

Standard Pharmaceutical Product Information (Rx Product Only)

| © August 2014 | | | | | Intro | duction Type: | Post Launch Change | | Final Version | | | Date: | 4/17/ | /2017 | |
|------------------------------------|------------------------|---------------------------|--------------------------------|------------------------------|-----------------|----------------------|---------------------------|--------------------------------------|--|-----------------|---------------|----------------|--------------|------------------|--|
| | | | PRODUCT INFORMA | ATION | | | | | SPECIAL HANDL | ING AND ST | ORAGE REQ | UIREMENTS* | ' | | |
| Company Name: | Camber Pharmaceutic | cals | | | | Application: | ANDA | a. Temperature – Indic | ate the USP temper | rature range | for this prod | uct. | | | |
| Application Number for NDA/ | /ANDA/BLA (drug); F | PMA/510(k)(med device |): | 90-515 | | | | Tempera | ature Range | - | Controlled R | oom – betwe | en 20 and 25 | C (68° – 77° I | |
| DUNS: 8 | 82-667-4775 | | | | | | | Other Te | emperature Range Re | quirement | | | | | |
| Proprietary Name (If Applicable | le) and Established N | Name: Levetirad | cetam 750MG/500CT | | | | | (wi | rite in) | | | | |] | |
| | 31722-538-05 | | Individual Unit NDC: | 31722-538-05 | | UPC: 331722538 | 053 | | | | | | | | |
| UDI | NA | | CVX Code: | | MVX | Code: NA | | Is this pr | oduct to be shipped t | to customers | on ice? | | No | _ | |
| Description: C | Orange oblong shape | d tablets embossed with ' | 'H' on one side and '90' on th | he other side with correspon | ding dyes | | | Is this pr | oduct to be shipped t | to customers | on dry ice? | | No | - | |
| Active Ingredient(s): | | Levetiracetam | | | | | | b. Contact for tempera Name: | ature excursion que | stions: | Soma Raju | | | | |
| URL for Additional Product Info | formation: | www.camberpharma.com | m | | | | | Number | : | | 732-529-04 | 23 | | | |
| Address: 1 | 1031 Centennial Aver | nue | | | Address | | | Group E | -mail: | | somaraju@h | eterousa.cor | n | | |
| | Piscataway | | | State: | NJ | Zip: | 08854 | | | | | | | | |
| | Customer Service | | | Email: | | rservice@camberpharr | na.com | c. Special regulations | | | | | No | _ | |
| Phone Number: 7 | 732-529-0430 | | | Fax: | 732-562- | -8788 | | Special r | returns requirements | for this produ- | ct? | | No | - | |
| Product Therapeutic Classifica | cation: | | | | | | | | | | | | | | |
| | L PRODUCT INFORM | ATION | | | PRODUCT | DESCRIPTION INFOR | ΜΑΤΙΟΝ | d. Store product (unit | of sale) upright? product (unit of sale | a) from light | | | No No | - | |
| | | ATION | • | | FRODUCT | DESCRIPTION INFOR | MATION | | product (unit of sale | | ſ | | | | |
| Is the Product a legend device? | | No | | | Г | | | e. Shelf life: | nelf life at launch (if (| differently | | | 24 | Months Months | |
| reverse numbered? | | No | | Size: | Ę | 500 | | initial St | ien me at laurich (in i | unerenty. | | | | Months | |
| co-licensed? | | No | | | | | | | (| ORDER INFO | RMATION | | | | |
| Is the Product | | Direct-Ship Only | | Strength: | 4 | 750 MG | | | | | | | | | |
| Is the Product | | Unit of Use | | Dosage Form | n• (| Oral solid tablet | | Unit of S | Sale | | | NDC selling | unit? | | |
| | | | | Decagoren | | | | | Bottle | | 1 box of 12 | | | | |
| If Unit Dose, is item bar coded t | to unit dose for hospi | ital scanning? | | | | | | x | Box/Carton | | (Write-in, e | .g. 1 Box of 1 | 0 Vials) | | |
| If Unit Dose NDC, indicate NDC | C horo: | - | | Product Shap | pe: o | oblong shaped | | | Ampule Glass | | Minimum o | rder quantity | | Yes | |
