



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

Version 2024 Introduction Type: New Item Final Version Date: 11/26/2024

PRODUCT INFORMATION

Company Name: Camber Pharmaceuticals, Inc. Application: ANDA
 Application Number for NDA/ANDA/BLA; PMA/510(k): 212204 NDA 505(b) Type: NOT APPLICABLE
 Medical Device Class, if applicable:
 DUNS: 11-856-3719
 Proprietary Name (If Applicable) and Established Name: Bortezomib for Injection 3.5 mg per vial (Single-Dose Vial)
 Selling Unit NDC: 31722-303-31 Unit of Use NDC: UPC: 331722303316
 UDI: CVX Code: MVX Code:
 Description: Bortezomib for Injection 3.5 mg per vial (Single-Dose Vial)
 Active Ingredient(s): Bortezomib
 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: Proteasome inhibitor

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):
 Notes: Unopened vials may be stored at controlled room temperature 25°C (77°F); excursions permitted from 15°C to 30°C (59°F to 86°F)
 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 *Yes
 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

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? Yes
 If Unit Dose, indicate NDC here: 31722-303-31
 Is the Product...
 Is the Product... Direct-Ship Only Unit Dose
 Orphan Drug Status
 FDA Approval Status
 Allergens Present: Corn
 Country of Origin: India
 Is this product covered under the Trade Agreements Act (TAA)? No

PRODUCT DESCRIPTION INFORMATION

Size: 1 single-dose vial
 Strength: 3.5 mg/vial
 Dosage Form: Lyophilized cake or powder
 Product Shape: N/A
 Product Color: White to off-white
 Product Imprint: N/A

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 Carton of 1 Single Dose Vial
 (Write-in, e.g. 1 Box of 10 Vials)
 Minimum order quantity? Yes
 If Yes, how many of which package type?
 1 Each
 Inner/Carton/Pack
 Case

FOR GENERIC DRUG PRODUCTS

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

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? Each Gram Milliliter
 (Write-in, e.g. 1 Vial)
 HCPCS J-Code: J9041

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: | 0.06 | 1.7 | 1.7 | 2.75 | 7.95 | 1 |
| Case: | 7.3 | 14 | 10.5 | 6.25 | 918.75 | 96 |
| 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 | | 00331722303316 | |
| <input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack | N | 96 | | 20331722303310 | |
| <input type="checkbox"/> Case | | | | | |
| <input type="checkbox"/> Pallet | | | | | |

COST INFORMATION

Regular Cost
 Invoice Cost (WAC) (\$) \$35.00
 As of date: 10/15/2024
WHOLESALE USE ONLY:
 Vendor #:
 Whsl. Code #:
 Fineline Code:

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? Yes

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? Yes

d. Does this product require special clean-up instructions?
 (If yes, attach SDS with special instructions.) Yes

e. Does the product contain DEHP? No

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

a. UN/Identification Number: UN 3249

b. Proper Shipping Name: Medicine, Solid, Toxic, n.o.s.(Bortezomib)

c. DOT Hazard Class: 6.1

d. Packing Group: II

e. Inhalation Hazard? Yes

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

a. UN/Identification Number: UN 3249

b. Proper Shipping Name: Medicine, Solid, Toxic, n.o.s.(Bortezomib)

c. DOT Hazard Class: 6.1

d. Packing Group: II

e. Inhalation Hazard? Yes

Is the product restricted for air shipment? If so, indicate restriction: No

Passenger

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 Controlled Substance Code:

Controlled by State(s)? No Listed Chemical (List I or II) No

ARCOS Reportable? No If yes, indicate which:

Schedule No. Is it a scheduled listed chemical product?: No

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

SDS Hazard Classification

Organic Corrosive

Inorganic Oxidizer

Steroid/Androgen Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No

NFPA Storage Level:

Is the product a NIOSH hazardous drug? Yes

If yes, indicate which: Group 1 items (antineoplastic)

Hazardous Waste Identification

EPA Hazardous Waste Code: Waste Characteristics:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

Med Guide Required No

Limited Distribution Requirement

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

REMS: No

REMS Program Manager Name: Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:

Provider Name: DEA #:

Site Enrollment Number assigned by Supplier: NCPDP#:

NPI #:

Comments:

Registry: No

Registry Program Contact Name: 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:

Follow guidelines for handling and disposal for hazardous drugs, including the use of gloves and other protective clothing to prevent skin contact.



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 | |
|---|--|--|--|
| 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 #: Name: <input type="text"/> Phone: <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: 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 and Priority Overnight PO Processing 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: 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: 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"/> | | Return Instructions 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"/> | |