



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: Pre-Approval Change Post Launch Change

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Camber Pharmaceuticals
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	90-515
DUNS:	82-667-4775
Proprietary Name (if Applicable) and Established Name:	Levetiracetam 750MG/12OCT
Selling Unit NDC:	31722-538-12
UDI	NA
Description:	Orange oblong shaped tablets embossed with 'H' on one side and '90' on the other side with corresponding dyes
Active Ingredient(s):	Levetiracetam
URL for Additional Product Information:	www.camberpharma.com
Address:	1031 Centennial Avenue
City:	Piscataway
Key Contact:	Customer Service
Phone Number:	732-529-0430
Product Therapeutic Classification:	

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
b. Contact for temperature excursion questions:	
Name:	Soma Raju
Number:	732-529-0423
Group E-mail:	somaraju@heterousa.com
c. Special regulations for product in any states?	
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	No
e. Shelf life:	
Initial shelf life at launch (if different):	24 Months

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	No
reverse numbered?	No
co-licensed?	No
Is the Product... Direct-Ship Only	
Is the Product... Unit of Use	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input checked="" type="checkbox"/>
If Unit Dose NDC, indicate NDC here:	
Country of Origin	India
Is this product covered under the Trade Agreements Act (TAA)?	No

PRODUCT DESCRIPTION INFORMATION	
Size:	120 ct
Strength:	750 mg
Dosage Form:	Tablet
Product Shape:	capsule
Product Color:	orange
Product Imprint:	H/90

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	1 box of 24 bottles
<input checked="" type="checkbox"/> Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	
<input type="checkbox"/> Vial Powder Sgl	
<input type="checkbox"/> Vial Power Multi	
<input type="checkbox"/> Other: Write In	
	Minimum order quantity? Yes
	If Yes, how many of which package type?
	Each
	Inner/ Carton/ Pack
	24 Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Keppra
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text" value="1 Vial"/>	<input type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	No
Has FDA granted waiver/exception/exemption for product?	No
GLN:	
If Yes, was original product purchased direct from mfr?	<input checked="" type="checkbox"/>
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/ Carton/ Bundle/ Inner Pack:	0.35		5	2		
Case:	8.85	13.5	6	9.75	0.544	24
Pallet:						1872
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	Yes	Level		Quantity	GTIN-14	Item
		Saleable Unit	Unit			
If not, when?		<input checked="" type="checkbox"/>	Box/ Carton/ Bundle/ Inner Pack	1	00331722538121	
Items aggregated?	Yes	<input checked="" type="checkbox"/>	Case	24	20331722538125	
		<input checked="" type="checkbox"/>	Pallet			

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$53.38	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic? No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant?

Is the product a CA Prop 65 carcinogen? No

Is the product a CA Prop 65 reproductive toxicant? _____

Does the product label bear a CA Prop 65 warning? _____

c. Contact Hazard? No

d. Does this product require special clean-up instructions? No
(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

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 _____

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? 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)

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? No

Controlled by State(s)? No

ARCOS Reportable? No

Schedule No. (inc. N for non-narcotic) _____

Controlled Substance Code _____

Listed Chemical (List I or II) No

If yes, indicate which: _____

Is it a scheduled listed chemical product?: No

CLASS OF TRADE RESTRICTION:

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

Restricted to retail pharmacy only: Yes

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments: _____

SDS Hazard Classification

Organic Corrosive

Inorganic Oxidizer

Steroid/Androgen Contact Hazard

Aerosol Class; Identify NFPA Storage Level: _____

Is the product a NIOSH hazardous drug? _____

If yes, indicate which: _____

Hazardous Waste Identification

EPA Hazardous Waste Code: NA

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? Yes

If Yes, is it managed with a pharmacy registry? No

Website URL: N/A

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

None

REMS: Yes

REMS Program Manager Name: _____ Phone: _____

Supplier Manages REMS registry exclusively: No

Wholesale distributor support: No

Provider Name: _____

Site Enrollment Number assigned by Supplier: _____ DEA #: No

PCPDP #: No

NPI #: No

Comments None

Registry: No

Registry Program Contact Name: _____ Phone: _____

Comments _____

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 732-529-0430

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:



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