



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

Version 2024

Introduction Type: New Item

☒ Final Version

Date: 12/31/2024

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Camber Pharmaceuticals, Inc.				Application: ANDA			
Application Number for NDA/ANDA/BLA; PMA/510(k): 206912				NDA 505(b) Type: NOT APPLICABLE			
Medical Device Class, if applicable:							
DUNS: 11-856-3719							
Proprietary Name (If Applicable) and Established Name: Pregabalin Capsules 100 mg							
Selling Unit NDC: 31722-613-05				Unit of Use NDC:			
UDI				UPC: 331722613057			
CVX Code:				MVX Code:			
Description: Pregabalin Capsules 100 mg							
Active Ingredient(s): Pregabalin							
URL for Additional Product Information: 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			
Phone Number: 1-866-827-3647				Fax: 732-562-8788			
Product Therapeutic Classification: Anticonvulsant neuropathic pain agent							
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is?		Is the Product...		Size:		500 ct	
a legend device?		Is the Product...		Strength:		100 mg	
if yes, enter class #		Orphan Drug Status		Dosage Form:		Hard gelatin capsule	
a product kit?				Product Shape:		Capsule	
if yes, list NDCs of component parts		FDA Approval Status		Product Color:		Light peach opaque cap and light peach opaque body	
reverse numbered?				Product Imprint:		Imprinted with '141' on cap and 'J' on body with black ink	
co-licensed?							
latex-free?							
preservative-free?							
correctional institution block?							
opioid?							
Cannabinoid?							
If Unit Dose, is item bar coded to unit dose for hospital scanning?		Country of Origin India					
If Unit Dose, indicate NDC here:		Is this product covered under the Trade Agreements Act (TAA)? No					
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?: Lyrica							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? Yes				GLN: 0843368117603			
Is product exempt from DSCSA? No							
If yes, select exemption:				GCP:			
Other exemption - Write in:							
Is product repackaged? No				If yes, was original product purchased direct from mfr?			
Is product sold by manufacturer's exclusive distributor? Yes				Provide source manufacturer for repackaged product			
Has FDA granted waiver/exception/exemption for product? No							
If yes, attach documentation from FDA.							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure		RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14	
☒ Item/Each		N	1		00331722613057		
☒ Box/ Carton/ Bundle/ Inner Pack		N	12		20331722613051		
☒ Case							
☒ Pallet							
ITEM AND PACKING INFORMATION							
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces	
		Depth	Width	Height			
Item/Each:	0.35	2.5	2.5	4.8	30	1	
Box/ Carton/ Bundle/ Inner Pack:							
Case:	4.8	10.6	8.8	5.9	550	12	
Pallet:							
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost				Vendor #:			
Invoice Cost (WAC) (\$)				Whsl. Code #:			
				Fineline Code:			
As of date: 5/25/2022							

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?
- 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? | <input type="text" value="Yes"/> | Controlled Substance Code | <input type="text" value="2782"/> |
| Controlled by State(s)? | <input type="text" value="Yes"/> | Listed Chemical (List I or II) | <input type="text" value="No"/> |
| ARCOS Reportable? | <input type="text" value="Yes"/> | If yes, indicate which: | <input type="text"/> |
| Schedule No. | <input type="text" value="5"/> | Is it a scheduled listed chemical product?: | <input type="text" value="No"/> |

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 | <input type="text" value="Corrosive"/> |
| ☐ Inorganic | <input type="text" value="Oxidizer"/> |
| ☐ Steroid/Androgen | <input type="text" value="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:

Supplier Manages REMS registry exclusively:

Phone:

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:

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



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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
Purchase orders may be accepted by: a. EDI ☐ b. Autofax ☐ c. Fax ☐ d. Phone only ☐ e. Supplier Web Site only ☐ Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone: Fax Number: Fax Number: Phone No.: Site Address:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships same day for next day receipt: ☐ Ships for second day receipt: ☐ Ships regular ground for 3-10 days receipt: ☐
Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight and Priority Overnight PO Processing Overnight receipt available: ☐ PO Receipt cut off time: Days of week overnight is available: ☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday Priority Overnight receipt available: ☐ PO Receipt Cut off time: Saturday Overnight receipt available: ☐ PO Receipt Cut off time: Order receipt method: Phone: Phone #: Fax: Fax #: EDI: Overnight Fees apply: ☐ Other fees apply: ☐
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:	
Other Data Information Required to Process PO: Patient Procedure Date: Physician Name: Physician/Clinic Phone #: Physician State License #: Physician/Clinic DEA #: Physician/Clinic Specialty:	Return Instructions Contact # if product is received damaged: Is product returnable for credit: ☐ URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? ☐ If so, which states? Other requirements? Comments?
Miscellaneous Notes:	ADDITIONAL INFORMATION Is product order for scheduled patient procedure? ☐ Is product order for restocking purposes? ☐