

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014 Introduction Type: Post Launch Change Final Version Date: 4/17/2017															
			PRODUCT INFORMA	TION						SPECIAL HANDL	ING AND STO	DRAGE REQ	UIREMENTS	*	
Company Name:	Camber Pharmaceuti	cale				Application	on:	ANDA	a. Temperature – Indio	ata the LICD temper	ratura rango	ior thio prod	uot		
Application Number for ND			١-	90-515		Арріюція	JII.	711071		ture Range	ature range			en 20 and 25	5 C (68° – 77° F
		mino rotk)(med device)	·	00 0.0					-	=		- COTRICUIO II	toom bottee	on to and to	- 0 (00 11 1
DUNS:	82-667-4775	. h								mperature Range Re	quirement				7
Proprietary Name (If Applical		Name: Levetirad	cetam 1000MG/60CT						_ (wi	rite in)					4
Selling Unit NDC:	31722-539-60 NA		Individual Unit NDC:	31722-539-6			72253960	•						NI.	
UDI			CVX Code:			Code: NA			≒ ∥ '	oduct to be shipped to				No	_
Description:	White oblong shpaed	tablets embossed with 'H	on one side and '91' on the	other side with correspond	ding dyes				Is this pr	oduct to be shipped to	o customers o	n dry ice?		No	_
									<u> </u>						
Active Ingredient(s):		Levetiracetam							b. Contact for tempera	ture excursion que	stions:				
				Name: Number:			Soma Raju 732-529-0423								
URL for Additional Product II Address:		www.camberpharma.com	11		Addross					somaraju@heterousa.com					
City:	1031 Centennial Avenue Address 2: Piscataway State: NJ Zip: 08854						Group E-mail: somaraju@heterousa.com								
Key Contact:	Customer Service			Email:					C Special regulations	for product in any c	tates?			No	
Phone Number:	Customer Service Email: customerservice@camberpharma.com 732-529-0430 Fax: 732-562-8788				00111	c. Special regulations for product in any states? Special returns requirements for this product? No									
Product Therapeutic Classifi									Special retains requirements for this product:						
Troduct Therapeutic Glassin	ication.								d. Store product (unit	of cala) upright?				No	
ADDITIONA	AL PRODUCT INFORM	IATION	1		PRODUCT	DESCRIPTION	LINEORMA	TION		product (unit of sale	a) from light?			No	-
	ALT RODOOT IN ORIN	ATION			TRODUCT	DECORM HOR	i ii di Oi (iii).	THOIL .	-	product (unit or sale	e) iroin ligitt:				ā
Is the Product					Ī				e. Shelf life:					24	Months
a legend device?		No		Size:		60			Initial sh	elf life at launch (if o	different):				Months
reverse numbered? co-licensed?		No No									ORDER INFO	MATION			
Is the Product		Direct-Ship Only		Strength:		1000 mg				•	ORDER IN O	MATION			
Is the Product		Unit of Use			ŀ				Unit of S	Salo		What is the	NDC selling	unit?	
is the Froduct		<u> </u>		Dosage For	m:	Oral solid tablet			III one	Bottle		1 box of 24		u	
II									х	Box/Carton			.g. 1 Box of 1	0 Vials)	
If Unit Dose, is item bar code	ed to unit dose for hosp	ital scanning?		D		at to a salar and t				Ampule			•	,	
If Unit Dose NDC, indicate NI	DC here:			Product Sha	ape:	oblong shaped				Glass		Minimum o	rder quantity	<i>i</i> ?	Yes
				Product Col	lor:	white				Tube					
Country of Origin		India		1 Todact oo	.01.	Willia				Vial Liquid Sgl					
Is this product covered under the Trade Agreements Act (TAA)?						Vial Liquid Multi		If Yes, how		ch package	type?				
