



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

Version 2024 Introduction Type: New Item Final Version Date: 10/10/2024

PRODUCT INFORMATION

Company Name: Camber Pharmaceuticals, Inc. Application: ANDA
 Application Number for NDA/ANDA/BLA; PMA/510(k): 214336 NDA 505(b) Type: NOT APPLICABLE
 Medical Device Class, if applicable:
 DUNS: 11-856-3719
 Proprietary Name (If Applicable) and Established Name: Lidocaine Hydrochloride Injection, USP 2% 1000 mg/50 mL (20 mg/mL) Multiple-Dose Vials
 Selling Unit NDC: 31722-217-32 Unit of Use NDC: 31722-217-50 UPC: 331722217323
 UDI
 CVX Code: MVX Code:
 Description: Lidocaine Hydrochloride Injection, USP 2% 1000 mg/50 mL (20 mg/mL) Multiple-Dose Vials
 Active Ingredient(s): Lidocaine hydrochloride, USP
 URL for Additional Product Information: www.camberpharma.com
 Address: 800 Centennial Ave, Suite 1 State: NJ Address 2:
 City: Piscataway Zip: 08854
 Key Contact: Customer Service Email: customerservice@camberpharma.com
 Phone Number: 1-866-827-3647 Fax: 732-562-8788
 Product Therapeutic Classification: Local anesthetic

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.
 Temperature Range: Controlled Room – between 20 and 25 C (68° – 77° F)
 Other Temperature Range Requirement: Can be resterilized by autoclaving (write in)
 Notes:
 Is this product to be shipped to customers on ice? No
 Is this product to be shipped to customers on dry ice? No
 b. Contact for temperature excursion questions:
 Name: Soma Raju
 Number: 732-529-0423
 Group E-mail: somaraju@heterousa.com
 c. Special regulations for product in any states?
 Special returns requirements for this product? No
 d. Store product (unit of sale) upright? No
 Protect product (unit of sale) from light? No
 e. Shelf life:
 Initial shelf life at launch (if different): 24 Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is? a legend device? if yes, enter class # a product kit? if yes, list NDCs of component parts reverse numbered? co-licensed? latex-free? preservative-free? correctional institution block? opioid? Cannabinoid?	<input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No	Is the Product... Is the Product... Orphan Drug Status FDA Approval Status Allergens Present Country of Origin	<input type="checkbox"/> Direct-Ship Only <input type="checkbox"/> Unit of Use <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> India
If Unit Dose, is item bar coded to unit dose for hospital scanning? If Unit Dose, indicate NDC here:	<input type="checkbox"/> <input type="checkbox"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/> No
Size:	25 x 50 mL multiple-dose vials	Strength:	1000 mg/50 mL (20 mg/mL) per multiple-dose vial
Dosage Form:	Sterile, nonpyrogenic, clear, isotonic, aqueous solution	Product Shape:	N/A
Product Color:	Colorless	Product Imprint:	N/A

ORDER INFORMATION

Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	1 Carton of 25 x 50 mL Multiple-Dose Vials
<input checked="" type="checkbox"/> Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input checked="" type="checkbox"/> Glass Tube	Minimum order quantity? <input type="checkbox"/> Yes
<input type="checkbox"/> Vial Liquid Sgl	
<input checked="" type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	1 Each
<input type="checkbox"/> Vial Powder Multi	Inner/ Carton/ Pack
<input type="checkbox"/> Other: Write In	Case

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AP Authorized Generic *If Authorized Generic, other section fields are not applicable
 II. Generic Equivalent to What Brand?: Xylocaine

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? Each
 Gram
 Milliliter
 (Write-in, e.g. 1 Vial)
 HCPCS J-Code: J2003

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes No
 Is product exempt from DSCSA?
 If yes, select exemption:
 Other exemption - Write in:
 Is product repackaged? No
 Is product sold by manufacturer's exclusive distributor? Yes
 Has FDA granted waiver/exception/exemption for product? No
 If yes, attach documentation from FDA.
 GLN: 0331722498975
 GCP:
 If yes, was original product purchased direct from mfr?
 Provide source manufacturer for repackaged product

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/ Carton/ Bundle/ Inner Pack:	6.35	9	9	3.5	283.50	1
Case:	27.15	18.75	9.9	8.25	1531.41	4
Pallet:						

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	N	1		00331722217323	00331722217323
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack	N	4		20331722217327	
<input type="checkbox"/> Case					
<input type="checkbox"/> Pallet					

COST INFORMATION

Regular Cost
 Invoice Cost (WAC) (\$) \$187.70
 As of date: 9/1/2024
WHOLESALE USE ONLY:
 Vendor #:
 Whsl. Code #:
 Fineline Code:

