



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

Version 2024

Introduction Type: Post Launch Change

x Final Version

Date: 12/30/2024

| PRODUCT INFORMATION                                                                                           |                    |                                                                      |                          | SPECIAL HANDLING AND STORAGE REQUIREMENTS*                                                                  |                      |                                                                                         |  |
|---------------------------------------------------------------------------------------------------------------|--------------------|----------------------------------------------------------------------|--------------------------|-------------------------------------------------------------------------------------------------------------|----------------------|-----------------------------------------------------------------------------------------|--|
| <b>Company Name:</b> Camber Pharmaceuticals, Inc.                                                             |                    |                                                                      |                          | <b>Application:</b> ANDA                                                                                    |                      |                                                                                         |  |
| <b>Application Number for NDA/ANDA/BLA; PMA/510(k):</b> 206912                                                |                    |                                                                      |                          | <b>NDA 505(b) Type:</b> NOT APPLICABLE                                                                      |                      |                                                                                         |  |
| <b>Medical Device Class, if applicable:</b>                                                                   |                    |                                                                      |                          |                                                                                                             |                      |                                                                                         |  |
| <b>DUNS:</b> 11-856-3719                                                                                      |                    |                                                                      |                          |                                                                                                             |                      |                                                                                         |  |
| <b>Proprietary Name (If Applicable) and Established Name:</b> Pregabalin Capsules 225 mg                      |                    |                                                                      |                          |                                                                                                             |                      |                                                                                         |  |
| <b>Selling Unit NDC:</b> 31722-616-90                                                                         |                    |                                                                      |                          | <b>Unit of Use NDC:</b> 31722-616-90                                                                        |                      | <b>UPC:</b> 331722616904                                                                |  |
| <b>UDI</b>                                                                                                    |                    |                                                                      |                          | <b>CVX Code:</b>                                                                                            |                      | <b>MVX Code:</b>                                                                        |  |
| <b>Description:</b> Pregabalin Capsules 225 mg                                                                |                    |                                                                      |                          |                                                                                                             |                      |                                                                                         |  |
| <b>Active Ingredient(s):</b> Pregabalin                                                                       |                    |                                                                      |                          |                                                                                                             |                      |                                                                                         |  |
| <b>URL for Additional Product Information:</b> <a href="http://www.camberpharma.com">www.camberpharma.com</a> |                    |                                                                      |                          |                                                                                                             |                      |                                                                                         |  |
| <b>Address:</b> 800 Centennial Ave, Suite 1                                                                   |                    |                                                                      |                          | <b>Address 2:</b>                                                                                           |                      |                                                                                         |  |
| <b>City:</b> Piscataway                                                                                       |                    |                                                                      |                          | <b>State:</b> NJ                                                                                            |                      | <b>Zip:</b> 08854                                                                       |  |
| <b>Key Contact:</b> Customer Service                                                                          |                    |                                                                      |                          | <b>Email:</b> <a href="mailto:customerservice@camberpharma.com">customerservice@camberpharma.com</a>        |                      | <b>Group E-mail:</b> <a href="mailto:somaraju@heterousa.com">somaraju@heterousa.com</a> |  |
| <b>Phone Number:</b> 1-866-827-3647                                                                           |                    |                                                                      |                          | <b>Fax:</b> 732-562-8788                                                                                    |                      |                                                                                         |  |
| <b>Product Therapeutic Classification:</b> Anticonvulsant neuropathic pain agent                              |                    |                                                                      |                          |                                                                                                             |                      |                                                                                         |  |
| ADDITIONAL PRODUCT INFORMATION                                                                                |                    |                                                                      |                          | PRODUCT DESCRIPTION INFORMATION                                                                             |                      |                                                                                         |  |
| <b>The product is?</b>                                                                                        |                    | <b>Is the Product...</b>                                             |                          | <b>Size:</b>                                                                                                |                      | <b>90 ct</b>                                                                            |  |
| <b>a legend device?</b>                                                                                       |                    | <b>Is the Product...</b>                                             |                          | <b>Strength:</b>                                                                                            |                      | <b>225 mg</b>                                                                           |  |
| <b>if yes, enter class #</b>                                                                                  |                    | <b>Orphan Drug Status</b>                                            |                          | <b>Dosage Form:</b>                                                                                         |                      | <b>Hard gelatin capsule</b>                                                             |  |
| <b>a product kit?</b>                                                                                         |                    |                                                                      |                          | <b>Product Shape:</b>                                                                                       |                      | <b>Capsule</b>                                                                          |  |
| <b>if yes, list NDCs of component parts</b>                                                                   |                    | <b>FDA Approval Status</b>                                           |                          | <b>Product Color:</b>                                                                                       |                      | <b>Light peach opaque cap and white opaque body</b>                                     |  |
| <b>reverse numbered?</b>                                                                                      |                    |                                                                      |                          | <b>Product Imprint:</b>                                                                                     |                      | <b>Imprinted with '144' on cap and 'J' on body with black ink</b>                       |  |
| <b>co-licensed?</b>                                                                                           |                    | <b>Allergens Present</b>                                             |                          |                                                                                                             |                      |                                                                                         |  |
| <b>latex-free?</b>                                                                                            |                    | <b>Corn, Sugar, Alcohol</b>                                          |                          |                                                                                                             |                      |                                                                                         |  |
| <b>preservative-free?</b>                                                                                     |                    | <b>Country of Origin</b>                                             |                          | <b>USA</b>                                                                                                  |                      |                                                                                         |  |
| <b>correctional institution block?</b>                                                                        |                    |                                                                      |                          |                                                                                                             |                      |                                                                                         |  |
| <b>opioid?</b>                                                                                                |                    |                                                                      |                          |                                                                                                             |                      |                                                                                         |  |
| <b>Cannabinoid?</b>                                                                                           |                    |                                                                      |                          |                                                                                                             |                      |                                                                                         |  |