	3	No No		•					<u> </u>	Vial Powder Sql			Each	-	
]						JI	Vial Power Multi			Inner/Cartor	/Pack	
			FOR GENERIC DRUG PR	ODUCTS						Other: Write In	_	24	Case		
			TOR GENERIC DROG FR	000013											
				Διπ	thorized Gen	eric *If Δ	uthorized (Seneric, other section		PHAR	RMACY ORDE	R / BILL UN	Т		
L Communication of the Communi	AB				anonized och		ls are not a								
I. Orange Book Rating: II. Generic Equivalent to Wha		Keppra							Rec. sell unit to customer? Rx billing unit to pharmacy:						
ii. Generic Equivalent to wha	at Brand?:	керріа							(Write-in, e.g. 1 Vial) Each						
		DRUG SUPPI	LY CHAIN SECURITY ACT (DSCSA) INFORMATION					(vviite-iii, e.g. i viai)				Milliliter		
				, , , , , , , , , , , , , , , , , , , ,									IVIIIIIIIII		
Does supplier meet DSCSA	definition of manufac	turer?	Yes	GLN:						ITEM A	ND PACKING	INFORMATI	ON		
Is product exempt from DSC			No												
If yes, select exemption:										Weight Lbs.	Dime	nsions (US n	nsmts.)	Volume	# Pieces:
Other exemption - Write in:	:									Weight Lbs.	Depth	Height	Width	(Cube)	# Fieces.
Is product repackaged?			No	If Yes, was origi	inal product	purchased dir	ect		Item:	0.25		4.5	2		
Is product sold by manufact			No	from mfr?											
Has FDA granted waiver/exc	eption/exemption for	product?	No	If yes, attach do	ocumentatio	on from FDA.			Box/Carton/Bundle/						
			OTHER PROPERTY INCOME	AATION					Inner Pack:						4
			GTIN PRODUCT INFORM	MATION Saleable					Case:	6.5	11.75	5	8.5	0.288	24
			Level	Unit		Qua	ntitu C	STIN-14	Pallet:		-				+
Serialized?	Yes	х	Item [X 2D		Linear 1		0331722539609	Fallet.						2688
If not, when?	163	1 ^ 	Box/Carton/Bundle/Inner Pack	2D 2D	-	Linear		333.72200000	UPC:	Case:		1		l	
Items aggregated?	Yes	x	Case	x x 2D	-	Linear 2	4 2	0331722539603	1110.0.	Carton:					
		- 	Pallet	2D		Linear				,					
				2D		Linear			COST	INFORMATION			WHOLESAL	ER USE ON	LY:
				2D		Linear									
				2D		Linear			Regular Cost			Vendor #:			
				2D		Linear			Invoice Cost (WAC) (\$		\$39.40				
									Federal Excise Tax Pe	r Unit of Sale		Fineline Co	de:		
						·		·	As of date:						
												İ			
1			Attach copy of SAFETY DA	ATA SHEET (SDS) or non h	nazard letter,	PACKAGE INS	ERT, LABE	L AND PHOTO OF PR	ODUCT PACKAGING and BA	ARCODE.					
								p Ship Only.	Signatu						



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL I	HAZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply):							
a. Cytotoxic?	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	CDO Hazara Glassinoation						
Is the product a CA Prop 65 carcinogen?	Organic Corrosive						
Is the product a CA Prop 65 carcinogen?	Inorganic Oxidizer						
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard						
a Contact Harand?	A grand Class Identify NEDA Starons Levels						
c. Contact Hazard?	Aerosol Class; Identify NFPA Storage Level:						
d. Does this product require special clean-up instructions? No	1.4. 1.4. 1100111						
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug?						
e. Does the product contain DEHP?	If yes, indicate which:						
Is this product regulated for shipment by DOT or IATA? No							
(if yes, answer a-e below and provide SDS)							
a. UN/Identification Number							
b. Proper Shipping Name	Hazardous Waste Identification						
c. DOT Hazard Class	EPA Hazardous Waste Code: NA						
d. Packing Group							
e. Inhalation Hazard?							
