

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

Version 2021					Introduction T	Type: N	lew Item	X	Final Version			Date:	5/5/2	2024
		PRODUCT INFORM	ATION						SPECIAL HAN	DLING AND STOP	RAGE REQUIR	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc.				Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/AN	DA/BLA (drug); PMA/510(k)(med device):	21	6463					erature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicable:														
DUNS:	11-856-3719							Other	Temperature Range I	Requirement				
Proprietary Name (If Applicable) a		Mexiletine Hydrochloride Capsule							(write in)					
Selling Unit NDC:	31722-036-01	Unit of Use NDC	:		UPC:	331722036016		Notes						
UDI		CVX Code:			MVX Code:									
Description:	Mexiletine Hydrochloride Ca	psules, USP 150 mg							product to be shipped				No	
A stice learned in state base of the shipped to customers on dry ice? No														
Active Ingredient(s): Mexiletine hydrochloride, USP b. Contact for temperature excursion questions:														
URL for Additional Product Inform	nation: www.cam	berpharma.com						Name		25110115.	Soma Raju			
Address:	800 Centennial Ave, Suite 1				Address 2:			Num			732-529-042	3		
City:	Piscataway			State:	NJ	Zip: 08854		Grou	p E-mail:		somaraju@h		<u>n</u>	
Key Contact:	Customer Service			Email:		@camberpharma.co	<u>m</u>							
Phone Number:	1-866-827-3647			Fax:	732-562-8788				ns for product in any				No	
Product Therapeutic Classification	n: Antiarrhy	thmic						Spec	al returns requirement	s for this product?			No	
					DROBUGE									
	ADDITIONAL PRO	ODUCT INFORMATION			PRODUCT	DESCRIPTION INF	ORMATION	d. Store product (ur					No	
The product is?		Is the Product	Direct-Ship C	Dnly					ct product (unit of sa	le) 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				150 mm		Initia	shelf life at launch (if different):				Months
a product kit? if yes, list NDCs of	No	FDA Approval Status			Strength:	150 mg				ORDER INFORM				
component parts		T DA Approvar Status				Hard gelati	in capsule			ORDER IN OR	ATION			
reverse numbered?	No	_			Dosage Forn	n:		Unit	of Sale		What is the	NDC selling	unit?	
co-licensed?	No	Allergens Present						x			1 Bottle of 10	00 Capsules		
latex-free?	Yes	Corn An	imal Products		Product Sha	Capsule			Box/Carton		(Write-in, e.	g. 1 Box of 10) Vials)	
preservative-free?	Yes	Coni, Ali	inar i roducio		i roduct onu				Ampule					
correctional institution block?	No				Product Cold		que / light blue		Glass		Minimum or	der quantity	?	yes
opioid?	No		Le d'a			opaque	54 B (41		Tube					
Cannabinoid? If Unit Dose, is item bar coded to u	No	Country of Origin	India		Product Imp	rint: and '30' on	vith 'V1' on cap		Vial Liquid Sgl Vial Liquid Multi		If Yes, how	many of whi	oh naokago (
hospital scanning?	Init dose for	Is this product covered	under the						Vial Powder Sql			Each	chi packaye i	yper
If Unit Dose, indicate NDC here:		Trade Agreements Act		No					Vial Powder Multi			Inner/Carton	/Pack	
									Other: Write In			Case		
		FOR GENERIC DRUG P	RODUCTS											
				Au	uthorized Generic	*If Authorized Ger				ARMACY ORDER				
I. Orange Book Rating:	AB					section fields are	not applicable	Rec. sell unit to cus	tomer?	_	Rx billing u	nit to pharma	acy:	
II. Generic Equivalent to What Bra	nd?: Mexitil											Each		
	ופח	UG SUPPLY CHAIN SECURITY ACT		MATION				(Write-in, e.g. 1 Vial)				Gram Milliliter		
	DIN		(DSCSA) IN OF	MATION				-				winning		
Does supplier meet DSCSA definit	tion of manufacturer?	Yes		GLN:	0331722498975				ITEN	I AND PACKING I	NFORMATION	N		
Is product exempt from DSCSA?		No												
If yes, select exemption:				GCP:					Malabella	Dimensi	ions (US msm	nts.)	Volume	Saleable #
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?		No			riginal product pure	chased		Item/Each:	0.15	1.88	1.88	4	14.14	1
Is product sold by manufacturer's		Yes		direct from n		a seven by seven to a	4	Box/Carton/Bundle/						
Has FDA granted waiver/exception If yes, attach documentation from		NO		Provide sour	ce manufacturer fo	or repackaged proc	duct	Inner Pack:						
in yes, attach uocumentation nor	III DA.							Case:						
		GTIN AND HIBCC PRODUCT	INFORMATION						4.1	12	8.25	5	495	24
								Pallet:						
Saleable Unit of Measure	Saleable Qu	uantity HIBCC			IN-14	Unit of Us	se GTIN-14							
X Item/Each	1			003	31722036016	_							ER USE ONL	N.
Box/Carton/Bundle/Inner Pack	24				31722036010	-		C	OST INFORMATION			WHOLESALI	ER USE ONL	r:
X Case Pallet	24			203	031722030010	-		Regular Cost			Vendor #:			
								Invoice Cost (WAC)	(\$)	\$35.00	Whsl. Code	#:		
											Fineline Cod			
						1		As of date:	6/8/2023		1			
											1			
μ											I			
		Attach copy of SAFETY D	DATA SHEET (SE	OS) or non haza										
*Please provide any additional inf	ormation on page 2.				See new p. 3 for	Designated Drop	Ship Only.	Signa	iture:					

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Version 2021 For Designated Drop Ship Only Products, Please Use Page 3								
MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION								
Is this product (check all that apply): a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? 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? (if yes, answer a-e below and provide SDS)	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, indicate which: Image: Storage Level:							
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics							
(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? 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 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	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: NI #:							
Special Permit, DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments							
SP#ADD'L STORAGE INFORMATION	Registry: No Registry Program Contact Name: Phone: Comments							
Is the Product Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS							
Controlled by State(s)? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: If yes, indicate which: Schedule No. Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged: 1-866-827-3647 Is product returnable for credit: Yes							
	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	contact - customerservice@camberpharma.com							
Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?							
Comments:								
	COUIS NOTES and/ar Image of Broduct Parendo.							
MISCELLAN	EOUS NOTES and/or Image of Product Barcode:							



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Version 2021 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: Image: Comparison of the co
Class of Trade Restriction:	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: Order receipt method: Phone: Fax: EDI: Overnight Fees apply: Other 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?