



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

Version 2021 Introduction Type: Final Version Date:

PRODUCT INFORMATION		SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
Company Name:	Camber Pharmaceuticals, Inc.	Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	214956		
Medical Device Class, if applicable:			
DUNS:	11-856-3719		
Proprietary Name (If Applicable) and Established Name:	Gabapentin Capsules, USP 100 mg		
Selling Unit NDC:	31722-148-05	Unit of Use NDC:	
UDI		CVX Code:	
		UPC:	331722148054
		MVX Code:	
Description:	Gabapentin Capsules, USP 100 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
Key Contact:	Customer Service	Zip:	08854
Phone Number:	1-866-827-3647	Email:	customerservice@camberpharma.com
Product Therapeutic Classification:	Anticonvulsant	Fax:	732-562-8788

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

Temperature Range

Other Temperature Range Requirement (write in)

Notes

Is this product to be shipped to customers on ice?

Is this product to be shipped to customers on dry ice?

b. Contact for temperature excursion questions:

Name:

Number:

Group E-mail:

c. Special regulations for product in any states?

Special returns requirements for this product?

d. Store product (unit of sale) upright?

Protect product (unit of sale) from light?

e. Shelf life: Months

Initial shelf life at launch (if different): Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class #	<input type="text" value="No"/>	Is the Product... Direct-Ship Only	<input type="text"/>
a product kit? if yes, list NDCs of component parts reverse numbered?	<input type="text" value="No"/>	Is the Product... Orphan Drug Status	<input type="text" value="Neither"/>
co-licensed?	<input type="text" value="No"/>	FDA Approval Status	<input type="text"/>
latex-free?	<input type="text" value="No"/>	Allergens Present	<input type="text" value="Corn, Alcohol, Animal, Wheat"/>
preservative-free?	<input type="text" value="Yes"/>	Country of Origin	<input type="text" value="India"/>
correctional institution block? opioid?	<input type="text" value="No"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>
Cannabinoid?	<input type="text" value="No"/>		
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>		
If Unit Dose, indicate NDC here:	<input type="text"/>		
		Size:	<input type="text" value="500 ct"/>
		Strength:	<input type="text" value="100 mg"/>
		Dosage Form:	<input type="text" value="Hard gelatin capsule"/>
		Product Shape:	<input type="text" value="Capsule"/>
		Product Color:	<input type="text" value="White opaque cap and white opaque body"/>
		Product Imprint:	<input type="text" value="Imprinted with 'A' on cap and '469' on body in black ink"/>

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 Bottle of 500 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="text" value="Yes"/>
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	If Yes, how many of which package type?
<input type="checkbox"/> Vial Liquid Multi	<input type="text" value="12"/> Each
<input type="checkbox"/> Vial Powder Sgl	<input type="text"/> Inner/ Carton/Pack
<input type="checkbox"/> Vial Powder Multi	<input type="text"/> Case
<input type="checkbox"/> Other: Write In	

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

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

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="text" value="Yes"/>
Is product exempt from DSCSA?	<input type="text" value="No"/>
If yes, select exemption: Other exemption - Write in:	<input type="text"/>
Is product repackaged?	<input type="text" value="No"/>
Is product sold by manufacturer's exclusive distributor?	<input type="text" value="Yes"/>
Has FDA granted waiver/exception/exemption for product? If yes, attach documentation from FDA.	<input type="text" value="No"/>
GLN:	<input type="text" value="0331722498975 shipments to non-controlled substance states 0860000397957 shipments to controlled substance states"/>
GCP:	<input type="text"/>
If yes, was original product purchased direct from mfr?	<input type="text"/>
Provide source manufacturer for repackaged product	<input type="text"/>

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/ Carton/ Bundle/ Inner Pack:						
Case:	4.9	11.5	8.75	7.5	754.69	12
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		00331722148054	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	12		20331722148058	
<input type="checkbox"/> Pallet				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text"/>	Vendor #:	<input type="text"/>
Invoice Cost (WAC) (\$)	<input type="text" value="\$25.00"/>	Whsl. Code #:	<input type="text"/>
As of date:	<input type="text" value="10/1/2021"/>	Fineline Code:	<input type="text"/>



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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 Yes
- ARCOS Reportable? No Yes If yes, indicate which:
- Schedule No. Is it a scheduled listed chemical product?: No Yes

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	
<input checked="" type="checkbox"/> Organic	<input type="checkbox"/> Corrosive
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard
Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="text"/>	No <input type="checkbox"/>
NFPA Storage Level: <input type="text"/>	
Is the product a NIOSH hazardous drug? If yes, indicate which: <input type="text"/>	No <input type="checkbox"/>

Hazardous Waste Identification	
EPA Hazardous Waste Code: <input type="text"/>	Waste Characteristics <input type="text"/>

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product? <input type="checkbox"/> No <input type="checkbox"/> Yes	
If Yes, is it managed with a pharmacy registry? <input type="checkbox"/> No <input type="checkbox"/> Yes	
Website URL: <input type="text"/>	
Med Guide Required <input type="checkbox"/> No <input type="checkbox"/> Yes	
Limited Distribution Requirement <input type="checkbox"/> No <input type="checkbox"/> Yes	
Comments / Details: (For example, iPledge program?) <input type="text"/>	
REMS:	
REMS Program Manager Name: <input type="text"/>	Phone: <input type="text"/>
Supplier Manages REMS registry exclusively: <input type="checkbox"/> No <input type="checkbox"/> Yes	
Wholesale distributor support: <input type="text"/>	
Provider Name: <input type="text"/>	DEA #: <input type="text"/>
Site Enrollment Number assigned by Supplier: <input type="text"/>	NCPDP#: <input type="text"/>
	NPI #: <input type="text"/>
Comments <input type="text"/>	
Registry:	
Registry Program Contact Name: <input type="text"/>	Phone: <input type="text"/>
Comments <input type="text"/>	

RETURN INSTRUCTIONS	
Contact tel. # if product received damaged: <input type="text"/>	1-866-827-3647
Is product returnable for credit: <input type="checkbox"/> No <input type="checkbox"/> Yes	
URL/Link to returns policy: <input type="text"/>	contact - customerservice@camberpharma.com
Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> No <input type="checkbox"/> Yes	
If so, which states? Other requirements? Comments? <input type="text"/>	
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:



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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 <input type="checkbox"/> b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/> c. Fax <input type="checkbox"/> Fax Number: <input type="text"/> d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/> e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/>	Purchase order daily receipt cut off time by supplier Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/>	Overnight receipt available: <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday Priority Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Saturday Overnight receipt available: <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/>
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/>	
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/>	Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<input type="text"/>	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>