



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

Version 2024

Introduction Type:  Post Launch Change

Final Version

Date: 7/22/2024

PRODUCT INFORMATION	
Company Name:	Camber Pharmaceuticals, Inc.
Application Number for NDA/ANDA/BLA; PMA/510(k):	206912
Application:	ANDA
Medical Device Class, if applicable:	
DUNS:	11-856-3719
Proprietary Name (If Applicable) and Established Name:	Pregabalin Capsules 225 mg
Selling Unit NDC:	31722-616-90
Unit of Use NDC:	31722-616-90
UPC:	331722616904
CVX Code:	
MXV Code:	
Description:	Pregabalin Capsules 225 mg
Active Ingredient(s):	Pregabalin
URL for Additional Product Information:	<a href="http://www.camberpharma.com">www.camberpharma.com</a>
Address:	800 Centennial Ave, Suite 1
City:	Piscataway
Key Contact:	Customer Service
Phone Number:	1-866-827-3647
Product Therapeutic Classification:	Anticonvulsant neuropathic pain agent

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	
Notes	
Is this product to be shipped to customers on ice?	<input type="checkbox"/> No
Is this product to be shipped to customers on dry ice?	<input type="checkbox"/> No
<b>b. Contact for temperature excursion questions:</b>	
Name:	Soma Raju
Number:	732-529-0423
Group E-mail:	<a href="mailto:somaraju@heterousa.com">somaraju@heterousa.com</a>
<b>c. Special regulations for product in any states?</b>	
Special returns requirements for this product?	<input type="checkbox"/> *Yes <input type="checkbox"/> No
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	<input type="checkbox"/> No
<b>e. Shelf life:</b>	<input type="checkbox"/> 24 Months
Initial shelf life at launch (if different):	<input type="checkbox"/> Months

ADDITIONAL PRODUCT INFORMATION	PRODUCT DESCRIPTION INFORMATION
The product is? a legend device? <input type="checkbox"/> No	Size: 90 ct
if yes, enter class #	Strength: 225 mg
a product kit? <input type="checkbox"/> No	Dosage Form: Hard gelatin capsule
if yes, list NDCs of component parts	Product Shape: Capsule
reverse numbered? <input type="checkbox"/> No	Product Color: Light peach opaque cap and white opaque body
co-licensed? <input type="checkbox"/> No	Product Imprint: Imprinted with '144' on cap and 'J' on body with black ink
latex-free? <input type="checkbox"/> Yes	
preservative-free? <input type="checkbox"/> Yes	
correctional institution block? <input type="checkbox"/> No	
opioid? <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="checkbox"/>	
Is the Product... Is the Product... Orphan Drug Status <input type="checkbox"/>	
FDA Approval Status <input type="checkbox"/>	
Allergens Present Corn, Sugar, Alcohol	
Country of Origin USA	
Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> Yes	

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Bottle of 90 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="checkbox"/> 24 Each
<input type="checkbox"/> Vial Powder Multi	<input type="checkbox"/> Inner/Carton/Pack
Other: Write In	<input type="checkbox"/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating: AB	<input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable
II. Generic Equivalent to What Brand?: Lyrica	

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="checkbox"/>	<input type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
HCPCS J-Code:	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes	GLN: 0860000397957
Is product exempt from DSCSA? <input type="checkbox"/> No	GCP: <input type="checkbox"/>
If yes, select exemption: Other exemption - Write in: <input type="checkbox"/>	
Is product repackaged? <input type="checkbox"/> No	If yes, was original product purchased direct from mfr? <input type="checkbox"/>
Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> Yes	Provide source manufacturer for repackaged product <input type="checkbox"/>
Has FDA granted waiver/exception/exemption for product? <input type="checkbox"/> No	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/Carton/Bundle/Inner Pack:	0.09	1.65	1.65	3.1	8	1
Case:	2.75	10.5	7	4.5	331	24
Pallet:						

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14
<input checked="" type="checkbox"/> Item/Each	N	1		00331722616904
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	N	24		30331722616905
<input type="checkbox"/> Pallet				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$10.50	Whsl. Code #:	
As of date:	9/1/2021	Fineline Code:	

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

\*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature: \_\_\_\_\_



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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?  Yes  No  Controlled Substance Code
- Controlled by State(s)?  Yes  No  Listed Chemical (List I or II)  No
- ARCOS Reportable?  Yes  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  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

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

### 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?   
Website URL:

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

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

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit:  Yes  No

URL/Link to returns policy:

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:

\*Storage of this product must abide by the federally mandated DEA requirements outlined in 21 CFR Part 1301.72.

