

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

Version 2024						Introduction Type:	New Item		x Final Version			Date:	11/20	0/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOP	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc.				Application:	ANDA	a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN	DA/BLA; PMA/510	(k): 217748				NDA 505(b) Type:	NOT APPLICABLE		emperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicat	ble:													
DUNS:	11-856-3719							0	other Temperature Range I	Requirement				
Proprietary Name (If Applicable) a		ame: Allopuri	nol Tablets, USP 300 mg						(write in)					
Selling Unit NDC:	31722-253-05		Unit of Use NDC:			UPC: 331 MVX Code:	722253055	N	lotes					
UDI			CVX Code:			WIVA Code.								
Description:	Allopurinol Tablets	s, USP 300 mg							this product to be shipped				No	-
Active Ingredient(s):		Allopurinol, USP						IS	s this product to be shipped	d to customers on o	try ice?		No	
Active ingredient(s).		Allopulliloi, USF						b Contact for te	emperature excursion qu	estions:				
URL for Additional Product Inform	mation:	www.camberpharma.	com						lame:	conona.	Soma Raju			
Address:	800 Centennial Av					Address 2:		N	lumber:		732-529-04	23		
City:	Piscataway				State:	NJ Zij	08854	G	iroup E-mail:		somaraju@	heterousa.cor	<u>n</u>	
Key Contact:	Customer Service	•			Email:	customerservice@can	hberpharma.com							-
Phone Number:	1-866-827-3647				Fax:	732-562-8788			ations for product in any				No	-
Product Therapeutic Classification	on:	Xanthine oxidase inh	ibitor					S	pecial returns requirement	ts for this product?			No	
		ONAL PRODUCT INF				PRODUCT DESC	CRIPTION INFORMATION		(unit of colo) unviented				No	7
	ADDITI			Discut Ohim C	No. 1	PRODUCT DESC			t (unit of sale) upright?					-
The product is? a legend device?		Na	Is the Product Is the Product	Direct-Ship C Neither	niy		500 ct	e. Shelf life:	rotect product (unit of sa	ale) from light?			No 24	Months
if yes, enter class #		No	Orphan Drug Status	INCIDICI		Size:	500 61		nitial shelf life at launch (if different).			24	Months
a product kit?		No	orphan Drug otatus			a	300 mg			il unicicity.				Months
if yes, list NDCs of			FDA Approval Status			Strength:				ORDER INFORM	IATION			
component parts						Dosage Form:	Tablet							
reverse numbered?		No				Dosuge Form.		U	nit of Sale			NDC selling	unit?	
co-licensed?		No	Allergens Present				Devend	_	x Bottle		1 Bottle of 5		0 1 (- 1 - 1	
latex-free? preservative-free?		Yes				Product Shape:	Round		Box/Carton Ampule		(vvrite-in, e	.g. 1 Box of 1	U VIAIS)	
correctional institution block?		No					White to off-white		Glass		Minimum o	rder quantity	2	Yes
opioid?		No				Product Color:		-	Tube			uoi quainity		
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Debossed with 'U' and '6' on one side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for					r roudet imprint.	and functional scored line with 'H' on the other side		Vial Liquid Multi			many of whi	ch package	type?
hospital scanning?			Is this product covered u		Nu				Vial Powder Sgl		12	Each	(D 1	
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	IAA)?	No				Vial Powder Multi Other: Write In			Inner/Carton Case	/Pack	
			FOR GENERIC DRUG PR	ODUCTS					Other. White In			Case		
			FOR GENERIC DRUG FR	000013				-						
					Au	uthorized Generic *If A	uthorized Generic, other		PH	IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						tion fields are not applicable	Rec. sell unit to customer?			Rx billing unit to pharmacy:			
II. Generic Equivalent to What Bra		Zyloprim									Each			
-								(Write-in, e.g. 1	Vial)	_		Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (DSCSA) INFOR	MATION			HCPCS J-Code:				Milliliter		
Daga sumplier mast DSCSA definit			Voo	_		0004700400075			ITEA	AND PACKING I		N		
Does supplier meet DSCSA definit Is product exempt from DSCSA?	ition of manufactur	rer ?	Yes	_	GLN:	0331722498975			11 EN	I AND PACKING I	NFORMATIO	N		
					CCD.			1		Dimensi	ione (110	nto)	V-k	Colorist .
If yes, select exemption: Other exemption - Write in:					GCP:			1	Weight Lbs.	Dimensi	ions (US msı Width	nts.) Height	Volume (Cube)	Saleable # Pieces
Is product repackaged?			No		If yes, was o	riginal product purchase	ed	Item/Each:						
Is product sold by manufacturer's	s exclusive distribu	itor?	Yes	-	direct from n				0.75	3	3	6	54.00	1
Has FDA granted waiver/exception			No		Provide sour	ce manufacturer for rep	ackaged product	Box/Carton/Bun	dle/					
If yes, attach documentation from	m FDA.	-						Inner Pack:						
		0.500						Case:	10.05	12.5	9.5	7	831.25	12
		GTIN	AND HIBCC PRODUCT I	NFORMATION				Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	HIBCC		GT	IN-14	Unit of Use GTIN-14	Panet:						
		Quantity			31		STILL OF 050 01111-14	L						1
X Item/Each	N	1			003	31722253055								
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESALI	ER USE ONL	.Y:
X Case	N	12			203	331722253059								
Pallet								Regular Cost Invoice Cost (W		000 75	Vendor #: Whsl. Code	м.		
								Invoice Cost (W	AC) (\$)	\$99.75	Fineline Co			
								As of date:	3/18/2024					
								As of date:	3/18/2024					
								As of date:	3/18/2024					
			Attach copy of SAFETY DA	TA SHEET (SD	PS) or non haza	ard letter, PACKAGE INSI	ERT, LABEL AND PHOTO OF F							
*Please provide any additional inf	formation on page		Attach copy of SAFETY DA	TA SHEET (SD	PS) or non haza		ERT, LABEL AND PHOTO OF F gnated Drop Ship Only.	PRODUCT PACKAG						

