



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

Version 2021 Introduction Type:  New Item  Final Version Date: 11/15/2022

**PRODUCT INFORMATION** **SPECIAL HANDLING AND STORAGE REQUIREMENTS\***

**Company Name:** Camber Pharmaceuticals, Inc. **Application:** ANDA  
**Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):** 213949  
**Medical Device Class, if applicable:** \_\_\_\_\_  
**DUNS:** 82-677-4775  
**Proprietary Name (If Applicable) and Established Name:** Lamotrigine Extended-Release Tablets USP 250mg 30ct  
**Selling Unit NDC:** 31722-244-30 **Unit of Use NDC:** \_\_\_\_\_ **UPC:** 331722244305  
**UDI** \_\_\_\_\_ **CVX Code:** \_\_\_\_\_ **MX Code:** \_\_\_\_\_  
**Description:** Oral Solid - Tablet, Caplet-shaped, biconvex, film-coated tablets, Purple, Upper: Printed with "Y35" in black ink Lower: No mark  
**Active Ingredient(s):** Lamotrigine  
**URL for Additional Product Information:** [www.camberpharma.com](http://www.camberpharma.com)  
**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:** Anticonvulsant

**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		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? <input type="checkbox"/> No	Is the Product... Direct-Ship Only <input type="checkbox"/>	Size:	30ct
if yes, enter class # a product kit? <input type="checkbox"/> No	Is the Product... Orphan Drug Status <input type="checkbox"/>	Strength:	250mg
if yes, list NDCs of component parts reverse numbered? <input type="checkbox"/> No	FDA Approval Status <input type="text"/>	Dosage Form:	Oral Solid - Tablet
co-licensed? <input type="checkbox"/> No	Allergens Present <input type="text"/>	Product Shape:	Caplet-shaped, biconvex, f
latex-free? <input type="checkbox"/> No	Country of Origin <input type="text" value="China"/>	Product Color:	Purple
preservative-free? <input type="checkbox"/> No	Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No	Product Imprint:	Upper: Printed with "Y35" i
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"/> No			
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	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	
<input type="checkbox"/> Vial Liquid Multi	
<input type="checkbox"/> Vial Powder Sgl	If Yes, how many of which package type?
<input type="checkbox"/> Vial Power Multi	<input type="text" value="24"/> Each
<input type="checkbox"/> Other: Write In	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?**   
 (Write-in, e.g. 1 Vial)  
**Rx billing unit to pharmacy:**  
 Each  
 Gram  
 Milliliter

**DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION**

Does supplier meet DSCSA definition of manufacturer?  Yes  No  
 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:** 00331722000000  
**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:	0.1		1.5	3.25		1
Box/Carton/Bundle/Inner Pack:						
Case:	3.2	12	9	4		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		00331722244305	10331722244302
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	24		10331722244302	
<input type="checkbox"/> Pallet				

**COST INFORMATION** **WHOLESALE USE ONLY:**

**Regular Cost** \_\_\_\_\_  
**Invoice Cost (WAC) (\$)**   
 As of date: \_\_\_\_\_  
**Vendor #:** \_\_\_\_\_  
**Whsl. Code #:** \_\_\_\_\_  
**Fineline Code:** \_\_\_\_\_



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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
- 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?

- (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
- Controlled by State(s)?  No
- ARCOS Reportable?
- Schedule No.
- Controlled Substance Code
- Listed Chemical (List I or II)  No
- 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:   
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

Limited Distribution Requirement

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

**REMS:**  No  
REMS Program Manager Name:  Phone:   
Supplier Manages REMS registry exclusively:   
Wholesale distributor support:   
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

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:



# 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> <ul style="list-style-type: none"> <li>a. EDI <input type="checkbox"/></li> <li>b. Autofax <input type="checkbox"/></li> <li>c. Fax <input type="checkbox"/></li> <li>d. Phone only <input type="checkbox"/></li> <li>e. Supplier Web Site only <input type="checkbox"/></li> </ul> <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><b>Purchase order daily receipt cut off time by supplier</b></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>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<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><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Monday</li> <li><input type="checkbox"/> Tuesday</li> <li><input type="checkbox"/> Wednesday</li> <li><input type="checkbox"/> Thursday</li> <li><input type="checkbox"/> Friday</li> </ul> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <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>
Class of Trade Restriction:	
<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>	
Other Data Information Required to Process PO:	Return Instructions
<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>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>
Miscellaneous Notes:	
<p><input type="text"/></p>	
	ADDITIONAL INFORMATION
	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>