



# 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):	217748
Medical Device Class, if applicable:	
DUNS:	11-856-3719
Proprietary Name (If Applicable) and Established Name:	Allopurinol Tablets, USP 300 mg
Selling Unit NDC:	31722-253-05
Unit of Use NDC:	
CVX Code:	
UPC:	331722253055
MX Code:	
Description:	Allopurinol Tablets, USP 300 mg
Active Ingredient(s):	Allopurinol, USP
URL for Additional Product Information:	<a href="http://www.camberpharma.com">www.camberpharma.com</a>
Address:	800 Centennial Ave, Suite 1
City:	Piscataway
Key Contact:	Customer Service
Phone Number:	1-866-827-3647
Product Therapeutic Classification:	Xanthine oxidase inhibitor

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	
Notes	
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>b. Contact for temperature excursion questions:</b>	
Name:	Soma Raju
Number:	732-529-0423
Group E-mail:	<a href="mailto:somaraju@heterousa.com">somaraju@heterousa.com</a>
<b>c. Special regulations for product in any states?</b>	
Special returns requirements for this product?	<input type="text" value="No"/>
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	<input type="text" value="No"/>
<b>e. Shelf life:</b>	
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... Neither	
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	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=""/>		
If Unit Dose, indicate NDC here:	<input type="text" value=""/>		
		Size:	500 ct
		Strength:	300 mg
		Dosage Form:	Tablet
		Product Shape:	Round
		Product Color:	White to off-white
		Product Imprint:	Debossed with 'U' and '6' on one side and functional scored line with 'H' on the other side.

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Bottle of 500 Tablets
<input type="checkbox"/> Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input 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	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="text" value="12"/> Each
<input type="checkbox"/> Vial Powder Multi	<input type="text" value=""/> Inner/ Carton/Pack
<input type="checkbox"/> Other: Write In	<input type="text" value=""/> Case

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

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

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:	0331722498975
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:	0.75	3	3	6	54.00	1
Case:	10.05	12.5	9.5	7	831.25	12
Pallet:						

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14
<input checked="" type="checkbox"/> Item/Each	N	1		00331722253055
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	N	12		20331722253059
<input type="checkbox"/> Pallet				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$99.75	Whsl. Code #:	
As of date:	3/18/2024	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?  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)  Yes

a. UN/Identification Number: UN3077  
 b. Proper Shipping Name: Environmentally hazardous substances, solid, n.o.s. (ALLOPURINOL), MARINE POLLUTANT  
 c. DOT Hazard Class: 9  
 d. Packing Group: III  
 e. Inhalation Hazard?  No

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

a. UN/Identification Number: UN3077  
 b. Proper Shipping Name: Environmentally hazardous substance, solid, n.o.s. (ALLOPURINOL)  
 c. DOT Hazard Class: 9  
 d. Packing Group: III  
 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?  Yes

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# \_\_\_\_\_

### 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  
 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: \_\_\_\_\_

### 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: \_\_\_\_\_

### 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:

\_\_\_\_\_

