

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

Version 2021					Introduction 1	Type: Ne	ew Item	x	Final Version			Date:	5/5/2	2024
		PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STOP	AGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc.				Applica	Application: ANDA a. Temperature – Indicate the USP temperature ra			erature range for t	ae for this product.					
Application Number for NDA/AN	DA/BLA (drug); PMA/510(k)(med device):	216	463		1			erature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicable:														
DUNS:	11-856-3719							Other	Temperature Range F	Requirement				
Proprietary Name (If Applicable) a		Mexiletine Hydrochloride Capsule							write in)					
Selling Unit NDC:	31722-038-01	Unit of Use NDC:			UPC:	331722038010		Notes						
UDI		CVX Code:			MVX Code:									
Description:	Mexiletine Hydrochloride Cap	osules, USP 250 mg							product to be shipped				No	
Is this product to be 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						b. Contact for tempe Name		estions:	Soma Raju			
Address:	800 Centennial Ave, Suite 1				Address 2:			Numb			732-529-042	23		
City:	Piscataway			State:	NJ	Zip: 08854		Group	E-mail:			neterousa.com	n	
Key Contact:	Customer Service			Email:	customerservice	@camberpharma.co	<u>m</u>						_	
Phone Number:	1-866-827-3647			Fax:	732-562-8788			c. Special regulation	s for product in any	states?			No	
Product Therapeutic Classification	n: Antiarrhyt	thmic						Specia	al returns requirement	s for this product?			No	
								.						
	ADDITIONAL PRO	DOUCT INFORMATION			PRODUCT	DESCRIPTION INFO	ORMATION	d. Store product (uni	t of sale) upright?				No	
The product is?		Is the Product	Direct-Ship Or	nly				Protec	t 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			0120.			Initial	shelf life at launch (i	if different):				Months
a product kit?	No				Strength:	250 mg								
if yes, list NDCs of		FDA Approval Status			•	Lined as letter				ORDER INFORM	ATION			
component parts reverse numbered?	No				Dosage Form	m: Hard gelatir	n capsule	Unit o	f Sala		What is the	NDC selling	unit?	
co-licensed?	No	Allergens Present						x			1 Bottle of 1		unit.	
latex-free?	Yes					Capsule			Box/Carton			g. 1 Box of 10) Vials)	
preservative-free?	Yes	Corn, Anir	nal Products		Product Sha	pe:			Ampule		(g		
correctional institution block?	No				Product Cole	White opaq	ue / light blue		Glass		Minimum or	der quantity	?	Yes
opioid?	No				FIGULE	opaque			Tube					
Cannabinoid?	No	Country of Origin	India		Product Imp		th 'V1' on cap		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for					and '34' on t	body		Vial Liquid Multi				ch package t	ype?
hospital scanning? If Unit Dose, indicate NDC here:		Is this product covered of Trade Agreements Act (No					Vial Powder Sgl Vial Powder Multi			Each Inner/Carton	(De ele	
Il Unit Dose, Indicate NDC here:		Trade Agreements Act (NO					Other: Write In			Case	Pack	
		FOR GENERIC DRUG PR	ODUCTS		1							Case		
		TOK CENERIO BROOT	000010											
			[Au	uthorized Generic	*If Authorized Gen	eric, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB		_			section fields are n		Rec. sell unit to cust	omer?		Rx billing u	nit to pharma	ncv.	
II. Generic Equivalent to What Bra										1		Each		
							(Write-in, e.g. 1 Vial) Gram							
	DRL	JG SUPPLY CHAIN SECURITY ACT	(DSCSA) INFOR	MATION								Milliliter		
			_								FORMER			
Does supplier meet DSCSA definit Is product exempt from DSCSA?	tion of manufacturer?	Yes No	_	GLN:	0331722498975				ITEN	I AND PACKING II	NFORMATION	N		
		NU								_				
If yes, select exemption:				GCP:					Weight Lbs.		ons (US msm		· · · · · · · · · · · · · · · · · · ·	Saleable #
Other exemption - Write in: Is product repackaged?		No		If you was a	riginal product	abasad		Item/Each:		Depth	Width	Height	(Cube)	Pieces
Is product sold by manufacturer's	exclusive distributor?	Yes		direct from n	riginal product pur	chased		item/Each:	0.19	2.18	2.18	3.87	18.39	1
Has FDA granted waiver/exception		No				or repackaged prod	uct	Box/Carton/Bundle/						
If yes, attach documentation from		L						Inner Pack:						
								Case:	5.25	13.5	9.5	5.25	673.31	24
		GTIN AND HIBCC PRODUCT I	NFORMATION						0.20	10.0	0.0	0.20	0/0.01	24
				_				Pallet:						
Saleable Unit of Measure	Saleable Qu	antity HIBCC			IN-14 31722038010	Unit of Us	e GTIN-14							
X Item/Each Box/Carton/Bundle/Inner Pack	1			003	031722036010				OST INFORMATION			WHOI ESALI	ER USE ONL	γ·
X Case	24			203	31722038014	-						MIGELOALI	IN OOL ONL	
Pallet	24			200	2.722000014	-		Regular Cost			Vendor #:			
								Invoice Cost (WAC) ((\$)	\$70.00	Whsl. Code	#:		
											Fineline Co			
								As of date:	6/8/2023		ļ			
μ								Ц			ļ			
		Attach copy of SAFETY D	ATA SHEET (SDS	S) or non haza										
*Please provide any additional info	ormation on page 2.				See new p. 3 for	Designated Drop S	Ship Only.	Signa	ture:					

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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?