| II ONIC DOSE NDC, INDICATE NDC | Chere. | | | | - | | | | Tube | | Wiiminum o | uer quantity | ſ | 165 | |
| Country of Origin | | India | | Product Colo | or: o | orange | | | Vial Liquid Sgl | | | | | | |
| Is this product covered under the | the Trade Agreements | Act (TAA)2 | | Product Impr | rint- | H'/'90' | | | Vial Liquid Multi | | If Yes, how | many of whi | ch package t | type? | |
| is this product covered under th | ine made Agreements | No No | | i toduct impi | | 17 50 | | | Vial Powder Sql | | | Each | | | |
| | | |] | | | | | | Vial Power Multi | | 12 | Inner/Carton | /Pack | | |
| | | | FOR GENERIC DRUG PR | | | | | ┛ └── | Other: Write In | 7 | | Case | | | |
| | | | TOR CENERIO DROGT | | | | | | | | | | | | |
| | | | | Auth | norized Gene | ric *If Authorize | ed Generic, other section | | PHAP | RMACY ORD | er / Bill Uni | T | | | |
| I. Orange Book Rating: | AB | | | 1 | | fields are no | ot applicable | Rec. sell unit to custo | mer? | | Rx billing u | nit to pharma | acv: | | |
| II. Generic Equivalent to What | | Keppra | | | | | | | | | | Each | | | |
| - | | | | | | | | (Write-in, e.g. 1 Vial) | | | | Gram | | | |
| | | DRUG SUPP | LY CHAIN SECURITY ACT | (DSCSA) INFORMATION | | | | | | | | Milliliter | | | |
| Does supplier meet DSCSA de | ofinition of monutoot | huror? | Yes | GLN: | | | | 1 | | | | ON | | | |
| Is product exempt from DSCSA de | | | No | GLN: | | | | ITEM AND PACKING INFORMATION | | | | | | | |
| If yes, select exemption: | | | | | | | | | | Dime | nsions (US m | ismts.) | Volume | | |
| Other exemption - Write in: | | | | | | | 7 | | Weight Lbs. | Depth | Height | Width | (Cube) | # Pieces: | |
| Is product repackaged? | | | No | | al product | purchased direct | | Item: | 1.1 | | 7 | 3.375 | | | |
| Is product sold by manufactur | | | No | from mfr? | | | | | | | | | | | |
| Has FDA granted waiver/excep | eption/exemption for | product? | No | If yes, attach doo | cumentation | n from FDA. | | Box/Carton/Bundle/ Inner Pack: | 16.4 | 14.75 | 9 | 11.5 | 0.883 | 12 | |
| | | | GTIN PRODUCT INFOR | | | | | Case: | | | | | | | |
| | | | | Saleable | | | | 11100000. | | | | | | | |
| 11 | | | Level | Unit | | Quantity | GTIN-14 | Pallet: | | 1 | | | | 480 | |
| Serialized? | Yes | x | Item | X 2D | | Linear 1 | 00331722538053 | | | | | | | 400 | |
| If not, when? | | x | Box/Carton/Bundle/Inner Pack | x x 2D | | Linear 12 | 30331722538054 | UPC: | Case: | | | | | | |
| Items aggregated? | Yes | | Case | 2D | | Linear | | | Carton: | | | | | | |
| | | | Pallet | 2D 2D | | Linear Linear | | | INFORMATION | | - | WHOI ESAL | ER USE ONL | v | |
| | | | | 2D 2D | | Linear | | | IN ORMATION | | | MIOLEGAL | ER OSE ONL | | |
| | | | | | | Linear | | Regular Cost | | | Vendor #: | | | | |
| | | ├──┤ | | 20 | | | | | | | | | | | |
| | | | | 2D 2D | | Linear | | Invoice Cost (WAC) (\$ | 5) | \$222.43 | Whsl. Code | #: | | | |
| | | | | | | Linear | | Federal Excise Tax Pe | | \$222.43 | | | | | |
| | | | | | | Linear | | | | \$222.43 | Whsl. Code | | | | |
| | | | | 2D | | | | Federal Excise Tax Pe As of date: | er Unit of Sale | \$222.43 | Whsl. Code | | | | |
| *Please provide any additional | | | Attach copy of SAFETY D | | azard letter, I | | | Federal Excise Tax Pe As of date: | ARCODE. | \$222.43 | Whsl. Code | | | | |



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

| le this product (check all that apply) | | | | | |
|--|--|--|--|--|--|
