

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

						Introduction 7	Гуре:	Post Launch Change		1 Final Version			Date:	6/23	/2024
			PRODUCT INFORMAT	ION						SPECIAL HAND	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharmace	uticals Inc				Applica	tion:	ANDA	a Tomporatus	re - Indicate the USP tempe	raturo rango for t	hie product			
Application Number for NDA/AN			co).	no	90515	Арриса	tion.	ANDA	a. remperatur		Controlled Room -		and 25 C (68	3° – 77° F)	
Medical Device Class, if applicat		Av310(k)(iiieu uevic	<i>,</i> e <sub>j</sub> .	100	70010				-	remperature rearige	Controlled Hoom	20111001120	una 20 0 (00	,	
DUNS:	11-856-3719								-	Other Temperature Range F	Poquiroment				
Proprietary Name (If Applicable) a		me: Levetir	acetam Tablets, USP 750 m	α					7	(write in)	Requirement				
Selling Unit NDC:	31722-538-12	ile. Leveura	Unit of Use NDC:	9	31722-538-12	UPC:	33172253	Q121		Notes					
UDI	31722-330-12		CVX Code:		31722-330-12	MVX Code:	33172233	0121	-	Notes					
						INVX COUC.			-						1
Description:	Levetiracetam Tabl	ets, USP 750 mg								Is this product to be shipped				No	
										Is this product to be shipped	to customers on d	Iry ice?		No	
Active Ingredient(s):		Levetiracetam, USP							11						
UDI for Additional Books to form									b. Contact for	temperature excursion que	estions:	Soma Raju			
URL for Additional Product Inform Address:		www.camberpharma	a.com			Address 2:			-	Name:		732-529-042			
	800 Centennial Ave Piscataway	I Ave, Suite 1			State:	NJ Zip: 08854		Number:			somaraju@heterousa.com				
City: Key Contact:	Customer Service				Email:	customerservice			Group E-mail: somaraju@hete			ieterousa.cor	<u>11</u>		
Phone Number:	1-866-827-3647				Fax:	732-562-8788	<u>@camberpr</u>	iaima.com	a Special rea	ulations for product in any	ctator?			No	1
		Antigonyudoont			I ax.	732-302-0700			c. Special reg						
Product Therapeutic Classificatio	n:	Anticonvulsant								Special returns requirement	s for this product?			No	ļ
	ADDITIO	NAL PROPUST IN	ODMATION			PROPUST	DECODIDE	ON INFORMATION							1
	ADDITIO	NAL PRODUCT INF				PRODUCT	DESCRIPTI	ON INFORMATION	a. Store produ	uct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship	Only					Protect product (unit of sa	ale) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	120	) ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status							Initial shelf life at launch (	if different):				Months
a product kit?		No				Strength:	750	) mg							
if yes, list NDCs of			FDA Approval Status								ORDER INFORM	ATION			
component parts						Dosage Fori	m: Filr	n coated tablet							
reverse numbered?		No				_				Unit of Sale		What is the		unit?	
co-licensed?		No	Allergens Present				-			x Bottle		1 Bottle of 12			
latex-free?		Yes	Dye,	Corn		Product Sha	ipe: Ob	long		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes					0			Ampule				-0	
correctional institution block?		No				Product Col	or:	ange		Glass		Minimum o	rder quantity	y?	Yes
opioid? Cannabinoid?		No No	Country of Origin	India			Dob	ossed with 'H' on one side with		Tube Vial Liquid Sgl					
If Unit Dose, is item bar coded to u		NO	Country of Origin	iriuia		Product Imp	orint: score	eline and '90' on the other side				If Vac have		iah maakama	4
hospital scanning?	init dose for		Is this product covered un	ador the						Vial Liquid Multi Vial Powder Sgl		If Yes, how	Each	ісп раскаде	type?
If Unit Dose, indicate NDC here:			Trade Agreements Act (T.		No					Vial Powder Sgi Vial Powder Multi			Inner/Cartor	/Pook	
Il Offit Dose, indicate NDC fiere.	I.		I rade Agreements Act (1)	AA):	INU					Other: Write In			Case	/rack	
			FOR OFNERIO PRUO PRO	PLIOTO						Other: Write iii			Case		
			FOR GENERIC DRUG PRO	DDUCTS											
							*16 A th			DU	ABMACY ORDER	/ DILL LIMIT			
				_	Auti	norized Generic		zed Generic, other			ARMACY ORDER				
I. Orange Book Rating:	AB				Auti	norized Generic		zed Generic, other lds are not applicable	Rec. sell unit	PH/ to customer?	ARMACY ORDER	/ BILL UNIT Rx billing u		асу:	
I. Orange Book Rating: II. Generic Equivalent to What Bra		Керрга			Auti	norized Generic				to customer?	ARMACY ORDER		Each	асу:	
						norized Generic			Rec. sell unit	to customer?	ARMACY ORDER		Each Gram	acy:	
			/ CHAIN SECURITY ACT (D	DSCSA) INFO		norized Generic				to customer?	ARMACY ORDER		Each	асу:	
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## **Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)**

#### Version 2021 For D

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HA	AZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	SDS Hazard Classification  X Organic Corrosive					
Is the product a CA Prop 65 carcinogen?  Is the product a CA Prop 65 reproductive toxicant?  No  Does the product label bear a CA Prop 65 warning?  No	x Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard					
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?	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  NFPA Storage Level:					
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	Is the product a NIOSH hazardous drug?  If yes, indicate which:					
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification					
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics					
Is this product regulated for shipment by IATA?  (if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS					
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product?  If Yes, is it managed with a pharmacy registry?  Website URL:					
Is the product restricted for air shipment? If so, indicate restriction:  Passenger  Cargo  Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)					
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)	REMS:  REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Registry: No					
	Registry Program Contact Name: Phone:					
ADD'L STORAGE INFORMATION	Comments					
Is the Product  Controlled Substance? No Controlled Substance Code  Controlled by State(s)? No Listed Chemical (List I or II) No	RETURN INSTRUCTIONS					
ARCOS Reportable?  Schedule No.  If yes, indicate which:  Is it a scheduled listed chemical product?:  No	Contact tel. # if product received damaged:  Is product returnable for credit:  Yes					
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Restricted to retail pharmacy only:  No	contact - customerservice@camberpharma.com					
Restricted to healin pharmacy only.  Restricted to hospital, clinics, and physician offices only:  Restricted from US territories? (explain in comments)  No	Special regulations or returns requirements for this product in certain states?  If so, which states? Other requirements? Comments?					
Comments:						
MISCELLANE	OUS NOTES and/or Image of Product Barcode:					



## **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 b. Autofax  Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time:
c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number:	Shipping lead time of PO:  Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #: Name: Phone:	
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:	Overnight receipt available:
Drop Ship service fee billed with each order:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed:  Comments:	Days of week overnight is available:  Monday Tuesday Wednesday Thursday Friday
	Priority Overnight receipt available:
Class of Trade Restriction:	PO Receipt Cut off time:
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:	Saturday Overnight receipt available:  PO Receipt Cut off time:  Phone: Fax: EDI:  Overnight Fees apply: Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:	Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy:  Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?
Miscellaneous Notes:	
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? Is product order for restocking purposes?