

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

Version 2024						Introduction Type	: New Item		x Final Version			Date:	10/23	/2025
			PRODUCT INFORMAT	ION					SPECIAL HAN	IDLING AND STOR	AGE REQUIR	REMENTS*		
Company Name:	Camber Pharmaceuticals, Inc.				Application: ANDA		a. Temperature – Indicate the USP temperature range for the			his product				
Application Number for NDA/ANI						NDA 505(b) Type:	NOT APPLICABLE		Temperature Range Store at 25°C (77°F)					
Medical Device Class, if applicab	le:								· -					
DUNS:	11-856-3719	'							Other Temperature Range F	Requirement	Excursions p	ermitted betv	veen 15° to 30	0°C (59° to
Proprietary Name (If Applicable) a		ame: Gabaper	ntin Tablets, USP 600 mg						(write in)		86°F)			
Selling Unit NDC:	31722-166-05		Unit of Use NDC:				1722166058		Notes					
UDI			CVX Code:			MVX Code:								
Description: Gabapentin Tablets, USP 600 mg								Is this product to be shipped	ce?		No			
									Is this product to be shipped	d to customers on d	Iry ice?		No	
Active Ingredient(s): Gabapentin, USP														
								temperature excursion que	estions:	Soma Raju				
URL for Additional Product Inform Address:		on: www.camberpharma.com 0 Centennial Ave, Suite 1			Address 2:				Name: Number:		732-529-042	3		
City:	Piscataway	ve, ouite i			State: NJ Zip: 08854				Group E-mail:		somaraju@h		n	
Key Contact:	Customer Service	9			Email:				or oup = mam				_	
Phone Number:	1-866-827-3647				Fax:				c. Special regulations for product in any states?				*Yes	
Product Therapeutic Classification	):	Anticonvulsant						'	Special returns requirement	ts for this product?			No	
•														
	ADDITI	IONAL PRODUCT INFO	DRMATION		PRODUCT DESCRIPTION INFORMATION			d. Store product (unit of sale) upright?			No			
The product is?			Is the Product	Direct-Ship Or	nly				Protect product (unit of sa	ale) from light?			No	
a legend device?		No	Is the Product	Neither		Ci	500 ct	e. Shelf life:		, , ,			24	Months
if yes, enter class #		Orphan Drug Status Size:			Size:		Initial shelf life at launch (if different):					Months		
a product kit?		No				Strength:	600 mg							
if yes, list NDCs of			FDA Approval Status							ORDER INFORM	MATION			
component parts		lat.				Dosage Form:	Film coated tablet		Unit of Sale		What is the I	NDC colling	unit?	
reverse numbered? co-licensed?		No No	Allergens Present					ı	x Bottle		1 Bottle of 50		unitr	
latex-free?		Yes					Oval. biconvex	Box/Carton					) Vials)	
preservative-free?		Yes	Corn, Alcol	hol, Wheat		Product Shape:	oval, picelivex	Ampule			(Write-in, e.g. 1 Box of 10 Vials)			
correctional institution block?		No				Product Color:	White		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Color:			Tube					
Cannabinoid?		No	Country of Origin	USA		Product Imprint	Debossed with 'T' on the left side of the bisect and '1' on the right side of the bisect on one side and		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for						bisect on other side		Vial Liquid Multi		If Yes, how I		ch package t	ype?
hospital scanning?			Is this product covered un						Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (TA	AA)?	Yes				Vial Powder Multi Other: Write In			Inner/Carton Case	/Pack	
			FOR GENERIC DRUG PRO	PLICTO				L I	Other, write in			Case		
		!	FOR GENERIC DRUG PRO	DUCIS										
					Διι	thorized Generic *If	Authorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:			section fields are not applicable			Rec. sell unit to customer?				Rx billing unit to pharmacy:				
I. Orange Book Rating: II. Generic Equivalent to What Brar		Neurontin						itee. sen unit to customer:			Each			
ii. Generie Equivalent to What Brai		rtouronan						(Write-in, e.g. 1 Vial)						
		DRUG SUPPLY	CHAIN SECURITY ACT (D	SCSA) INFOR	MATION			HCPCS J-Code				Milliliter		
				_										
Does supplier meet DSCSA definit	ion of manufactu	rer?	Yes		GLN:	0331722498975 shipments to 0865624000382 shipments to	non-controlled substance states		ITEN	AND PACKING IN	NFORMATION			
Is product exempt from DSCSA?			No			COCCUE TOCOCCE SIMPINGING TO	SOM ONCE SUBSTRICT STATES							
If yes, select exemption:					GCP:				Weight Lbs.		ons (US msm	•	Volume	Saleable #
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No Yes			iginal product purcha	sed	Item/Each:	1.05	3.46	3.46	6.75	80.81	1
Is product sold by manufacturer's			No Yes	4	direct from m			Box/Carton/Bu						
Has FDA granted waiver/exception If yes, attach documentation fron		roduct?	140	1	Provide source	ce manufacturer for re	раскадей ргодист	Inner Pack:	indle/					
ii yes, attacii accanicitation fron	II DA.							Case:						
		GTIN	AND HIBCC PRODUCT IN	FORMATION					13.5	14.25	10.75	7.5	1148.91	12
								Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GTII	N-14	Unit of Use GTIN-14							
		Quantity												
x Item/Each N 1				003	00331722166058			COST INFORMATION			WHOLESALER USE ONLY:			
Box/Carton/Bundle/Inner Pack  X Case	N	12			102	31722166055			COST INFORMATION		,	WHOLESALI	-K USE UNL	1.
X Case Pallet	IN	12			103	31722100000		Regular Cost			Vendor #:			
1 5000								Invoice Cost (\	WAC) (\$)	\$80.00	Whsl. Code	#:		
										722.00	Fineline Cod			
								As of date:	11/18/2021					
1														
			Attach copy of SAFETY DAT	A SHEET (SD	S) or non haza		SERT, LABEL AND PHOTO OF P							
*Please provide any additional info	rmation on nago	7				See new n 3 for De	signated Drop Ship Only.		Signature:					



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

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For Designated Drop Ship Only Products, Please Use Page 3

WATERIAL	HAZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply):						
a. Cytotoxic?	SDS Hazard Classification					
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	4					
Is the product a CA Prop 65 carcinogen?	x Organic Corrosive					
Is the product a CA Prop 65 reproductive toxicant?						
Does the product label bear a CA Prop 65 warning?						
c. Contact Hazard?	Does the product have an Aerosol class? If yes, No					
d. Does this product require special clean-up instructions?						
(If yes, attach SDS with special instructions.)	NFPA Storage Level:					
e. Does the product contain DEHP?	, and the second					
·						
Is this product regulated for shipment by DOT?						
(if yes, answer a-e below and provide SDS)	If yes, indicate which:					
a. UN/Identification Number						
b. Proper Shipping Name	Hazardous Waste Identification					
c. DOT Hazard Class	Hazardous Waste Identification					
d. Packing Group e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics					
Is this product regulated for shipment by IATA?						
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS					
a. UN/Identification Number						
b. Proper Shipping Name	Is there a REMS on this product?					
c. DOT Hazard Class	If Yes, is it managed with a pharmacy registry?					
d. Packing Group	Website URL:					
e. Inhalation Hazard?						
Is the product restricted for air shipment? If so, indicate restriction:	Med Guide Required No					
Passenger	Limited Distribution Requirement					
Cargo	Comments / Details: (For example, iPledge program?)					
Passenger & Cargo						
Is this a reportable quantity? No	REMS: No					
RQ Threshold:	REMS Program Manager Name: Phone:					
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:					
Is this product shipped utilizing an authorized DOT exception or Special Permit?	Wholesale distributor support:					
No (if yes, identify method below)	Provider Name: DEA #:					
Limited Quantity	Site Enrollment Number assigned NCPDP#:					
Consumer Commodity, ORM-D	by Supplier: NPI #:					
Small Quantity (49 CFR 173.4)						
Special Permit; DOT-SP	Comments					
Special Provision (listed in Column 7 of 49 CFR 172.101);						
SP#	Registry: No					
	Registry Program Contact Name: Phone:					
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Priorie:					
	Connection					
Is the Product	DETURN WATRIATION					
Controlled Substance?  No Controlled Substance Code	RETURN INSTRUCTIONS					
Controlled by State(s)?  Yes  Listed Chemical (List I or II)  No						
ARCOS Reportable?  No If yes, indicate which:	Contact tel. # if product received damaged: 1-866-827-3647					
Schedule No. Is it a scheduled listed chemical product?: No.	Is product returnable for credit:					
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes	contact - customerservice@camberpharma.com					
	- i					
Restricted to retail pharmacy only:	opedial regulations of retains requirements for this					
Restricted to hospital, clinics, and physician offices only:	product in certain states?					
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?					
Comments:	This product is classified as a Schedule V controlled substance in Alabama, Kentucky, Montana, North Dakota, Tennessee, Utah,					
	Virginia, and West Virginia.					
MISCELL	ANEOUS NOTES and/or Image of Product Barcode:					



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