



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

Version 2024

Introduction Type: Final Version

Date: 1/15/2026

| | | | | | | | | |
|--|--|---------------|---|-------|----------------|--|-------------------|--------|
| PRODUCT INFORMATION | | | | | | SPECIAL HANDLING AND STORAGE REQUIREMENTS* | | |
| Company Name: Camber Pharmaceuticals, Inc. | | | Application: ANDA | | | | | |
| Application Number for NDA/ANDA/BLA; PMA/510(k): 217557 | | | NDA 505(b) Type: NOT APPLICABLE | | | | | |
| Medical Device Class, if applicable: | | | | | | | | |
| DUNS: 11-856-3719 | | | | | | a. Temperature – Indicate the USP temperature range for this product. | | |
| Proprietary Name (If Applicable) and Established Name: Furosemide Injection, USP 40 mg/4 mL (10 mg/mL) Single-Dose Vials | | | | | | Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F) | | |
| Selling Unit NDC: 31722-310-32 | | | Other Temperature Range Requirement (write in) | | | Excursions permitted to 15° to 30°C (59° to 86°F) | | |
| UDI | | | Notes | | | | | |
| Description: Furosemide Injection, USP 40 mg/4 mL (10 mg/mL) Single-Dose Vials | | | | | | | | |
| Active Ingredient(s): Furosemide, USP | | | | | | Is this product to be shipped to customers on ice? | | |
| | | | | | | Is this product to be shipped to customers on dry ice? | | |
| URL for Additional Product Information: www.camberpharma.com | | | | | | <input type="checkbox"/> No | | |
| Address: 800 Centennial Ave, Suite 1 | | | Address 2: NJ Zip: 08854 | | | <input type="checkbox"/> No | | |
| City: Piscataway | | | Email: customerservice@camberpharma.com | | | | | |
| Key Contact: Customer Service | | | Fax: 732-562-8788 | | | | | |
| Phone Number: 1-866-827-3647 | | | | | | | | |
| Product Therapeutic Classification: Anthranilic acid derivative loop diuretic | | | | | | | | |
| ADDITIONAL PRODUCT INFORMATION | | | | | | b. Contact for temperature excursion questions: | | |
| The product is? a legend device? <input type="checkbox"/> No | | | Is the Product... Direct-Ship Only | | | Name: Soma Raju | | |
| if yes, enter class # | | | Is the Product... Unit Dose | | | Number: 732-529-0423 | | |
| a product kit? <input type="checkbox"/> No | | | Orphan Drug Status | | | Group E-mail: somaraju@heterousa.com | | |
| if yes, list NDCs of component parts reverse numbered? <input type="checkbox"/> No | | | FDA Approval Status | | | | | |
| co-licensed? <input type="checkbox"/> No | | | Allergens Present | | | | | |
| latex-free? <input type="checkbox"/> Yes | | | | | | | | |
| preservative-free? <input type="checkbox"/> Yes | | | | | | | | |
| correctional institution block? <input type="checkbox"/> No | | | | | | | | |
| opioid? <input type="checkbox"/> No | | | | | | | | |
| Cannabinoid? <input type="checkbox"/> No | | | | | | | | |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/> Yes | | | Country of Origin India | | | | | |
| If Unit Dose, indicate NDC here: 31722-310-31 | | | Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No | | | | | |
| PRODUCT DESCRIPTION INFORMATION | | | | | | c. Special regulations for product in any states? | | |
| Is the Product... Direct-Ship Only | | | Size: 25 x 4 mL single-dose vials | | | Special returns requirements for this product? | | |
| Is the Product... Unit Dose | | | Strength: 40 mg/4 mL (10 mg/mL) per single-dose vial | | | | | |
| Orphan Drug Status | | | Dosage Form: Sterile, clear solution | | | | | |
| FDA Approval Status | | | | | | | | |
| Allergens Present | | | | | | | | |
| Product Shape: N/A | | | | | | | | |
| Product Color: Colorless | | | | | | | | |
| Product Imprint: N/A | | | | | | | | |
| Unit of Sale | | | | | | What is the NDC selling unit? | | |
| <input type="checkbox"/> Bottle | | | 1 Box of 25 x 4 mL Single-Dose Vials | | | (Write-in, e.g. 1 Box of 10 Vials) | | |
| <input checked="" type="checkbox"/> Box/Carton | | | | | | | | |
| <input type="checkbox"/> Ampule | | | | | | | | |
| <input checked="" type="checkbox"/> Glass | | | | | | Minimum order quantity? | | |
| <input type="checkbox"/> Tube | | | | | | <input type="checkbox"/> Yes | | |
| <input checked="" type="checkbox"/> Vial Liquid Sgl | | | | | | | | |
| <input type="checkbox"/> Vial Liquid Multi | | | | | | | | |
| <input type="checkbox"/> Vial Powder Sgl | | | | | | | | |
| <input type="checkbox"/> Vial Powder Multi | | | | | | | | |
| <input type="checkbox"/> Other: Write In | | | | | | | | |
| If Yes, how many of which package type? | | | | | | | | |
| <input type="checkbox"/> 1 Each | | | | | | | | |
| <input type="checkbox"/> Inner/Carton/Pack | | | | | | | | |
| <input type="checkbox"/> Case | | | | | | | | |
| ORDER INFORMATION | | | | | | | | |
| FOR GENERIC DRUG PRODUCTS | | | | | | d. Store product (unit of sale) upright? | | |
| | | | | | | Protect product (unit of sale) from light? | | |
| e. Shelf life: | | | | | | Initial shelf life at launch (if different): | | |
| | | | | | | | | |
| PHARMACY ORDER / BILL UNIT | | | | | | | | |
| Rec. sell unit to customer? | | | | | | Rx billing unit to pharmacy: | | |
| | | | | | | <input type="checkbox"/> Each | | |
| (Write-in, e.g. 1 Vial) | | | | | | <input type="checkbox"/> Gram | | |
| HCPCS J-Code: J1938 | | | | | | <input type="checkbox"/> Milliliter | | |
| | | | | | | | | |
| ITEM AND PACKING INFORMATION | | | | | | | | |
| | | | | | | Weight Lbs. | | |
| | | | | | | Dimensions (US mssmts.) | | |
| | | | | | | Depth | Width | Height |
| | | | | | | Volume (Cube) | Saleable # Pieces | |
| Item/Each: | | 0.67 | 3.4 | 3.4 | 2.3 | 26.59 | 1 | |
| Box/Carton/Bundle/Inner Pack: | | | | | | | | |
| Case: | | 13.35 | 11 | 11 | 6.25 | 756.25 | 18 | |
| Pallet: | | | | | | | | |
| COST INFORMATION | | | | | | WHOLESALER USE ONLY: | | |
| Regular Cost | | | | | | Vendor #: | | |
| Invoice Cost (WAC) (\$) | | | | | | <input type="checkbox"/> \$33.75 | | |
| As of date: 12/22/2025 | | | | | | Whs. Code #: <input type="checkbox"/> | | |
| | | | | | | Fineline Code: <input type="checkbox"/> | | |
| 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 | | 00331722310321 | | | |
| <input type="checkbox"/> Box/Carton/Bundle/Inner Pack | | N | 18 | | 20331722310325 | | | |
| <input checked="" type="checkbox"/> Case | | | | | | | | |
| <input type="checkbox"/> Pallet | | | | | | | | |
| 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: <input type="checkbox"/> | | |
| *Please provide any additional information on page 2. | | | | | | | | |



