



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

Version 2021

Introduction Type:  New Item

Final Version

Date: 6/23/2024

## PRODUCT INFORMATION

**Company Name:** Camber Pharmaceuticals **Application:** ANDA

**Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):** 203825

**Medical Device Class, if applicable:**

**DUNS:** 11-856-3719

**Proprietary Name (If Applicable) and Established Name:** Nebivolol Tablets 2.5 mg

**Selling Unit NDC:** 31722-585-30 **Unit of Use NDC:** 31722-585-30 **UPC:** 331722585309

**UDI** **CVX Code:** **MX Code:**

**Description:** Nebivolol Tablets 2.5 mg

**Active Ingredient(s):** Nebivolol hydrochloride

**URL for Additional Product Information:** [www.camberpharma.com](http://www.camberpharma.com)

**Address:** 800 Centennial Ave, Suite 1 **Address 2:**

**City:** Piscataway **State:** NJ **Zip:** 08854

**Key Contact:** Customer Service **Email:** [customerservice@camberpharma.com](mailto:customerservice@camberpharma.com)

**Phone Number:** 1-866-827-3647 **Fax:** 732-562-8788

**Product Therapeutic Classification:** Beta-adrenergic blocking agent

## 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 to 15–30°C (59–86°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:** [somaraju@heterousa.com](mailto:somaraju@heterousa.com)

**c. Special regulations for product in any states?**  No

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:**  24 **Months**

Initial shelf life at launch (if different):  **Months**

## ADDITIONAL PRODUCT INFORMATION

**The product is?**

a legend device?  No

if yes, enter class #

a product kit?  No

if yes, list NDCs of component parts reverse numbered?

co-licensed?  No

latex-free?  Yes

preservative-free?  Yes

correctional institution block?  No

opioid?  No

Cannabinoid?  No

If Unit Dose, is item bar coded to unit dose for hospital scanning?

If Unit Dose, indicate NDC here:

**Is the Product... Direct-Ship Only**

**Is the Product... Unit of Use**

**Orphan Drug Status**

**FDA Approval Status**

**Allergens Present**

**Country of Origin**  India

Is this product covered under the Trade Agreements Act (TAA)?  No

**PRODUCT DESCRIPTION INFORMATION**

**Size:** 30 ct

**Strength:** 2.5 mg

**Dosage Form:** Tablet

**Product Shape:** Triangular, biconvex

**Product Color:** White to off-white

**Product Imprint:** Debossed with 'J' on one side and '8' on the other side

## ORDER INFORMATION

**Unit of Sale**

Bottle

Box/Carton

Ampule

Glass

Tube

Vial Liquid Sgl

Vial Liquid Multi

Vial Powder Sgl

Vial Powder Multi

Other: Write In

**What is the NDC selling unit?**  1 Bottle of 30 Tablets

(Write-in, e.g. 1 Box of 10 Vials)

**Minimum order quantity?**  Yes

**If Yes, how many of which package type?**

24 Each

Inner/Carton/Pack

Case

## FOR GENERIC DRUG PRODUCTS

Authorized Generic \*If Authorized Generic, other section fields are not applicable

**I. Orange Book Rating:**  AB

**II. Generic Equivalent to What Brand?:**  Bystolic

## PHARMACY ORDER / BILL UNIT

**Rec. sell unit to customer?**

(Write-in, e.g. 1 Vial)

**Rx billing unit to pharmacy:**

Each

Gram

Milliliter

## 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.**

**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		
Item/Each:	0.06	1.52	1.52	2.54	5.87	1
Box/Carton/Bundle/Inner Pack:						
Case:	1.75	10	6.75	4.25	286.88	24
Pallet:						

## GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00331722585309	331722585309
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	24		20331722585303	
<input type="checkbox"/> Pallet				

## COST INFORMATION

**Regular Cost**

**Invoice Cost (WAC) (\$)**  \$7.00

**As of date:** 4/15/2024

**WHOLESALE USE ONLY:**

**Vendor #:**

**Whsl. Code #:**

**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:



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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?  No
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
  - Is the product a CA Prop 65 carcinogen?  No
  - Is the product a CA Prop 65 reproductive toxicant?  No
  - Does the product label bear a CA Prop 65 warning?  No

- c. Contact Hazard?  No
- d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)  No
- e. Does the product contain DEHP?  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?  No

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?  No

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

- Passenger  No
- Cargo
- Passenger & Cargo

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

### CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes  No
- Restricted to retail pharmacy only:  No  Yes
- Restricted to hospital, clinics, and physician offices only:  No  Yes
- Restricted from US territories? (explain in comments)  No  Yes

Comments:

### SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard

Does the product have an Aerosol class? If yes, identify 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?  No  Yes

If Yes, is it managed with a pharmacy registry? Website URL:

Med Guide Required  No  Yes

Limited Distribution Requirement  No  Yes

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

REMS:  No  Yes

REMS Program Manager Name:  Phone:

Supplier Manages REMS registry exclusively:  No  Yes

Wholesale distributor support:

Provider Name:  DEA #:

Site Enrollment Number assigned by Supplier:  NCPDP#:

Comments:

Registry:  No  Yes

Registry Program Contact Name:  Phone:

Comments:

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:  732-529-0430

Is product returnable for credit:  Yes  No

URL/Link to returns policy:

contact email: customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states?  No  Yes

If so, which states? Other requirements? Comments?

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