| <b>If Unit Dose, is item bar coded to unit dose for hospital scanning?</b>                                    |                    | <b>Is this product covered under the Trade Agreements Act (TAA)?</b> |                          | <b>Yes</b>                                                                                                  |                      |                                                                                         |  |
| <b>If Unit Dose, indicate NDC here:</b>                                                                       |                    |                                                                      |                          |                                                                                                             |                      |                                                                                         |  |
| FOR GENERIC DRUG PRODUCTS                                                                                     |                    |                                                                      |                          |                                                                                                             |                      |                                                                                         |  |
| <b>I. Orange Book Rating:</b> AB                                                                              |                    |                                                                      |                          | <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable |                      |                                                                                         |  |
| <b>II. Generic Equivalent to What Brand?:</b> Lyrica                                                          |                    |                                                                      |                          |                                                                                                             |                      |                                                                                         |  |
| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION                                                            |                    |                                                                      |                          |                                                                                                             |                      |                                                                                         |  |
| <b>Does supplier meet DSCSA definition of manufacturer?</b>                                                   |                    |                                                                      |                          | <b>GLN:</b> 0843368117603                                                                                   |                      |                                                                                         |  |
| <b>Is product exempt from DSCSA?</b>                                                                          |                    |                                                                      |                          |                                                                                                             |                      |                                                                                         |  |
| <b>If yes, select exemption:</b>                                                                              |                    |                                                                      |                          | <b>GCP:</b>                                                                                                 |                      |                                                                                         |  |
| <b>Other exemption - Write in:</b>                                                                            |                    |                                                                      |                          |                                                                                                             |                      |                                                                                         |  |
| <b>Is product repackaged?</b>                                                                                 |                    |                                                                      |                          | <b>If yes, was original product purchased direct from mfr?</b>                                              |                      |                                                                                         |  |
| <b>Is product sold by manufacturer's exclusive distributor?</b>                                               |                    |                                                                      |                          | <b>Provide source manufacturer for repackaged product</b>                                                   |                      |                                                                                         |  |
| <b>Has FDA granted waiver/exception/exemption for product?</b>                                                |                    |                                                                      |                          |                                                                                                             |                      |                                                                                         |  |
| <b>If yes, attach documentation from FDA.</b>                                                                 |                    |                                                                      |                          |                                                                                                             |                      |                                                                                         |  |
| GTIN AND HIBCC PRODUCT INFORMATION                                                                            |                    |                                                                      |                          |                                                                                                             |                      |                                                                                         |  |
| <b>Saleable Unit of Measure</b>                                                                               |                    | <b>RFID tag(Y/N)</b>                                                 | <b>Saleable Quantity</b> | <b>HIBCC</b>                                                                                                | <b>GTIN-14</b>       | <b>Unit of Use GTIN-14</b>                                                              |  |
| <input checked="" type="checkbox"/> Item/Each                                                                 |                    | N                                                                    | 1                        |                                                                                                             | 00331722616904       | 00331722616904                                                                          |  |
| <input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack                                           |                    | N                                                                    | 24                       |                                                                                                             | 30331722616905       |                                                                                         |  |
| <input checked="" type="checkbox"/> Case                                                                      |                    |                                                                      |                          |                                                                                                             |                      |                                                                                         |  |
| <input checked="" type="checkbox"/> Pallet                                                                    |                    |                                                                      |                          |                                                                                                             |                      |                                                                                         |  |
| <b>ITEM AND PACKING INFORMATION</b>                                                                           |                    |                                                                      |                          |                                                                                                             |                      |                                                                                         |  |
|                                                                                                               | <b>Weight Lbs.</b> | <b>Dimensions (US msmts.)</b>                                        |                          |                                                                                                             | <b>Volume (Cube)</b> | <b>Saleable # Pieces</b>                                                                |  |
|                                                                                                               |                    | <b>Depth</b>                                                         | <b>Width</b>             | <b>Height</b>                                                                                               |                      |                                                                                         |  |
| <b>Item/Each:</b>                                                                                             | 0.09               | 1.65                                                                 | 1.65                     | 3.1                                                                                                         | 8                    | 1                                                                                       |  |
| <b>Box/ Carton/ Bundle/ Inner Pack:</b>                                                                       |                    |                                                                      |                          |                                                                                                             |                      |                                                                                         |  |
| <b>Case:</b>                                                                                                  | 2.75               | 10.5                                                                 | 7                        | 4.5                                                                                                         | 331                  | 24                                                                                      |  |
| <b>Pallet:</b>                                                                                                |                    |                                                                      |                          |                                                                                                             |                      |                                                                                         |  |
| COST INFORMATION                                                                                              |                    |                                                                      |                          | WHOLESALE USE ONLY:                                                                                         |                      |                                                                                         |  |
| <b>Regular Cost</b>                                                                                           |                    |                                                                      |                          | <b>Vendor #:</b>                                                                                            |                      |                                                                                         |  |
| <b>Invoice Cost (WAC) (\$)</b>                                                                                |                    | \$10.50                                                              |                          | <b>Whsl. Code #:</b>                                                                                        |                      |                                                                                         |  |
| <b>As of date:</b> 9/1/2021                                                                                   |                    |                                                                      |                          | <b>Fineline Code:</b>                                                                                       |                      |                                                                                         |  |

