

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

Version 2024						Introduction 7	Type: New Item			x Final Version			Date:	7/22/	2024
			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/AN	IDA/BLA; PMA/510	0(k): 21	7682			NDA 505(b) Type	: NOT APPLICABLE	E		Temperature Range	Cold – between 2		– 46° F)		
Medical Device Class, if applical	ble:														
DUNS:	11-856-3719									Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) a		lame: Ga	abapentin Oral Solution 250 mg/5	5 mL						(write in)					
Selling Unit NDC:	31722-069-47		Unit of Use NDC:			UPC: MVX Code:	331722069472		. 	Notes		*To be shipped methods (e.g. C	to customers usi old Packs, Cold	ng proper cold st Storage Trucks)	orage shipping
UDI			CVX Code:			MVX Code:							ola i dollo, cola		
Description:	Gabapentin Oral	Solution 250 mg/s	5 mL							ls this product to be shipped				No*	
Active Ingredient(s): Gabapentin, USP								Is this product to be shipped to customers on dry ice?							
									emperature excursion que	estions:					
URL for Additional Product Inform Address:		www.camberph	arma.com			Address 2:				Name:		Soma Raju	20		
City:	800 Centennial A Piscataway	Ave, Suite 1			State:	NJ	Zip: 08854			Number:		732-529-042		•	
Key Contact:	Customer Service				Email:	-	@camberpharma.com		Group E-mail: somaraju@heterousa.com						
Phone Number:	1-866-827-3647				732-562-8788					states?			*Yes		
Product Therapeutic Classificatio		Anticonvulsant								Special returns requirement				No	
l round morapound diagonicans	•••									opoolar rotarrio roquiromoni	o for ano product.			110	
	ADDIT	IONAL PRODUC	T INFORMATION			PRODUCT	DESCRIPTION INFORMAT	ION _	d. Store product (unit of sale) upright?						
The product is?			Is the Product	Direct-Ship C	Only					Protect product (unit of sa	ile) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	470 mL		e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			Size:				Initial shelf life at launch (if different):				Months
a product kit?		No				Strength:	250 mg/5 mL								
if yes, list NDCs of			FDA Approval Status								ORDER INFORM	IATION			
component parts reverse numbered?		No				Dosage Form	m: Oral solution			Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						l i	x Bottle			70 mL Oral S		
latex-free?		Yes					N/A			Box/Carton			g. 1 Box of 10		
preservative-free?		No	Gluten, Corn, Sugar	, Wheat, Spelt,	Barley	Product Sha	pe:			Ampule		, , , ,		,	
correctional institution block?		No				Product Col	Clear, colorless to	slightly		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Froduct Con	yellow			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imp	rint: N/A			Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for									Vial Liquid Multi				ch package t	ype?
hospital scanning? If Unit Dose, indicate NDC here:			Is this product covered u Trade Agreements Act (1		No					Vial Powder Sgl Vial Powder Multi		24	Each Inner/Carton	/Deals	
II Onit Dose, indicate NDC here:			Trade Agreements Act (IAA)!	INO				-	Other: Write In			Case	Pack	
			FOR GENERIC DRUG PR	ODUCTS					_	Guion vinto in			Joaco		
			TOR CENERIO DROCT R	000010								1			
					Au	uthorized Generic	*If Authorized Generic, oth	ner		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AA						section fields are not appli	icable	Rec. sell unit to customer? Rx billing unit to pharmacy:						
II. Generic Equivalent to What Brand?: Neurontin							Each								
									(Write-in, e.g. 1	Vial)			Gram		
		DRUG SU	PPLY CHAIN SECURITY ACT (DSCSA) INFOR	RMATION				HCPCS J-Code	:	7		Milliliter		
Does supplier meet DSCSA defini	ition of manufactu	ıror?	Yes	_	GLN:	0860000397957				ITEN	AND PACKING I	IFORMATIO	V		
Is product exempt from DSCSA?	ition of manaracta		No	_	OLIV.	000000000000000000000000000000000000000					.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		•		
If yes, select exemption:					GCP:						Dimensi	ons (US msn	nts)	Volume	Saleable #
Other exemption - Write in:					JUI .					Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was o	riginal product pur	chased		Item/Each:	1.35	2.8	2.8	7.50	58.59	1
Is product sold by manufacturer's	s exclusive distrib	outor?	Yes		direct from n	nfr?				1.35	2.0	2.0	7.50	56.59	'
Has FDA granted waiver/exceptio		product?	No		Provide sour	ce manufacturer fo	or repackaged product		Box/Carton/Bu	ndle/					
If yes, attach documentation from	m FDA.								Inner Pack:						
			GTIN AND HIBCC PRODUCT II	VEORMATION					Case:	33.95	18.20	13.00	7.95	1881.44	24
			CTIN AND TIBOUT RODUCT II	u onmanon					Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GT	IN-14	Unit of Use GTIN-	-14							
	J. ,	Quantity													
x Item/Each	N	1			003	331722069472									
Box/Carton/Bundle/Inner Pack	N.I	24				24722000 470				COST INFORMATION			WHOLESAL	ER USE ONL	Υ:
X Case Pallet	N	24			203	331722069476			Regular Cost			Vendor #:			
Pallet							-		Invoice Cost (V	VAC) (\$)	\$60.80	Vendor #: Whsl. Code	#-		
									IIIVOICE COST (V	······································	φυσ.δυ	Fineline Co			
									As of date:	6/17/2024					
												1			
		_	Attach copy of SAFETY DA	TA SHEET (SE	S) or non haza		INSERT, LABEL AND PHO		RODUCT PACKAG	SING and BARCODE.					
*Please provide any additional inf	formation on nage					See new n 3 for	Designated Drop Ship On	NV.		Signature:					



