



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

Version 2021

Introduction Type:  New Item

Final Version

Date: 3/17/2022

## PRODUCT INFORMATION

**Company Name:** Camber Pharmaceuticals, Inc. **Application:** ANDA

**Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):** 204787

**Medical Device Class, if applicable:**

**DUNS:** 82-677-4775

**Proprietary Name (If Applicable) and Established Name:** Lacosamide Tablets 150mg 60ct

**Selling Unit NDC:** 31722-814-60 **Unit of Use NDC:** **UPC:** 331722814607

**UDI** **CVX Code:** **MXV Code:**

**Description:** Oral Solid - Tablet, oval shaped, salmon, Upper: '14' Lower: 'J'

**Active Ingredient(s):** Lacosamide

**URL for Additional Product Information:**

**Address:** 1031 Centennial Ave (and) 800 Centennial Ave, Suite 1 **Address 2:**

**City:** Piscataway **State:** NJ **Zip:** 08854

**Key Contact:** Customer Service **Email:** [customerservice@camberpharma.com](mailto:customerservice@camberpharma.com)

**Phone Number:** 1-866-827-3647 **Fax:** 732-562-8788

**Product Therapeutic Classification:**

## SPECIAL HANDLING AND STORAGE REQUIREMENTS\*

**a. Temperature – Indicate the USP temperature range for this product.**

Temperature Range:

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](mailto:somaraju@heterousa.com)

**c. Special regulations for product in any states?**  No

Special returns requirements for this product?  No

**d. Store product (unit of sale) upright?**  No

Protect product (unit of sale) from light?  No

**e. Shelf life:**  Months

Initial shelf life at launch (if different):  Months

## ADDITIONAL PRODUCT INFORMATION

The product is a legend device?  No

If yes, enter class # a product kit?  No

If yes, list NDCs of component parts reverse numbered?  No

co-licensed?  No

latex-free?  Yes

preservative-free?  Yes

correctional institution block?  No

opioid?  No

Cannabinoid?  No

If Unit Dose, is item bar coded to unit dose for hospital scanning?

If Unit Dose, indicate NDC here:

**Is the Product... Direct-Ship Only**

**Is the Product... Neither**

**Orphan Drug Status**

**FDA Approval Status**

**Allergens Present**

**Country of Origin**

Is this product covered under the Trade Agreements Act (TAA)?  No

## PRODUCT DESCRIPTION INFORMATION

**Size:** 60ct

**Strength:** 150mg

**Dosage Form:** Oral Solid - Tablet

**Product Shape:** Oval

**Product Color:** Salmon

**Product Imprint:** Upper: '14' Lower: 'J'

## ORDER INFORMATION

**Unit of Sale**

Bottle

Box/Carton

Ampule

Glass

Tube

Vial Liquid Sgl

Vial Liquid Multi

Vial Powder Sgl

Vial Power Multi

Other: Write In

**What is the NDC selling unit?**

(Write-in, e.g. 1 Box of 10 Vials)

**Minimum order quantity?**  Yes

**If Yes, how many of which package type?**

Each

Inner/Carton/Pack

Case

## FOR GENERIC DRUG PRODUCTS

Authorized Generic \*If Authorized Generic, other section fields are not applicable

**I. Orange Book Rating:**

**II. Generic Equivalent to What Brand?:**

## PHARMACY ORDER / BILL UNIT

**Rec. sell unit to customer?**

**Rx billing unit to pharmacy:**

Each

Gram

Milliliter

## 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?  No

Has FDA granted waiver/exception/exemption for product?  No

If yes, attach documentation from FDA.

**GLN:** 0331722000000

**GCP:**

If yes, was original product purchased direct from mfr?

Provide source manufacturer for repackaged product:

## ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.11		1.6	2.98	0	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	2.84	9.75	6.75	4.5	0	24
Pallet:					0	

## GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00331722814607	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	24		20331722814601	
<input type="checkbox"/> Pallet				

## COST INFORMATION

**Regular Invoice Cost (WAC) (\$)**

As of date:

**WHOLESALE USE ONLY:**

**Vendor #:**

**Whsl. Code #:**

**Fineline Code:**

\*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

See new p. 3 for Designated Drop Ship Only.

Signature:



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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?
  - 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?  No

- c. Contact Hazard?  No
- d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)  No
- 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
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?  No

Is this product regulated for shipment by IATA? (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?  No

Is the product restricted for air shipment? If so, indicate restriction:

- Passenger  No
- Cargo  No
- Passenger & Cargo  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?

- (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  No  No  No
- Controlled Substance Code  2746
- Controlled by State(s)?  Yes  No
- Listed Chemical (List I or II)  Yes  No
- ARCOS Reportable?  Yes  No
- If yes, indicate which:
- Schedule No.  5
- Is it a scheduled listed chemical product?:  Yes  No

### CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes  No
- Restricted to retail pharmacy only:  Yes  No
- Restricted to hospital, clinics, and physician offices only:  Yes  No
- Restricted from US territories? (explain in comments)  Yes  No

Comments:

### SDS Hazard Classification

- Organic  Corrosive
- Inorganic  Oxidizer
- Steroid/Androgen  Contact Hazard

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

Is the product a NIOSH hazardous drug?  No  Yes  
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  Yes  
If Yes, is it managed with a pharmacy registry?  Yes  No  
Website URL:

Med Guide Required  Yes  No  
Limited Distribution Requirement  Yes  No  
Comments / Details: (For example, iPledge program?)

**REMS:**  No  Yes  
REMS Program Manager Name:  Phone:   
Supplier Manages REMS registry exclusively:  Yes  No  
Wholesale distributor support:  Yes  No  
Provider Name:  DEA #:   
Site Enrollment Number assigned by Supplier:  NCPDP#:   
NPI #:

Comments

**Registry:**  No  Yes  
Registry Program Contact Name:  Phone:   
Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:  1-866-827-3647  
Is product returnable for credit:  Yes  No

URL/Link to returns policy:  contact - customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states?  No  Yes  
If so, which states? Other requirements? Comments?

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