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

See new p. 3 for Designated Drop Ship Only.

Signature:

\*Please provide any additional information on page 2.



# 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?
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  
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?

- 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?

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?

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?

Is the product restricted for air shipment? If so, indicate restriction:

- Passenger  
 Cargo  
 Passenger & Cargo

Is this a reportable quantity?

RQ Threshold:

Is this a marine pollutant?

Is this product shipped utilizing an authorized DOT exception or Special Permit?

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

### CLASS OF TRADE RESTRICTION:

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 from US territories? (explain in comments)

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?  
If yes, indicate which:

### Hazardous Waste Identification

EPA Hazardous Waste Code:

Waste Characteristics

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required

Limited Distribution Requirement

Comments / Details: (For example, iPledge program?)

#### REMS:

REMS Program Manager Name:

Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

DEA #:

Site Enrollment Number assigned

NCPDP#:

by Supplier:

NPI #:

Comments

#### Registry:

Registry Program Contact Name:

Phone:

Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit:

URL/Link to returns policy:

contact - customerservice@camberpharma.com

Special regulations or returns requirements for this  
product in certain states?

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.

Release DATE



# 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.

| Order Method for Designated Drop Ship Product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Standard Order Receipt and Processing                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/></p> <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>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <p><b>Expedited Freight Charges or Other Designated Drop Ship Fees:</b></p> <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 and Priority Overnight PO Processing</b></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> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <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> |
| <p><b>Class of Trade Restriction:</b></p> <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>Other Data Information Required to Process PO:</b></p> <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><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>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <p><b>Miscellaneous Notes:</b></p> <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>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |