

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

Version 2024						Introduction T	уре:	New Item		x Final Version			Date:	10/23	3/2025
PRODUCT INFORMATION							SPECIAL HANDLING AND STORAGE REQUIREMENTS*								
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): 214957			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	Requirement		permitted bety	veen 15°C to	30°C (59°F
Proprietary Name (If Applicable) ar		ame: Gaba	apentin Tablets, USP 600 mg							(write in)		to 86°F)			
	31722-166-01		Unit of Use NDC:			UPC:	33172216601	0		Notes					
UDI			CVX Code:			MVX Code:									
Description:	Gabapentin Table	ets, USP 600 mg							Is this product to be shippe	d to customers on i	ce?		No		
										Is this product to be shippe	d to customers on o	Iry ice?		No	
Active Ingredient(s):		Gabapentin, USP							h Contact for temperature evaluation questions:						
URL for Additional Product Inform	ation:	www.camberpharr							b. Contact for temperature excursion questions: Name: Soma Raju						
Address:	800 Centennial A		Ha.com		Address 2:				Number:		732-529-042	23			
City:	Piscataway	iro, cano i			State: NJ Zip: 08854				Group E-mail:			neterousa.con	n		
Key Contact:	Customer Service	9			Email:	customerservice@			Straig Entertain						
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regulations for product in any states? *Yes				*Yes			
Product Therapeutic Classification	1:	Anticonvulsant								Special returns requiremen	ts for this product?			No	
	ADDITI	IONAL PRODUCT I	NFORMATION		PRODUCT DESCRIPTION INFORMATION			d. Store produ	uct (unit of sale) upright?			No			
The product is?	The product is?		Is the Product Direct-Ship C		nly	1			Protect product (unit of sale) 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			GIZC.				Initial shelf life at launch	(if different):				Months
a product kit?		No				Strength:	600 mg		ORDER INFORMATION						
if yes, list NDCs of			FDA Approval Status			_					ORDER INFORM	IATION			
component parts reverse numbered?		No				Dosage Form	n: Film co	pated tablet		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							x Bottle		1 Bottle of 1		uiiit.	
latex-free?		Yes					Oval. b	piconvex		Box/Carton			g. 1 Box of 10) Vials)	
preservative-free?		Yes	Corn, Alco	hol, Wheat	Product		t Snape:			Ampule			•	,	
correctional institution block?		No	-			Product Cold	White			Glass		Minimum or	der quantity	?	Yes
opioid?		No				1 Todact Gold				Tube					
Cannabinoid?		No	Country of Origin	USA		Product Impr	rint: Debossed with	'T' on the left side of the bisect and '1' on f the bisect on one side and bisect on other		Vial Liquid Sgl					
If Unit Dose, is item bar coded to un hospital scanning?	nit dose for		In this was don't account to		5600			Vial Liquid Multi If Yes, how many of which package type?					type?		
If Unit Dose, indicate NDC here:			Is this product covered un Trade Agreements Act (T.		Yes			Vial Powder Sql 24 Each Vial Power Multi Inner/Carton/Pack							
ii Oliit Dose, ilidicate NDC liele.			Trade Agreements Act (1)		es				Other: Write In			Case	/I dok		
			FOR GENERIC DRUG PRO	DDUCTS						Guidi: William			Journal		
				,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,											
					Authorized Generic *If Authorized Generic, other section fields are not applicable			PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating:	AB			T				Rec. sell unit to customer? Rx billing unit to pharmacy:							
II. Generic Equivalent to What Bran	nd?:	Neurontin													
								(Write-in, e.g. 1 Vial) Gram							
		DRUG SUPF	PLY CHAIN SECURITY ACT (DSCSA) INFOR	MATION				HCPCS J-Cod	e:			Milliliter		
Does supplier meet DSCSA definit	ion of manufactur	ror?	Yes	Т	GLN:	0331722498975 shipmen	nts to non-controlled s	ubstance states		ITE	M AND PACKING II	NEORMATIO	V		
Is product exempt from DSCSA?	.c or manaractur		No	+	V=11.		0843368117603 shipments to controlled substance states								
If yes, select exemption:					GCP:						Nimonei	ons (US msn	nts)	Volume	Saleable #
Other exemption - Write in:					GGF.					Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was or	riginal product puro	chased		Item/Each:	0.26	2.2	1	4		
Is product sold by manufacturer's	exclusive distribu	utor?	Yes	1	direct from m					0.26	2.2	2.2	4	19.36	1
Has FDA granted waiver/exception	/exemption for pi		No		Provide sour	ce manufacturer fo	r repackaged	product	Box/Carton/Bi	undle/					
If yes, attach documentation from	n FDA.								Inner Pack:						
		0	TIN AND HIBCC PRODUCT IN	EODMATION.					Case:	6.85	14.5	10.25	4.75	705.97	24
		G	TIN AND HIBCC PRODUCT IN	FORMATION					Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GTI	N-14	Unit	of Use GTIN-14	Pallet:						
Calcable Cliff of Modelin	ra ib tag(1/14)	Quantity	THEOO		011	14-14	Office	01 030 01114-14							
x Item/Each N 1				003	00331722166010										
Box/Carton/Bundle/Inner Pack X Case N 24 Pallet			10331722166017			COST INFORMATION				WHOLESALI	ER USE ONL	.Y:			
							Regular Cost Invoice Cost (WAC) (\$) \$16.00			Vendor #:) Whsl. Code #: Fineline Code:					
							As of date:	11/18/2021		rineline Co	ue:				
							7.5 Of Gate.	11/10/2021							
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza	rd letter, PACKAGE	INSERT, LAB	EL AND PHOTO OF PI	RODUCT PACKA	GING and BARCODE.					
						See new n 3 for									