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION																	
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? <input type="checkbox"/> No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? <input type="checkbox"/> No Is the product a CA Prop 65 reproductive toxicant? <input type="checkbox"/> No Does the product label bear a CA Prop 65 warning? <input type="checkbox"/> No</p> <p>c. Contact Hazard? <input type="checkbox"/> No</p> <p>d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) <input type="checkbox"/> No</p> <p>e. Does the product contain DEHP? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is the product restricted for air shipment? If so, indicate restriction: <input type="checkbox"/> No</p> <p><input type="checkbox"/> Passenger <input type="checkbox"/> Cargo <input type="checkbox"/> Passenger & Cargo</p> <p>Is this a reportable quantity? <input type="checkbox"/> No RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? <input type="checkbox"/> No</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit? <input type="checkbox"/> No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity <input type="checkbox"/> Consumer Commodity, ORM-D <input type="checkbox"/> Small Quantity (49 CFR 173.4) <input type="checkbox"/> Special Permit; DOT-SP <input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101); SP# <input type="text"/></p>	<div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">SDS Hazard Classification</div> <table style="width:100%; border: none;"> <tr> <td style="width: 50%; border: none;"><input checked="" type="checkbox"/> Organic</td> <td style="width: 50%; border: none;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Inorganic</td> <td style="border: none;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Steroid/Androgen</td> <td style="border: none;"><input type="checkbox"/> Contact Hazard</td> </tr> </table> <p>Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="checkbox"/> No NFPA Storage Level: <input type="text"/></p> <p>Is the product a NIOSH hazardous drug? <input type="checkbox"/> No If yes, indicate which: <input type="text"/></p>	<input checked="" type="checkbox"/> Organic	<input type="checkbox"/> Corrosive	<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer	<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard										
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<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard																
Hazardous Waste Identification																	
EPA Hazardous Waste Code: <input type="text"/> Waste Characteristics: <input type="text"/>																	
REMS or REGISTRY RESTRICTIONS																	
<p>Is there a REMS on this product? <input type="checkbox"/> No If Yes, is it managed with a pharmacy registry? Website URL: <input type="text"/></p> <p>Med Guide Required <input type="checkbox"/> No Limited Distribution Requirement Comments / Details: (For example, iPledge program?) <input type="text"/></p> <p>REMS:</p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="checkbox"/> No Wholesale distributor support: <input type="text"/></p> <p>Provider Name: <input type="text"/> DEA #: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/> NCPDP#: <input type="text"/> NPI #: <input type="text"/></p> <p>Comments <input type="text"/></p> <p>Registry: <input type="checkbox"/> No Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments <input type="text"/></p>																	
RETURN INSTRUCTIONS																	
<p>Contact tel. # if product received damaged: <input type="text"/> 1-866-827-3647</p> <p>Is product returnable for credit: <input type="checkbox"/> Yes</p> <p>URL/Link to returns policy: <input type="text"/> contact - customerservice@camberpharma.com</p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> No</p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>																	
ADD'L STORAGE INFORMATION																	
<p>Is the Product...</p> <table style="width:100%; border: none;"> <tr> <td style="width: 30%;">Controlled Substance?</td> <td style="width: 10%;"><input type="checkbox"/> No</td> <td style="width: 30%;">Controlled Substance Code</td> <td style="width: 30%;"><input type="text"/></td> </tr> <tr> <td>Controlled by State(s)?</td> <td><input type="checkbox"/> No</td> <td>Listed Chemical (List I or II)</td> <td><input type="checkbox"/> No</td> </tr> <tr> <td>ARCOS Reportable?</td> <td><input type="checkbox"/> No</td> <td>If yes, indicate which:</td> <td><input type="text"/></td> </tr> <tr> <td>Schedule No.</td> <td><input type="text"/></td> <td>Is it a scheduled listed chemical product?:</td> <td><input type="checkbox"/> No</td> </tr> </table>		Controlled Substance?	<input type="checkbox"/> No	Controlled Substance Code	<input type="text"/>	Controlled by State(s)?	<input type="checkbox"/> No	Listed Chemical (List I or II)	<input type="checkbox"/> No	ARCOS Reportable?	<input type="checkbox"/> No	If yes, indicate which:	<input type="text"/>	Schedule No.	<input type="text"/>	Is it a scheduled listed chemical product?:	<input type="checkbox"/> No
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ARCOS Reportable?	<input type="checkbox"/> No	If yes, indicate which:	<input type="text"/>														
Schedule No.	<input type="text"/>	Is it a scheduled listed chemical product?:	<input type="checkbox"/> No														
CLASS OF TRADE RESTRICTION:																	
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes</p> <p>Restricted to retail pharmacy only: <input type="checkbox"/> No</p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No</p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/> No</p> <p>Comments: <input type="text"/></p>																	
MISCELLANEOUS NOTES and/or Image of Product Barcode:																	
<input type="text"/>																	



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
<p>Purchase orders may be accepted by:</p> <ul style="list-style-type: none"> a. EDI <input type="checkbox"/> b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/> c. Fax <input type="checkbox"/> Fax Number: <input type="text"/> d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/> e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday <p>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>	
Other Data Information Required to Process PO:	Return Instructions
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<p><input type="text"/></p>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>