



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

Version 2024

Introduction Type: New Item

Final Version

Date: 11/15/2024

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 100 mg
Selling Unit NDC:	31722-252-01
Unit of Use NDC:	
UDI	
UPC:	331722252010
CVX Code:	
MXV Code:	
Description:	Allopurinol Tablets, USP 100 mg
Active Ingredient(s):	Allopurinol, USP
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:	Xanthine oxidase 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	
Is this product to be shipped to customers on ice?	<input type="checkbox"/> No
Is this product to be shipped to customers on dry ice?	<input type="checkbox"/> 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?	<input type="checkbox"/> No
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="checkbox"/> No
e. Shelf life:	
Initial shelf life at launch (if different):	<input type="text"/> 24 Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?		Is the Product... Direct-Ship Only	
a legend device?	<input type="checkbox"/> No	Is the Product... Neither	
if yes, enter class #		Orphan Drug Status	
a product kit?	<input type="checkbox"/> No	FDA Approval Status	
if yes, list NDCs of component parts		Allergens Present	
reverse numbered?	<input type="checkbox"/> No	Country of Origin	India
co-licensed?	<input type="checkbox"/> No	Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/> No
latex-free?	<input type="checkbox"/> Yes	Size:	100 ct
preservative-free?	<input type="checkbox"/> Yes	Strength:	100 mg
correctional institution block?	<input type="checkbox"/> No	Dosage Form:	Tablet
opioid?	<input type="checkbox"/> No	Product Shape:	Round
Cannabinoid?	<input type="checkbox"/> No	Product Color:	White to off-white
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>	Product Imprint:	Debossed with 'U' and '5' on one side and functional scored line with 'H' on the other side.
If Unit Dose, indicate NDC here:			

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Bottle of 100 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="checkbox"/> 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"/> 48 Each
<input type="checkbox"/> Vial Powder Multi	<input type="text"/> Inner/ Carton/ Pack
<input type="checkbox"/> Other: Write In	<input type="text"/> 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"/>	<input type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
HCPCS J-Code:	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="checkbox"/> Yes
Is product exempt from DSCSA?	<input type="checkbox"/> No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	<input type="checkbox"/> No
Is product sold by manufacturer's exclusive distributor?	<input type="checkbox"/> Yes
Has FDA granted waiver/exception/exemption for product?	<input type="checkbox"/> No
If yes, attach documentation from FDA.	
GLN:	0331722498975
GCP:	
If yes, was original product purchased direct from mfr?	<input type="checkbox"/>
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:	0.09	1.5	1.5	2.5	5.63	1
Case:	4.9	12.75	9.75	4.25	528.33	48
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		00331722252010
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	N	48		20331722252014
<input type="checkbox"/> Pallet				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$11.00	Whsl. Code #:	
As of date:	3/18/2024	Fineline Code:	

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

*Please provide any additional information on page 2.

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) 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# _____

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
- 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: _____

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:



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

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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> <ul style="list-style-type: none"> a. EDI <input type="checkbox"/> b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/> c. Fax <input type="checkbox"/> Fax Number: <input type="text"/> d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/> e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/> <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> <ul style="list-style-type: none"> <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday <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>