

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

Version 2024						Introduction Type:	Post Launch Change	1	Final Version			Date:	6/23/	2024	
			PRODUCT INFORMAT	ION					SPECIAL HAN	IDLING AND STOR	AGE REQUIF	REMENTS*			
Company Name:	Camber Pharmaceuticals, Inc. Application: ANDA						ANDA	a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/ANI	DA/BLA; PMA/510				NDA 505(b) Type: NOT APPLICABLE			Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)							
Medical Device Class, if applicab	ole:					·			=						
DUNS:	11-856-3719	'						Othe	r Temperature Range	Requirement	Excursions p	ermitted betv	een 15°C to	30°C (59°F	
Proprietary Name (If Applicable) a		ame: Gabapei	ntin Capsules, USP 100 mg						(write in)		to 86°F)				
Selling Unit NDC:	31722-148-01		Unit of Use NDC:				722148016	Note	s						
UDI			CVX Code:			MVX Code:									
Description:	Gabapentin Caps	sules, USP 100 mg						Is thi	s product to be shippe	d to customers on ic	e?		No		
								Is thi	s product to be shippe	d to customers on d	ry ice?		No		
Active Ingredient(s):		Gabapentin, USP								_					
URL for Additional Product Inform									erature excursion qu	estions:	Soma Raju				
Address:	nation: www.camberpharma.com  800 Centennial Ave, Suite 1			Address 2:			Nam Num			732-529-042	3				
City:	Piscataway	ve, ouite i			State:		: 08854		ip E-mail:			eterousa.con	)		
Key Contact:	Customer Service	9			Email:	customerservice@cam		0.00	ıp E maii.		<u>oomaraja on</u>	0.0.0000.00.	<u>.</u>		
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regulation	ns for product in any	states?			*Yes		
Product Therapeutic Classification	n:	Anticonvulsant						Spec	ial returns requirement	ts for this product?			No		
Special relation (square) and product.															
	ADDIT	IONAL PRODUCT INFO	RMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store product (u	nit of sale) upright?				No		
The product is?			Is the Product	Direct-Ship Or	nly			Prote	ect product (unit of sa	ale) from light?			No		
a legend device?		No	Is the Product	Neither		Size:	100 ct	e. Shelf life:					24	Months	
if yes, enter class #			Orphan Drug Status			Size:		Initia	Il shelf life at launch (	if different):				Months	
a product kit?		No				Strength:	100 mg								
if yes, list NDCs of			FDA Approval Status			<b>3</b>				ORDER INFORM	IATION				
component parts		1.1				Dosage Form:	Hard, gelatin capsule	11-24	of Sale		What is the	NDC aallina			
reverse numbered? co-licensed?		No No	Allergens Present					X			1 Bottle of 10		umr		
latex-free?		Yes					Capsule		Box/Carton			g. 1 Box of 10	(Vials)		
preservative-free?		Yes	Corn, Alcohol,	Animal, Wheat		Product Shape:	Capoaio		Ampule		(**************************************	g. 1 Box 01 10	· · · · · · · · · · · · · · · · · · ·		
correctional institution block?		No				Product Color:	White opaque cap and		Glass		Minimum or	der quantity	?	Yes	
opioid?		No				Product Color:	white opaque body		Tube						
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Printed with 'A' on cap and		Vial Liquid Sgl						
If Unit Dose, is item bar coded to u	nit dose for						'469' on body in black ink		Vial Liquid Multi		If Yes, how		ch package t	ype?	
hospital scanning?			Is this product covered un Trade Agreements Act (Ta		No				Vial Powder Sgl Vial Powder Multi			Each	D I		
If Unit Dose, indicate NDC here:			Trade Agreements Act (Tr	AA)?	NO				Other: Write In			Inner/Carton Case	Раск		
			FOR GENERIC DRUG PRO	DUCTE					Other. Write in			Case			
			OK GENERIC DRUG FRO	DUCIS											
				Ī	Au	thorized Generic *If A	uthorized Generic, other		Pŀ	HARMACY ORDER	/ BILL UNIT				
I. Orange Book Rating:	AB			т '			ion fields are not applicable	Rec. sell unit to cus	stomer?		Rx billing ur	nit to pharms	cv:		
II. Generic Equivalent to What Brai		Neurontin		1				rece. Sen unit to cus	otomer :		IXX Dilling ui	Each	cy.		
Conone Equivalent to Tinat Brai								(Write-in, e.g. 1 Vial	)	_		Gram			
		DRUG SUPPLY	CHAIN SECURITY ACT (E	SCSA) INFORI	MATION			HCPCS J-Code:				Milliliter			
				_											
Does supplier meet DSCSA definit	tion of manufactu	rer?	Yes		GLN:	0331722498975 shipments to r 0860000397957 shipments to c			ITEN	AND PACKING IN	IFORMATION				
Is product exempt from DSCSA?			No			- Jacobs San Graphica to C		1							
If yes, select exemption:					GCP:				Weight Lbs.		ons (US msm		Volume	Saleable #	
Other exemption - Write in:										Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?		10	No Yes		If yes, was or direct from m	iginal product purchase	d	Item/Each:	0.1	1.88	1.88	2.6	9.19	1	
Is product sold by manufacturer's Has FDA granted waiver/exception			No	4		ir r se manufacturer for repa	ackaged product	Box/Carton/Bundle	,						
If yes, attach documentation from		Toduct?	140	1	riovide sourc	e manufacturer for repa	ackaged product	Inner Pack:	<b>'</b>						
. , ,								Case:							
		GTIN	AND HIBCC PRODUCT IN	FORMATION					5.75	11.75	7.75	7	637.44	48	
								Pallet:							
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GTII	N-14	Unit of Use GTIN-14								
H		Quantity						1							
					0033	31722148016			OST INFORMATION		_	NHOLES ALE	R USE ONL	v	
X Item/Each	N	1											TO JE UNL	1.	
Box/Carton/Bundle/Inner Pack		1			203	31722148010			OOT IN ORMATION		,	MHOLESALI			
	N N				203	31722148010			OST IN CHIMATION			WHOLESALE			
Box/Carton/Bundle/Inner Pack X Case		1			203	81722148010		Regular Cost Invoice Cost (WAC)		\$5.00	Vendor #:				
Box/Carton/Bundle/Inner Pack X Case		1			203	31722148010		Regular Cost	(\$)	\$5.00	Vendor #:	#:			
Box/Carton/Bundle/Inner Pack X Case		1			203	31722148010		Regular Cost		\$5.00	Vendor #: Whsl. Code	#:			
Box/Carton/Bundle/Inner Pack X Case		1			203	31722148010		Regular Cost Invoice Cost (WAC)	(\$)	\$5.00	Vendor #: Whsl. Code	#:			
Box/Carton/Bundle/Inner Pack X Case		48						Regular Cost Invoice Cost (WAC) As of date:	10/1/2021	\$5.00	Vendor #: Whsl. Code	#:			
Box/Carton/Bundle/Inner Pack X Case	N	48	Attach copy of SAFETY DA	TA SHEET (SDS		rd letter, PACKAGE INSE	RT, LABEL AND PHOTO OF P	Regular Cost Invoice Cost (WAC) As of date:	10/1/2021	\$5.00	Vendor #: Whsl. Code	#:			



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

#### Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

WATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply):							
a. Cytotoxic?	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?							
Is the product a CA Prop 65 carcinogen?	x Organic Corrosive						
Is the product a CA Prop 65 reproductive toxicant?	Inorganic Oxidizer						
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard						
c. Contact Hazard?	Does the product have an Aerosol class? If yes, No						
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:						
(If yes, attach SDS with special instructions.)	NFPA Storage Level:						
e. Does the product contain DEHP?							
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug?						
(if yes, answer a-e below and provide SDS)	If yes, indicate which:						
a. UN/Identification Number	ii yes, ii ulcate wiiicii.						
b. Proper Shipping Name							
c. DOT Hazard Class	Hazardous Waste Identification						
d. Packing Group	TIGERIOGO WASIC INCIRINGATION						
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics						
	REMS or REGISTRY RESTRICTIONS						
(if yes, answer a-e below and provide SDS)	REMO OF REGISTRY RESTRICTIONS						
a. UN/Identification Number	Is there a REMS on this product?						
b. Proper Shipping Name c. DOT Hazard Class	Is there a REMS on this product?  If Yes, is it managed with a pharmacy registry?						
d. Packing Group	ir res, is it intarraged with a pharmacy registry? Website URL:						
e. Inhalation Hazard?	Website ONL.						
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)	Comments						
Special Permit; DOT-SP	Comments						
Special Provision (listed in Column 7 of 49 CFR 172.101);							
SP#	Registry: No						
ADDII CTODAGE INFORMATION	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	Comments						
Is the Product							
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						
Restricted to retail pharmacy only:  No							
	Special regulations or returns requirements for this product in certain states?						
Restricted to hospital, clinics, and physician offices only:	les les						
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, North Dakota, Utah, Tennessee, Virginia, and						
	West Virginia.						
MISCELLANE	OUS NOTES and/or Image of Product Barcode:						
INIOGEEEATE							



## **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
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:	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:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:  Drop Ship service fee billed with each order:  Drop Ship miscellaneous fees billed:  Comments:	Overnight receipt available:  PO Receipt cut off time:  Days of week overnight is available:  Monday Tuesday Wednesday Thursday Friday
	Priority Overnight receipt available:
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:	PO Receipt Cut off time:  Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:  Miscellaneous Notes:	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?
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? Is product order for restocking purposes?