

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

| Version 2024  |                                      |                      |                           |                |                 | Introduction Type:       | New Item                             | X                        | Final Version           |                      |               | Date:          | 3/11/        | /2025                                   |
|---|--------------------------------------|----------------------|---------------------------|----------------|-----------------|--------------------------|--------------------------------------|--------------------------|-------------------------|----------------------|---------------|----------------|--------------|---|
|   |                                      |                      | PRODUCT INFORMA           | TION           |                 |                          |                                      |                          | SPECIAL HAN             | DLING AND STOR       | AGE REQUI     | REMENTS*       |              |   |
| Company Name:   | Camber Pharmac                       | euticals, Inc.       |                           |                |                 | Application:             | ANDA                                 | a. Temperature – Indic   | ate the USP tempe       | rature range for the | nis product.  |                |              |   |
| Application Number for NDA/ANI                        | IDA/BLA; PMA/510                     | (k): 09051           | 5                         |                |                 | NDA 505(b) Type:         | NOT APPLICABLE                       |                          |                         | Controlled Room -    |               | and 25 C (68   | ° – 77° F)   |   |
|   | Medical Device Class, if applicable: |                      |                           |                |                 |                          |                                      |                          |                         |                      |               |                |              |   |
| DUNS:   | 11-856-3719                          |                      |                           |                |                 |                          |                                      | Other Te                 | emperature Range R      | Requirement          |               |                |              |   |
| Proprietary Name (If Applicable) a                    |                                      | ame: Levetir         | acetam Tablets, USP 750 n |                |                 |                          |                                      |                          | rite in)                |                      |               |                |              |   |
| Selling Unit NDC:                                     | 31722-538-12                         |                      | Unit of Use NDC:          |                | 31722-538-12    |                          | 22538121                             | Notes                    |                         |                      |               |                |              |   |
| UDI   |                                      |                      | CVX Code:                 |                |                 | MVX Code:                |                                      |                          |                         |                      |               |                |              |   |
| Description:  | Levetiracetam Tal                    | blets, USP 750 mg    |                           |                |                 |                          |                                      | Is this pr               | roduct to be shipped    | I to customers on ic | ce?           |                | No           |   |
|   |                                      |                      |                           |                |                 |                          |                                      | Is this pr               | roduct to be shipped    | I to customers on d  | ry ice?       |                | No           |   |
| Active Ingredient(s):                                 |                                      | Levetiracetam, USF   | •                         |                |                 |                          |                                      |                          |                         |                      |               |                |              |   |
|   |                                      |                      |                           |                |                 |                          |                                      | b. Contact for tempera   | ture excursion que      | estions:             |               |                |              |   |
| URL for Additional Product Inform                     |                                      | www.camberpharma     | a.com                     |                |                 | Address                  |                                      | Name:                    |                         |                      | Soma Raju     |                |              |   |
| Address:  | 800 Centennial Av<br>Piscataway      | ve, Suite 1          |                           |                | State:          | Address 2:               | : 08854                              | Number<br>Group E        |                         |                      | 732-529-042   | isterousa.con  |              |   |
| City:<br>Key Contact:                                 | Customer Service                     | <u> </u>             |                           |                | Email:          | customerservice@cam      |                                      | Group E                  | :-maii:                 |                      | Somarajuer    | leterousa.com  | <u>u</u>     |   |
| Phone Number:   | 1-866-827-3647                       | •                    |                           |                | Fax:            | 732-562-8788             | <u>berpriama.com</u>                 | c. Special regulations   | for product in any      | states?              |               |                | No           | 1                                       |
| Product Therapeutic Classification                    |                                      | Anticonvulsant       |                           |                |                 |                          |                                      |                          | returns requirements    |                      |               |                | No           |   |
| Trouder Therapeutic Glassification                    |                                      | 7 il ilioon 7 diodin |                           |                |                 |                          |                                      | Ореска                   | returns requirement     | o for tino product:  |               |                | 140          | 1                                       |
|   | ADDITI                               | ONAL PRODUCT IN      | FORMATION                 |                |                 | PRODUCT DESC             | RIPTION INFORMATION                  | d. Store product (unit   | of sale) unright?       |                      |               |                | No           | 1                                       |
| The product is?                                       |                                      |                      | Is the Product            | Direct-Ship Or | oly             |                          |                                      | - I                      | product (unit of sa     | la) from light?      |               |                | No           | 1                                       |
| a legend device?                                      |                                      | No                   | Is the Product            | Unit of Use    | iiy iiiy        |                          | 120 ct                               | e. Shelf life:           | product (unit or sa     | ie) iroin light?     |               |                | 24           | Months                                  |
| if yes, enter class #                                 |                                      | INO                  | Orphan Drug Status        | Still of O3e   |                 | Size:                    | 120 01                               |                          | helf life at launch (i  | f different).        |               |                | 24           | Months                                  |
| a product kit?  |                                      | No                   | - prior sing status       |                |                 |                          | 750 mg                               | uu si                    | (1                      |                      |               |                |              |   |
| if yes, list NDCs of                                  |                                      |                      | FDA Approval Status       |                |                 | Strength:                |                                      |                          |                         | ORDER INFORM         | IATION        |                |              |   |
| component parts                                       |                                      |                      |                           |                |                 | Dosage Form:             | Film coated tablet                   |                          |                         |                      |               |                |              |   |
| reverse numbered?                                     |                                      | No                   |                           |                |                 | Dosage Form.             |                                      | Unit of S                |                         |                      |               | NDC selling    | unit?        |   |
| co-licensed?  |                                      | No                   | Allergens Present         |                |                 |                          |                                      | x                        | Bottle                  |                      | 1 Bottle of 1 |                |              |   |
| latex-free?   |                                      | Yes                  | Cor                       | n, Dye         |                 | Product Shape:           | Oblong                               |                          | Box/Carton              |                      | (Write-in, e. | g. 1 Box of 10 | ) Vials)     |   |
| preservative-free?                                    |                                      | Yes                  |                           |                |                 | •                        |                                      |                          | Ampule                  |                      |               |                | _            |   |
| correctional institution block?                       |                                      | No                   |                           |                |                 | Product Color:           | Orange                               |                          | Glass                   |                      | Minimum oi    | der quantity   | 7            | Yes                                     |
| opioid?<br>Cannabinoid?                               |                                      | No<br>No             | Country of Origin         | India          |                 |                          | Debossed with 'H' on one side with   |                          | Tube<br>Vial Liquid Sgl |                      |               |                |              |   |
