



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

Version 2021

Introduction Type:  Post Launch Change

Final Version

Date: 6/23/2024

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Camber Pharmaceuticals, Inc.		Application: ANDA		a. Temperature – Indicate the USP temperature range for this product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 213949				Temperature Range: <input type="text"/> Controlled Room – between 20 and 25 C (68° – 77° F)			
Medical Device Class, if applicable:				Other Temperature Range Requirement (write in): <input type="text"/> Excursions permitted to 15° to 30° C (59° to 86°F)			
DUNS: 11-856-3719				Notes: <input type="text"/>			
Proprietary Name (If Applicable) and Established Name: Lamotrigine Extended-Release Tablets, USP 100 mg				Is this product to be shipped to customers on ice? <input type="checkbox"/> No			
Selling Unit NDC: 31722-242-30		Unit of Use NDC: 31722-242-30		UPC: 331722242301		Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No	
UDI: <input type="text"/>		CVX Code: <input type="text"/>		MVX Code: <input type="text"/>			
Description: Lamotrigine Extended-Release Tablets, USP 100 mg				b. Contact for temperature excursion questions:			
Active Ingredient(s): Lamotrigine, USP				Name: <input type="text"/> Soma Raju			
URL for Additional Product Information: <a href="http://www.camberpharma.com">www.camberpharma.com</a>				Number: <input type="text"/> 732-529-0423			
Address: 800 Centennial Ave, Suite 1		Address 2: <input type="text"/>		Group E-mail: <input type="text"/> somaraju@heterousa.com			
City: Piscataway		State: NJ		Zip: 08854			
Key Contact: Customer Service		Email: <a href="mailto:customerservice@camberpharma.com">customerservice@camberpharma.com</a>					
Phone Number: 1-866-827-3647		Fax: 732-562-8788					
Product Therapeutic Classification: Phenytriazone anticonvulsant				c. Special regulations for product in any states? <input type="checkbox"/> No			
				Special returns requirements for this product? <input type="checkbox"/> No			
				d. Store product (unit of sale) upright? <input type="checkbox"/> No			
				Protect product (unit of sale) from light? <input type="checkbox"/> No			
				e. Shelf life: <input type="text"/> 24 Months			
				Initial shelf life at launch (if different): <input type="text"/> Months			
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is a legend device? <input type="checkbox"/> No		Is the Product... Direct-Ship Only <input type="checkbox"/>		Size: <input type="text"/> 30 ct			
if yes, enter class # <input type="text"/>		Is the Product... Unit of Use <input type="checkbox"/>		Strength: <input type="text"/> 100 mg			
a product kit? <input type="checkbox"/> No		Orphan Drug Status <input type="checkbox"/>		Dosage Form: <input type="text"/> Film-coated tablet			
if yes, list NDCs of component parts reverse numbered? <input type="text"/>		FDA Approval Status <input type="text"/>		Product Shape: <input type="text"/> Round, biconvex			
co-licensed? <input type="checkbox"/> No		Allergens Present <input type="text"/> Lactose, Animal Products		Product Color: <input type="text"/> Orange			
latex-free? <input type="checkbox"/> Yes		Country of Origin <input type="text"/> China		Product Imprint: <input type="text"/> Printed with "Y33" on one side in black ink and no mark on the reverse side			
preservative-free? <input type="checkbox"/> Yes		Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No					
correctional institution block? <input type="checkbox"/> No							
opioid? <input type="checkbox"/> No							
Cannabinoid? <input type="checkbox"/> No							
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/>							
If Unit Dose, indicate NDC here: <input type="text"/>							
ORDER INFORMATION							
Unit of Sale		What is the NDC selling unit?					
<input checked="" type="checkbox"/> Bottle		<input type="text"/> 1 Bottle of 30 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="checkbox"/> Yes					
<input type="checkbox"/> Tube							
<input type="checkbox"/> Vial Liquid Sgl		If Yes, how many of which package type?					
<input type="checkbox"/> Vial Liquid Multi		<input type="text"/> 24 Each					
<input type="checkbox"/> Vial Powder Sgl		Inner/ Carton/Pack					
<input type="checkbox"/> Vial Powder Multi		Case					
<input type="checkbox"/> Other: Write In <input type="text"/>							
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: <input type="text"/> AB		Authorized Generic <input type="checkbox"/>		*If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: <input type="text"/> Lamictal XR							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes		GLN: <input type="text"/> 0331722498975					
Is product exempt from DSCSA? <input type="checkbox"/> No		GCP: <input type="text"/>					
If yes, select exemption: <input type="text"/>		If yes, was original product purchased direct from mfr? <input type="checkbox"/>					
Other exemption - Write in: <input type="text"/>		Provide source manufacturer for repackaged product <input type="text"/>					
Is product repackaged? <input type="checkbox"/> No							
Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> Yes							
Has FDA granted waiver/exception/exemption for product? <input type="checkbox"/> No							
If yes, attach documentation from FDA. <input type="text"/>							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure		Saleable Quantity		HIBCC		GTIN-14	
<input checked="" type="checkbox"/> Item/Each		<input type="text"/> 1				<input type="text"/> 00331722242301	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack						<input type="text"/> 10331722242308	
<input checked="" type="checkbox"/> Case		<input type="text"/> 24				Unit of Use GTIN-14 <input type="text"/> 00331722242301	
<input type="checkbox"/> Pallet							
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost <input type="text"/>		Invoice Cost (WAC) (\$) <input type="text"/> \$45.11		Vendor #: <input type="text"/>		Whsl. Code #: <input type="text"/>	
As of date: <input type="text"/> 11/14/2022				Fineline Code: <input type="text"/>			

\*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
- 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?  No  Yes
- Controlled by State(s)?  No  Yes
- ARCOS Reportable?  No  Yes
- Schedule No.
- Controlled Substance Code
- Listed Chemical (List I or II)  No  Yes
- If yes, indicate which:
- 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:

### 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?  No  
Website URL:

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

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

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?

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



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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
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"/>	<b>Purchase order daily receipt cut off time by supplier</b> 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"/>	<b>Overnight receipt available:</b> <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 <b>Priority Overnight receipt available:</b> <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> <b>Saturday Overnight receipt available:</b> <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:	
<input type="text"/>	<b>ADDITIONAL INFORMATION</b> Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>