces			
		Depth		Width		Height					
Item/Each:</											

Signature:



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

Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic?

No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant?

No

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?

No

d. Does this product require special clean-up instructions?

No

(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP?

No

Is this product regulated for shipment by DOT?

Yes

(if yes, answer a-e below and provide SDS)

a. UN/Identification Number

UN2811

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

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

Not Regulated

d. Packing Group

III

e. Inhalation Hazard?

No

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 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 Provision (listed in Column 7 of 49 CFR 172.101);

SP#

ADD'L STORAGE INFORMATION

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:

Schedule No.

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

Restricted to retail pharmacy only:

☐ No

Restricted to hospital, clinics, and physician offices only:

☐ No

Restricted from US territories? (explain in comments)

☐ No

Comments:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Part 1301.72.

SDS Hazard Classification

☒

Organic

☐

Inorganic

☐

Steroid/Androgen

☐

Corrosive

☐

Oxidizer

☐

Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:

No

NFPA Storage Level:

Is the product a NIOSH hazardous drug?

No

If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code:

Waste Characteristics

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

No

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required

No

Limited Distribution Requirement

Comments / Details: (For example, iPledge program?)

REMS:

REMS Program Manager Name:

No

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned

by Supplier:

Phone:

DEA #:

NCPDP#:

NPI #:

Comments

Registry:

No

Registry Program Contact Name:

Phone:

Comments

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

Special regulations or returns requirements for this product in certain states?

No

If so, which states? Other requirements? Comments?

Release DATE



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

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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
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
<p>Expedited Freight Charges or Other Designated Drop Ship Fees:</p> <p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p>Overnight and Priority Overnight PO Processing</p> <p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
<p>Class of Trade Restriction:</p> <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>	
<p>Other Data Information Required to Process PO:</p> <p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Return Instructions</p> <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
<p>Miscellaneous Notes:</p> <p><input type="text"/></p>	<p>ADDITIONAL INFORMATION</p> <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>