| If Unit Dose, is item bar coded to u                  | unit dose for                        | 140                  | Country of Origin         | iridia         |                 | Product Imprint:         | scoreline and '90' on the other side |                          | Vial Liquid Multi       |                      | If Yes how    | many of whi    | ch package t | tyne?                                   |
| hospital scanning?                                    | ann 4000 101                         |                      | Is this product covered u | inder the      |                 |                          |                                      |                          | Vial Powder Sql         |                      |               | Each           | on paonago i | .,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, |
| If Unit Dose, indicate NDC here:                      |                                      |                      | Trade Agreements Act (    |                | No              |                          |                                      |                          | Vial Powder Multi       |                      |               | Inner/Carton   | /Pack        |   |
|   |                                      | -                    | _                         |                |                 |                          |                                      |                          | Other: Write In         |                      |               | Case           |              |   |
|   |                                      |                      | FOR GENERIC DRUG PR       | ODUCTS         |                 |                          |                                      |                          |                         |                      |               |                |              |   |
|   |                                      |                      |                           |                |                 |                          |                                      |                          |                         |                      | 4             |                |              |   |
|   |                                      |                      |                           |                | Aut             |                          | uthorized Generic, other             |                          | PH                      | ARMACY ORDER         | / BILL UNIT   |                |              |   |
| I. Orange Book Rating:                                | AB                                   |                      |                           |                |                 | secti                    | on fields are not applicable         | Rec. sell unit to custor | mer?                    |                      | Rx billing u  | nit to pharma  | асу:         |   |
| II. Generic Equivalent to What Bra                    | ınd?:                                | Keppra               |                           |                |                 |                          |                                      |                          |                         |                      |               | Each           |              |   |
|   |                                      |                      |                           |                |                 |                          |                                      | (Write-in, e.g. 1 Vial)  |                         |                      |               | Gram           |              |   |
|   |                                      | DRUG SUPPL           | Y CHAIN SECURITY ACT      | (DSCSA) INFORI | MATION          |                          |                                      | HCPCS J-Code:            |                         | 1                    |               | Milliliter     |              |   |
| Does supplier meet DSCSA definit                      | ition of manufactur                  | -0.2                 | Yes                       | _              | GLN:            | 0331722498975            |                                      |                          | ITEM                    | AND PACKING IN       | JEOPMATIO     | J              |              |   |
| Is product exempt from DSCSA?                         | ition of manufactur                  | rer?                 | No                        | _              | GLN:            | 0331722496975            |                                      |                          | IIEW                    | AND FACKING II       | NFORWATIO     | V              |              |   |
| · ·   |                                      |                      |                           |                |                 |                          |                                      |                          |                         | <b>5</b> 1           | (110          |                |              |   |
| If yes, select exemption:                             |                                      |                      |                           |                | GCP:            |                          |                                      |                          | Weight Lbs.             |                      | ons (US msn   |                | Volume       | Saleable #<br>Pieces                    |
| Other exemption - Write in:<br>Is product repackaged? |                                      |                      | No                        |                | If you was or   | iginal product purchase  | А                                    | Item/Each:               |                         | Depth                | Width         | Height         | (Cube)       | rieces                                  |
| Is product repackaged:                                | exclusive distribu                   | itor?                | Yes                       |                | direct from m   |                          | u                                    | item/Lacii.              | 0.31                    | 2.2                  | 2.2           | 4.67           | 22.60        | 1                                       |
| Has FDA granted waiver/exception                      |                                      |                      | No                        | _              |                 | ce manufacturer for repa | ckaged product                       | Box/Carton/Bundle/       |                         |                      |               |                |              |   |
| If yes, attach documentation from                     |                                      |                      |                           |                |                 |                          |                                      | Inner Pack:              |                         |                      |               |                |              |   |
|   |                                      |                      |                           |                |                 |                          |                                      | Case:                    | 8.25                    | 13.5                 | 9.5           | 6              | 769.50       | 24                                      |
|   |                                      | GTII                 | N AND HIBCC PRODUCT I     | NFORMATION     |                 |                          |                                      |                          | 0.25                    | 15.5                 | 3.3           |                | 703.30       | 24                                      |
| II  |                                      |                      |                           |                |                 |                          |                                      | Pallet:                  |                         |                      |               |                |              |   |
| Saleable Unit of Measure                              | RFID tag(Y/N)                        |                      | HIBCC                     |                | GTI             | N-14                     | Unit of Use GTIN-14                  |                          |                         |                      |               |                |              |   |
| II  |                                      | Quantity             |                           |                | 2000            | 31722538121              | 331722538121                         |                          |                         |                      |               |                |              |   |
| x Item/Each Box/Carton/Bundle/Inner Pack              | N                                    | 1                    |                           |                | 0033            | 31722538121              | 331722536121                         | COS                      | T INFORMATION           |                      |               | WHOLESALE      | ER USE ONL   | ٧.                                      |
| X Case  | N                                    | 24                   |                           |                | 2033            | 31722538125              |                                      | 000                      | T IN ORMATION           |                      |               | WIIOEESAEI     | IN USE ONE   | ١.                                      |
| A   0030  | IV                                   | 27                   |                           |                | 2030            | 32000120                 |                                      | Regular Cost             |                         |                      | Vendor #:     |                |              |   |
| Pallet  |                                      |                      |                           |                |                 |                          |                                      | Invoice Cost (WAC) (\$)  | )                       | \$19.66              |               | #:             |              |   |
| Pallet  |                                      |                      |                           |                |                 |                          |                                      |                          |                         | Ψ.0.00               |               |                |              |   |
| Pallet  |                                      |                      |                           |                |                 |                          |                                      |                          |                         |                      | Fineline Co   |                |              |   |
| Pallet  |                                      |                      |                           |                |                 |                          |                                      | As of date:              | 4/15/2024               |                      |               |                |              |   |
| Pallet  |                                      |                      |                           |                |                 |                          |                                      | As of date:              |                         |                      |               |                |              |   |
| Pallet  |                                      |                      |                           |                |                 |                          |                                      |                          | 4/15/2024               |                      |               |                |              |   |
| Pallet  *Please provide any additional info           |                                      |                      | Attach copy of SAFETY D   | ATA SHEET (SDS | S) or non hazar |                          | RT, LABEL AND PHOTO OF               |                          | 4/15/2024               |                      |               |                |              |   |



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

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For Designated Drop Ship Only Products, Please Use Page 3

| MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION  |   |  |  |  |  |  |
|--|---|--|--|--|--|--|
| Is this product (check all that apply):  a. Cytotoxic?  b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  | SDS Hazard Classification   |  |  |  |  |  |
| 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 e. Inhalation Hazard?   | Hazardous Waste Identification  EPA Hazardous Waste Code:  Waste Characteristics  |  |  |  |  |  |
| ls this product regulated for shipment by IATA?  | EFA Hazaiuous waste Code.   |  |  |  |  |  |
| (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: No Phone:  DEA #: NCPDP#: NCPDP#: NPI #: |  |  |  |  |  |
| Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#   | Comments  Registry:  No   |  |  |  |  |  |
|  | Registry Program Contact Name: Phone:   |  |  |  |  |  |
| ADD'L STORAGE INFORMATION  | Comments  |  |  |  |  |  |
| Is the Product  Controlled Substance?  Controlled Substance Code  Controlled by State(s)?  ARCOS Reportable?  Schedule No.  No  Controlled Substance Code  Listed Chemical (List I or II)  No  If yes, indicate which:  Is it a scheduled listed chemical product?:  No      | RETURN INSTRUCTIONS  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  Yes   | contact - customerservice@camberpharma.com  |  |  |  |  |  |
| Restricted to retail pharmacy only:  Restricted to hospital, clinics, and physician offices only:  No 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:  |   |  |  |  |  |  |
| MISCELLAN  | EOUS 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 Phone No.:   | Shipping lead time of PO: Hours Days   |
| e. Supplier Web Site only  Minimum Order Quantity:  Supplier's Customer Service Number:  Contracted 3PL company / contact #:  Name: Phone:  | Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:   |
| 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/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?  |