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS						
Passenger	Is there a REMS on this product?						
Cargo	If Yes, is it managed with a pharmacy registry?						
Passenger & Cargo	Website URL:						
	Website ORL.						
Is this a reportable quantity? No							
RQ Threshold:	Comments / Details: (For example, iPledge program?)						
Is this a marine pollutant? No	None						
Is this product shipped utilizing an authorized DOT exception or Special Permit?							
No (if yes, identify method below)	REMS: Yes						
Limited Quantity	REMS Program Manager Name:	Phone:					
Consumer Commodity, ORM-D	Supplier Manages REMS registry exclusively: No						
Small Quantity (49 CFR 173.4)	Wholesale distributor support: No						
Special Permit; DOT-SP	Provider Name:						
Special Provision (listed in Column 7 of 49 CFR 172.101);	Site Enrollment Number assigned	DEA #: No					
SP#	by Supplier:	PCPDP #: No					
		NPI#: No					
ADD'L STORAGE INFORMATION							
Is the Product	Comments None						
Controlled Substance? No							
Controlled by State(s)?	Registry: No						
ARCOS Reportable? No	Registry Program Contact Name:	Phone:					
Schedule No. (inc. N for non-narcotic)	Comments						
Controlled Substance Code							
Listed Chemical (List I or II) No	RETURN INSTRUCTIONS						
If yes, indicate which:							
Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: 732-529-0430						
CLASS OF TRADE RESTRICTION:	Is product returnable for credit:						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	URL/Link to returns policy: contact - customerservice@ca	ombornbormo com					
		,					
Restricted to retail pharmacy only: Yes	Special regulations or returns requirements for this product in certain states?	No					
Restricted to hospital, clinics, and physician offices only:	If so, which states? Other requirements? Comments?						
Restricted from US territories? (explain in comments) No							
Comments:							
Comments.							
MISCELLAR	NEOUS NOTES and/or Image of Product Barcode:						



Standard Pharmaceutical Product Information (Page 3)

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 Yes No Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time: 2:30PM Eastern					
c. Fax d. Phone only No Phone No.:	Shipping lead time of PO: 24/48 Hours Days					
e. Supplier Web Site only No Site Address:	Ships same day for next day receipt: No					
Minimum Order Quantity: case pack	Ships for second day receipt: No					
Supplier's Customer Service Number: 732-529-0430 x466 x465 x467 x470	Ships regular ground for 3-10 days receipt: Yes					
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: No No	Overnight receipt available: Yes					
Drop Ship service fee billed with each order: No No	PO Receipt cut off time: 2:30PM Eastern					
Drop Ship miscellaneous fees billed: No	Days of week overnight is available:					
Comments:	x Tuesday x Wednesday Thursday x Friday					
	Priority Overnight receipt available: Yes					
Class of Trade Restriction:	PO Receipt Cut off time: 2:30PM EST					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No	Saturday Overnight receipt available: No					
Restricted to retail pharmacy only: Yes	PO Receipt Cut off time:					
Restricted to hospital, clinics, and physician offices only: No	Order receipt method: No Phone #:					
Restricted from US territories? (explain in comments) No	Fax: Yes Fax #: 732-562-8788					
Comments:	EDI: Yes					
	Overnight Fees apply: Other fees apply: No					
Other Data Information Demoired to Decree DO						
Other Data Information Required to Process PO:	Return Instructions					
Patient Procedure Date: Physician Name:	Contact # if product is received damaged: Is product returnable for credit: Yes					
Physician/Clinic Phone #	URL/Link to returns policy:					
Physician State License #	Special regulations or returns requirements for this product in certain states? Yes					
Physician/Clinic DEA #:	If so, which states? Other requirements? Comments?					
Physician/Clinic Specialty:	·					
Miscellaneous Notes:						
	ADDITIONAL INFORMATION					
	Is product order for scheduled patient procedure?					
	Is product order for restocking purposes?					