

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

Version 2021						Introduction ⁻	Туре:	Post Launch Change		x Final Versio	1		Date:	12/23	3/2024		
			PRODUCT INFORMAT	ION						SPECIAL	HANDLING AND ST	ORAGE REQUI	REMENTS*				
Company Name: Camber Pharmaceuticals, Inc.					Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.									
Application Number for NDA/AN			evice):	090)515					Temperature Range		om – between 20		8° – 77° F)			
Medical Device Class, if applicable:																	
DUNS:	11-856-3719								1	Other Temperature R	inge Requirement						
Proprietary Name (If Applicable) a	nd Established Na	me: Leve	etiracetam Tablets, USP 750 m	ıg						(write in)							
Selling Unit NDC:	31722-538-05		Unit of Use NDC:			UPC:	331722	2538053		Notes							
UDI			CVX Code:			MVX Code:											
Description:	Levetiracetam Tabl	lets, USP 750 mg							1	Is this product to be s	ipped to customers	on ice?		No	1		
Is this product to be shipped to customers on dry ice? No																	
Active Ingredient(s): Levetiracetam, USP																	
b. Contact for temperature excursion questions:																	
URL for Additional Product Inform		www.camberp	oharma.com			Address 2:								Soma Raju			
Address: City:	800 Centennial Ave, Suite 1			State:	Address 2:			Number: Group E-mail:				732-529-0423 somaraju@heterousa.com					
Key Contact:	Customer Service	Piscataway			Email:	customerservice@camberpharma.com			Group E-mail:			somarajue	<u>somaraju e neterousa.com</u>				
Phone Number:	1-866-827-3647				Fax:	732-562-8788				c. Special regulations for product in any states?				No			
Product Therapeutic Classificatio							02 002 0700			Special returns requirements for this product?				No			
		7 th to Contract to								Openiai returno regun	ments for this produ	iot:		110	1		
	ADDITIO	NAL PRODUCT I	INFORMATION			PRODUCT	DESCRI	PTION INFORMATION	d. Store prod	uct (unit of sale) uprig	ht?			No	1		
The product is?			Is the Product	Direct-Ship C	nly					Protect product (uni		2		No	1		
a legend device?		No	Is the Product	Neither	A III y		- 1	500 ct	e. Shelf life:	Frotect product (uni	or sale) from fight	r		24	Months		
if yes, enter class #		140	Orphan Drug Status	14010101		Size:		500 01	C. Onen me.	Initial shelf life at lau	nch (if different):			2-7	Months		
a product kit?		No				Ot		750 mg			,.						
if yes, list NDCs of			FDA Approval Status			Strength:					ORDER INFO	RMATION					
component parts						Dosage For	m.	Film coated tablet									
reverse numbered?		No				Doodgo . o				Unit of Sale			NDC selling	g unit?			
co-licensed?		No	Allergens Present							x Bottle		1 Bottle of 5					
latex-free?		Yes	Corn	, Dye		Product Sha	ape:	Oblong		Box/Carton		(Write-in, e	.g. 1 Box of 1	0 Vials)			
preservative-free? correctional institution block?		Yes No						Orange		Ampule Glass		Minimum	order quantit	v2	Yes		
opioid?		No				Product Col	lor:	Orange		Tube		William	ruer quantit	y:	165		
Cannabinoid?		No	Country of Origin	India				Debossed with 'H' on one side with		Vial Liquid S	al						
If Unit Dose, is item bar coded to u			, 3			Product Imp	print:	scoreline and '90' on the other side		Vial Liquid N		If Yes, how	many of wh	ich package	type?		
hospital scanning?			Is this product covered up	nder the			,			Vial Powder		12	Each		•		
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	AA)?	No				Vial Powder Multi				Inner/Carton/Pack				
										Other: Write	In		Case				
FOR GENERIC DRUG PRODUCTS																	
											DUADAMACY ODD	ED / DU L LINUT					
				Au	Authorized Generic *If Authorized Generic, other			PHARMACY ORDER / BILL UNIT									
I. Orange Book Rating:	AB				section fields are not applicable			Rec. sell unit to customer?			Rx billing u	Rx billing unit to pharmacy:					
II. Generic Equivalent to What Bra	ind?:	Keppra							(Maite in a set Viel)				Each				
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION (Wi							(Write-in, e.g. 1 Vial) Gram Milliliter										
		DR00 0011	ET OTTATION OF THE TOTAL	occa, iii cit	MATION								Ivillilitei				
Does supplier meet DSCSA defini	tion of manufacture	er?	Yes		GLN:	0331722498975					ITEM AND PACKIN	G INFORMATIO	N				
Is product exempt from DSCSA?			No														
If yes, select exemption:					GCP:				İ		Dime	nsions (US ms	mts.)	Volume	Saleable #		
Other exemption - Write in:										Weight L	os. Depth	Width	Height	(Cube)	Pieces		
Is product repackaged?			No		If yes, was or	iginal product			Item/Each:	1.15	3.5	3.5	7	85.75	1		
Is product sold by manufacturer's			Yes			rect from mfr?					3.3	3.5	'	03.73			
Has FDA granted waiver/exceptio		oduct?	No		Provide sour	ce manufacturer f	for repac	ckaged product	Box/Carton/B	undle/							
If yes, attach documentation fro	m FDA.								Inner Pack:								
		GT	IN AND HIBCC PRODUCT IN	FORMATION					Case:	14.4	14.5	11.25	8	1305	12		
		GI	IN AND HIBCC PRODUCT IN	FORMATION					Pallet:								
Saleable Unit of Measure	Sa	aleable Quantity	HIBCC		GTII	N-14		Unit of Use GTIN-14	anet.								
X Item/Each		1	500			31722538053	T	5 5. 555 OTH 14									
Box/Carton/Bundle/Inner Pack					31722538057			COST INFORMATION				WHOLESALER USE ONLY:					
x Case																	
Pallet									Regular Cost			Vendor #:					
									Invoice Cost	(WAC) (\$)	\$82	.78 Whsl. Code					
									, , , , ,	4/45/0004		Fineline Co	ode:				
	-						-		As of date:	4/15/2024							
	1 1																
			Attach copy of SAFETY DAT	A SHEET (SDS	() or non hazor	d letter PACKACE	INSED	T I AREL AND DHOTO OF	DRUDITOT DACK								
*Please provide any additional inf		_	, macricopy of SAFETT DAT	A OFFICE (SDS	, or nonnazar			nated Drop Ship Only.	LICEDUUI FACIN	CING and DARCODE							



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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 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? No	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:						



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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 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?					