

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

Version 2024					Introduction T	ype: New Item		x Final Version			Date:	10/10	0/2024	
PRODUCT INFORMATION							SPECIAL HANDLING AND STORAGE REQUIREMENTS*							
Company Name: Camber Pharmaceuticals, Inc.					Applicat	on: ANDA	a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/ANDA/BLA; PMA/510(k): 214336						NDA 505(b) Type: NOT APPLICABLE			Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)					
Medical Device Class, if applicab	le:							Ī						
	11-856-3719							Ot	her Temperature Range R	Requirement	Can be reste	rilized by aut	oclaving	
Proprietary Name (If Applicable) ar	nd Established Na	me: Lic	docaine Hydrochloride Injection, L	ISP 2% 1000 n					(write in)					
	31722-217-33		Unit of Use NDC:		31722-217-50		331722217330	No	otes					
UDI			CVX Code:			MVX Code:		l						
Description:	Lidocaine Hydroch	hloride Injection, I	USP 2% 1000 mg/50 mL (20 mg/i	nL) Multiple-Do	ose Vials				this product to be shipped				No	
Is this product to be shipped to customers on dry ice?														
Active Ingredient(s): Lidocaine hydrochloride, USP														
URL for Additional Product Information: www.camberpharma.com								b. Contact for temperature excursion questions: Name: Soma Raju						
Address:	800 Centennial Ave, Suite 1			Address 2:			Number: 732-529-0423							
City:	Piscataway					NJ	Zip: 08854	Group E-mail: somaraju@heterousa.com						
Key Contact:	Customer Service	outuna)				customerservice@	camberpharma.com							
Phone Number:	1-866-827-3647					732-562-8788		c. Special regulations for product in any states?					No	
Product Therapeutic Classification	1:	Local anesthetic	С					Special returns requirements for this product?				No		
	ADDITIO	ONAL PRODUCT	TINFORMATION			PRODUCT D	ESCRIPTION INFORMATION	d. Store product	(unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	nly				otect product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	10 x 50 mL multiple-dose	e. Shelf life:					24	Months
if yes, enter class #		Is.	Orphan Drug Status				vials	lni	itial shelf life at launch (i	f different):				Months
a product kit? if yes, list NDCs of		No	FDA Approval Status			Strength: 1000 mg/50 mL (20 mg/mL per multiple-dose vial				ORDER INFORM	AATION			
component parts			FDA Approvai Status				Sterile, nonpyrogenic, clear,			ORDER IN ORI	IATION			
reverse numbered?		No				Dosage Form	isotonic, aqueous solution	l l ur	nit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						Bottle			10 x 50 mL M		Vials
latex-free?		Yes	_			Product Shap	N/A		x Box/Carton			g. 1 Box of 10		
preservative-free?		No				r roduct Snap			Ampule					
correctional institution block?		No				Product Colo	r: Colorless		x Glass		Minimum o	der quantity	?	Yes
opioid?		No		L. P.				_	Tube					
Cannabinoid? If Unit Dose, is item bar coded to un	-:-	No	Country of Origin	India		Product Impr	int: N/A	_	Vial Liquid Sgl x Vial Liquid Multi		16 Vaa ha	many of whi		4
hospital scanning?	nit dose for		Is this product covered ur	der the					x Vial Liquid Multi Vial Powder Sgl		ir res, now	Each	т раскаде і	type?
If Unit Dose, indicate NDC here:			Trade Agreements Act (Ta		No				Vial Powder Multi			Inner/Carton	Pack Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PRO	DUCTS										
											_			
				_	Aut	thorized Generic	*If Authorized Generic, other			ARMACY ORDER				
	AP						section fields are not applicable	Rec. sell unit to customer? Rx billing unit to pharmacy:						
II. Generic Equivalent to What Brand?: Xylocaine						Each								
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORI			RMATION			(Write-in, e.g. 1 Vial) HCPCS J-Code: Gram Milliliter								
		DRUG 30	TTET CHAIN SECONTT ACT (E	JOCSA) INI ON	MATION			ncrcs 3-code.	J2003	1		wiiiiiter		
Does supplier meet DSCSA definit	ion of manufactur	er?	Yes	T	GLN:	0331722498975				AND PACKING I	NFORMATIO	N		_
Is product exempt from DSCSA?			No											
If yes, select exemption:					GCP:			1	Martala II	Dimensi	ons (US msn	nts.)	Volume	Saleable #
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			iginal product purc	hased	Item/Each:	2.55	9.2	3.6	3.5	115.9	1
Is product sold by manufacturer's			Yes	-	direct from m									
Has FDA granted waiver/exception If yes, attach documentation from		oduct?	No	1	Provide source	e manufacturer for	repackaged product	Box/Carton/Bund Inner Pack:	ile/					
ii yes, attacii documentation iron	III DA.							Case:						
			GTIN AND HIBCC PRODUCT IN	FORMATION					27.3	18.75	9.9	8.25	1531.4	10
								Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GTIN	N-14	Unit of Use GTIN-14							
		Quantity			1 2000		20001300013000							
x tem/Each N 1					31722217330	00331722217330	COST INFORMATION WHOLESALER USE ONLY:							
X Case	N	10			2033	31722217334			COST IN ORMATION			WIIOLLOALI	IN USL ONL	
Pallet	.,	10			2030			Regular Cost			Vendor #:			
								Invoice Cost (WA	(C) (\$)	\$75.08	Whsl. Code	#:		
]]			Fineline Co			
								As of date:	9/1/2024					
<u> </u>			Attack convert CAFETY DA	EA CLIEFT (OD	C) as san b	d laws DACKAGE	INSERT, LABEL AND PHOTO OF P	DODUCT DACKACH	NC and DADCODE		<u> </u>			
	ormation on nage		Attach copy of SAFETY DA	IN SHEET (SD	o oi non nazar		INSERT, LABEL AND PHOTO OF P Designated Drop Ship Only	- NODUCI PACKAGII	NG AND DARCODE.					



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

Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic? No	SDS Hazard Classification					
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? No 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?	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 SDS) 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); SP#	Comments					
ADD'L STORAGE INFORMATION	Registry: Registry Program Contact Name: Comments No Phone:					
Is the Product						
Controlled Substance Code 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:	RETURN INSTRUCTIONS Contact tel. # if product received damaged: I-866-827-3647 Is product returnable for credit: Yes					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	URL/Link to returns policy: contact - customerservice@camberpharma.com					
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: No	Special regulations or returns requirements for this product in certain states?					
Restricted from US territories? (explain in comments) No Comments:	If so, which states? Other requirements? Comments?					
MISCELLANE	DUS 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 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: 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: 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 State License # Physician/Clinic DEA #: Physician/Clinic Specialty: Miscellaneous Notes:	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?					
	ADDITIONAL INFORMATION					
	Is product order for scheduled patient procedure? Is product order for restocking purposes?					