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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?
- c. Is the product a CA Prop 65 reproductive toxicant?
- d. Does the product label bear a CA Prop 65 warning?

No

No
 No
 No

No
 No

No
 No

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?

SDS Hazard Classification

Organic
 Inorganic
 Steroid/Androgen

Corrosive
 Oxidizer
 Contact Hazard

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

NFPA Storage Level:

No

| |
|--|
| |
| |

Is the product a NIOSH hazardous drug?

If yes, indicate which:

No

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:

No

Med Guide Required

Limited Distribution Requirement

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

No

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#:
NPI #:

Comments:

Registry:

Registry Program Contact Name:

No

Phone:

Comments:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

1-866-827-3647

Is product returnable for credit:

Yes

URL/Link to returns policy:

contact - customerservice@camberpharma.com

Special regulations or returns requirements for this
product in certain states?

No

If so, which states? Other requirements? Comments?

| |
|--|
| |
| |

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE



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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 | | Purchase order daily receipt cut off time by supplier Cut off time: <input type="text"/> | |
| Fax Number: <input type="text"/> Fax Number: <input type="text"/> Phone No.: <input type="text"/> Site Address: <input type="text"/> | | Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days | |
| Minimum Order Quantity: <input type="text"/> | | Ships same day for next day receipt: <input type="text"/> | |
| Supplier's Customer Service Number: <input type="text"/> | | Ships for second day receipt: <input type="text"/> | |
| Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/> | | Ships regular ground for 3-10 days receipt: <input type="text"/> | |
| Expedited Freight Charges or Other Designated Drop Ship Fees: | | | |
| Expedited freight fees billed with each order: <input type="text"/> | | Overnight and Priority Overnight PO Processing | |
| Drop Ship service fee billed with each order: <input type="text"/> | | Overnight receipt available: <input type="text"/> | |
| Drop Ship miscellaneous fees billed: <input type="text"/> | | PO Receipt cut off time: <input type="text"/> | |
| Comments: <input type="text"/> | | Days of week overnight is available: Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday <input type="checkbox"/> | |
| Class of Trade Restriction: | | | |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices | | Priority Overnight receipt available: PO Receipt Cut off time: <input type="text"/> | |
| Restricted to retail pharmacy only: <input type="checkbox"/> | | Saturday Overnight receipt available: PO Receipt Cut off time: <input type="text"/> | |
| Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> | | Order receipt method: Phone: <input type="text"/> Fax: <input type="text"/> EDI: <input type="text"/> | |
| Restricted from US territories? (explain in comments) | | Phone #: <input type="text"/> Fax #: <input type="text"/> | |
| Comments: <input type="text"/> | | Overnight Fees apply: <input type="text"/> Other fees apply: <input type="text"/> | |
| Other Data Information Required to Process PO: | | | |
| Patient Procedure Date: <input type="text"/> | | Return Instructions | |
| Physician Name: <input type="text"/> | | Contact # if product is received damaged: <input type="text"/> | |
| Physician/Clinic Phone # <input type="text"/> | | Is product returnable for credit: <input type="text"/> | |
| Physician State License # <input type="text"/> | | URL/Link to returns policy: <input type="text"/> | |
| Physician/Clinic DEA #: <input type="text"/> | | Special regulations or returns requirements for this product in certain states? <input type="text"/> | |
| Physician/Clinic Specialty: <input type="text"/> | | If so, which states? Other requirements? Comments? <input type="text"/> | |
| Miscellaneous Notes: <input type="text"/> | | | |
| ADDITIONAL INFORMATION | | | |
| Is product order for scheduled patient procedure? <input type="text"/> | | Is product order for restocking purposes? <input type="text"/> | |