

HDA Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

| Version 2024 | | | | | | Introduction 1 | Туре: | New Item | | x Final Version | | | Date: | 11/25 | /2024 |
|--|-----------------------------|-----------------|--------------------------------|---------------|------------------|--|---------------------|--|---|--------------------------------|----------------------|-----------------|----------------|--------------|------------|
| PRODUCT INFORMATION | | | | | | | | | SPECIAL HAN | DLING AND STOR | RAGE REQUI | REMENTS* | | | |
| Company Name: | Camber Pharma | ceuticals, Inc. | | | | Applica | ation: | ANDA | a. Temperature – Indicate the USP temperature range for this product. | | | | | | |
| Application Number for NDA/AN | IDA/BLA; PMA/51 | 0(k): 2 | 14957 | | | NDA 505(b) Type | : NO | T APPLICABLE | | Temperature Range | Store at 25°C (77° | °F) | | | |
| Medical Device Class, if applical | ble: | | | | | | | | | | | | | | |
| DUNS: | 11-856-3719 | | | | | | | | | Other Temperature Range | Requirement | | permitted bety | ween 15°C to | 30°C (59°F |
| Proprietary Name (If Applicable) a | | lame: | Sabapentin Tablets, USP 800 mg | | | | | | | (write in) | | to 86°F) | | | |
| Selling Unit NDC: | 31722-167-05 | | Unit of Use NDC: | | | UPC: | 331722167 | 055 | | Notes | | | | | |
| UDI | | | CVX Code: | | | MVX Code: | | | | | | | | | |
| Description: | Gabapentin Table | ets, USP 800 mg | J | | | | | | | Is this product to be shipped | | | | No | |
| Active Ingredient(s): Gabapentin, USP | | | | | | | | Is this product to be shippe | d to customers on d | Iry ice? | | No | | | |
| | | | | | | | b. Contact for | temperature excursion qu | estions: | | | | | | |
| URL for Additional Product Inform | | www.camberp | harma.com | | | | | | | Name: | | Soma Raju | | | |
| Address: | 800 Centennial A | Ave, Suite 1 | | | | Address 2: | | 054 | | Number: | | 732-529-042 | | | |
| City: Key Contact: | Piscataway Customer Servic | | | | State: Email: | NJ | Zip : 08 | | Group E-mail: somaraju@heterousa.com | | | | | | |
| Phone Number: | 1-866-827-3647 | .e | | | Fax: | customerservice@camberpharma.com 732-562-8788 | | | c. Special regulations for product in any states? *Yes | | | | | | |
| Product Therapeutic Classification | | Anticonvulsar | t | | - un | 702-002-0700 | | | c. opeciai reg | Special returns requirement | | | | No | |
| Froduct Therapeutic Classificatio | ···. | Anticonvuisar | | | | | | | | Special returns requiremen | is for this product? | | | INU | |
| | ADDIT | IONAL PRODUC | CT INFORMATION | | | PRODUCT | DESCRIPTION | ON INFORMATION | d Store produ | uct (unit of sale) upright? | | | | No | |
| The product is? | | | Is the Product | Direct-Ship C | nly | | | | | Protect product (unit of sa | ala) from light? | | | No | |
| a legend device? | | No | Is the Product | Neither | , iny | | 500 | ct | e. Shelf life: | Frotect product (unit of se | iie) iroiii iigiit: | | | 24 | Months |
| if yes, enter class # | | 140 | Orphan Drug Status | | | Size: | 000 | | 0. 0 | Initial shelf life at launch (| if different): | | | | Months |
| a product kit? | | No | | | | 04 | 800 | mg | | | , | | | | |
| if yes, list NDCs of | | | FDA Approval Status | | | Strength: | | - | | | ORDER INFORM | MATION | | | |
| component parts | | | | | | Dosage Form | m: Film | coated tablet | | | | | | | |
| reverse numbered? | | No | | | | | | | | Unit of Sale | | | NDC selling | unit? | |
| co-licensed? latex-free? | | No | Allergens Present | | | | Our | I, biconvex | | x Bottle | | 1 Bottle of 5 | | 0.1/(=1=1 | |