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For Designated Drop Ship Only Products, Please Use Page 3

WAI	ERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply):								
a. Cytotoxic?	No	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?		To Mazara Glassinoation						
	No		Corrosive					
Is the product a CA Prop 65 carcinogen?		x Organic						
Is the product a CA Prop 65 reproductive toxicant?	No	Inorganic	Oxidizer					
Does the product label bear a CA Prop 65 warning?	No	Steroid/Androgen Contact Hazard						
c. Contact Hazard?	No	Does the product have an Aerosol class? If yes, No						
d. Does this product require special clean-up instructions?	No	identify NFPA Storage Level:						
(If yes, attach SDS with special instructions.)		NFPA Storage Level:						
e. Does the product contain DEHP?	No							
Is this product regulated for shipment by DOT?	No	Is the product a NIOSH hazardous drug?	No					
(if yes, answer a-e below and provide SDS)		If yes, indicate which:						
a. UN/Identification Number								
b. Proper Shipping Name								
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?	No	-						
	INU	DEMS or	REGISTRY RESTRICTIONS					
(if yes, answer a-e below and provide SDS)		REIVIS OF	REGISTRY RESTRICTIONS					
a. UN/Identification Number								
b. Proper Shipping Name		Is there a REMS on this product?	No					
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:	No	Med Guide Required	No					
Passenger		Limited Distribution Requirement						
Cargo		Comments / Details: (For example, iPledge program?)						
Passenger & Cargo		Confinents / Details: (For example, iPreage program?)						
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					
OF#								
ADD'L STORAGE INFORMATION		Registry Program Contact Name:	Phone:					
ADD L STURAGE INFURMATION		Comments						
Is the Product								
Controlled Substance? No Controlled Substance Code		RE	TURN 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:	Yes					
CLASS OF TRADE RESTRICTION:			100					
-		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:	No	'	Yes					
Restricted from US territories? (explain in comments)	No	If so, which states? Other requirements? Comments?						
Comments:		This product is classified as a Schedule V controlled subst	tance in Alabama, Kentucky, North Dakota, Utah, Tennessee, Virginia, and					
		West Virginia.						
MIS	CELLANEO	US NOTES and/or Image of Product Barcode:						



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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	Purchase order daily receipt cut off time by supplier Cut off time:						
b. Autofax c. Fax d. Phone only Phone No.:	Shipping lead time of PO: Hours Days						
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	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:	Overnight receipt available:						
Drop Ship service fee billed with each order:	PO Receipt cut off time:						
Drop Ship miscellaneous fees billed: Comments:	Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday						
Class of Trade Restriction:	Priority Overnight receipt available: PO Receipt Cut off time:						
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:	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/Clinic DEA #: Physician/Clinic Specialty:	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? Is product order for restocking purposes?						