



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

Version 2021 Introduction Type:  New Item  Final Version Date: 5/29/2024

**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): 216749  
 Medical Device Class, if applicable:  
 DUNS: 11-856-3719  
 Proprietary Name (If Applicable) and Established Name: Oxcarbazepine Oral Suspension, USP 300 mg/5 mL  
 Selling Unit NDC: 31722-687-25 Unit of Use NDC: 31722-687-25 UPC: 331722687256  
 UDI: CVX Code: MVX Code:  
 Description: Oxcarbazepine Oral Suspension, USP 300 mg/5 mL  
 Active Ingredient(s): Oxcarbazepine, USP  
 URL for Additional Product Information: [www.camberpharma.com](http://www.camberpharma.com)  
 Address: 800 Centennial Ave, Suite 1 Address 2:  
 City: Piscataway State: NJ Zip: 08854  
 Key Contact: Customer Service Email: [customerservice@camberpharma.com](mailto:customerservice@camberpharma.com)  
 Phone Number: 1-866-827-3647 Fax: 732-562-8788  
 Product Therapeutic Classification: Antiepileptic

**a. Temperature – Indicate the USP temperature range for this product.**  
 Temperature Range:  Controlled Room – between 20 and 25 C (68° – 77° F)  
 Other Temperature Range Requirement (write in): Excursions permitted to 15°C to 30°C (59°F to 86°F)  
 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](mailto: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:**  24 Months  
 Initial shelf life at launch (if different):  Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class # a product kit?	<input type="checkbox"/> No	Is the Product... Direct-Ship Only	Size: 250 mL
if yes, list NDCs of component parts reverse numbered?	<input type="checkbox"/> No	Is the Product... Unit of Use	Strength: 300 mg/5 mL
co-licensed?	<input type="checkbox"/> No	Orphan Drug Status	Dosage Form: Oral suspension
latex-free?	<input type="checkbox"/> Yes	FDA Approval Status	Product Shape: N/A
preservative-free?	<input type="checkbox"/> No	Allergens Present	Product Color: Off-white to slightly brown or slightly red
correctional institution block? opioid?	<input type="checkbox"/> No	Alcohol	Product Imprint: N/A
Cannabinoid?	<input type="checkbox"/> No	Country of Origin	India
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/> No
If Unit Dose, indicate NDC here:			

**ORDER INFORMATION**

Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Bottle of 250 mL Oral Suspension
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input checked="" type="checkbox"/> Glass Tube	Minimum order quantity? <input type="checkbox"/> Yes
<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="checkbox"/> 12 Each
<input type="checkbox"/> Vial Powder Multi	<input type="checkbox"/> Inner/ Carton/ Pack
<input type="checkbox"/> Other: Write In	<input type="checkbox"/> Case

**FOR GENERIC DRUG PRODUCTS**

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

**PHARMACY ORDER / BILL UNIT**

Rec. sell unit to customer?  (Write-in, e.g. 1 Vial)  
 Rx billing unit to pharmacy:  
 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  
 Has FDA granted waiver/exception/exemption for product?  No  
 If yes, attach documentation from FDA.  
 GLN: 0331722498975  
 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:	1.16	3	3	6.75	60.75	1
Box/ Carton/ Bundle/ Inner Pack:						
Case:	14.4	12.25	9.25	7.25	821.52	12
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		00331722687256	00331722687256
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	12		30331722687257	
<input type="checkbox"/> Pallet				

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

Regular Cost  
 Invoice Cost (WAC) (\$) \$165.00  
 As of date: 1/24/2024  
 Vendor #:  
 Whsl. Code #:  
 Finline Code:



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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?  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  No
- 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  Yes      Controlled Substance Code
- Controlled by State(s)?  No  Yes      Listed Chemical (List I or II)  No  Yes
- ARCOS Reportable?  No  Yes      If yes, indicate which:
- Schedule No.       Is it a scheduled listed chemical product?:  No  Yes

### CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes  No
- Restricted to retail pharmacy only:  No  Yes
- Restricted to hospital, clinics, and physician offices only:  No  Yes
- Restricted from US territories? (explain in comments)  No  Yes

Comments:

### SDS Hazard Classification

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

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  No  Yes

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

### Hazardous Waste Identification

EPA Hazardous Waste Code:  Waste Characteristics:

### REMS or REGISTRY RESTRICTIONS

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

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

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

Comments

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

### RETURN INSTRUCTIONS

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

Is product returnable for credit:  No  Yes   
URL/Link to returns policy:

contact - customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states?  No  Yes

If so, which states? Other requirements? Comments?

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

