



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

Version 2021 Introduction Type: New Item Final Version Date: 6/1/2024

PRODUCT INFORMATION **SPECIAL HANDLING AND STORAGE REQUIREMENTS***

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 20 mg
 Selling Unit NDC: 31722-588-90 Unit of Use NDC: 31722-588-90 UPC: 331722588904
 UDI CVX Code: MVX Code:
 Description: Nebivolol Tablets 20 mg
 Active Ingredient(s): Nebivolol hydrochloride
 URL for Additional Product Information: www.camberpharma.com
 Address: 800 Centennial Ave, Suite 1 Address 2:
 City: Piscataway State: NJ 08854
 Key Contact: Customer Service Email: customerservice@camberpharma.com
 Phone Number: 1-866-827-3647 Fax: 732-562-8788
 Product Therapeutic Classification: Beta-adrenergic blocking agent

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
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 **PRODUCT DESCRIPTION INFORMATION**

The product is? a legend device? <input type="checkbox"/> No if yes, enter class # a product kit? <input type="checkbox"/> No if yes, list NDCs of component parts reverse numbered? <input type="checkbox"/> No co-licensed? <input type="checkbox"/> No 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"/> If Unit Dose, indicate NDC here:	Is the Product... Direct-Ship Only <input type="checkbox"/> Is the Product... Unit of Use <input type="checkbox"/> Orphan Drug Status <input type="checkbox"/> FDA Approval Status Allergens Present Country of Origin: India Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No	Size: 90 ct Strength: 20 mg Dosage Form: Tablet Product Shape: Triangular, biconvex Product Color: White to off-white Product Imprint: Debossed with 'J' on one side and '11' on the other side
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ORDER INFORMATION

Unit of Sale <input checked="" type="checkbox"/> Bottle <input type="checkbox"/> Box/Carton <input type="checkbox"/> Ampule <input type="checkbox"/> Glass <input type="checkbox"/> Tube <input 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	What is the NDC selling unit? 1 Bottle of 90 Tablets (Write-in, e.g. 1 Box of 10 Vials) Minimum order quantity? <input type="checkbox"/> Yes If Yes, how many of which package type? <input type="checkbox"/> 24 Each <input type="checkbox"/> Inner/Carton/Pack <input type="checkbox"/> Case
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FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AB Authorized Generic *If Authorized Generic, other section fields are not applicable
 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 No
 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: 0031722498975
 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:	0.12	1.74	1.74	3.36	10.17	1
Box/Carton/Bundle/Inner Pack:						
Case:	3.15	11.5	8	4.5	414	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		00331722588904	00331722588904
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	24		20331722588908	
<input type="checkbox"/> Pallet				

COST INFORMATION **WHOLESALE USE ONLY:**

Regular Cost
 Invoice Cost (WAC) (\$) \$21.00
 As of date: 4/15/2024
 Vendor #:
 Whsl. Code #:
 Finline Code:



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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	
<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
Does the product have an Aerosol class? If yes, identify NFPA Storage Level:	<input type="checkbox"/> No
NFPA Storage Level:	<input type="text"/>
Is the product a NIOSH hazardous drug? If yes, indicate which:	<input type="checkbox"/> No <input type="text"/>

Hazardous Waste Identification	
EPA Hazardous Waste Code:	<input type="text"/>
Waste Characteristics	<input type="text"/>

REMS or REGISTRY RESTRICTIONS	
Is there a REMS on this product?	<input type="checkbox"/> No <input type="checkbox"/> Yes
If Yes, is it managed with a pharmacy registry? Website URL:	<input type="text"/>
Med Guide Required	<input type="checkbox"/> No <input type="checkbox"/> Yes
Limited Distribution Requirement	<input type="checkbox"/> No <input type="checkbox"/> Yes
Comments / Details: (For example, iPledge program?)	<input type="text"/>
REMS:	<input type="checkbox"/> No <input type="checkbox"/> Yes
REMS Program Manager Name:	<input type="text"/>
Supplier Manages REMS registry exclusively:	<input type="checkbox"/> No <input type="checkbox"/> Yes
Wholesale distributor support:	<input type="checkbox"/> No <input type="checkbox"/> Yes
Provider Name:	<input type="text"/>
Site Enrollment Number assigned by Supplier:	<input type="text"/>
DEA #:	<input type="text"/>
NCPDP#:	<input type="text"/>
NPI #:	<input type="text"/>
Comments	<input type="text"/>
Registry:	<input type="checkbox"/> No <input type="checkbox"/> Yes
Registry Program Contact Name:	<input type="text"/>
Phone:	<input type="text"/>
Comments	<input type="text"/>

RETURN INSTRUCTIONS	
Contact tel. # if product received damaged:	<input type="text"/> 732-529-0430
Is product returnable for credit:	<input type="checkbox"/> Yes <input type="checkbox"/> No
URL/Link to returns policy:	<input type="text"/>
contact email: customerservice@camberpharma.com	<input type="text"/>
Special regulations or returns requirements for this product in certain states?	<input type="checkbox"/> No <input type="checkbox"/> Yes
If so, which states? Other requirements? Comments?	<input type="text"/>

MISCELLANEOUS NOTES and/or Image of Product Barcode:



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