



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

Version 2021 Introduction Type: Final Version Date:

PRODUCT INFORMATION	
Company Name:	Camber Pharmaceuticals, Inc.
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	204787
Medical Device Class, if applicable:	
DUNS:	11-856-3719
Proprietary Name (If Applicable) and Established Name:	Lacosamide Tablets, USP 50 mg
Selling Unit NDC:	31722-812-60
Unit of Use NDC:	31722-812-60
UPC:	331722812603
CVX Code:	
MVX Code:	
Description:	Lacosamide Tablets, USP 50 mg
Active Ingredient(s):	Lacosamide, USP
URL for Additional Product Information:	www.camberpharma.com
Address:	800 Centennial Ave, Suite 1
City:	Piscataway
Key Contact:	Customer Service
Phone Number:	1-866-827-3647
Product Therapeutic Classification:	Anticonvulsant

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
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?	<input type="text" value="No"/>
Is this product to be shipped to customers on dry ice?	<input type="text" value="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?	<input type="text" value="No"/>
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="text" value="No"/>
e. Shelf life:	<input type="text" value="24"/> Months
Initial shelf life at launch (if different):	<input type="text" value="24"/> Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class #	<input type="text" value="No"/>	Is the Product... Direct-Ship Only	<input type="text" value="No"/>
a product kit?	<input type="text" value="No"/>	Is the Product... Unit of Use	<input type="text" value="No"/>
if yes, list NDCs of component parts reverse numbered?		Orphan Drug Status	
co-licensed?	<input type="text" value="No"/>	FDA Approval Status	
latex-free?	<input type="text" value="No"/>	Allergens Present	Soy
preservative-free?	<input type="text" value="Yes"/>	Country of Origin	India
correctional institution block?	<input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>
opioid?	<input type="text" value="No"/>	Size:	60 ct
Cannabinoid?	<input type="text" value="No"/>	Strength:	50 mg
If Unit Dose, is item bar coded to unit dose for hospital scanning?		Dosage Form:	Film coated tablet
If Unit Dose, indicate NDC here:		Product Shape:	Oval, biconvex
		Product Color:	Pink
		Product Imprint:	Debossed with 'J' on one side and '12' on the other side

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Bottle of 60 Tablets
<input type="checkbox"/> Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? <input type="text" value="Yes"/>
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="text" value="24"/> Each
<input type="checkbox"/> Vial Powder Multi	<input type="text" value=""/> Inner/ Carton/ Pack
<input type="checkbox"/> Other: Write In	<input type="text" value=""/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Vimpat
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
(Write-in, e.g. 1 Vial)	<input type="text" value=""/> Each
	<input type="text" value=""/> Gram
	<input type="text" value=""/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="text" value="Yes"/>
Is product exempt from DSCSA?	<input type="text" value="No"/>
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	<input type="text" value="No"/>
Is product sold by manufacturer's exclusive distributor?	<input type="text" value="Yes"/>
Has FDA granted waiver/exception/exemption for product?	<input type="text" value="No"/>
If yes, attach documentation from FDA.	
GLN:	0860000397957
GCP:	
If yes, was original product purchased direct from mfr?	<input type="text" value="No"/>
Provide source manufacturer for repackaged product	

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/ Carton/ Bundle/ Inner Pack:	0.06	1.5	1.5	3	6.75	1
Case:	1.96	9.5	6.5	4	247	24
Pallet:						

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		00331722812603	00331722812603
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	24		20331722812607	
<input type="checkbox"/> Pallet				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$6.38	Whsl. Code #:	
As of date:	12/1/2024	Fineline Code:	

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:

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION																																																							
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? <input type="checkbox"/> No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? <input type="checkbox"/> No Is the product a CA Prop 65 reproductive toxicant? <input type="checkbox"/> No Does the product label bear a CA Prop 65 warning? <input type="checkbox"/> No</p> <p>c. Contact Hazard? <input type="checkbox"/> No</p> <p>d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) <input type="checkbox"/> No</p> <p>e. Does the product contain DEHP? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/></p> <p>Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/></p> <p>Is the product restricted for air shipment? If so, indicate restriction: <input type="checkbox"/> No</p> <p><input type="checkbox"/> Passenger <input type="checkbox"/> Cargo <input type="checkbox"/> Passenger & Cargo</p> <p>Is this a reportable quantity? <input type="checkbox"/> No RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? <input type="checkbox"/> No</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit? <input type="checkbox"/> No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity <input type="checkbox"/> Consumer Commodity, ORM-D <input type="checkbox"/> Small Quantity (49 CFR 173.4) <input type="checkbox"/> Special Permit; DOT-SP <input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101); SP# <input type="text"/></p>	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr style="background-color: #002060; color: white;"> <th colspan="2" style="text-align: center; padding: 2px;">SDS Hazard Classification</th> </tr> </thead> <tbody> <tr> <td style="width: 50%; padding: 2px;"><input checked="" type="checkbox"/> Organic</td> <td style="width: 50%; padding: 2px;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="padding: 2px;"><input type="checkbox"/> Inorganic</td> <td style="padding: 2px;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="padding: 2px;"><input type="checkbox"/> Steroid/Androgen</td> <td style="padding: 2px;"><input type="checkbox"/> Contact Hazard</td> </tr> <tr> <td colspan="2" style="padding: 2px;">Does the product have an Aerosol class? 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<p>Is the Product...</p> <p>Controlled Substance? <input type="checkbox"/> Yes <input type="checkbox"/> No Controlled Substance Code <input type="text" value="2746"/></p> <p>Controlled by State(s)? <input type="checkbox"/> Yes <input type="checkbox"/> No Listed Chemical (List I or II) <input type="checkbox"/> No</p> <p>ARCOS Reportable? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, indicate which: <input type="text"/></p> <p>Schedule No. <input type="text" value="5"/> Is it a scheduled listed chemical product?: <input type="checkbox"/> No</p>	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr style="background-color: #002060; color: white;"> <th colspan="2" style="text-align: center; padding: 2px;">RETURN INSTRUCTIONS</th> </tr> </thead> <tbody> <tr> <td style="width: 60%; padding: 2px;">Contact tel. # if product received damaged: <input type="text" value="1-866-827-3647"/></td> <td style="padding: 2px;"></td> </tr> <tr> <td style="padding: 2px;">Is product returnable for credit: <input type="checkbox"/> Yes <input type="checkbox"/> No</td> <td style="padding: 2px;"></td> </tr> <tr> <td style="padding: 2px;">URL/Link to returns policy: <input type="text" value="contact - customerservice@camberpharma.com"/></td> <td style="padding: 2px;"></td> </tr> <tr> <td style="padding: 2px;">Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> No</td> <td style="padding: 2px;"></td> </tr> <tr> <td colspan="2" style="padding: 2px;">If so, which states? Other requirements? Comments? <input type="text"/></td> </tr> </tbody> </table>	RETURN INSTRUCTIONS		Contact tel. # if product received damaged: <input type="text" value="1-866-827-3647"/>		Is product returnable for credit: <input type="checkbox"/> Yes <input type="checkbox"/> No		URL/Link to returns policy: <input type="text" value="contact - customerservice@camberpharma.com"/>		Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> No		If so, which states? Other requirements? Comments? <input type="text"/>																																											
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<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Restricted to retail pharmacy only: <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Comments: <input type="text"/></p>	<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr style="background-color: #002060; color: white;"> <th colspan="2" style="text-align: center; padding: 2px;">MISCELLANEOUS NOTES and/or Image of Product Barcode:</th> </tr> </thead> <tbody> <tr> <td colspan="2" style="padding: 2px; height: 40px;"><input type="text"/></td> </tr> </tbody> </table>	MISCELLANEOUS NOTES and/or Image of Product Barcode:		<input type="text"/>																																																			
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Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

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