

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

Company Name	Version 2024					Introduction T	ype: New Item] [x Final Version			Date:	10/10	/2024	
Might black blac	PRODUCT INFORMATION								SPECIAL HANDLING AND STORAGE REQUIREMENTS*						
Make Solicy Control	Company Name: Camber Pharmaceuticals, Inc.				Applicat	ion: ANDA	a. Temperature – Indicate the USP temperature range for this product.								
Description	. ,						NOT APPLICABLE								
Populario Application part Registration Name	Medical Device Class, if applicab	le:							I						
Section 1900										Other Temperature Range F	Requirement	Can be reste	rilized by auto	oclaving	
Control		nd Established Na	ime: L		ISP 2% 400 mg										
Action large infection Learner in Product (All Product) Learner in Product (All Product) Learner in Product (All Product) Learner in Product) Learner in Product (All Product) Learner in Product (All Product) Learner in Product Learner in Product) Learner in Product Learner in Product)		31722-217-31				31722-217-20		331722217316		Notes					
Autorize Agricultus Septiminary Septim							MVX Code:								
Address Section Sect	Description:	Lidocaine Hydroch	hloride Injection,	, USP 2% 400 mg/20 mL (20 mg/m	L) Multiple-Dos	se Vials									
Control for Cont															
Minimal Mini	Active Ingredient(s): Lidocaine hydrochloride, USP								h Contact for temporature everysion questions:						
Address Occinitation Fig. Septimized	LIPI for Additional Product Inform	otion:	www.camberni	harma com							estions:	Soma Paiu			
Section Sect				nama.com		1	Address 2:		4				3		
Marches Mar	City:		.,			State:	NJ	Zip: 08854)	
Second classification Seco						Email:	customerservice@								
## ADDITIONAL PRODUCT INCOMATION The product ISP*	Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regulations for product in any states?					No	
Product In Face In In In In In In In I	Product Therapeutic Classification	n:	Local anesther	tic					:	Special returns requirements for this product?			No		
Product In Face In In In In In In In I															
a legend device? No. Use of Use Use Use of Use Use		ADDITIO	ONAL PRODUC	CT INFORMATION			PRODUCT D	DESCRIPTION INFORMATION	d. Store produc	ct (unit of sale) upright?				No	
Section Sect						only				Protect product (unit of sa	le) from light?				
System class Syst			No		Unit of Use		Size:							24	
Secretaria Part P				Orphan Drug Status						Initial shelf life at launch (i	f different):				Months
The contract of the contract			No	FD 4 4			Strength:				ORDER INFORM	MATION			
Disage Form:				FDA Approvai Status				F-0			ORDER INFORM	IATION			
L Crange Book Rating: L Crange Book Rating: L Crange Book Rating: L Crange Book Rating: L Grange Book Rating:			No				Dosage Form			Unit of Sale		What is the	NDC selling	unit?	
Secretive Yes Product Shape: NA Product Shape: NA Product Shape: NA Product Object Shape: NA Product Object Shape: NA Product Object Shape: NA Product Object Shape: NA Product Imprint: NA NA Na Na Na Na Na Na	co-licensed?			Allergens Present					Г						/ials
preservative-free/ No Conceits of Institution block? No Country of Origin (India Product Calor: NA Product Calor: NA Product Imprint: NA Product I	latex-free?						Due divet Ches	N/A		x Box/Carton					
spoid? No Courtey of Origin India Product (Morris) No Courtey of Origin India Product (Morris) No Visit Liquid Sig Visit Liq			No				Froduct Sna								
Generalization of Product Imprint: Country of Origin Free							Product Colo	r: Colorless				Minimum or	der quantity	?	Yes
Value Valu															
Saleable Water Segurate No. No. Interview Generic Vision For Addition of manufacturer? Ves. Saleable For Outer 1 No. No. Saleable For Outer 1 No. Saleable For Outer 1 No. Saleable For Outer 2 No. No. Saleable For Outer 2 No. Saleable For Outer 2 No. Saleable For Outer 2 No. No. Saleable For Outer 3 No. Saleable For Out			No	Country of Origin	India		Product Impr	int: N/A				W. V 1			
Multi-Dose, indicate NDC here:		nit dose for		la this product covered up	dor the									сп раскаде т	ype?
