

Standard Pharmaceutical Product Information (Rx Product Only)

| © August 2014 | | | | | Introductio | n Type: | New Item | х | Final Version | | | Date: | | | |
|---|--|--------------------------|--------------------------------------|--|--|-------------------|---|---|---|--|---------------------------|---------------|------------|-----------|--|
| PRODUCT INFORMATION | | | | | | | | | SPECIAL HANDLING AND STORAGE REQUIREMENTS* | | | | | | |
| Company Name: | Camber Pharmaceuticals Application: ANDA | | | | | | | a. Temperature – Indicate the USP temperature range for this product. | | | | | | | |
| Application Number for ND | DA/ANDA/BLA (drug); PMA/510(k)(med device): | | | 213519 | 13519 | | | Tempera | • | Controlled Room - between 20 and 25 C (68° - 77° I | | | | | |
| DUNS: | 826774775 | | | | | | | Other Temperature Range Requirement | | | | | | | |
| Proprietary Name (If Applica | e (if Applicable) and Established Name: Vigabatrin Powder Packet, USP for Oral Sol 500mg | | | | | | | | rite in) | • | | | | | |
| Selling Unit NDC: 31722-009-50 Individual Unit NDC: | | | | | UPC: 331722009508 | | | | | | | | | •' | |
| UDI CVX Code: | | | | MVX Code: | | | Is this pr | roduct to be shipped | to customers | on ice? | | No | | | |
| Description: White to Off-White, Granular Powder for Oral Solution (Orals) | | | | | | | | | Is this product to be shipped to customers on dry ice? No | | | | | | |
| Active Ingredient(s): Vigabatrin | | | | | | | b. Contact for temperature excursion questions: | | | | | | | | |
| UBL for Additional Braduct | | | w.camberpharma.com | | | | | Name: Number: | | | Soma Raju 732-529-0423 | | | | |
| URL for Additional Product Information: www.camberpha Address: 1031 Centennial Avenue | | | in . | | Address 2: | | | Group E-mail: | | | somaraju@heterousa.com | | | | |
| City: | Piscataway | | | State: | State: NJ Zip: 08854 Email: customerservice@camberpharma.com | | | - Group E | IIIaII. | | 30IIIai aju@i | ieterousa.co | | | |
| Key Contact: | Customer Service | | | | | | | c. Special regulations for product in any states? | | | | | | | |
| Phone Number: | 732-529-0430 | | | Fax: | Fax: 732-562-8788 | | | Special | returns requirements | for this produ | ict? | | No | | |
| Product Therapeutic Classification: | | | | | | | | | | | | | | | |
| d. Store product (unit of sale) upright? No | | | | | | | | | | | | | | | |
| ADDITIONA | AL PRODUCT INFORM | IATION | A | F | PRODUCT DESCI | RIPTION INFORI | MATION | Protect product (unit of sale) from light? No | | | | | | | |
| Is the Product | | | | | | | | e. Shelf life: 24 Months | | | | | Months | | |
| a legend device? | | | | Size: | Size: 50 packets | | | Initial sl | helf life at launch (if | different): | | | 24 | Months | |
| reverse numbered? | | No | | 0.20. | ou packets | | | | | | | | | | |
| co-licensed? | No | | | Strength: 500mg | | | ORDER INFORMATION | | | | | | | | |
| Is the Product | | Direct-Ship Only Neither | | _ | _ | | | Unit of S | Pala | | What is the | NDC selling | unit? | | |
| is the Floduct | | HOILIO | | Dosage Form | n: Granula | ar Powder for Ora | al Solution (Orals) | Onit of s | Bottle | | 1 carton of 5 | | uiii. | | |
| | | | | | | | x | Box/Carton | | | g. 1 Box of 1 | 0 Vials) | | | |
| If Unit Dose, is item bar code | ed to unit dose for hosp | ital scanning? No | | Product Shar | Product Shape: N/A | | | | Ampule | | | • | • | | |
| If Unit Dose NDC, indicate N | IDC here: | | | r rounct ona | Froduct Shape. | | | | Glass | | Minimum o | rder quantity | /? | Yes | |
| | | F | | Product Colo | r: White t | to Off-White | | | Tube | | | | | | |
| Country of Origin | | India | | | | | | | Vial Liquid Sgl Vial Liquid Multi | | If Van have | | :-bb | | |
| Is this product covered under the Trade Agreements Act (TAA)? | | | Product Impr | Product Imprint: N/A | | | | Vial Powder Sql | | 1 Tes, now | Each | ich package 1 | ype r | | |
| INO INO | | | | | | | | Vial Power Multi | | | Inner/Cartor | /Pack | | | |
| | | | | | | | | · | Other: Write In | | | Case | | | |
| | | | FOR GENERIC DRUG PRODUCT | TS | | | | | | | | • | | | |
| | | | | | | | | | DUAD | MAOY OPPE | D / DULL LIN | T | | | |
| | | | Auth | Authorized Generic *If Authorized Generic, other section fields are not applicable | | | | | | DER / BILL UNIT | | | | | |
| I. Orange Book Rating: | AA | In-t-di | | lieids are not applicable | | | Rec. sell unit to customer? | | _ | Rx billing unit to pharmacy: | | | | | |
| II. Generic Equivalent to What Brand?: Sabril | | | | | | | (Write-in, e.g. 1 Vial) | | | | Each Gram | | | | |
| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION | | | | | | | | (vviite-iii, e.g. i viai) | | | | Milliliter | | | |
| | | | (| , | | | | | | | | .v | | | |
| Does supplier meet DSCSA | definition of manufact | turer? | Yes | GLN: | 033172200000 | 0 | | | ITEM A | ND PACKING | INFORMAT | ION | | | |
| Is product exempt from DSC | SA? | | No | | | | | | | | | | | | |
| If yes, select exemption: | | | | | | | 1 | | Weight Lbs. | | nsions (US m | | Volume | # Pieces: | |
| Other exemption - Write in: Is product repackaged? | | | No | If Yes, was origin | | | | Item: | <u>-</u> | Depth | Height | Width | (Cube) | | |
| Is product repackaged? | urer's exclusive distri | | No | from mfr? | iai product purci | เลอชน นเเชน | | nem. | | | | | | | |
| Has FDA granted waiver/exc | | | No | If yes, attach doo | cumentation from | r FDA. | | Box/Carton/Bundle/ | 0.1 | 4 | 2.75 | 2.5 | | 4 | |
| 3 | | | | • | | | | Inner Pack: | 0.1 | 4 | 2.75 | 2.5 | | 1 | |
| | | | GTIN PRODUCT INFORMATION | | | | | Case: | 3.04 | 12.5 | 8.25 | 9.75 | | 24 | |
| | | | Salea | | | | | | 0.01 | 12.0 | 0.20 | 0.70 | | | |
| Serialized? | Vee | | Level e Uni | | Linear | Quantity 1 | GTIN-14 | Pallet: | | | | | | | |
| If not, when? | Yes | , <u>x</u> | Item X Box/Carton/Bundle/Inner Pack | X 2D 2D | Linear | - ' | 00331722009508 | UPC: | Case: | | | | | | |
| Items aggregated? | Yes | X | Case | X 2D | Linear | 24 | 20331722009502 | | Carton: | | | | | | |
| | Pallet 20 Linear 27 | | | | | | | | | | | | | | |
| | | | | 2D | Linear | | | COST | INFORMATION | | | WHOLESAL | ER USE ONL | .Y: | |
| | | | | 2D | Linear | | | | | | | | | | |
| | | | | 2D | Linear | | | Regular Cost | | 4000 | Vendor #: | и. | | | |
|]] | | | | 2D | Linear | | | Invoice Cost (WAC) (\$) Federal Excise Tax Pe | | \$300.00 | Whsl. Code Fineline Co | | | | |
| [| | | | | | | | As of date: | onit of Jale | | - menne co | uc. | | | |
| | | | | | | | | | | | 1 | | | | |
| | | A | Attach copy of SAFETY DATA SHE | ET (SDS) or non haz | ard letter, PACKA | GE INSERT, LA | BEL AND PHOTO OF PR | ODUCT PACKAGING and I | BARCODE. | | • | | | | |
| *Please provide any addition | nal information on pag | | ., | . , | | or Designated D | | Signatu | | | | | | | |



