



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

Version 2024 Introduction Type: Final Version Date:

PRODUCT INFORMATION	
Company Name:	Camber Pharmaceuticals, Inc.
Application Number for NDA/ANDA/BLA; PMA/510(k):	216413
Medical Device Class, if applicable:	
DUNS:	11-856-3719
Proprietary Name (If Applicable) and Established Name:	Daptomycin for Injection 500 mg Single-Dose vial
Selling Unit NDC:	31722-216-01
Unit of Use NDC:	
UPC:	331722216012
CVX Code:	
MXV Code:	
Description:	Daptomycin for Injection 500 mg Single-Dose vial
Active Ingredient(s):	Daptomycin
URL for Additional Product Information:	www.camberpharma.com
Address:	800 Centennial Ave, Suite 1
City:	Piscataway
Key Contact:	Customer Service
Phone Number:	1-866-827-3647
Product Therapeutic Classification:	Lipopeptide antibacterial

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	Temperature Range: <input type="text" value="Cold – between 2 and 8 C (36° – 46° F)"/>
Other Temperature Range Requirement (write in)	
Notes	Avoid excessive heat. Reconstituted solution is stable in the vial for 12 hours at room temperature and up to 48 hours if stored under refrigeration between 2° and 8°C (36° and 46°F). To be shipped to customers using proper cold storage shipping methods (e.g. Cold Packs, Cold Storage Trucks)
Is this product to be shipped to customers on ice?	<input type="text" value="No"/>
Is this product to be shipped to customers on dry ice?	<input type="text" value="No"/>
b. Contact for temperature excursion questions:	Name: <input type="text" value="Soma Raju"/> Number: <input type="text" value="732-529-0423"/> Group E-mail: <input type="text" value="somaraju@heterousa.com"/>
c. Special regulations for product in any states?	<input type="text" value="No"/> Special returns requirements for this product? <input type="text" value="No"/>
d. Store product (unit of sale) upright?	<input type="text" value="No"/>
Protect product (unit of sale) from light?	<input type="text" value="No"/>
e. Shelf life:	Initial shelf life at launch (if different): <input type="text" value="24"/> Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?		Is the Product... Direct-Ship Only	
a legend device?	<input type="text" value="No"/>	Is the Product... Unit Dose	
if yes, enter class #		Orphan Drug Status	
if yes, list NDCs of component parts		FDA Approval Status	
reverse numbered?	<input type="text" value="No"/>	Allergens Present	
co-licensed?	<input type="text" value="No"/>	Country of Origin	<input type="text" value="India"/>
latex-free?	<input type="text" value="Yes"/>	Is this product covered under the Trade Agreements Act (TAA)?	<input type="text" value="No"/>
preservative-free?	<input type="text" value="Yes"/>		
correctional institution block?	<input type="text" value="No"/>		
opioid?	<input type="text" value="No"/>		
Cannabinoid?	<input type="text" value="No"/>		
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text" value="Yes"/>		
If Unit Dose, indicate NDC here:	<input type="text" value="31722-216-01"/>		
		Size:	<input type="text" value="1 single dose vial"/>
		Strength:	<input type="text" value="500 mg/vial"/>
		Dosage Form:	<input type="text" value="Sterile, lyophilized cake for infusion or injection"/>
		Product Shape:	<input type="text" value="Single dose vial"/>
		Product Color:	<input type="text" value="Pale yellow to light brown"/>
		Product Imprint:	<input type="text" value="N/A"/>

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	<input type="text" value="1 Box of 1 Single Dose Vial"/>
<input checked="" type="checkbox"/> Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input checked="" type="checkbox"/> Glass	Minimum order quantity? <input type="text" value="Yes"/>
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	
<input checked="" type="checkbox"/> Vial Powder Sgl	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Multi	<input type="text" value="1"/> Each
<input type="checkbox"/> Other: Write In	<input type="text" value="Inner/ Carton/ Pack"/>
	<input type="text" value="Case"/>

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value="AP"/> <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable
II. Generic Equivalent to What Brand?:	<input type="text" value="Cubicin"/>

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text" value="Box/ Carton"/>	<input type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
HCPCS J-Code:	<input type="checkbox"/> Milliliter
<input type="text" value="J0878"/>	

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="text" value="Yes"/>
Is product exempt from DSCSA?	<input type="text" value="No"/>
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	<input type="text" value="No"/>
Is product sold by manufacturer's exclusive distributor?	<input type="text" value="Yes"/>
Has FDA granted waiver/exception/exemption for product?	<input type="text" value="No"/>
If yes, attach documentation from FDA.	
GLN:	<input type="text" value="0843368117603"/>
GCP:	
If yes, was original product purchased direct from mfr?	<input type="text" value=""/>
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:	0.03	1.65	1.65	2.56	6.97	1
Case:	2.98	13.78	10.63	3.93	575.67	48
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		00331722216012	
<input checked="" type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack					
<input checked="" type="checkbox"/> Case	N	48		20331722216016	
<input type="checkbox"/> Pallet					

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	<input type="text" value="\$30.00"/>	Whsl. Code #:	
As of date:	<input type="text" value="6/22/2023"/>	Fineline 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) No

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) No

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: 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:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

*To be shipped to customers using proper cold storage shipping methods (e.g. Cold Packs, Cold Storage Trucks)

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? No
 If yes, indicate which:

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?



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