



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

Version 2024

Introduction Type: New Item

☒ Final Version

Date: 3/11/2025

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
<b>Company Name:</b> Camber Pharmaceuticals, Inc.				<b>Application:</b> ANDA			
<b>Application Number for NDA/ANDA/BLA; PMA/510(k):</b> 090515				<b>NDA 505(b) Type:</b> NOT APPLICABLE			
<b>Medical Device Class, if applicable:</b>							
<b>DUNS:</b> 11-856-3719							
<b>Proprietary Name (If Applicable) and Established Name:</b> Levetiracetam Tablets, USP 1000 mg							
<b>Selling Unit NDC:</b> 31722-539-60				<b>Unit of Use NDC:</b> 31722-539-60		<b>UPC:</b> 331722539609	
<b>UDI</b>				<b>CVX Code:</b>		<b>MVX Code:</b>	
<b>Description:</b> Levetiracetam Tablets, USP 1000 mg							
<b>Active Ingredient(s):</b> Levetiracetam, USP							
<b>URL for Additional Product Information:</b> <a href="http://www.camberpharma.com">www.camberpharma.com</a>							
<b>Address:</b> 800 Centennial Ave, Suite 1				<b>Address 2:</b>			
<b>City:</b> Piscataway				<b>State:</b> NJ		<b>Zip:</b> 08854	
<b>Key Contact:</b> Customer Service				<b>Email:</b> <a href="mailto:customerservice@camberpharma.com">customerservice@camberpharma.com</a>			
<b>Phone Number:</b> 1-866-827-3647				<b>Fax:</b> 732-562-8788			
<b>Product Therapeutic Classification:</b> Anticonvulsant							
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
<b>The product is?</b>		<b>Is the Product...</b>		<b>Size:</b>			
a legend device?		Direct-Ship Only		60 ct			
if yes, enter class #		Unit of Use		1000 mg			
a product kit?		Orphan Drug Status		Strength:			
if yes, list NDCs of component parts				Dosage Form:			
reverse numbered?				Film coated tablet			
co-licensed?				Product Shape:			
latex-free?				Oblong			
preservative-free?				Product Color:			
correctional institution block?				White			
opioid?				Product Imprint:			
Cannabinoid?				Debossed with 'H' on one side with scoreline and '91' on other side			
If Unit Dose, is item bar coded to unit dose for hospital scanning?		Country of Origin		India			
If Unit Dose, indicate NDC here:		Is this product covered under the Trade Agreements Act (TAA)?		No			
FOR GENERIC DRUG PRODUCTS							
<b>I. Orange Book Rating:</b> AB				<input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable			
<b>II. Generic Equivalent to What Brand?:</b> Keppra							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
<b>Does supplier meet DSCSA definition of manufacturer?</b>				<b>GLN:</b> 0331722498975			
<b>Is product exempt from DSCSA?</b>							
<b>If yes, select exemption:</b>				<b>GCP:</b>			
<b>Other exemption - Write in:</b>							
<b>Is product repackaged?</b>				<b>If yes, was original product purchased direct from mfr?</b>			
<b>Is product sold by manufacturer's exclusive distributor?</b>				<b>Provide source manufacturer for repackaged product</b>			
<b>Has FDA granted waiver/exception/exemption for product?</b>							
<b>If yes, attach documentation from FDA.</b>							
GTIN AND HIBCC PRODUCT INFORMATION							
<b>Saleable Unit of Measure</b>		<b>RFID tag(Y/N)</b>	<b>Saleable Quantity</b>	<b>HIBCC</b>	<b>GTIN-14</b>	<b>Unit of Use GTIN-14</b>	
<input checked="" type="checkbox"/> Item/Each		N	1		00331722539609	00331722539609	
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack		N	24		20331722539603		
<input checked="" type="checkbox"/> Case							
<input checked="" type="checkbox"/> Pallet							
ITEM AND PACKING INFORMATION							
	<b>Weight Lbs.</b>	<b>Dimensions (US msmts.)</b>			<b>Volume (Cube)</b>	<b>Saleable # Pieces</b>	
		<b>Depth</b>	<b>Width</b>	<b>Height</b>			
<b>Item/Each:</b>	0.22	1.86	1.86	3.93	13.60	1	
<b>Box/ Carton/ Bundle/ Inner Pack:</b>							
<b>Case:</b>	5.95	11.5	7.9	5.25	476.96	24	
<b>Pallet:</b>							
COST INFORMATION				WHOLESALE USE ONLY:			
<b>Regular Cost</b>				<b>Vendor #:</b>			
<b>Invoice Cost (WAC) (\$)</b>				<b>Whsl. Code #:</b>			
As of date: 4/15/2024				<b>Fineline Code:</b>			

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:



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

Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION			
<b>Is this product (check all that apply):</b>			
a. Cytotoxic?	<input type="text" value="No"/>		
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	<input type="text" value="No"/>		
Is the product a CA Prop 65 carcinogen?	<input type="text" value="No"/>		
Is the product a CA Prop 65 reproductive toxicant?	<input type="text" value="No"/>		
Does the product label bear a CA Prop 65 warning?	<input type="text" value="No"/>		
c. Contact Hazard?	<input type="text" value="No"/>		
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	<input type="text" value="No"/>		
e. Does the product contain DEHP?	<input type="text" value="No"/>		
<b>Is this product regulated for shipment by DOT?</b> (if yes, answer a-e below and provide SDS)			
a. UN/Identification Number	<input type="text"/>		
b. Proper Shipping Name	<input type="text"/>		
c. DOT Hazard Class	<input type="text"/>		
d. Packing Group	<input type="text"/>		
e. Inhalation Hazard?	<input type="text"/>		
<b>Is this product regulated for shipment by IATA?</b> (if yes, answer a-e below and provide SDS)			
a. UN/Identification Number	<input type="text"/>		
b. Proper Shipping Name	<input type="text"/>		
c. DOT Hazard Class	<input type="text"/>		
d. Packing Group	<input type="text"/>		
e. Inhalation Hazard?	<input type="text"/>		
<b>Is the product restricted for air shipment? If so, indicate restriction:</b>		<input type="text" value="No"/>	
<input type="checkbox"/> Passenger			
<input type="checkbox"/> Cargo			
<input type="checkbox"/> Passenger & Cargo			
<b>Is this a reportable quantity?</b> <input type="text" value="No"/>			
RQ Threshold: <input type="text"/>			
<b>Is this a marine pollutant?</b> <input type="text" value="No"/>			
<b>Is this product shipped utilizing an authorized DOT exception or Special Permit?</b>			
<input type="checkbox"/> No (if yes, identify method below)			
<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"/>		
<b>ADD'L STORAGE INFORMATION</b>			
<b>Is the Product...</b>			
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"/>	Is it a scheduled listed chemical product?:	<input type="text" value="No"/>
<b>CLASS OF TRADE RESTRICTION:</b>			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices		<input type="text" value="Yes"/>	
Restricted to retail pharmacy only:		<input type="text" value="No"/>	
Restricted to hospital, clinics, and physician offices only:		<input type="text" value="No"/>	
Restricted from US territories? (explain in comments)		<input type="text" value="No"/>	
Comments:		<input type="text"/>	
<b>MISCELLANEOUS NOTES and/or Image of Product Barcode:</b>			
<input type="text"/>			

SDS Hazard Classification	
<input checked="" type="checkbox"/> Organic	<input type="text" value="Corrosive"/>
<input type="checkbox"/> Inorganic	<input type="text" value="Oxidizer"/>
<input type="checkbox"/> Steroid/Androgen	<input type="text" value="Contact Hazard"/>
Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="text" value="No"/>	
NFPA Storage Level: <input type="text"/>	
Is the product a NIOSH hazardous drug? <input type="text" value="No"/>	
If yes, indicate which: <input type="text"/>	

Hazardous Waste Identification	
EPA Hazardous Waste Code:	<input type="text"/>
Waste Characteristics	<input type="text"/>

REMS or REGISTRY RESTRICTIONS	
<b>Is there a REMS on this product?</b> <input type="text" value="No"/>	
If Yes, is it managed with a pharmacy registry? <input type="text"/>	
Website URL: <input type="text"/>	
<b>Med Guide Required</b> <input type="text" value="No"/>	
Limited Distribution Requirement <input type="text"/>	
Comments / Details: (For example, iPledge program?) <input type="text"/>	
<b>REMS:</b> <input type="text" value="No"/>	
REMS Program Manager Name: <input type="text"/>	
Supplier Manages REMS registry exclusively: <input type="text"/>	
Wholesale distributor support: <input type="text"/>	
Provider Name: <input type="text"/>	
Site Enrollment Number assigned by Supplier: <input type="text"/>	
Comments <input type="text"/>	
<b>Registry:</b> <input type="text" value="No"/>	
Registry Program Contact Name: <input type="text"/>	
Phone: <input type="text"/>	
Comments <input type="text"/>	

RETURN INSTRUCTIONS	
Contact tel. # if product received damaged:	<input type="text" value="1-866-827-3647"/>
Is product returnable for credit:	<input type="text" value="Yes"/>
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="text" value="No"/>	
If so, which states? Other requirements? Comments: <input type="text"/>	



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

Version 2024

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><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>
<p><b>Expedited Freight Charges or Other Designated Drop Ship Fees:</b></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><b>Overnight and Priority Overnight PO Processing</b></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> <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><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>
<p><b>Class of Trade Restriction:</b></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><b>Other Data Information Required to Process PO:</b></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><b>Return Instructions</b></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><b>Miscellaneous Notes:</b></p> <p><input type="text"/></p>	<p><b>ADDITIONAL INFORMATION</b></p> <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>