

Version 2024

Introduction Type: 

|          |               |
|----------|---------------|
| <b>x</b> | Final Version |
|----------|---------------|

Date: 4/29/2025

| PRODUCT INFORMATION                                    |   |   |  |
|--|---|---|--|
| Company Name:  |   | Camber Pharmaceuticals, Inc.  |  |
| Application Number for NDA/ANDA/BLA; PMA/510(k):       |   | 217821  |  |
| Medical Device Class, if applicable:                   |   |   |  |
| DUNS:  | 11-856-3719   | Application:  | ANDA   |
| Proprietary Name (If Applicable) and Established Name: |   | Bupivacaine Hydrochloride Injection, USP 0.5% 50 mg/10 mL (5 mg/mL) Single-Dose Vials |  |
| Selling Unit NDC:                                      | 31722-276-32  | NDA 505(b) Type:  | NOT APPLICABLE   |
| UDI  |   | Unit of Use NDC:  |  |
|  |   | UPC:  | 331722276320   |
|  |   | CVX Code:   |  |
|  |   | MVX Code:   |  |
| Description:   | Bupivacaine Hydrochloride Injection, USP 0.5% 50 mg/10 mL (5 mg/mL) Single-Dose Vials |   |  |
| Active Ingredient(s):                                  | Bupivacaine hydrochloride, USP  |   |  |
| URL for Additional Product Information:                | <a href="http://www.camberpharma.com">www.camberpharma.com</a>                        |   |  |
| Address:   | 800 Centennial Ave, Suite 1   |   | Address 2:   |
| City:  | Piscataway  | State:  | NJ   |
| Key Contact:   | Customer Service  | Zip:  | 08854  |
| Phone Number:  | 1-866-827-3647  | Email:  | <a href="mailto:customerservice@camberpharma.com">customerservice@camberpharma.com</a> |
|  |   | Fax:  | 732-562-8788   |
| Product Therapeutic Classification:                    | Amide local anesthetic  |   |  |

| ADDITIONAL PRODUCT INFORMATION                                      |              | PRODUCT DESCRIPTION INFORMATION                               |                  |
|---|--------------|---|------------------|
| The product is?   |              | Is the Product...   | Direct-Ship Only |
| a legend device?  | No           | Is the Product...   | Unit Dose        |
| if yes, enter class #   |              | Orphan Drug Status  |                  |
| a product kit?  | No           | FDA Approval Status   |                  |
| if yes, list NDCs of component parts reverse numbered?              |              | Allergens Present   |                  |
| co-licensed?  | No           |   |                  |
| latex-free?   | Yes          | Country of Origin   | India            |
| preservative-free?  | Yes          |   |                  |
| correctional institution block?                                     | No           |   |                  |
| opioid?   | No           |   |                  |
| Cannabinoid?  | No           |   |                  |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | Yes          | Is this product covered under the Trade Agreements Act (TAA)? | No               |
| If Unit Dose, indicate NDC here:                                    | 31722-276-10 |   |                  |

| FOR GENERIC DRUG PRODUCTS              |          |
|--|----------|
| I. Orange Book Rating:                 | AP       |
| II. Generic Equivalent to What Brand?: | Marcaine |
|  |          |

| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION       |     |
|--|-----|
| Does supplier meet DSCSA definition of manufacturer?     | Yes |
| Is product exempt from DSCSA?                            | No  |
| 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.                   |     |

| GTIN AND HIBCC PRODUCT INFORMATION |               |                   |       |                |                     |
|------------------------------------|---------------|-------------------|-------|----------------|---------------------|
| Saleable Unit of Measure           | RFID tag(Y/N) | Saleable Quantity | HIBCC | GTIN-14        | Unit of Use GTIN-14 |
| x Item/Each                        | N             | 1                 |       | 00331722276320 |                     |
| x Box/Carton/Bundle/Inner Pack     |               |                   |       |                |                     |
| x Case                             | N             | 8                 |       | 20331722276324 |                     |
|                                    |               |                   |       |                |                     |
|                                    |               |                   |       |                |                     |
|                                    |               |                   |       |                |                     |
|                                    |               |                   |       |                |                     |
|                                    |               |                   |       |                |                     |

| 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 (write in)                        |  | Excursions permitted between 15 °C to 30 °C (59 °F to 86 °F)       |  |  |  |  |
| 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:   |  | <a href="mailto:somaraju@heterousa.com">somaraju@heterousa.com</a> |  |  |  |  |
| c. Special regulations for product in any states?                     |  |  |  |  |  |  |
| Special returns requirements for this product?                        |  | No   |  |  |  |  |
| d. Store product (unit of sale) upright?                              |  |  |  |  |  |  |
| Protect product (unit of sale) from light?                            |  | No   |  |  |  |  |
| e. Shelf life:  |  |  |  |  |  |  |
| Initial shelf life at launch (if different):                          |  | 24 Months  |  |  |  |  |

