

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

| Version 2021 | | | | | | Introduction 7 | Гуре: | New Item | | x Fi | inal Version | | | Date: | 3/20 | /2024 |
|--|--|--------------------|-------------------------------|-----------------------------------|----------------|---|--|--|---|--|------------------------------------|---------------------|------------------------|----------------------|-------------|------------|
| PRODUCT INFORMATION | | | | | | | SPECIAL HANDLING AND STORAGE REQUIREMENT | | | | | REMENTS* | | | | |
| Company Name: Camber Pharmaceuticals, Inc. Application: ANDA | | | | | | a. Temperature – Indicate the USP temperature range for this product. | | | | | | | | | | |
| Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 217748 Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F) | | | | | | | | | | | | | | | | |
| Medical Device Class, if applical | ble: | | | | | | | | | | | | | | | |
| DUNS: | 11-856-3719 | | | | | | | | | | perature Range F | Requirement | | | | |
| Proprietary Name (If Applicable) a | | ame: Allop | urinol Tablets, USP 100 mg | | | | | | | (write | in) | | | | | |
| Selling Unit NDC: UDI | 31722-252-10 | | Unit of Use NDC: CVX Code: | | | UPC: MVX Code: | 33172 | 22252102 | | Notes | | | | | | |
| | | | | | | | l I | | | | _ | | | 1 | | |
| Description: Allopurinol Tablets, USP 100 mg | | | | | | | Is this product to be shipped to customers on ice? Is this product to be shipped to customers on dry ice? No | | | | | | | | | |
| Active Ingredient(s): Allopurinol, USP | | | | | | | | is this prodi | uct to be snipped | i to customers on t | ily ice? | | INO | | | |
| Active ingredient(s). | | | | | | b. Contact for temperature excursion questions: | | | | | | | | | | |
| URL for Additional Product Information: www.camberpharma.com | | | | | | | | Name: Soma Raju | | | | | | | | |
| Address: | | | | | Address 2: | | | Number: | | | | 732-529-0423 | | | | |
| City: | Piscataway | | | | State: | NJ | | 08854 | Group E-mail: | | | | somaraju@heterousa.com | | | |
| Key Contact: Phone Number: | 1-866-827-3647 | | | | Email: | customerservice@camberpharma.com 732-562-8788 | | | a Cuasial sa | | | -1-12 | | | No | 1 |
| | | Yanthina avidasa i | inhihitor | | rax. | X: /32-302-0700 | | | c. Special regulations for product in any states? | | | | | | | |
| Froduct Therapeutic Classificatio | Product Therapeutic Classification: Xanthine oxidase inhibitor Special returns requirements for this product? No | | | | | | | | | | | | | | | |
| | ADDITI | ONAL PRODUCT IN | NFORMATION | | | PRODUCT | DESCR | IPTION INFORMATION | d. Store prod | luct (unit of s | sale) upright? | | | | No | 1 |
| The product is? | | | Is the Product | Direct-Ship C | nly | | | | u. 0.0.0 p. 00 | - | oduct (unit of sa | la) from light? | | | No |] |
| a legend device? | | No | Is the Product | Neither | , | | | 1000 ct | e. Shelf life: | r rotect pro | oduct (dilit of sa | iie) iioiii iigiit: | | | 24 | Months |
| if yes, enter class # | | 110 | Orphan Drug Status | | | Size: | | 1000 00 | 0.0.0 | Initial shelf | f life at launch (i | if different): | | | | Months |
| a product kit? | | No | | | | Strength: | 100 mg | | | | | <u> </u> | | | 4 | |
| if yes, list NDCs of | | | | | Suengui. | | | | | | ORDER INFORM | MATION | | | | |
| component parts | | | | | | Dosage Forn | m: | Tablet | | 11-24-40-1 | | | \A/l= a4 != 4l= a | NDC selling | | |
| reverse numbered? co-licensed? | | No No | Allergens Present | | | | | | | Unit of Sale | e ottle | | 1 Bottle of 1 | | unit? | |
| latex-free? | | Yes | Allergens riesent | | | | | Round | | | ox/Carton | | | g. 1 Box of 1 | 0 Vials) | |
| preservative-free? | | Yes | | | | Product Sha | ipe: | | | | mpule | | (| 3 | | |
| correctional institution block? | | No | | | | Product Cole | or. | White to off white | | | lass | | Minimum o | rder quantity | ı? | Yes |
| opioid? | | No | | | | r roduct con | oi. | | | | ube | | | | | |
| Cannabinoid? | | No | Country of Origin | India | | Product Imp | rint: | Debossed with "U" and "5" on one side and functional | | | ial Liquid Sgl | | | | | |
| If Unit Dose, is item bar coded to u | unit dose for | | Is this product covered u | ador the | | | | scored line with "H" on the | | | ial Liquid Multi ial Powder Sql | | | | ich package | type? |
| hospital scanning? If Unit Dose, indicate NDC here: | | | Trade Agreements Act (T | | No | | | other side. | | | ial Powder Sqi | | 12 | Each Inner/Cartor | /Pack | |
| II OTHE BOSE, INCIDENCE INDO NOTE. | | | Trado rigidomento riot (1 | , , , , | 140 | | | | | | ther: Write In | | | Case | in don | |
