

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

						Introduction Type	New Item	х	Final Version			Date:	4/29/	2025
			PRODUCT INFORMAT	TION					SPECIAL HAND	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Camber Pharmac	euticals. Inc.				Application:	ANDA	a. Temperature – Indica	ate the USP tempe	rature range for th	nis product.			
Application Number for NDA/AND	A/BLA: PMA/510	(k): 217821				NDA 505(b) Type:	NOT APPLICABLE			Controlled Room -		and 25 C (68	– 77° F)	
Medical Device Class, if applicab		.,,				, ,,		1				(
DUNS:	11-856-3719							Other Te	mperature Range R	equirement	Excursions	ermitted hetv	veen 15 °C to	30 °C (59
Proprietary Name (If Applicable) ar		me: Bupiyac	aine Hydrochloride Injection	n. USP 0.75% 7	5 ma/10 mL (7	.5 mg/mL) Single-Dose \	/ials		ite in)		°F to 86 °F)			(
	31722-277-32		Unit of Use NDC:	.,			722277327	Notes	,		,			
UDI			CVX Code:			MVX Code:		1						
Description:	Punivaccina Hudr	achlarida Injection IIC	P 0.75% 75 mg/10 mL (7.5	ma/ml) Cinalo	Dogo Viole			In this pr	oduct to be shipped	to quotomore on in	102		No	
Description.	Dupivacame riyun	ocilionae injection, oo	0.737673111g/10111L (7.3	ing/inc) Single-	Dose viais				oduct to be shipped				No	
Active Ingredient(s):		Bupivicaine hydrochle	oride LISP					is this pir	oduct to be shipped	to customers on u	ly loc:	I	140	
nouro mgroulom(o).		Bapirioanio nyarooni	01100, 001					b. Contact for temperar	ture excursion que	stions:				
URL for Additional Product Informa	ation:	www.camberpharma.	com					Name:			Soma Raju			
Address:	800 Centennial Av					Address 2:		Number	:		732-529-042	3		
City:	Piscataway				State:	NJ Zi	p: 08854	Group E	-mail:		somaraju@l	eterousa.com	1	
Key Contact:	Customer Service	Customer Service Email:				customerservice@car	nberpharma.com							
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regulations f	for product in any	states?			No	
Product Therapeutic Classification	:	Amide local anesthet	tic					Special r	eturns requirements	s for this product?			No	
	ADDITIO	ONAL PRODUCT INFO	ORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store product (unit of	of sale) upright?				No	
The product is?			Is the Product	Direct-Ship O	nly			Protect	product (unit of sal	le) from light?			No	
a legend device?		No	Is the Product	Unit Dose	-	Size:	25 x 10 mL single-dose	e. Shelf life:	•	, .			24	Months
if yes, enter class #			Orphan Drug Status			Size:	vials	Initial sh	elf life at launch (if	f different):				Months
a product kit?		No				Strength:	75 mg/10 mL per single-							
if yes, list NDCs of			FDA Approval Status			Su engui.	dose vial			ORDER INFORM	ATION			
component parts						Dosage Form:	Clear, sterile, isotonic							
reverse numbered?		No				Dosage Form.	solution	Unit of S				NDC selling		
co-licensed?		No	Allergens Present						Bottle				ngle-Dose Via	als
latex-free?		Yes				Product Shape:	N/A	x	Box/Carton		(Write-in, e.	g. 1 Box of 10	Vials)	
preservative-free?		Yes							Ampule					
correctional institution block?		No				Product Color:	Colorless	X	Glass		Minimum o	der quantity	?	Yes
opioid?		No							Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	N/A	x	Vial Liquid Sgl					_
If Unit Dose, is item bar coded to un hospital scanning?	nit dose for	V	Leade to see about a second con-	a death a					Vial Liquid Multi		If Yes, how		ch package t	ype?
If Unit Dose, indicate NDC here:		Yes 31722-277-10	Is this product covered un Trade Agreements Act (T		No				Vial Powder Sgl Vial Powder Multi		- 8	Each Inner/Carton	/Dook	
ii Offit Dose, indicate NDC fiere.		31722-277-10	Trade Agreements Act (1	AA):	INU				Other: Write In			Case	Fack	
			FOR GENERIC DRUG PRO	ODUCTO					Other. Write in			Case		
			FOR GENERIC DRUG FRO	DDUCIS										
							Authorized Generic, other		PH	ARMACY ORDER	/ DILL LINET			
					Ι Δι	thorized Generic *If.								
I. Oranga Basis Basinas	AD			_	Au			Poo cell unit to queton				it to ubound		
	AP	Marcaine			Au		tion fields are not applicable	Rec. sell unit to custon				nit to pharma	су:	
I. Orange Book Rating: II. Generic Equivalent to What Brar		Marcaine			Au							Each	icy:	
			CHAIN SECURITY ACT (I	DSCSA) INFOR				(Write-in, e.g. 1 Vial)				Each Gram	cy:	
			CHAIN SECURITY ACT (I	DSCSA) INFOR					ner?			Each	ey:	
	nd?:	DRUG SUPPLY	' CHAIN SECURITY ACT (I	DSCSA) INFOR				(Write-in, e.g. 1 Vial) HCPCS J-Code:	ner?	AND PACKING IN	Rx billing u	Each Gram Milliliter	ecy:	
