

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

						Introduction Type	e: New Item	]	x Final Version			Date:	11/15	5/2024
			PRODUCT INFORMAT	TION					SPECIAL HAN	DLING AND STOP	AGE REQUI	REMENTS*		
Company Name:	Camber Pharmace	euticals, Inc.				Application	: ANDA	a. Temperatur	e – Indicate the USP tempe	rature range for t	his product.			
Application Number for NDA/ANI						NDA 505(b) Type:	NOT APPLICABLE		Temperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab	ole:							T						
	11-856-3719							_	Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) and		me: Allopurir	ol Tablets, USP 100 mg					Ι	(write in)					
Selling Unit NDC:	31722-252-10		Unit of Use NDC:				1722252102		Notes					
UDI			CVX Code:			MVX Code:		1						
Description:	Allopurinol Tablets	s, USP 100 mg						T	Is this product to be shipped	I to customers on i	ce?		No	]
									Is this product to be shipped	to customers on o	Iry ice?		No	
Active Ingredient(s):		Allopurinol, USP												
URL for Additional Product Inform	etlen.	www.camberpharma.						b. Contact for	temperature excursion que Name:	estions:	Soma Raju			
Address:	800 Centennial Av		20111			Address 2:			Number:		732-529-042	23		
City:	Piscataway	o, outo i			State:		ip: 08854	-	Group E-mail:			neterousa.cor	n	
Key Contact:	Customer Service				Email:	customerservice@ca							_	
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special reg	ulations for product in any	states?			No	]
Product Therapeutic Classification	n:	Xanthine oxidase inh	bitor						Special returns requirement	s for this product?			No	
														_
	ADDITIC	ONAL PRODUCT INFO	ORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store produ	uct (unit of sale) upright?				No	]
The product is?			Is the Product	Direct-Ship O	nly				Protect product (unit of sa	le) from light?			No	1
a legend device?		No	Is the Product	Neither		Size:	1000 ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			0.201			Initial shelf life at launch (i	f different):				Months
a product kit?		No				Strength:	100 mg			ORDER INFORM				
if yes, list NDCs of component parts			FDA Approval Status				Tablet			ORDER INFORM	TATION			
reverse numbered?		No				Dosage Form:	Tablet		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 1			
latex-free?		Yes				Draduct Change	Round		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		Yes				Product Shape:			Ampule					
correctional institution block?		No				Product Color:	White to off-white		Glass		Minimum o	rder quantity	?	Yes
opioid?		No					Debossed with 'U' and '5' on one side		Tube					
Cannabinoid? If Unit Dose, is item bar coded to u	nik dana ƙar	No	Country of Origin	India		Product Imprint	and functional scored line with 'H' on		Vial Liquid Sgl Vial Liquid Multi		K Vaa haw			4
hospital scanning?	nit dose for		Is this product covered u	nder the			the other side		Vial Powder Sgl			many of whi Each	ch package	type?
If Unit Dose, indicate NDC here:			Trade Agreements Act (T		No				Vial Powder Multi		12	Inner/Carton	/Pack	
			, i	,					Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS				-				1		
			FOR GENERIC DRUG PR	ODUCTS		1								
		I	FOR GENERIC DRUG PRO	ODUCTS	Au		Authorized Generic, other			ARMACY ORDER		1		
I. Orange Book Rating:	AB		FOR GENERIC DRUG PRO	ODUCTS	Αι		Authorized Generic, other ction fields are not applicable	Rec. sell unit	PH	ARMACY ORDER	/ BILL UNIT	nit to pharma	acy:	
I. Orange Book Rating: II. Generic Equivalent to What Brai		Zyloprim	FOR GENERIC DRUG PR	ODUCTS	Αι			[	PH to customer?	ARMACY ORDER	/ BILL UNIT	nit to pharma	acy:	
		Zyloprim						(Write-in, e.g.	PH to customer? 1 Vial)	ARMACY ORDER	/ BILL UNIT	nit to pharma Each Gram	acy:	
		Zyloprim	FOR GENERIC DRUG PR					[	PH to customer? 1 Vial)	ARMACY ORDER	/ BILL UNIT	nit to pharma	acy:	
II. Generic Equivalent to What Bran	nd?:	Zyloprim DRUG SUPPLY	CHAIN SECURITY ACT (	DSCSA) INFOR	MATION	se		(Write-in, e.g.	PH to customer? 1 Vial) le:	]	/ BILL UNIT Rx billing u	nit to pharma Each Gram Milliliter	acy:	
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## **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:					



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

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:					
		Is product order for scheduled patient procedure? Is product order for restocking purposes?				