

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

Version 2021						Introduction Type:	New Item		X Final Version			Date:	5/5/	/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STO	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN	NDA/BLA (drug); PN	IA/510(k)(med devi	ce):	210	6463				Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applica								İ	_					
DUNS:	11-856-3719								Other Temperature Range I	Requirement				
Proprietary Name (If Applicable)	and Established Na	me: Mexile	etine Hydrochloride Capsule					I	(write in)					
Selling Unit NDC:	31722-037-01		Unit of Use NDC				722037013		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Mexiletine Hydrocl	hloride Capsules, US	SP 200 mg					Ţ	Is this product to be shipped	to customers on	ce?		No	1
									Is this product to be shipped				No	1
Active Ingredient(s):		Mexiletine hydroch	loride, USP											
								b. Contact fo	r temperature excursion qu	estions:	-			
URL for Additional Product Inform		www.camberpharma	a.com						Name:		Soma Raju			
Address:	800 Centennial Av	re, Suite 1			State:	Address 2: NJ Zip	00054		Number:		732-529-042			
City: Key Contact:	Piscataway Customer Service				Email:	customerservice@cam	: 08854		Group E-mail:		somaraju@h	eterousa.cor	<u>n</u>	
Phone Number:	1-866-827-3647				Fax:	732-562-8788	berpriama.com	c Special rea	gulations for product in any	states?			No	7
Product Therapeutic Classification		Antiarrhythmic			i ux.	702 002 0700		c. opeciai re	Special returns requirement				No	-
Troduct Therapeutic Glassification	Jii.	ruidannyannio							opecial returns requirement	s for this product:			140	1
	ADDITIO	ONAL PRODUCT IN	IFORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store prod	luct (unit of sale) upright?				No	1
The medicatic C	7,551110			Direct-Ship C	nly			1		la) from U-1-10				i
The product is? a legend device?		No	Is the Product Is the Product	Neither	лпу		100 ct	e. Shelf life:	Protect product (unit of sa	ile) from light?			No 24	Mantha
if yes, enter class #		INO	Orphan Drug Status	Neither		Size:	100 Ct	e. Shelf life:	Initial shelf life at launch (if different).			24	Months Months
a product kit?		No	Orphan Drug Status				200 mg		illitial stiell life at lautich (ii dillerelli).				Wionins
if yes, list NDCs of		140	FDA Approval Status			Strength:	200 mg			ORDER INFORI	MATION			
component parts						B	Hard gelatin capsule							
reverse numbered?		No				Dosage Form:			Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 10	00 Capsules		
latex-free?		Yes	Corn Ani	nal Products		Product Shape:	Capsule		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	Oom, Am	ilai i roducis		i roddet onape.			Ampule					
correctional institution block?		No				Product Color:	White opaque / light blue		Glass		Minimum or	der quantity	/?	Yes
opioid?		No					opaque		Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	imprinted with 'V1' on cap and '33' on body		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for		In this was don't account	and an the		· ·	and 33 on body		Vial Liquid Multi Vial Powder Sql			many of whi	ich package	type?
hospital scanning? If Unit Dose, indicate NDC here:			Is this product covered Trade Agreements Act		No				Vial Powder Sgi Vial Powder Multi			Inner/Carton	/Pook	
II Offit Dose, indicate NDC fiere.			Trade Agreements Act	IAA):	NO				Other: Write In			Case	I/Fack	
			FOR GENERIC DRUG PR	ODUCTS				J	Guier. Write in			Odoc		
			TOR GENERIC DROG FI	ODUCIO										
					Au	thorized Generic *If A	uthorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I Oronno Book Botinos	AB						ion fields are not applicable	Pac sall unit	to customer?					
I. Orange Book Rating: II. Generic Equivalent to What Bra		Mexitil					•••	ixec. sen unit	to customer:	1	Rx billing u	Each	acy:	
II. Generic Equivalent to What Bra	anu r.	IVICAILII						(Write-in, e.g	1 Vial)	1		Gram		
		DRUG SUPPI	LY CHAIN SECURITY ACT	(DSCSA) INFOR	RMATION			(**************************************				Milliliter		
				,										
Does supplier meet DSCSA defin	ition of manufactur	er?	Yes		GLN:	0331722498975			ITEN	I AND PACKING I	NFORMATION	1		
Is product exempt from DSCSA?			No						·					
If yes, select exemption:					GCP:			1		Dimens	ions (US msm	its.)	Volume	Saleable #
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was or	riginal product purchase	ed	Item/Each:	0.17	1.91	1.91	4	14.59	1
Is product sold by manufacturer's			Yes	_	direct from m					1.91	1.91	4	14.08	'
Has FDA granted waiver/exception		oduct?	No		Provide sour	ce manufacturer for repa	ackaged product	Box/Carton/E	Bundle/					
If yes, attach documentation fro	om FDA.							Inner Pack:						
		0.7	IN AND LUDGO PRODUCT	NEODMATION				Case:	4.7	12	8.25	5	495	24
		GI	IN AND HIBCC PRODUCT	NFORMATION				Pallet:						
Saleable Unit of Measure	c.	aleable Quantity	HIBCC		CTI	N-14	Unit of Use GTIN-14	Pallet:						
X Item/Each	5	aleable Quantity	ПІВСС			N-14 31722037013	OTHE OF USE GTHN-14							
Box/Carton/Bundle/Inner Pack					003				COST INFORMATION			WHOLESAL	ER USE ONL	LY:
X Case		24			203	31722037017								
Pallet								Regular Cost	t		Vendor #:			
								Invoice Cost		\$50.00	Whsl. Code	#:		
											Fineline Co			
								As of date:	6/8/2023					
								As of date:	6/8/2023					
*Please provide any additional in			Attach copy of SAFETY D	ATA SHEET (SD	S) or non haza		RT, LABEL AND PHOTO OF F							



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL I	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? No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:					
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide a. UN/Identification Number b. Proper Shipping Name	Is the product a NIOSH hazardous drug? If yes, indicate which:					
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification					
e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	EPA Hazardous Waste Code: Waste Characteristics					
(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? 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: DEA #: NCPDP#: NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments					
SP# ADD'L STORAGE INFORMATION	Registry: Registry Program Contact Name: Phone:					
Is the Product	Comments					
Controlled Substance? Controlled by State(s)? ARCOS Reportable? Schedule No. No Controlled Substance Code Listed Chemical (List I or II) No If yes, indicate which: Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged: Is product returnable for credit: 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:						
MISCELLAI	NEOUS 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 S	nip 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 e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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 Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order:		Overnight receipt available: PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:		Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
		Priority Overnight receipt available:
Class of Trade Restriction		PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # 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?