

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

Version 2021						Introduction Ty	pe: New Item			x Final Version			Date:	3/20/	2024
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STOR	AGE REQUIR	EMENTS*		
Company Name: Camber Pharmaceuticals, Inc. App				Application	on: ANDA		a Temperature	- Indicate the USP tempe	rature range for th	is product					
Application Number for NDA/AN			e):	21	7748					Temperature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applica													· · · · · ·		
DUNS:	11-856-3719									Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) a	and Established N	ame: Allopur	rinol Tablets, USP 100 mg							(write in)	•				
Selling Unit NDC:	31722-252-05		Unit of Use NDC:			UPC:	331722252058			Notes					
UDI			CVX Code:			MVX Code:									
Description:	Allopurinol Table	ts. USP 100 ma								Is this product to be shipped	to customers on ic	e?		No	1
,		.,								Is this product to be shipped				No	
Active Ingredient(s):		Allopurinol, USP										•			
								b. Contact for temperature excursion questions:							
URL for Additional Product Inform		www.camberpharma.								Name:		Soma Raju			
Address:		Ave (and) 800 Centen	nial Ave, Suite 1			Address 2:				Number:		732-529-042			
City:	Piscataway State:			NJ	<b>Zip</b> : 08854		Group E-mail: somaraju@heterousa.com								
Key Contact:	Customer Service	9			Email:		camberpharma.com								1
Phone Number:	1-866-827-3647	lar ar in in			Fax:	732-562-8788				lations for product in any				No	
Product Therapeutic Classification	on:	Xanthine oxidase in	hibitor							Special returns requirement	s for this product?			No	
	4.5.5.17														1
	ADDIII	IONAL PRODUCT INF				PRODUCT DI	ESCRIPTION INFORMATION	ON	-	ct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	Only					Protect product (unit of sa	ile) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	500 ct		e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status							Initial shelf life at launch (i	if different):				Months
a product kit?		No	EDA 4			Strength:	100 mg				ORDER INFORM	ATION			
if yes, list NDCs of component parts			FDA Approval Status				Tablet				ORDER INFORM	ATION			
reverse numbered?		No				Dosage Form:	Tablet			Unit of Sale		What is the I	NDC selling	unit?	
co-licensed?		No	Allergens Present						Г	x Bottle		1 Bottle of 50			
latex-free?		Yes	7 morgono i rocom				Round			Box/Carton		(Write-in, e.g		) Vials)	
preservative-free?		Yes				Product Shap	e:			Ampule		(			
correctional institution block?		No				Product Color	White to off white			Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Color	•			Tube					
Cannabinoid?		No	Country of Origin	India		Product Impri	Debossed with "U" and			Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for					1 Toddot IIIIpri	one side and functional scored line with "H" on			Vial Liquid Multi		If Yes, how I		ch package	type?
hospital scanning?			Is this product covered u	inder the				IIIC		Vial Powder Sql		24	Each		
							other side.		-						
If Unit Dose, indicate NDC here:			Trade Agreements Act (	TAA)?	No		other side.			Vial Power Multi			Inner/Carton	/Pack	
If Unit Dose, indicate NDC here:					No		other side.		-					/Pack	
If Unit Dose, indicate NDC here:			Trade Agreements Act (1) FOR GENERIC DRUG PR		No		other side.		-	Vial Power Multi			Inner/Carton	/Pack	
If Unit Dose, indicate NDC here:						the street Occasion				Vial Power Multi Other: Write In	AADMACY ODDED		Inner/Carton	/Pack	
							*If Authorized Generic, othe			Vial Power Multi Other: Write In	ARMACY ORDER	/ BILL UNIT	Inner/Carton, Case		
I. Orange Book Rating:	AB								Rec. sell unit to	Vial Power Multi Other: Write In		/ BILL UNIT Rx billing ur	Inner/Carton Case it to pharma		
		Zyloprim					*If Authorized Generic, othe			Vial Power Multi Other: Write In  PH o customer?		/ BILL UNIT Rx billing ur	Inner/Carton Case it to pharma Each		
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## **Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)**

#### Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply): a. Cytotoxic?  No	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  Is the product a CA Prop 65 carcinogen?  Is the product a CA Prop 65 reproductive toxicant?  No  Does the product label bear a CA Prop 65 warning?  No	x     Organic     Corrosive       Inorganic     Oxidizer       Steroid/Androgen     Contact Hazard						
c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP?  No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  NFPA Storage Level:						
Is this product regulated for shipment by DOT?  (if yes, answer a-e below and provide SDS)  a. UN/Identification Number  b. Proper Shipping Name	Is the product a NIOSH hazardous drug?  If yes, indicate which:						
c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification						
e. Inhalation Hazard?  Is this product regulated for shipment by IATA?  No	EPA Hazardous Waste Code: Waste Characteristics						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMS or REGISTRY RESTRICTIONS						
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product?  If Yes, is it managed with a pharmacy registry?  Website URL:						
Is the product restricted for air shipment? If so, indicate restriction:  Passenger Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)						
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)	REMS:  REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier:  No Phone:  DEA #: NCPDP#: NCPDP#: NPI #:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments						
SP# ADD'L STORAGE INFORMATION	Registry:  Registry Program Contact Name:  Comments  No  Phone:						
Is the Product							
Controlled Substance? Controlled Substance Code Controlled by State(s)? ARCOS Reportable? Schedule No.  No If yes, indicate which: Is it a scheduled listed chemical product?:  CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged:  Is product returnable for credit:  Yes						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes	URL/Link to returns policy: contact - customerservice@camberpharma.com						
Restricted to retail pharmacy only:  Restricted to hospital, clinics, and physician offices only:  No	Special regulations or returns requirements for this product in certain states?						
Restricted from US territories? (explain in comments)  Comments:	If so, which states? Other requirements? Comments?						
MISCELLANE	OUS NOTES and/or Image of Product Barcode:						



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

#### Version 2021

#### FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Dro	Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:
c. Fax Nd. Phone only	umber: umber: No.: ddress:	Shipping lead time of PO:  Hours  Days  Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Expedited Freight Charges or Other Design	nated Dron Shin Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:	inaced Brop Only Feed.	Overnight receipt available:
Drop Ship service fee billed with each order:  Drop Ship miscellaneous fees billed:  Comments:		PO Receipt cut off time:  Days of week overnight is available:  Monday  Tuesday  Wednesday  Thursday  Friday
		Priority Overnight receipt available:
Class of Trade Restrict	on:	PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals, cl Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	inics and physician offices	Saturday Overnight receipt available:  PO Receipt Cut off time:  Phone: Fax: EDI:  Overnight Fees apply: Other fees apply:
Other Data Information Required	o 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?
Miscellaneous Notes		
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure? Is product order for restocking purposes?