| preservative-free? | | Yes | Corn, Alco | hol, Wheat | | Product Sha | ape: | i, diconvex | | Box/Carton Ampule | | (vvrite-iri, e. | g. 1 Box of 1 | o viais) | |
| correctional institution block? | | No | | | | | Whi | te | | Glass | | Minimum o | rder quantity | 2 | Yes |
| opioid? | | No | | | | Product Col | lor: | | | Tube | | | ao. quantity | | 100 |
| Cannabinoid? | | No | Country of Origin | USA | | Product Imp | Deboss '3' on th | ed with 'T' on the left side of the bisect and e right side of the bisect on one side and | | Vial Liquid Sgl | | | | | |
| If Unit Dose, is item bar coded to u | unit dose for | | | | | Froductilip | bisect o | n other side | | Vial Liquid Multi | | If Yes, how | many of whi | ch package t | ype? |
| hospital scanning? | | | Is this product covered u | nder the | | | | | | Vial Powder Sql | | 12 | Each | | |
| If Unit Dose, indicate NDC here: | | | Trade Agreements Act (T | 'AA)? | Yes | | | | | Vial Power Multi | | | Inner/Carton | /Pack | |
| | | | | | | | | | | Other: Write In | | | Case | | |
| | | | FOR GENERIC DRUG PRO | DDUCTS | | | | | | | | | | | |
| | | | | | Aı | thorized Generic | *If Authoriz | ed Generic, other | | Pŀ | IARMACY ORDER | / BILL UNIT | | | |
| I. Orange Book Rating: | AB | | | П | | | | ds are not applicable | Rec. sell unit | | | | nit to pharma | acv. | |
| II. Generic Equivalent to What Bra | | Neurontin | | | | | | Each | | | | | | | |
| | | | | | | | | | (Write-in, e.g. | 1 Vial) | | | Gram | | |
| | | DRUG S | UPPLY CHAIN SECURITY ACT (| DSCSA) INFOF | RMATION | | | | HCPCS J-Cod | e: | _ | | Milliliter | | |
| | | | | - | | | | | | | | | | | |
| Does supplier meet DSCSA defini Is product exempt from DSCSA? | ition of manufactu | ırer'? | Yes No | + | GLN: | 0331722498975 shipme 0843368117603 shipme | | | | ITEN | I AND PACKING II | NEURMATIO | N | | |
| | | | INO | | | | | | | | | | | | |
| If yes, select exemption: | | | | | GCP: | | | | | Weight Lbs. | | ons (US msn | | Volume | Saleable # |
| Other exemption - Write in: Is product repackaged? | | | No | | If you | riginal product pur | robood - | | Item/Each: | | Depth | Width | Height | (Cube) | Pieces |
| Is product repackaged? Is product sold by manufacturer's | s exclusive dietrib | utor? | Yes | + | direct from n | | Cilaseu | | nem/Each: | 1.4 | 3.7 | 3.7 | 7.4 | 101.31 | 1 |
| Has FDA granted waiver/exception | | | No | + | | ce manufacturer fo | or repackage | ed product | Box/Carton/B | undle/ | | | | | |
| If yes, attach documentation from | | _ | | | | | | | Inner Pack: | | | | | | |
| | | | | | | | | | Case: | 17.6 | 15 | 11.75 | 7.75 | 1,365.94 | 12 |
| | | | GTIN AND HIBCC PRODUCT IN | IFORMATION | | | | | | 17.0 | 15 | 11.75 | 7.75 | 1,505.54 | 12 |
| | | | | | | | | | Pallet: | | | | | | |
| Saleable Unit of Measure | RFID tag(Y/N) | | HIBCC | | GTI | N-14 | Un | it of Use GTIN-14 | | | | | | | |
| X Item/Each | N | Quantity 1 | | | nna | 31722167055 | | | | | | | | | |
| Box/Carton/Bundle/Inner Pack | IN | ' | | | - 500 | | | | | COST INFORMATION | | | WHOLESAL | ER USE ONL | Y: |
| X Case | N | 12 | | | 103 | 31722167052 | | | | | | | | | |
| Pallet | | | | | | | | | Regular Cost | | | Vendor #: | | | |
| | | | | | | | | | Invoice Cost (| WAC) (\$) | \$100.00 | Whsl. Code | | | |
| | | | | | | | | | | 441/010001 | | Fineline Co | de: | | |
| | | | | | | | _ | | As of date: | 11/18/2021 | | 1 | | | |
| | | | | | | | | | | | | | | | |
| | | | Attach copy of SAFETY DA | TA SHEET (SF | S) or non haza | rd letter, PACKAGE | INSERT 14 | BEL AND PHOTO OF P | RODUCT PACKA | GING and BARCODE | | 1 | | | |
| *Please provide any additional inf | formation on nage | | , | 0 (00 | | See new n 3 for | | | | Cianatura | | | | | |