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II. Generic Equivalent to What Branch Does supplier meet DSCSA definit Is product exempt from DSCSA?	nd?:	DRUG SUPPLY	Yes	DSCSA) INFOR	MATION	sec		(Write-in, e.g. 1 Vial) HCPCS J-Code:	ner?	AND PACKING IN	Rx billing u	Each Gram Milliliter		Saleable #
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II. Generic Equivalent to What Brar Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	id?: ion of manufactur	DRUG SUPPLY	Yes No	DSCSA) INFOR	MATION GLN: GCP:	0331722498975	tion fields are not applicable	(Write-in, e.g. 1 Vial) HCPCS J-Code: J0665	ner?	AND PACKING IN	Rx billing u	Each Gram Milliliter	Volume	
II. Generic Equivalent to What Brar Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception	ion of manufactur exclusive distribu /exemption for pr	DRUG SUPPLY	Yes No	DSCSA) INFOR	MATION GLN: GCP: If yes, was or direct from m	0331722498975	ed	(Write-in, e.g. 1 Vial) HCPCS J-Code: J0665	TEM	AND PACKING IN Dimensio Depth	Rx billing u IFORMATIO DOES (US msn Width	Each Gram Milliliter tts.) Height	Volume (Cube)	Pieces
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II. Generic Equivalent to What Brar Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from	d?: ion of manufactur exclusive distribu /exemption for pr i FDA.	DRUG SUPPLY er? tor? oduct?	Yes No No Yes No AND HIBCC PRODUCT IN		MATION GLN: GCP: If yes, was or direct from m Provide sour	0331722498975 riginal product purchas fir? ce manufacturer for rej	ed	(Write-in, e.g. 1 Vial) HCPCS J-Code: J0665 Item/Each: Box/Carton/Bundle/ Inner Pack:	Weight Lbs.	AND PACKING IN Dimension Depth 5	Rx billing u IFORMATIO DOES (US men Width	Each Gram Milliliter tts.) Height 2.75	Volume (Cube) 68.75	Pieces 1
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II. Generic Equivalent to What Brar Does supplier meet DSCSA definit is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product sold by manufacturer's Has FDA granted waiver/exception if yes, attach documentation from Saleable Unit of Measure X	exclusive distribu /exemption for pr n FDA. RFID tag(Y/N) N	DRUG SUPPLY er? ttor? oduct? GTIN Saleable Quantity 1 8	No No Yes No AND HIBCC PRODUCT IN HIBCC	NFORMATION	MATION GLN: GCP: If yes, was or direct from m Provide sour. GTI 003	0331722498975 riginal product purchastifr? ce manufacturer for rej N-14 31722277327 31722277321	ed	(Write-in, e.g. 1 Vial) HCPCS J-Code: J0665 Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet: COS Regular Cost Invoice Cost (WAC) (\$) As of date:	Weight Lbs. 1.3 11.75 TINFORMATION 2/14/2025	AND PACKING IN Dimension Depth 5	Rx billing u IFORMATIO Ons (US msn Width 5 11 Vendor #:	Each Gram Milliliter Its.) Height 2.75 6.25	Volume (Cube) 68.75	Pieces 1 8



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

Version 2024

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL 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? 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 e. Inhalation Hazard?	Hazardous Waste Identification						
ls this product regulated for shipment by IATA?	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? 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#: NCPDP#: NPI #:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments Registry: No						
	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	Comments						
Is the Product Controlled Substance? 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	RETURN INSTRUCTIONS Contact tel. # if product received damaged: 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 - customerservice@camberpharma.com						
Restricted to retail pharmacy only: 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:							
MISCELLAN	EOUS 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	Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only Phone No.:	Shipping lead time of PO: Hours Days
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	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:	Overnight receipt available:
Drop Ship service fee billed with each order:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:	Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
Class of Trade Restriction:	Priority Overnight receipt available: 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: 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/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?