



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

Version 2024

Introduction Type: New Item

☒ Final Version

Date: 11/25/2024

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: Camber Pharmaceuticals, Inc.				Application: ANDA			
Application Number for NDA/ANDA/BLA; PMA/510(k): 214957				NDA 505(b) Type: NOT APPLICABLE			
Medical Device Class, if applicable:							
DUNS: 11-856-3719							
Proprietary Name (If Applicable) and Established Name: Gabapentin Tablets, USP 600 mg							
Selling Unit NDC: 31722-166-01				Unit of Use NDC:			
UDI				UPC: 331722166010			
CVX Code:				MVX Code:			
Description: Gabapentin Tablets, USP 600 mg							
Active Ingredient(s): Gabapentin, USP							
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							
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is?		Is the Product...		Size:			
a legend device?		Direct-Ship Only		100 ct			
if yes, enter class #		Neither		600 mg			
a product kit?		Orphan Drug Status		Strength:			
if yes, list NDCs of component parts				Film coated tablet			
reverse numbered?		FDA Approval Status		Dosage Form:			
co-licensed?				Oval, biconvex			
latex-free?		Allergens Present		Product Color:			
preservative-free?		Corn, Alcohol, Wheat		White			
correctional institution block?		Country of Origin		Product Imprint:			
opioid?		USA		Debossed with "1" on the left side of the tablet and "1" on the right side of the tablet on one side and tablet on other side			
Cannabinoid?		Is this product covered under the Trade Agreements Act (TAA)?		Yes			
If Unit Dose, is item bar coded to unit dose for hospital scanning?							
If Unit Dose, indicate NDC here:							
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?: Neurontin							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer?				GLN:			
Is product exempt from DSCSA?				0331722498975 shipments to non-controlled substance states			
If yes, select exemption:				0843368117603 shipments to controlled substance states			
Other exemption - Write in:				GCP:			
Is product repackaged?				If yes, was original product purchased			
Is product sold by manufacturer's exclusive distributor?				direct from mfr?			
Has FDA granted waiver/exception/exemption for product?				Provide source manufacturer for repackaged product			
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		00331722166010		
☒ Box/ Carton/ Bundle/ Inner Pack		N	24		10331722166017		
☒ Case							
☒ Pallet							
ITEM AND PACKING INFORMATION							
	Weight Lbs.	Dimensions (US msmts.)	Volume (Cube)	Saleable # Pieces			
		Depth	Width	Height			
Item/Each:	0.26	2.2	2.2	4	19.36	1	
Box/ Carton/ Bundle/ Inner Pack:							
Case:	6.85	14.5	10.25	4.75	705.97	24	
Pallet:							
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost				Vendor #:			
Invoice Cost (WAC) (\$)				Whsl. Code #:			
As of date: 11/18/2021				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?	No		
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?			
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:		No	
☐ 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	Controlled Substance Code	
Controlled by State(s)?	Yes	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		☐ Corrosive	
☐ Inorganic		☐ Oxidizer	
☐ Steroid/Androgen		☐ 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, North Dakota, Utah, Tennessee, Virginia, and West Virginia.			
MISCELLANEOUS NOTES and/or Image of Product Barcode:			

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? ☐