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

Version 2024

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? | No | SD | S Hazard Classification | | | |
| Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? | 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? | No No | 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 | No | Is the product a NIOSH hazardous drug? If yes, indicate which: | No | | | |
| c. DOT Hazard Class d. Packing Group | | Hazardous Waste Identification | | | | |
| e. Inhalation Hazard? Is this product regulated for shipment by IATA? | No | EPA Hazardous Waste Code: | | Waste Characteristics | | |
| (if yes, answer a-e below and provide SDS) a. UN/Identification Number | | REMS or | REGISTRY RESTRICTIONS | | | |
| 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: | No | | | |
| Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo | No | Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?) | No | | | |
| 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#: NPI #: | | |
| Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); | | Comments | | | | |
| SP# ADD'L STORAGE INFORMATION | | Registry: Registry Program Contact Name: | No | Phone: | | |
| Is the Product | | Comments | | | | |
| Controlled Substance? Controlled by State(s)? ARCOS Reportable? Schedule No. No If yes, indicate which: Is it a scheduled listed chemical product?: CLASS OF TRADE RESTRICTION: | No No | Contact tel. # if product received damaged: Is product returnable for credit: | 1-866-827-3647 Yes | | | |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices | Yes | URL/Link to returns policy: | rvice@camberpharma.com | | | |
| Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: | No No | Special regulations or returns requirements for this product in certain states? Yes | | | | |
| Restricted from US territories? (explain in comments) Comments: | No | If so, which states? Other requirements? Comments? This product is classified as a Schedule V controlled substance in Alabama, Kentucky, North Dakota, Utah, Tennessee, Virginia, and | | | | |
| | | West Virginia. | . ,, | | | |
| MISCE | LLANEOU | S NOTES and/or Image of Product Barcode: | | | | |
| | | | | | | |



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

Version 2024

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

| Purchase order ally receipt cut off time by supplier a. EDI b. Autofax C. Fax Fax Number: C. Fax d. Phone only Phone only Supplier Veb Sile only Supplier Veb S | Order Method | for Designated Drop Ship Product | Standard Order Receipt and Processing | | | | |
|--|--|---|---|--|--|--|--|
| b. Autofax c. Fax d. Phone only e. Supplier Web Site only e. Supplier Web Site only supplier Subserver Service Number: Contracted 3PL company / contact #: Name: Phone Phone Phone Phone Phone Site Address Ships aame day for next day receipt: Ships regular ground for 3-10 days receipt: S | Purchase orders may be accepted by: | | Purchase order daily receipt cut off time by supplier | | | | |
| d. Phone only e. Supplier Web Site only Site Address: Supplier Soustomer Service Number: Contracted 3PL company / contact # Name: Phone No. Expedited freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee billed: Drop Ship service fee billed: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee billed: Drop Ship ser | a. EDI | | Cut off time: | | | | |
| d. Phone only e. Suppler Web Site only Site Address: Ships same day for next day receipt: Ships for second day receipt wallabe: Drownight for ships for ceipt: Ships for second day receipt wallabe: Drownight for ceipt valiable: Days of week overnight for ceipt: Days of week overnight for ships for ceipt files: Days of week overnight for ships for ceipt files: Days of week overnight for ceipt files: Days of week overnight for ceipt files: Days of week overnight for ceipt files: Days | | | | | | | |
| e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL. company / contact #: Name: Phone: Expedited Freight Carlanges or Other Designated Drop Ship Fees: Expedited Freight Carlanges or Other Designated Drop Ship Fees: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Drop Ship miscellaneous fees bi | | | Shipping lead time of PO: Hours Days | | | | |
| Minimum Order Quantity: Supplier's Coutement Service Number: Contracted 3PL company / contact #: Name: Phone: Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited freight (Fees pilled) with each order: Drop Ship service fee billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments: 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 to robspital, clinics, and physician offices only: Comments: Other Data Information Required to Process PO: Patient Procedure Data: Physician Clinic Pance # Physician Clinic Specially: Mitcellaneous Notes: Mitcellaneous Notes: Ships rescond day receipt: Overnight receipt available: Po Receipt Cut off time: Drop Repetited to robspit, clinics, and physician offices only: Po Receipt Cut off time: Po Receipt Cut off time: Saturday Overnight receipt available: Po Receipt Cut off time: Po Receipt Cut off time: Saturday Overnight receipt available: Po Receipt Cut off time: Order receipt method: Po Receipt Cut off time: Order receipt method: Ponce # Physician Clinic Specially: Other Data Information Required to Process PO: Return Instructions AbDitrional Information Is product order for scheduled patent procedure? AbDitrional Information Is product order for scheduled patent procedure? | , | | China annua dan faranat dan mariat | | | | |
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| Restricted from US territories? (explain in comments) Comments: Other Data Information Required to Process PO: Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician/Clinic DEA #: Physician/Clinic Specialty: Miscellaneous Notes: Miscellaneous Notes: ADDITIONAL INFORMATION Is product reduct patientou. Fax: EDI: Overnight Fees apply: Other fees a | | o offices only | Phone: Phone # | | | | |
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