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

Version 2024 For Design	ated Drop Ship Only Products, Please Use Page 3
MATERIAL H	AZARD CLASSIFICATION and TRANSPORTATION
MATERIAL H Is this product (check all that apply): a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No 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? No (If yes, attach SDS with special instructions.) No e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? Yes (if yes, answer a-e below and provide SDS) UN3077 b. Proper Shipping Name Environmentally hazardous substances, solid, n.o.s. (ALLOPURNOL), MARINE POLLUTANT	AZARD CLASSIFICATION and TRANSPORTATION
c. DOT Hazard Class 9	Hazardous Waste Identification
d. Packing Group	
e. Inhalation Hazard? No	EPA Hazardous Waste Code: Waste Characteristics
Is this product regulated for shipment by IATA? Yes	
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS
a. UN/Identification Number UN3077	
b. Proper Shipping Name Environmentally hazardous substance, solid, n.o.s. (ALLOPURINOL) c. DOT Hazard Class 9	Is there a REMS on this product? No
c. DOT Hazard Class 9 d. Packing Group III	If Yes, is it managed with a pharmacy registry? Website URL:
e. Inhalation Hazard?	Website ONL.
	Med Guide Required
Is the product restricted for air shipment? If so, indicate restriction: No Passenger	Med Guide Required No Limited Distribution Requirement Image: Comparison of the second seco
Cargo	Common Drains (For example, iPledge program?)
Passenger & Cargo	
Is this a reportable quantity? No	REMS: No
RQ Threshold:	REMS Program Manager Name: Phone:
Is this a marine pollutant? Yes	Supplier Manages REMS registry exclusively:
Is this product shipped utilizing an authorized DOT exception or Special Permit?	Wholesale distributor support:
No (if yes, identify method below)	Provider Name: DEA #:
Limited Quantity	Site Enrollment Number assigned NCPDP#:
Consumer Commodity, ORM-D	by Supplier: NPI #:
Small Quantity (49 CFR 173.4)	
Special Permit; DOT-SP	Comments
Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Registry: No
3F#	
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone: Comments
	Cumments
Is the Product	RETURN INSTRUCTIONS
Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No	KETOKA INSTRUCTIONS
ARCOS Reportable? No If yes, indicate which:	Contact tel. # if product received damaged: 1-866-827-3647
Schedule No. Is it a scheduled listed chemical product?: No	
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	contact - customerservice@camberpharma.com
Restricted to retail pharmacy only: No	Special regulations or returns requirements for this
Restricted to hospital, clinics, and physician offices only: No	product in certain states? No
Restricted from US territories? (explain in comments) No	If so, which states? Other requirements? Comments?
Comments:	
MISCELLAN	EOUS NOTES and/or Image of Product Barcode:



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Version 2024	FOR DESIGNATED DROP SHIP PRODUCT ONLY - if r	ot a designated drop ship, do not complete.	
Order Method for Des	signated Drop Ship Product	Standard Order Receipt and Processing	
Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name Phone Expedited Freight Charges o		Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Da Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt: Overnight and Priority Overnight PO Processing	ays
Expedited freight fees billed with each order:		Overnight receipt available:	
Drop Ship service fee billed with each order:		PO Receipt cut off time:	
Drop Ship miscellaneous fees billed:		Days of week overnight is available: Monday	
Comments:	s only:	Days of week overnight is available: Tuesday Tuesday Wednessi Priority Overnight receipt available: Friday PO Receipt Cut off time: PO Receipt Cut off time: Order receipt method: Phone: Fax: Fax: EDI: Policitie Overnight Fees apply: Tuesday	/ day
Other Data Informati	ion Required to Process PO:	Return Instructions	
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty:		Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?	
Miscell	aneous Notes:		
		ADDITIONAL INFORMATION	
		Is product order for scheduled patient procedure? Is product order for restocking purposes?	