



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

Version 2021 Introduction Type:  New Item  Final Version Date: 6/2/2023

**PRODUCT INFORMATION** **SPECIAL HANDLING AND STORAGE REQUIREMENTS\***

Company Name: Camber Pharmaceuticals, Inc. Application: ANDA  
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 216463  
 Medical Device Class, if applicable:  
 DUNS: 82-677-4775  
 Proprietary Name (If Applicable) and Established Name: Mexiletine HCl Capsules, USP 150mg  
 Selling Unit NDC: 31722-036-01 Unit of Use NDC: UPC: 331722036016  
 UDI: CVX Code: MVX Code:  
 Description: Mexiletine HCl Capsules, USP 150mg  
 Active Ingredient(s): Mexiletine HCl  
 URL for Additional Product Information: www.camberpharma.com  
 Address: 1031 Centennial Ave (and) 800 Centennial Ave, Suite 1 Address 2:  
 City: Piscataway State: NJ Zip: 08854  
 Key Contact: Customer Service Email: customerservice@camberpharma.com  
 Phone Number: 1-866-827-3647 Fax: 732-562-8788  
 Product Therapeutic Classification: Antiarrhythmic

**a. Temperature – Indicate the USP temperature range for this product.**  
 Temperature Range:   
 Other Temperature Range Requirement (write in):  
 Notes:  
 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?**  No  
 Special returns requirements for this product?  No  
**d. Store product (unit of sale) upright?**  No  
 Protect product (unit of sale) from light?  No  
**e. Shelf life:** Initial shelf life at launch (if different):  Months

| ADDITIONAL PRODUCT INFORMATION   |   | PRODUCT DESCRIPTION INFORMATION |                                |
|--|---|---------------------------------|--------------------------------|
| The product is a legend device? <input type="checkbox"/> No                                  | Is the Product... Direct-Ship Only <input type="checkbox"/>                               | Size:                           | 100ct                          |
| if yes, enter class # a product kit? <input type="checkbox"/> No                             | Is the Product... Neither <input type="checkbox"/>  | Strength:                       | 150mg                          |
| if yes, list NDCs of component parts reverse numbered? <input type="checkbox"/> No           | Orphan Drug Status <input type="checkbox"/>   | Dosage Form:                    | Hard gelatin capsule           |
| co-licensed? <input type="checkbox"/> No   | FDA Approval Status <input type="checkbox"/>  | Product Shape:                  | Size '2' Capsule               |
| latex-free? <input type="checkbox"/> Yes   | Allergens Present <input type="checkbox"/>  | Product Color:                  | White opaque/Light blue opaque |
| preservative-free? <input type="checkbox"/> Yes  | corn, animal products <input type="checkbox"/>  | Product Imprint:                | "V1" on cap and "30" on body   |
| correctional institution block? <input type="checkbox"/> No                                  | Country of Origin <input type="text" value="India"/>                                      |                                 |                                |
| opioid? <input type="checkbox"/> No  | Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No |                                 |                                |
| Cannabinoid? <input type="checkbox"/> No   |   |                                 |                                |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/> |   |                                 |                                |
| If Unit Dose, indicate NDC here: <input type="text"/>  |   |                                 |                                |

**ORDER INFORMATION**

| Unit of Sale                               | What is the NDC selling unit?                        |
|--|--|
| <input checked="" type="checkbox"/> Bottle | 1 bottle of 100 capsules                             |
| <input type="checkbox"/> Box/Carton        | (Write-in, e.g. 1 Box of 10 Vials)                   |
| <input type="checkbox"/> Ampule            |  |
| <input type="checkbox"/> Glass             | Minimum order quantity? <input type="checkbox"/> yes |
| <input type="checkbox"/> Tube              |  |
| <input type="checkbox"/> Vial Liquid Sgl   |  |
| <input type="checkbox"/> Vial Liquid Multi | If Yes, how many of which package type?              |
| <input type="checkbox"/> Vial Powder Sgl   | <input type="text" value="24"/> Each                 |
| <input type="checkbox"/> Vial Power Multi  | <input type="text"/> Inner/ Carton/Pack              |
| <input type="checkbox"/> Other: Write In   | <input type="text"/> Case                            |

**FOR GENERIC DRUG PRODUCTS**

I. Orange Book Rating:  Authorized Generic  \*If Authorized Generic, other section fields are not applicable  
 II. Generic Equivalent to What Brand?:

**PHARMACY ORDER / BILL UNIT**

Rec. sell unit to customer?  Rx billing unit to pharmacy:  
 (Write-in, e.g. 1 Vial)  Each   
 Gram   
 Milliliter

**DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION**

Does supplier meet DSCSA definition of manufacturer?  Yes  No  
 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?  Yes  No  
 Has FDA granted waiver/exception/exemption for product?  No  
 If yes, attach documentation from FDA.  
 GLN: 0331722000000  
 GCP:   
 If yes, was original product purchased direct from mfr?   
 Provide source manufacturer for repackaged product

**ITEM AND PACKING INFORMATION**

| Item/Each:                    | Weight Lbs. | Dimensions (US msmts.) |       |        | Volume (Cube) | Saleable # Pieces |
|-------------------------------|-------------|------------------------|-------|--------|---------------|-------------------|
|                               |             | Depth                  | Width | Height |               |                   |
| Item/Each:                    | 0.151       | 1.75                   | 1.75  | 4      | 12.25         | 1                 |
| Box/Carton/Bundle/Inner Pack: |             |                        |       |        |               |                   |
| Case:                         | 4.2         | 12                     | 8.5   | 5      | 510           | 24                |
| Pallet:                       |             |                        |       |        |               |                   |

**GTIN AND HIBCC PRODUCT INFORMATION**

| Saleable Unit of Measure                              | Saleable Quantity | HIBCC | GTIN-14        | Unit of Use GTIN-14 |
|---|-------------------|-------|----------------|---------------------|
| <input checked="" type="checkbox"/> Item/Each         | 1                 |       | 00331722036016 |                     |
| <input type="checkbox"/> Box/Carton/Bundle/Inner Pack |                   |       |                |                     |
| <input checked="" type="checkbox"/> Case              | 24                |       | 20331722036010 |                     |
| <input type="checkbox"/> Pallet                       |                   |       |                |                     |

**COST INFORMATION** **WHOLESALE USE ONLY:**

Regular Cost   
 Invoice Cost (WAC) (\$)   
 As of date: 3/23/2023  
 Vendor #:   
 Whsl. Code #:   
 Fineline Code:



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

Version 2021

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?  No
  - Does the product label bear a CA Prop 65 warning?  No

- c. Contact Hazard?  No
- d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)  No
- e. Does the product contain DEHP?  No

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
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?  No

Is this product regulated for shipment by IATA? (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?  No

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.
- 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  Yes
- Restricted to retail pharmacy only:  No
- Restricted to hospital, clinics, and physician offices only:  No
- Restricted from US territories? (explain in comments)  No

Comments:

### SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:   
NFPA Storage Level:

Is the product a NIOSH hazardous drug?  No  
If yes, indicate which:

### Hazardous Waste Identification

EPA Hazardous Waste Code:  Waste Characteristics:

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  No  
If Yes, is it managed with a pharmacy registry?   
Website URL:

Med Guide Required  No  
Limited Distribution Requirement   
Comments / Details: (For example, iPledge program?)

**REMS:**  No  
REMS Program Manager Name:  Phone:   
Supplier Manages REMS registry exclusively:   
Wholesale distributor support:   
Provider Name:  DEA #:   
Site Enrollment Number assigned by Supplier:  NCPDP#:   
NPI #:

Comments

**Registry:**  No  
Registry Program Contact Name:  Phone:   
Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:  1-866-827-3647

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:



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Version 2021

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   |
|--|---|
| <p>Purchase orders may be accepted by:</p> <ul style="list-style-type: none"> <li>a. EDI <input type="checkbox"/></li> <li>b. Autofax <input type="checkbox"/></li> <li>c. Fax <input type="checkbox"/></li> <li>d. Phone only <input type="checkbox"/></li> <li>e. Supplier Web Site only <input type="checkbox"/></li> </ul> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p> | <p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>  |
| Expedited Freight Charges or Other Designated Drop Ship Fees:  | Overnight and Priority Overnight PO Processing  |
| <p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>  | <p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Monday</li> <li><input type="checkbox"/> Tuesday</li> <li><input type="checkbox"/> Wednesday</li> <li><input type="checkbox"/> Thursday</li> <li><input type="checkbox"/> Friday</li> </ul> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p> |
| Class of Trade Restriction:  |   |
| <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>   |   |
| Other Data Information Required to Process PO:   | Return Instructions   |
| <p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>   | <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>  |
| Miscellaneous Notes:   |   |
| <p><input type="text"/></p>  | <p><b>ADDITIONAL INFORMATION</b></p> <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>  |