



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

Version 2021 Introduction Type:  New Item  Final Version Date: 3/5/2024

## PRODUCT INFORMATION

**Company Name:** Camber Pharmaceuticals, Inc. **Application:** ANDA

**Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):**

**Medical Device Class, if applicable:**

**DUNS:** 11-856-3719

**Proprietary Name (If Applicable) and Established Name:** Gabapentin Tablets (Once Daily) 600 mg

**Selling Unit NDC:** 31722-092-90 **Unit of Use NDC:** 31722-092-90 **UPC:** 331722092906

**UDI**

**CVX Code:** **MVX Code:**

**Description:** Gabapentin Tablets (Once Daily) 600 mg

**Active Ingredient(s):** Gabapentin

**URL for Additional Product Information:** [www.camberpharma.com](http://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](mailto:customerservice@camberpharma.com)

**Phone Number:** 1-866-827-3647 **Fax:** 732-562-8788

**Product Therapeutic Classification:** Anticonvulsant

## SPECIAL HANDLING AND STORAGE REQUIREMENTS\*

**a. Temperature – Indicate the USP temperature range for this product.**

Temperature Range:  Excursions permitted to 15° to 30°C (59° to 86°F)

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](mailto:somaraju@heterousa.com)

**c. Special regulations for product in any states?**  \*Yes  No

Special returns requirements for this product?

**d. Store product (unit of sale) upright?**  No

Protect product (unit of sale) from light?  No

**e. Shelf life:**  Months

Initial shelf life at launch (if different):  Months

## ADDITIONAL PRODUCT INFORMATION

**The product is?**

a legend device?  No

if yes, enter class #

a product kit?  No

if yes, list NDCs of component parts reverse numbered?

co-licensed?  No

latex-free?  Yes

preservative-free?  Yes

correctional institution block?  No

opioid?  No

Cannabinoid?  No

If Unit Dose, is item bar coded to unit dose for hospital scanning?

If Unit Dose, indicate NDC here:

**Is the Product... Direct-Ship Only**

**Is the Product... Unit of Use**

**Orphan Drug Status**

**FDA Approval Status**

**Allergens Present** Soy

**Country of Origin** India

Is this product covered under the Trade Agreements Act (TAA)?  No

## PRODUCT DESCRIPTION INFORMATION

**Size:** 90 ct

**Strength:** 600 mg

**Dosage Form:** Film coated tablet

**Product Shape:** Oval

**Product Color:** Yellow

**Product Imprint:** Debossed with "G7" on one side and "V1" on other side

## ORDER INFORMATION

**Unit of Sale**

Bottle

Box/Carton

Ampule

Glass

Tube

Vial Liquid Sgl

Vial Liquid Multi

Vial Powder Sgl

Vial Power Multi

Other: Write In

**What is the NDC selling unit?** 1 Bottle of 90 Tablets (Write-in, e.g. 1 Box of 10 Vials)

**Minimum order quantity?**  Yes

**If Yes, how many of which package type?**

Each

Inner/ Carton/ Pack

Case

## FOR GENERIC DRUG PRODUCTS

Authorized Generic \*If Authorized Generic, other section fields are not applicable

**I. Orange Book Rating:** AB2

**II. Generic Equivalent to What Brand?:** Gralise

## 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?**

**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?**

**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:	0.29	2.21	2.21	4.7	22.96	1
Box/ Carton/ Bundle/ Inner Pack:						
Case:	7.8	13.25	9.25	5.75	704.73	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		00331722092906	00331722092906
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	24		20331722092900	
<input type="checkbox"/> Pallet				

## COST INFORMATION

**Regular Cost**

**Invoice Cost (WAC) (\$)** \$250.00

**As of date:** 3/1/2024

**WHOLESALE USE ONLY:**

**Vendor #:**

**Whsl. Code #:**

**Fineline Code:**



# 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?  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  Yes
- Controlled Substance Code
- Controlled by State(s)?  Yes  No
- Listed Chemical (List I or II)  No
- ARCOS Reportable?  No
- If yes, indicate which:
- Schedule No.
- 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:  No  
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?  Yes

If so, which states? Other requirements? Comments?

This product is classified as a schedule V controlled substance in Alabama, Kentucky, Michigan, North Dakota, Tennessee, Virginia, and West Virginia

### MISCELLANEOUS 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
<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>	<p><b>Return Instructions</b></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>
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION
<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>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>
Miscellaneous Notes:	
<p><input type="text"/></p>	