| | | | FOR GENERIC DRUG PRO | DDUCTS | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | |
| | | | | | Au | thorized Generic | | thorized Generic, other | | | PH | ARMACY ORDER | / BILL UNIT | | | |
| I. Orange Book Rating: AB | | | | section fields are not applicable | | | Rec. sell unit to customer? | | | | Rx billing unit to pharmacy: | | | | | |
| II. Generic Equivalent to What Brand?: Zyloprim | | | | | | | | | | | Each | | | | | |
| DDUC CURRLY CHAIN SECURITY ACT (DSCCA) INFORMATIO | | | | MATION | (Write | | | | (Write-in, e.g. 1 Vial) | | | | Gram Milliliter | | | |
| DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION | | | | | | | | | | | | wiiiiiter | | | | |
| Does supplier meet DSCSA defini | ition of manufactu | rer? | Yes | Т | GLN: | 0331722000000 | | | | | ITEN | I AND PACKING II | NFORMATIO | N | | |
| Is product exempt from DSCSA? | | | No | | | | | | | | | | | | | |
| If yes, select exemption: | | | | | GCP: | | | | | | | Dimensi | ons (US msn | nts.) | Volume | Saleable # |
| Other exemption - Write in: | | | | | | | | | ' | | Weight Lbs. | Depth | Width | Height | (Cube) | Pieces |
| Is product repackaged? | | | No | | | riginal product pur | chased | | Item/Each: | | 0.55 | 2.61 | 2.61 | 4.85 | 33.04 | 1 |
| Is product sold by manufacturer's | | | Yes | - | direct from m | | | de es d'es e de e | D/2 : - | No. of the Control of | | | | | 00.04 | |
| Has FDA granted waiver/exception If yes, attach documentation from | | rouuct? | No | | Provide sour | ce manufacturer fo | or repac | kayea product | Box/Carton/E | ounale/ | | | | | | |
| ii yes, attacii documentation noi | III I DA. | | | | | | | | Case: | | | | | | | |
| | | GT | TIN AND HIBCC PRODUCT IN | IFORMATION | | | | | | | 7.55 | 11 | 8.5 | 6 | 561.00 | 12 |
| | | | | | | | | | Pallet: | | | | | | | |
| Saleable Unit of Measure | 8 | Saleable Quantity | HIBCC | | | N-14 | _ | Unit of Use GTIN-14 | | | | | | | | |
| X Item/Each | | 1 | | | 003 | 31722252102 | | | | COST | NFORMATION | | | WHOLESAL | ER USE ONL | V |
| Box/Carton/Bundle/Inner Pack X Case | | 12 | | | 203 | 31722252106 | - | | | C0311 | NFORMATION | | | WHOLESAL | ER USE UNL | .T: |
| X Case Pallet | | 12 | | | 203 | 01122202100 | | | Regular Cost | t | | | Vendor #: | | | |
| | | | | | 1 | | | | Invoice Cost | | | \$99.33 | Whsl. Code | #: | | |
| | | | | | | | | | | | | | Fineline Co | de: | | |
| | | | | | | | | | As of date: | 2/ | /23/2024 | | | | | |
| | | | | | | | | | | | | | | | | |
| ∤ ¹ | | | Attack convet CAFETY DA | TA CHEET (OF |)C) as san b | ad lawar DACKACE | INICES | OT LABEL AND DUOTS OF S | DODUCT DACK | ACINIC and D | ARCORE | | ļ | | | |
| | | | Allacti copy of SAFETY DA | IN OFFET (SL | ט נטי uon naza | iiu ieller, PAUKAGE | : IINOEK | RT, LABEL AND PHOTO OF F | KUDUCI PACK | AGIING and B | MKCODE. | | | | | |



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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 | 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: No Registry Program Contact Name: Phone: Comments | | | | | | |
| Is the Product | | | | | | | |
| Controlled Substance Code Controlled by State(s)? ARCOS Reportable? Schedule No. No Controlled Substance Code Listed Chemical (List I or II) No If yes, indicate which: Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION: | RETURN INSTRUCTIONS Contact tel. # if product received damaged: Is product returnable for credit: 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: Restricted from US territories? (explain in comments) No | product in certain states? If so, which states? Other requirements? Comments? | | | | | | |
| Comments: | | | | | | | |
| MISCELLANE | OUS NOTES and/or Image of Product Barcode: | | | | | | |
| | | | | | | | |



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

| Order Method for Designated Drop S | nip 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: |
| b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone: | per: | 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 Designa | ed Drop Ship Fees: | Overnight and Priority Overnight PO Processing |
| Expedited freight fees billed with each order: Drop Ship service fee billed with each order: | | Overnight receipt available: PO Receipt cut off time: |
| Drop Ship miscellaneous fees billed: Comments: | | Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday |
| | | Priority Overnight receipt available: |
| Class of Trade Restriction | | PO Receipt Cut off time: |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments: | s 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 to F | rocess 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? |