Concerning Con						No			-					Pack	
Authorized Generic, other section fields are not applicable Il. Generic Equivalent to What Brand?: Xylocaine PRUS SUPPLY CHAIN SECURITY ACT (OSCSA) INFORMATION	ii oint 2000, maioato 1120 noio.				,-	.10								. don	
Corange Book Rating: AP				FOR GENERIC DRUG PRO	DUCTS										
Corange Book Rating: AP															
Control Equivalent to What Brand?: Xylocaine Surgest Sur						Aut	horized Generic				ARMACY ORDER	/ BILL UNIT			
Visit Continue C								section fields are not applicable	Rec. sell unit to	o customer?		Rx billing ur		cy:	
Copy	II. Generic Equivalent to What Brand?: Xylocaine														
Does supplier meet DSCSA definition of manufacturer?	DDUC CURRI V CUAIN CECURITY ACT (DCCCA) INFORMATION			MATION	ATION			(Write-in, e.g. 1 Vial)							
Does supplier meet DSCSA definition of manufacturer?			DRUG 3	OFFET CHAIN SECORITT ACT (L	SCSA) INFOR	IWATION			HCPCS J-Code		1		Milliter		
S product exempt from DSCSA? No Saleable Subject Subje	Does supplier meet DSCSA definiti	ion of manufactur	er?	Yes	Т	GLN:	0331722498975				AND PACKING IN	NFORMATION			
Saleable Unit of Measure RFID tag(YN) Saleable Cost invoice Cost (WAC) (S) Saleable Cost (WAC) (S) Saleable Cost (WAC) (S) Saleable Cost (WAC) (S) Saleable Saleabl			<u> </u>		1										
Saleable Unit of Measure RFID tag(YN) Saleable Cost invoice Cost (WAC) (S) Saleable Cost (WAC) (S) Saleable Cost (WAC) (S) Saleable Cost (WAC) (S) Saleable Saleabl	If ves. select exemption:					GCP:			1		Dimensi	ons (US msm	its.)	Volume	Saleable #
Report Spring S										Weight Lbs.		•	•		
Spring and waiverfected executive distributor? No Provide source manufacturer for repackaged product If yes, attach documentation from FDA. Provide source manufacturer for repackaged product If yes, attach documentation from FDA. Provide source manufacturer for repackaged product If yes, attach documentation from FDA. Box/Carton/Bundle/ Inner Pack: Case: 21.15 13.25 13.25 6.4 1123.60 8	Is product repackaged?							hased	Item/Each:	2.45					1
Saleable Unit of Measure RFID tag(Y/N) Saleable Quantity											0.20	0.20	2.70	107.42	
Case 21.15 13.25 13.25 6.4 1123.60 8			oduct?	No No		Provide source	e manufacturer fo	r repackaged product		ndle/					
Saleable Unit of Measure RFID tag(Y/N) Saleable Countity Fallet Countity C	If yes, attach documentation from	n FDA.													
Saleable Unit of Measure RFID tag(Y/N) Saleable Quantity X				GTIN AND HIBCC PRODUCT IN	FORMATION				Lase.	21.15	13.25	13.25	6.4	1123.60	8
X									Pallet:						
X	Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GTIN	I-14	Unit of Use GTIN-14							
Box/Carton/Bundle/Inner Pack X Case N 8 20331722217310 Regular Cost Invoice Cost (WAC) (\$) \$101.07 Whist. Code #: Fineline Code: Soft date: 9/1/2024 Soft date: Soft dat	ll		Quantity												
X Case		N	1			0033	1722217316	00331722217316		OCCUPATION OF THE PARTY OF THE			MIOI EQ	D HOE eve	
Pallet Regular Cost Nuncice Cost (WAC) (\$) \$101.07 Whsl. Code #: Fineline Code: As of date: 9/1/2024 Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.		N.					1700017010			COST INFORMATION		1	NHOLESALE	R USE ONL	Y:
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.		IN	8			2033	11/2221/310		Pogular Cast			Vendor #			
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.	Pallet					-				VAC) (\$)	\$101.07		# -		
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.										, (*)	Ψ101.07				
						1		1	As of date:	9/1/2024					
	1								Ш						
	*Please provide any additional info	ormation on page	2	Attach copy of SAFETY DAT	TA SHEET (SD	S) or non hazar			PRODUCT PACKAG	GING and BARCODE.					