| Is this product (check all that apply): a. Cytotoxic? No | SDS Hazard Classification | | | | |
| | | | | | |
| b. CA Prop. 65 Carcinogen or Reproductive Toxicant? | | | | | |
| Is the product a CA Prop 65 carcinogen? No | Organic | | | | |
| Is the product a CA Prop 65 reproductive toxicant? | Inorganic Oxidizer | | | | |
| Does the product label bear a CA Prop 65 warning? | Steroid/Androgen Contact Hazard | | | | |
| | | | | | |
| c. Contact Hazard? No | Aerosol Class; Identify NFPA Storage Level: | | | | |
| d. Does this product require special clean-up instructions? No | | | | | |
| (If yes, attach SDS with special instructions.) | Is the product a NIOSH hazardous drug? | | | | |
| e. Does the product contain DEHP? No | 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 Is there a REMS on this product? Yes | | | | |
| Passenger | | | | | |
| Cargo | If Yes, is it managed with a pharmacy registry? No | | | | |
| Passenger & Cargo | Website URL: N/A | | | | |
| 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)? No | - Registry: No | | | | |
| ARCOS Reportable? No | Registry Program Contact Name: Phone: | | | | |
| Schedule No. (inc. N for non-narcotic) | Comments | | | | |
| Controlled Substance Code | 1 | | | | |
| 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: Yes | | | | |
| | | | | | |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No | URL/Link to returns policy: contact - customerservice@camberpharma.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: No | If so, which states? Other requirements? Comments? | | | | |
| Restricted from US territories? (explain in comments) No | | | | | |
| Comments: | | | | | |
| comments: | | | | | |
| | | | | | |
| | | | | | |
| MISCELL | ANEOUS NOTES and/or Image of Product Barcode: | | | | |
| | | | | | |
| | | | | | |
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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: Autofax Yes b. Autofax No Fax Number: c. Fax Yes Fax Number: d. Phone only No Phone No.: e. Supplier Web Site only No Site Address: Minimum Order Quantity: case pack 732-529-0430 x466 x465 x467 x470 Contracted 3PL company / contact #: Name: Phone: | Purchase order daily receipt cut off time by supplier Cut off time: 2:30PM Eastern Shipping lead time of PO: 24/48 Hours Days Ships same day for next day receipt: No No Ships for second day receipt: No No Ships regular ground for 3-10 days receipt: Yes |
| Expedited Freight Charges or Other Designated Drop Ship Fees: | Overnight and Priority Overnight PO Processing |
| Expedited freight fees billed with each order: No Drop Ship service fee billed with each order: No Drop Ship miscellaneous fees billed: No Comments: Image: No Comments: Image: No Class of Trade Restriction: No Restricted to retail pharmacy, hospitals, clinics and physician offices No Yes Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No | Overnight receipt available: Yes PO Receipt cut off time: 2:30PM Eastern Days of week overnight is available: X Monday X Tuesday Wednesday X Thursday Friday Priority Overnight receipt available: Yes PO Receipt Cut off time: 2:30PM EST Saturday Overnight receipt available: No PO Receipt Cut off time: No Order receipt method: Phone: No Fax: Yes Fax #: |
| Comments: | rax. res rax #. res EDI: Yes Overnight Fees apply: Yes Other fees apply: No |
| Other Data Information Required to Process PO: | Return Instructions |
| Patient Procedure Date: | Contact # if product is received damaged: 732-529-0430 Is product returnable for credit: Yes URL/Link to returns policy: |
| | |
| | |
| | ADDITIONAL INFORMATION |