

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

Version 2024						Introduction	Type: N	ew Item		x Final Version			Date:	10/23	/2025	
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*			
Company Name: Camber Pharmaceuticals, Inc.					Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/ANDA/BLA; PMA/510(k): 217682					NDA 505(b) Type: NOT APPLICABLE			Temperature Range Cold – between 2 and 8 C (36° – 46° F)								
Medical Device Class, if applica	ble:								Ţ							
DUNS:	11-856-3719									Other Temperature Range F	Requirement					
Proprietary Name (If Applicable) a		lame: Ga	abapentin Oral Solution 250 mg/s	5 mL						(write in)						
Selling Unit NDC:	31722-069-47		Unit of Use NDC:			UPC:	331722069472		1	Notes		*To be shipped methods (e.g. C	to customers usi	ing proper cold st Storage Trucks)	torage shipping	
UDI						MVX Code:			methods (e.g. Cold Packs, Cold Storage Trucks)							
Description:	Gabapentin Oral Solution 250 mg/5 mL								Is this product to be shipped to customers on ice?							
Active Ingredient(s): Gabapentin, USP							Is this product to be shipped to customers on dry ice?  No									
								b. Contact for t	emperature excursion que	estions:						
URL for Additional Product Information: www.camberpharma.com			Address 2:			Name: Soma Raju										
Address:	800 Centennial Ave, Suite 1				Address 2:			Number: 732-529-0423								
City: Key Contact:	Piscataway  Customer Service				State: Email:	customerservice@camberpharma.com			Group E-mail: somaraju@heterousa.com							
Phone Number:	1-866-827-3647	.e				Fax: 732-562-8788			c. Special regulations for product in any states?							
Product Therapeutic Classification		Anticonvulsant			132-302-0700											
Froduct Therapeutic Classificatio	···.	Anticonvulsant							Special returns requirements for this product?							
	ADDIT	IONAL PRODUCT	T INFORMATION			PRODUCT	DESCRIPTION INF	ORMATION	d. Store produc	t (unit of sale) upright?				No		
The product is?			Is the Product	Direct-Ship (	nlv				Protect product (unit of sale) from					No		
a legend device?		No	Is the Product	Neither	7111y		470 mL		e. Shelf life:	Totect product (unit or sa	iie) iroiii iigiit:			24	Months	
if yes, enter class #		INO	Orphan Drug Status			Size:				nitial shelf life at launch (i	if different):				Months	
a product kit?		No			250			nL	[ ]							
if yes, list NDCs of			FDA Approval Status			Strength:	_		ORDER INFOR			MATION				
component parts						Dosage Fori	m: Clear, oral	solution								
reverse numbered?		No								Jnit of Sale			NDC selling			
co-licensed?		No	Allergens Present				<b>N1/A</b>		_	x Bottle			70 mL Oral S			
latex-free? preservative-free?		Yes No	Gluten, Corn, Sugar	, Wheat, Spelt,	Barley	Product Sha	Product Shape: N/A			Box/Carton Ampule	(Write-in, e.g. 1 Box of 10 Vials)		u viais)			
correctional institution block?		No					Colorless to	o slightly	-	Glass		Minimum o	rder quantity	12	Yes	
opioid?		No				Product Col	or: yellow	o slightly		Tube		William Ci	der quartity	•	103	
Cannabinoid?		No	Country of Origin	India		Due do et les	N/A			Vial Liquid Sgl						
If Unit Dose, is item bar coded to u	unit dose for		, ,			Product Imp	orint:			Vial Liquid Multi		If Yes, how	many of whi	ch package t	type?	
hospital scanning?			Is this product covered u							Vial Powder Sgl		24	Each			
If Unit Dose, indicate NDC here:			Trade Agreements Act (	ГАА)?	No				Vial Powder Multi Inner/Carton/Pack							
									<u>l</u>	Other: Write In			Case			
			FOR GENERIC DRUG PR	ODUCTS												
					Δ.	thorized Ceneric	*If Authorized Gen	perio other	PHARMACY ORDER / BILL UNIT							
I Common Barata Bartinana	AA			_	Authorized Generic *If Authorized Generic, other section fields are not applicable											
I. Orange Book Rating: II. Generic Equivalent to What Bra		Neurontin							Rec. Sell utilit to customer?			Rx billing unit to pharmacy:				
ii. Generic Equivalent to What Bra	iliu i .	recuronan						(Write-in, e.g. 1 Vial)				-				
		DRUG SU	PPLY CHAIN SECURITY ACT (	DSCSA) INFO	RMATION				HCPCS J-Code	: ′			Milliliter			
													4			
Does supplier meet DSCSA defini	ition of manufactu	ırer?	Yes	_	GLN:	0865624000382		ITEM AND PACKING INFORMATION								
Is product exempt from DSCSA?			No													
If yes, select exemption:					GCP:					Weight Lbs.		ons (US msn		Volume	Saleable #	
Other exemption - Write in:			No		W	ululual uu- 44	abassa		Items/F t-	-	Depth	Width	Height	(Cube)	Pieces	
Is product repackaged? Is product sold by manufacturer's	ovelucive dietrib	utor?	Yes	+	If yes, was o	riginal product pur	cnased		Item/Each:	1.35	2.8	2.8	7.50	58.59	1	
Has FDA granted waiver/exceptio			No	-			or repackaged prod	luct	Box/Carton/Bu	ndle/						
If yes, attach documentation fro							or repueragea proc		Inner Pack:							
									Case:	33.95	18.20	13.00	7.95	1881.44	24	
			GTIN AND HIBCC PRODUCT I	NFORMATION						33.93	10.20	15.00	7.55	1001.44	2.4	
									Pallet:							
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GT	IN-14	Unit of Us	se GTIN-14								
X Item/Each	N	Quantity 1			nns	331722069472			[]							
Box/Carton/Bundle/Inner Pack				JUSS 11 ZZUUS41 Z			COST INFORMATION				WHOLESALER USE ONLY:					
X Case N 24 Pallet			20331722069476						mioleoneen ool onem							
							Regular Cost			Vendor #:						
							Invoice Cost (WAC) (\$) \$69.80			Whsl. Code #:						
									II	0/47/0004		Fineline Co	de:			
							-		As of date:	6/17/2024		1				
									[]							
			Attach copy of SAFETY DA	TA SHEET (SI	S) or non haza	ard letter. PACKAGE	INSERT, I ARFI A	ND PHOTO OF F	PRODUCT PACKAG	ING and BARCODE						
			, maon sopy of or it ETT Dr	(01	_, 5		Designated Drop :		JJJJJ I MOINAC							



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

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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?	SDS Hazard Classification							
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?  No	x     Organic     Corrosive       Inorganic     Oxidizer       Steroid/Androgen     Contact Hazard							
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?	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  NFPA Storage Level:  Is the product a NIOSH hazardous drug?  No							
(if yes, answer a-e below and provide SDS)  a. UN/dentification Number  b. Proper Shipping Name	If yes, indicate which:							
c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Hazardous Waste Identification  EPA Hazardous Waste Code:  Waste Characteristics							
	El 711 IZZI GOLG VIGLE GOLG.							
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 c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product?  If Yes, is it managed with a pharmacy registry?  Website URL:							
Is the product restricted for air shipment? If so, indicate restriction:  Passenger Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)							
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)	REMS:  REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier:  No Phone:  Phone:  DEA #: NCPDP#: NCPDP#: NPI #:							
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments							
SP#	Registry:  Registry Program Contact Name:  No  Phone:							
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone: 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:	Special regulations or returns requirements for this							
Restricted to hospital, clinics, and physician offices only:  Restricted from US territories? (explain in comments)  No	product in certain states?  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.							
MISCELLANEC	OUS NOTES and/or Image of Product Barcode:							



## **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:		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 rotatino 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?						