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For Designated Drop Ship Only Products, Please Use Page 3

M	ATERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic?	No	SDS Hazard Classification					
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?		SSO Hazara Statistication					
Is the product a CA Prop 65 carcinogen?	x Organic	Corrosive					
Is the product a CA Prop 65 reproductive toxicant?	No	Inorganic	Oxidizer				
Does the product label bear a CA Prop 65 warning?	No	Steroid/Androgen	Contact Hazard				
c. Contact Hazard?	No	Does the product have an Aerosol class? If yes,	No				
d. Does this product require special clean-up instructions?	No	identify NFPA Storage Level:					
(If yes, attach SDS with special instructions.)		NFPA Storage Level:					
e. Does the product contain DEHP?	No						
Is this product regulated for shipment by DOT?	No	Is the product a NIOSH hazardous drug?	No				
(if yes, answer a-e below and provide SDS) a. UN/Identification Number		If yes, indicate which:					
b. Proper Shipping Name							
c. DOT Hazard Class	Hazardous Waste Identification						
d. Packing Group		EDA II. W. J. O. J.		W + 21 + 1 : :			
e. Inhalation Hazard?	No	EPA Hazardous Waste Code:		Waste Characteristics			
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)	No	PEMS	r REGISTRY RESTRICTIONS				
a. UN/Identification Number		REIVIS 0	I REGISTRY RESTRICTIONS				
b. Proper Shipping Name		Is there a REMS on this product?	No				
c. DOT Hazard Class		If Yes, is it managed with a pharmacy registry?					
d. Packing Group e. Inhalation Hazard?	No	Website URL:					
	No	Mad Cuida Daguirad	No				
Is the product restricted for air shipment? If so, indicate restriction: Passenger	INU	Med Guide Required Limited Distribution Requirement	INO				
Cargo		Comments / Details: (For example, iPledge program?)					
Passenger & Cargo							
Is this a reportable quantity? No		REMS:	No				
RQ Threshold: Is this a marine pollutant? No		REMS Program Manager Name: Supplier Manages REMS registry exclusively:		Phone:			
Is this a manne politicant: 140 Is this product shipped utilizing an authorized DOT exception or Special Permit?		Wholesale distributor support:					
No (if yes, identify method below)		Provider Name:		DEA #:			
Limited Quantity		Site Enrollment Number assigned		NCPDP#:			
Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4)		by Supplier:		NPI #:			
Special Permit; DOT-SP		Comments					
Special Provision (listed in Column 7 of 49 CFR 172.101);							
SP#		Registry:	No	_			
ADD'L STORAGE INFORMATION		Registry Program Contact Name:		Phone:			
		Comments					
Is the Product Controlled Substance? No Controlled Substance Code		R	ETURN INSTRUCTIONS				
Controlled by State(s)? No Listed Chemical (List I or II)	No						
ARCOS Reportable? No If yes, indicate which:		Contact tel. # if product received damaged:	1-866-827-3647				
Schedule No. Is it a scheduled listed chemical product?:	No	Is product returnable for credit:	Yes				
CLASS OF TRADE RESTRICTION:		URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes	contact - customerse	rvice@camberpharma.com				
Restricted to retail pharmacy only:	No	Special regulations or returns requirements for this					
Restricted to hospital, clinics, and physician offices only:	product in certain states?	No					
Restricted from US territories? (explain in comments)	No	If so, which states? Other requirements? Comments?					
Comments:							
	ISCELLANEC	OUS 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 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?					