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Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

In this product (clinical and make apply) 3. C. A Type SS Centrogene or Reproduction Training? 5. C. A Type SS Centrogene or Reproduction to concern? No. C. A Type SS Centrogene or Reproduction to concern? No. C. Central Reproduction for Central Politics 1. In the product of A Physics Street Central Reproduction to concern? No. C. Central Reproduction for Central	MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION							
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No Control Comment Control								
e. Does the product contain DEHP? No (if yes, answer a= bloke and provide SDS) Is the product regulated for shipment by DOT? No (if yes, answer a= bloke and provide SDS) Is the product and provide SDS) Is the product and provide SDS) Is the product and provide SDS Is the provide Information of the provide SDS Is the provide Information SDS Is th		, , , , , , , , , , , , , , , , , , , ,						
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If yes, nativar a e below and provide SUS) a. NNINIORITION Claise b. Proper Shipping Name c. POT Hazard Claise c. Standing Croup c. Standi		Is the product a NICCU harvardaya days?						
a. UNiderafication Number b. Proper Signale for shipment by IATA? No (if yes, answer are below and provide SDS) c. DOT Hazard Class d. Pasking Group a. Inhalation Hazard? No (if yes, answer are below and provide SDS) c. Inhalation Hazard? No (if yes, answer are below and provide SDS) c. Inhalation Hazard? No (if yes, answer are below and provide SDS) c. Inhalation Hazard? No (if yes, answer are below and provide SDS) c. Inhalation Hazard? No (if yes, answer are below and provide SDS) c. Inhalation Hazard? No (if yes, answer are below and provide SDS) c. Inhalation Hazard? No (if yes, answer are below and provide SDS) c. Inhalation Hazard? No (if yes, internal provider) No (if yes, internal provider) No (if yes, int								
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d. Packing Group	b. Proper Shipping Name							
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(if yes, answer ae below and provide SDS) a. UNIdentification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group list the product restricted for air shipment? If so, indicate restriction: No Passenger Cargo Passenger A Cargo Is this a reportable quantity? No (if yes, dentify method below) Special Provision (listed in Column 7 of 48 CFR 172.101):		EFA Hazarutus waste Coue.						
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e. Inhalation Hazard? Is the product restricted for air shipment? If so, indicate restriction: No Add Guide Required Limited Distribution Requirement Comments? Details: (For example, iPledge program?) ReMS: REMS: REMS: REMS: REMS: REMS: REMS: REMS: Special Product. Consumer Commodity, ORM-D Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); Special Provision (listed in Column 7 of 49								
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Limited Quantity Consumer Commodity, ORN-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? Controlled Sy State(s)? ARCOS Reportable? She will be selected from Using the paramacy, hospitale, clinics and physician offices only: No restricted to retail pharmacy only: Restricted from US territories? (explain in comments) Site Enrollment Number assigned by Supplier: No Comments Registry: No Registry Program Contact Name: Comments RETURN INSTRUCTIONS Registry: No RETURN INSTRUCTIONS Contact tel. # if product received damaged: 1-866-827-3647 Is product returnable for credit: URL/Link to returns policy: Comments Comments Special regulations or returns requirements for this product in certain states? Yes Restricted from US territories? (explain in comments) If so, which states? Other requirements? Comments? This product is classified as a Schedule V controlled substance in Alabama, Kentucky, Montana, North Dakota, Tennessee, Utah, Virginia, and West Virginia.								
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Controlled by State(s)? Yes	Is the Product							
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Virginia, and West Virginia.	,							
	Comments:							
MISCELLANEOUS NOTES and/or Image of Product Barcode:								
	MISCELLANE	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						
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 priarmacy 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?						