

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

Version 2024						Introduction T	ype: New Item		x Final Version			Date:	10/10)/2024	
			PRODUCT INFORMAT	ION					SPECIAL HAN	IDLING AND STOP	RAGE REQUI	REMENTS*			
Company Name: Camber Pharmaceuticals, Inc. ANDA							a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/ANI	DA/BLA; PMA/510(k): 214336				NDA 505(b) Type:	NOT APPLICABLE	Terr	perature Range	Controlled Room	- between 20	and 25 C (68	° – 77° F)		
Medical Device Class, if applicab	le:							I							
	11-856-3719							Othe	er Temperature Range	Requirement	Can be rest	erilized by aut	toclaving		
Proprietary Name (If Applicable) and		me: Lidocair	ne Hydrochloride Injection, U	JSP 1% 500 m				-	(write in)						
Selling Unit NDC: UDI	31722-116-34		Unit of Use NDC: CVX Code:		31722-116-50	UPC: MVX Code:	331722116343	Note	es						
						WYX Couc.								1	
Description:	Lidocaine Hydroch	loride Injection, USP	1% 500 mg/50 mL (10 mg/m	nL) Multiple-Do	se Vials				is product to be shippe				No No		
Active Ingredient(s): Lidocaine hydrochloride, USP															
b. Contact for temperature excursion questions:															
URL for Additional Product Inform		www.camberpharma.	.com					Nan			Soma Raju				
Address:	800 Centennial Av	e, Suite 1			Charles	Address 2:			nber:		732-529-042				
City: Key Contact:	Piscataway Customer Service					NJ	Zip: 08854 camberpharma.com	Gro	Group E-mail:				araju@heterousa.com		
Phone Number:	1-866-827-3647				Fax:	732-562-8788	camberphanna.com	c. Special regulations for product in any states? No				1			
Product Therapeutic Classification		Local anesthetic				102 002 0100							No		
	Product Therapeutic Classification: Local anesthetic Special returns requirements for this product? No														
	ADDITIC	ONAL PRODUCT INF	ORMATION			PRODUCT D	ESCRIPTION INFORMATION	d. Store product (u	init of sale) upright?				No]	
The product is?			Is the Product	Direct-Ship C	Dnly			Prot	tect product (unit of s	ale) from light?			No	1	
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 #			Orphan Drug Status			0120.	vials	Initi	al shelf life at launch	(if different):				Months	
a product kit?		No	5DA A			Strength:	500 mg/50 mL (10 mg/mL) per multiple-dose vial			ORDER INFOR					
if yes, list NDCs of component parts			FDA Approval Status				Sterile, nonpyrogenic, clear,			OKDER INFORI	MATION				
reverse numbered?		No				Dosage Form	isotonic, aqueous solution	Unit	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		(Write-in, e	.g. 1 Box of 1	0 Vials)		
preservative-free?		No				i roudet onap			Ampule						
correctional institution block?		No				Product Colo	r: Colorless		x Glass		Minimum o	rder quantity	?	Yes	
opioid? Cannabinoid?		No No	Country of Origin	India			N/A		Tube Vial Liquid Sgl						
If Unit Dose, is item bar coded to u		NO	Country of Origin	Inula		Product Impr	int:		x Vial Liquid Sgl		If Yes, how	many of whi	ch package	type?	
hospital scanning?			Is this product covered ur	nder the					Vial Powder Sgl		1	Each	p=3-		
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	AA)?	No				Vial Powder Multi			Inner/Cartor	/Pack		
		-							Other: Write In			Case			
			FOR GENERIC DRUG PRO	DUCTS											
						the size of Quantum in	*If Authorized Operation of the		DI						
L One and Deals Define	AP				Au	thorized Generic	*If Authorized Generic, other section fields are not applicable	PHARMACY ORDER / BILL UNIT Rec. sell unit to customer? Rx billing unit to pharmacy:							
I. Orange Book Rating: II. Generic Equivalent to What Brar		Xylocaine						Rec. sell unit to cu	istomer ?	Rx billing unit to pharmacy: Each					
II. Generic Equivalent to What Brai	iur.	Aylocalite						(Write-in, e.g. 1 Via	al)			Gram			
-		DRUG SUPPLY	Y CHAIN SECURITY ACT (I	OSCSA) INFOR	RMATION			HCPCS J-Code:				Milliliter			
								J	2003			-			
Does supplier meet DSCSA definit	ion of manufacture	er?	Yes	-	GLN:	0331722498975			ITE	I AND PACKING I	NFORMATIO	N			
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:				Weight Lbs.		ions (US msr	-	Volume	Saleable #	
Other exemption - Write in: Is product repackaged?			No		If yos was a	iginal product purc	hased	Item/Each:	-	Depth	Width	Height	(Cube)	Pieces	
Is product sold by manufacturer's	exclusive distribut	tor?	Yes	-	direct from m				2.55	9	3.6	3.5	113.4	1	
Has FDA granted waiver/exception			No	1			repackaged product	Box/Carton/Bundle	e/						
If yes, attach documentation from	n FDA.							Inner Pack:							
		CTIN	I AND HIBCC PRODUCT IN	FORMATION				Case:	27.3	19	10.25	8	1558	10	
		GTIN	FAND HIBCC PRODUCT IN	FORMATION				Pallet:							
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GTI	N-14	Unit of Use GTIN-14	Fallet.							
		Quantity			511										
x Item/Each	N	1			003	31722116343	00331722116343								
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESAL	ER USE ONL	Y:	
X Case	N	10			203	31722116347					Man days 7				
Pallet								Regular Cost Invoice Cost (WAC	:) (\$)	\$60.40	Vendor #: Whsl. Code	#-			
								INVOICE COSI (WAC	7) (#)		Fineline Co				
								As of date:	9/1/2024						
					_										
			Attach copy of SAFETY DA	TA SHEET (SE	S) or non haza		INSERT, LABEL AND PHOTO OF F								
*Please provide any additional info	ormation on page 2	2				See new p. 3 for	Designated Drop Ship Only.	Sigr	nature:						

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Version 2024 For Designa	ted Drop Ship Only Products, Please Use Page 3					
MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic? 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	SDS Hazard Classification x Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard					
c. Contact Hazard? d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? No	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, answer a-e below and provide SDS) a. UN/dentification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group	If yes, indicate which: Hazardous Waste Identification					
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics					
Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) (if Unit for the North Context of the Nor	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: 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)	REMS: No REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: DEA #: Provider Name: NCPDP#: Site Enrollment Number assigned NPI #:					
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 Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: If Schedule No. Is it a scheduled listed chemical product?: No	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					
No No Restricted from US territories? (explain in comments) No	Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?					
Comments:						
MISCELLANE	OUS NOTES and/or Image of Product Barcode:					



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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 Fax Number: c. Fax Fax Number: d. Phone only Phone No.: e. Supplier Web Site only Site Address: Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name:	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:
Phone:	Overnight and Drivity Overnight DO Broossing
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: PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: PO Receipt Cut off time: Phone: Order receipt method: Phone: Fax: EDI: EDI: Covernight Fees apply: Other fees apply: Image: Covernight 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?