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): a. Cytotoxic? SDS Hazard Classification No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No X Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? Oxidizer No Inorganic Does the product label bear a CA Prop 65 warning? No Steroid/Androgen Contact Hazard c. Contact Hazard? Nο 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? Yes Group 3 items (primarily adverse reproductive effects) 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 Hazardous Waste Identification b. Proper Shipping Name c. DOT Hazard Class EPA Hazardous Waste Code: d. Packing Group e. Inhalation Hazard? No REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: Passenger Is there a REMS on this product? Yes Cargo If Yes, is it managed with a pharmacy registry? Website URL: Passenger & Cargo Is this a reportable quantity? RQ Threshold: Comments / Details: (For example, iPledge program?) Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) REMS: Yes Limited Quantity REMS Program Manager Name: Phone: Consumer Commodity, ORM-D Supplier Manages REMS registry exclusively: Small Quantity (49 CFR 173.4) Wholesale distributor support: Special Permit: DOT-SP Provider Name: Special Provision (listed in Column 7 of 49 CFR 172.101); Site Enrollment Number assigned DEA #: by Supplier: PCPDP #: NPI#: ADD'L STORAGE INFORMATION Is the Product... Comments Please visit https://www.vigabatrinrems.com/#Information for full REMs inforamtion. Controlled Substance? No Controlled by State(s)? No Registry: 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: 732-529-0430 Is it a scheduled listed chemical product?: No Contact tel. # if product received damaged: **CLASS OF TRADE RESTRICTION:** Is product returnable for credit: contact - customerservice@camberpharma.com No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes URL/Link to returns policy: No Restricted to retail pharmacy only: No Special regulations or returns requirements for this product in certain states? 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: 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 | Purchase order daily receipt cut off time by supplier Cut off time: Eastern | | | | | | |
| b. Autofax c. Fax d. Phone only Fax Number: 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 #: 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: Eastern | | | | | | |
| 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? | | | | | | |