| ORDER INFORMATION |  |
|-------------------|--|
| Unit of Sale      | What is the NDC selling unit?            |
| Bottle            | 1 Carton of 25 x 10 mL Single-Dose Vials |
| x Box/Carton      | (Write-in, e.g. 1 Box of 10 Vials)       |
| Ampule            |  |
| x Glass           | Minimum order quantity? Yes              |
| Tube              |  |
| x Vial Liquid Sgl |  |
| Vial Liquid Multi | If Yes, how many of which package type?  |
| Vial Powder Sgl   | 8 Each                                   |
| Vial Powder Multi | Inner/Carton/Pack                        |
| Other: Write In   | Case                                     |
|                   |  |

| PHARMACY ORDER / BILL UNIT  |                              |
|-----------------------------|------------------------------|
| Rec. sell unit to customer? | Rx billing unit to pharmacy: |
|                             | Each                         |
| (Write-in, e.g. 1 Vial)     | Gram                         |
| HCPCS J-Code:               | Milliliter                   |
| J0665                       |                              |

| ITEM AND PACKING INFORMATION  |             |                        |       |        |               |                   |
|-------------------------------|-------------|------------------------|-------|--------|---------------|-------------------|
|                               | Weight Lbs. | Dimensions (US msmts.) |       |        | Volume (Cube) | Saleable # Pieces |
|                               |             | Depth                  | Width | Height |               |                   |
| Item/Each:                    | 1.3         | 5                      | 5     | 2.75   | 68.75         | 1                 |
| Box/Carton/Bundle/Inner Pack: |             |                        |       |        |               |                   |
| Case:                         | 11.75       | 11                     | 11    | 6.25   | 756.25        | 8                 |
| Pallet:                       |             |                        |       |        |               |                   |

| COST INFORMATION        |           | WHOLESALER USE ONLY: |  |
|-------------------------|-----------|----------------------|--|
| Regular Cost            |           | Vendor #:            |  |
| Invoice Cost (WAC) (\$) | \$65.75   | Whsl. Code #:        |  |
| As of date:             | 2/14/2025 | Fineline Code:       |  |

\*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE

**See new p. 3 for Designated Drop Ship Only.**

**Signature:**



# 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?  
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?

- 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?

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
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?

Is this product regulated for shipment by IATA?  
(if yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?

Is the product restricted for air shipment? If so, indicate restriction:

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

Is this a reportable quantity?

RQ Threshold:

Is this a marine pollutant?

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)
- ☐ Special Permit; DOT-SP
- ☐ Special Provision (listed in Column 7 of 49 CFR 172.101);  
SP#

### ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance?  Controlled Substance Code
- Controlled by State(s)?  Listed Chemical (List I or II)
- ARCOS Reportable?  If yes, indicate which:
- Schedule No.  Is it a scheduled listed chemical product?:

### 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:

### SDS Hazard Classification

- ☒ Organic
- ☐ Inorganic
- ☐ Steroid/Androgen

Does the product have an Aerosol class? If yes,  
identify NFPA Storage Level:

NFPA Storage Level:

Is the product a NIOSH hazardous drug?  
If yes, indicate which:

### Hazardous Waste Identification

EPA Hazardous Waste Code:

Waste Characteristics

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required

Limited Distribution Requirement

Comments / Details: (For example, iPledge program?)

#### REMS:

REMS Program Manager Name:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name:

Site Enrollment Number assigned  
by Supplier:

Phone:

DEA #:

NCPDP#:

NPI #:

Comments

#### Registry:

Registry Program Contact Name:

Phone:

Comments

### RETURN INSTRUCTIONS

Contact tel. # if product 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 and/or Image of Product Barcode:

Release DATE



# 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> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/></p> <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>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p> | <p><b>Purchase order daily receipt cut off time by supplier</b></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>  |
| <p><b>Expedited Freight Charges or Other Designated Drop Ship Fees:</b></p> <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><b>Overnight and Priority Overnight PO Processing</b></p> <p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <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> |
| <p><b>Class of Trade Restriction:</b></p> <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>  |   |
| <p><b>Other Data Information Required to Process PO:</b></p> <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><b>Return Instructions</b></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>  |
| <p><b>Miscellaneous Notes:</b></p> <p><input type="text"/></p>  | <p><b>ADDITIONAL INFORMATION</b></p> <p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>  |