

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 STOP	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. ANDA Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/AN	DA/BLA; PMA/510(k)	: 214956				NDA 505(b) Type:	NOT APPLICABLE		emperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applical														
DUNS:	11-856-3719							Ot	her Temperature Range	Requirement		permitted betw	ween 15°C to	30°C (59°F
Proprietary Name (If Applicable) a		e: Gabape	entin Capsules, USP 400 mg	1					(write in)		to 86°F)			
Selling Unit NDC:	31722-150-01		Unit of Use NDC:				722150019	No	otes					
UDI			CVX Code:			MVX Code:								
Description:	Gabapentin Capsule	s, USP 400 mg							this product to be shippe				No	
	Is this product to be shipped to customers on dry ice? No													
Active Ingredient(s): Gabapentin, USP b. Contact for temperature excursion guestions:														
URL for Additional Product Inform	nation:	ww.camberpharma	com						ame:	estions.	Soma Raju			
Address:	800 Centennial Ave,					Address 2:			umber:		732-529-042	23		
City:	Piscataway				State:	NJ Zij	08854		roup E-mail:			neterousa.cor	<u>n</u>	
Key Contact:	Customer Service				Email:	customerservice@can	hberpharma.com							
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regula	tions for product in any	states?			*Yes	
Product Therapeutic Classification	n: A	Inticonvulsant						Sp	pecial returns requiremen	ts for this product?			No	
	ADDITION	IAL PRODUCT INF	ORMATION			PRODUCT DESC	CRIPTION INFORMATION	d. Store product	(unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship O	nly			Pr	otect product (unit of sa	ale) from light?			No]
a legend device?	N	lo	Is the Product	Neither		Size:	100 ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status					Ini	itial shelf life at launch (if different):				Months
a product kit? if yes, list NDCs of	N	10	FDA Approval Status			Strength:	400 mg			ORDER INFORM				
component parts			FDA Approval Status				Hard, gelatin capsule			ORDER INFORM	ATION			
reverse numbered?	N	lo				Dosage Form:	nard, gelaun capsule	Ur	nit of Sale		What is the	NDC selling	unit?	
co-licensed?		10	Allergens Present						x Bottle		1 Bottle of 1			
latex-free?	Y	′es	Corn, Alcohol, Ar	imal Wheat D	h co	Product Shape:	Capsule		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		'es	Com, Alconol, Al	innai, wheat, D	ye	rioduct Snape.			Ampule					
correctional institution block?		10				Product Color:	Orange opaque cap and		Glass		Minimum o	rder quantity	?	Yes
opioid?		lo		India			orange opaque body Printed with 'A' on cap and		Tube					
Cannabinoid? If Unit Dose, is item bar coded to u		10	Country of Origin	India		Product Imprint:	'471' on body in black ink		Vial Liquid Sgl Vial Liquid Multi		If Yee, how	many of whi	ch package	turno?
hospital scanning?	unit dose for		Is this product covered ur	der the					Vial Powder Sgl			Each	сп раскауе	typer
If Unit Dose, indicate NDC here:			Trade Agreements Act (T		No				Vial Powder Multi			Inner/Carton	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PRO	DUCTS								-		
					Au		authorized Generic, other		Pł	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB					sec	tion fields are not applicable	Rec. sell unit to a	customer?		Rx billing u	nit to pharma	acy:	
II. Generic Equivalent to What Bra	ind?: N	leurontin										Each		
								(Write-in, e.g. 1 V	/ial)			Gram		
		DRUG SUPPLY	Y CHAIN SECURITY ACT (I	DSCSA) INFOR	MATION			HCPCS J-Code:		-		Milliliter		
Does supplier meet DSCSA defini	tion of manufacturer	2	Yes		GLN:	0331722498975 shipments to	non-controlled substance states		ITEN	AND PACKING I	NEORMATIO	N		
Is product exempt from DSCSA?		•	No	_	OLN.	0860000397957 shipments to	controlled substance states							
If yes, select exemption:				_	GCP:					Dimensi	ions (US msn	nts)	Volume	Saleable #
Other exemption - Write in:					GCF.				Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was or	riginal product purchase	ed	Item/Each:	0.22	2.21	2.21		19.34	1
Is product sold by manufacturer's	exclusive distributo	r?	Yes		direct from m	nfr?			0.22	2.21	2.21	3.96	19.34	
Has FDA granted waiver/exception		luct?	No	<u> </u>	Provide sour	ce manufacturer for rep	ackaged product	Box/Carton/Bund	dle/					
If yes, attach documentation from	m FDA.							Inner Pack:						
		CTIN	I AND HIBCC PRODUCT IN					Case:	6.05	14.5	9.5	5	688.75	24
		GTIN		FORMATION				Pallet:						
Saleable Unit of Measure	RFID tag(Y/N) S	aleable	HIBCC		GTI	N-14	Unit of Use GTIN-14	r allet.						
		Quantity	111200		0.1			L						
X Item/Each	N	1			003	31722150019								
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESAL	ER USE ONL	.Y:
X Case	N	24			203	31722150013								
Pallet								Regular Cost			Vendor #:			
								Invoice Cost (WA	AC) (\$)	\$9.00	Whsl. Code			
								As of date:	10/1/2021		Fineline Co	ue:		
								no or date.	10/1/2021					
μ			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza	ard letter, PACKAGE INSI	ERT, LABEL AND PHOTO OF P	RODUCT PACKAGI	NG and BARCODE.					
*Please provide any additional inf	ormation on page 2.				-,		gnated Drop Ship Only.		gnature:					
							• ··· · · · ·							

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Version 2024 For Design	nated Drop Ship Only Products, Please Use Page 3				
MATERIAL H	IAZARD CLASSIFICATION and TRANSPORTATION				
Is this product (check all that apply): a. Cytotoxic? 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	x Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard				
c. Contact Hazard? No d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? No (functional structure description of the product of the	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No NFPA Storage Level: Image: Storage Level: Is the product a NIOSH hazardous drug? No				
(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?	If yes, indicate which: Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics				
Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMS or REGISTRY RESTRICTIONS				
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? Website URL:				
Is the product restricted for air shipment? If so, indicate restriction: No Passenger Cargo Passenger & Cargo	Med Guide Required No Limited Distribution Requirement Image: 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) Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	REMS: No REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: DEA #: Provider Name: DEA #: Site Enrollment Number assigned NCPDP#: by Supplier: NPI #:				
SP#	Registry: No Registry Program Contact Name: Phone:				
ADD'L STORAGE INFORMATION	Comments				
Controlled Substance? No Controlled Substance Code Controlled by State(s)? Yes Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: Is it a scheduled listed chemical product?: No	RETURN INSTRUCTIONS Contact tel. # if product received damaged: 1-866-827-3647 Is product returnable for credit: Yes				
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:				
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes Restricted to retail pharmacy only: No Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No Comments:	contact - customerservice@camberpharma.com Special regulations or returns requirements for this product in certain states? Yes If so, which states? Other requirements? Comments? This product is classified as a Schedule V controlled substance in Alabama, Kentucky, North Dakota, Utah, Tennessee, Virginia, and				
MISCELLAN	West Virginia. IEOUS 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: a. EDI b. Autofax Fax Number: c. Fax Fax Number: d. Phone only Phone No.: e. Supplier Web Site only Site Address: Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name:	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:
Phone:	Overnight and Drivity Overnight DO Broossing
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: PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: PO Receipt Cut off time: Phone: Order receipt method: Phone: Fax: EDI: EDI: Covernight Fees apply: Other fees apply: Image: Covernight Fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?
Miscellaneous Notes:	
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure?