



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

Version 2024

Introduction Type: New Item

☒ Final Version

Date: 2/23/2025

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Camber Pharmaceuticals, Inc.				Application: ANDA			
Application Number for NDA/ANDA/BLA; PMA/510(k): 203052		NDA 505(b) Type: NOT APPLICABLE		Temperature – Indicate the USP temperature range for this product.			
Medical Device Class, if applicable:				Temperature Range: Controlled Room – between 20 and 25 C (68° – 77° F)			
DUNS: 11-856-3719				Other Temperature Range Requirement (write in):			
Proprietary Name (If Applicable) and Established Name: Levetiracetam Oral Solution, USP 100 mg/mL				Notes:			
Selling Unit NDC: 31722-574-47		Unit of Use NDC:		UPC: 331722574471		Is this product to be shipped to customers on ice? <input type="checkbox"/> No	
CVX Code:		MVX Code:				Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No	
Description: Levetiracetam Oral Solution, USP 100 mg/mL				b. Contact for temperature excursion questions:			
Active Ingredient(s): Levetiracetam, USP				Name: Soma Raju			
URL for Additional Product Information: www.camberpharma.com				Number: 732-529-0423			
Address: 800 Centennial Ave, Suite 1		Address 2:		Group E-mail: somaraju@heterousa.com			
City: Piscataway		State: NJ					
Key Contact: Customer Service		Email: customerservice@camberpharma.com					
Phone Number: 1-866-827-3647		Fax: 732-562-8788					
Product Therapeutic Classification: 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: 24 Months			
				Initial shelf life at launch (if different): Months			
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is?		Is the Product...		Size: 473 mL			
a legend device? <input type="checkbox"/> No		Is the Product... <input type="checkbox"/> Neither		Strength: 100 mg/mL			
if yes, enter class #		Orphan Drug Status		Dosage Form: Clear, oral solution			
a product kit? <input type="checkbox"/> No				Product Shape: N/A			
if yes, list NDCs of component parts		FDA Approval Status		Product Color: Colorless			
reverse numbered? <input type="checkbox"/> No				Product Imprint: N/A			
co-licensed? <input type="checkbox"/> No		Allergens Present					
latex-free? <input type="checkbox"/> Yes							
preservative-free? <input type="checkbox"/> No							
correctional institution block? <input type="checkbox"/> No		Country of Origin India					
opioid? <input type="checkbox"/> No							
Cannabinoid? <input type="checkbox"/> No							
If Unit Dose, is item bar coded to unit dose for hospital scanning?		Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No					
If Unit Dose, indicate NDC here:							
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: AA				<input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: Keppra							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes				GLN: 0331722498975			
Is product exempt from DSCSA? <input type="checkbox"/> No				GCP:			
If yes, select exemption:				If yes, was original product purchased direct from mfr? <input type="checkbox"/>			
Other exemption - Write in:				Provide source manufacturer for repackaged product			
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.							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure		RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14	
<input checked="" type="checkbox"/> Item/Each		N	1		00331722574471		
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack		N	9		30331722574472		
<input checked="" type="checkbox"/> Case							
<input checked="" type="checkbox"/> Pallet							
ITEM AND PACKING INFORMATION							
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces	
		Depth	Width	Height			
Item/Each:	1.4	2.75	2.75	7	52.94	1	
Box/ Carton/ Bundle/ Inner Pack:							
Case:	13.5	9	9	8.5	688.50	9	
Pallet:							
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost				Vendor #:			
Invoice Cost (WAC) (\$)		\$30.00		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:



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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?
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
Is the product a CA Prop 65 carcinogen?
Is the product a CA Prop 65 reproductive toxicant?
Does the product label bear a CA Prop 65 warning?

- c. Contact Hazard?
- d. Does this product require special clean-up instructions?
(If yes, attach SDS with special instructions.)
- e. Does the product contain DEHP?

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?

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?

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

- Passenger
 Cargo
 Passenger & Cargo

Is this a reportable quantity?

RQ Threshold:

Is this a marine pollutant?

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? | <input type="text" value="No"/> | Controlled Substance Code | <input type="text"/> |
| Controlled by State(s)? | <input type="text" value="No"/> | Listed Chemical (List I or II) | <input type="text" value="No"/> |
| ARCOS Reportable? | <input type="text" value="No"/> | If yes, indicate which: | <input type="text"/> |
| Schedule No. | <input type="text" value="No"/> | Is it a scheduled listed chemical product?: | <input type="text" value="No"/> |

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices

Restricted to retail pharmacy only:

Restricted to hospital, clinics, and physician offices only:

Restricted from US territories? (explain in comments)

Comments:

SDS Hazard Classification

- | | |
|---|--|
| <input checked="" type="checkbox"/> Organic | <input type="text" value="No"/> Corrosive |
| <input type="checkbox"/> Inorganic | <input type="text" value="No"/> Oxidizer |
| <input type="checkbox"/> Steroid/Androgen | <input type="text" value="No"/> 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?

If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code:

Waste Characteristics

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required

Limited Distribution Requirement

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

REMS:

REMS Program Manager Name:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned by Supplier:

Phone:

DEA #:

NCPDP#:

NPI #:

Comments

Registry:

Registry Program Contact Name:

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:

Release DATE



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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>