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

Version 2021 | Introduction Type: Post Launch Change | x Final Version | Date: 6/23/2024

## PRODUCT INFORMATION

| | |
|---|---|
| Company Name: | Camber Pharmaceuticals, Inc. |
| Application: | ANDA |
| Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): | 214420 |
| Medical Device Class, if applicable: | |
| DUNS: | 11-856-3719 |
| Proprietary Name (If Applicable) and Established Name: | Potassium Citrate Extended-Release Tablets, USP 15 mEq (1620 mg) |
| Selling Unit NDC: | 31722-132-01 |
| Unit of Use NDC: | |
| UPC: | 331722132015 |
| UDI | |
| CVX Code: | |
| MVX Code: | |
| Description: | Potassium Citrate Extended-Release Tablets, USP 15 mEq (1620 mg) |
| Active Ingredient(s): | Potassium citrate, USP |
| URL for Additional Product Information: | www.camberpharma.com |
| Address: | 800 Centennial Ave, Suite 1 |
| Address 2: | |
| City: | Piscataway |
| State: | NJ |
| Zip: | 08854 |
| Key Contact: | Customer Service |
| Email: | customerservice@camberpharma.com |
| Phone Number: | 1-866-827-3647 |
| Fax: | 732-562-8788 |
| Product Therapeutic Classification: | Urinary alkalinizer |

## ADDITIONAL PRODUCT INFORMATION

| | |
|---|---|
| The product is? | |
| a legend device? | No |
| if yes, enter class # | |
| a product kit? | No |
| if yes, list NDCs of component parts | |
| reverse numbered? | No |
| co-licensed? | No |
| latex-free? | Yes |
| preservative-free? | Yes |
| correctional institution block? | No |
| opioid? | No |
| Cannabinoid? | No |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | |
| If Unit Dose, indicate NDC here: | |
| Is the Product… | Direct-Ship Only |
| Is the Product… | Neither |
| Orphan Drug Status | |
| FDA Approval Status | |
| Allergens Present | |
| Country of Origin | USA |
| Is this product covered under the Trade Agreements Act (TAA)? | Yes |

## PRODUCT DESCRIPTION INFORMATION

| | |
|---|---|
| Size: | 100 ct |
| Strength: | 15 mEq (1620 mg) |
| Dosage Form: | Extended-release, uncoated tablet |
| Product Shape: | Oval |
| Product Color: | Off white to tan yellowish |
| Product Imprint: | Debossed with 'T' on one side and '401' on the other side |

## FOR GENERIC DRUG PRODUCTS

Authorized Generic | *If Authorized Generic, other section fields are not applicable

| | |
|---|---|
| I. Orange Book Rating: | AB |
| II. Generic Equivalent to What Brand?: | Urocit-K |

## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

| | |
|---|---|
| Does supplier meet DSCSA definition of manufacturer? | Yes |
| Is product exempt from DSCSA? | No |
| If yes, select exemption: | |
| Other exemption - Write in: | |
| Is product repackaged? | No |
| Is product sold by manufacturer's exclusive distributor? | Yes |
| Has FDA granted waiver/exception/exemption for product? | No |
| If yes, attach documentation from FDA. | |
| GLN: | 0331722498975 |
| GCP: | |
| If yes, was original product purchased direct from mfr? | |
| Provide source manufacturer for repackaged product | |

## GTIN AND HIBCC PRODUCT INFORMATION

| | Saleable Unit of Measure | Saleable Quantity | HIBCC | GTIN-14 | Unit of Use GTIN-14 |
|---|---|---|---|---|---|
| x | Item/Each | 1 | | 00331722132015 | |
| | Box/Carton/Bundle/Inner Pack | | | | |
| x | Case | 12 | | 10331722132012 | |
| | Pallet | | | | |

## 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) | Excursions permitted between 15°C to 30°C (59°F to 86°F) |
| Notes | |
| Is this product to be shipped to customers on ice? | No |
| Is this product to be shipped to customers on dry ice? | 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? | No |
| Special returns requirements for this product? | No |
| d. Store product (unit of sale) upright? | No |
| Protect product (unit of sale) from light? | No |
| e. Shelf life: | 24 Months |
| Initial shelf life at launch (if different): | Months |

## ORDER INFORMATION

| Unit of Sale | | What is the NDC selling unit? |
|---|---|---|
| x | Bottle | 1 Bottle of 100 Tablets |
| | Box/Carton | (Write-in, e.g. 1 Box of 10 Vials) |
| | Ampule | |
| | Glass | Minimum order quantity? Yes |
| | Tube | |
| | Vial Liquid Sgl | |
| | Vial Liquid Multi | If Yes, how many of which package type? |
| | Vial Powder Sgl | 12 Each |
| | Vial Powder Multi | Inner/Carton/Pack |
| | Other: Write In | Case |

## PHARMACY ORDER / BILL UNIT

| | |
|---|---|
| Rec. sell unit to customer? | Rx billing unit to pharmacy: |
| (Write-in, e.g. 1 Vial) | Each |
| | Gram |
| | Milliliter |

## ITEM AND PACKING INFORMATION

| | Weight Lbs. | Dimensions (US msmts.) Depth | Width | Height | Volume (Cube) | Saleable # Pieces |
|---|---|---|---|---|---|---|
| Item/Each: | 0.22 | 2.75 | 2.75 | 5.5 | 41.59 | 1 |
| Box/Carton/Bundle/ Inner Pack: | | | | | | |
| Case: | 3.14 | 11.5 | 9 | 6 | 621.00 | 12 |
| Pallet: | | | | | | |

## COST INFORMATION

| | |
|---|---|
| Regular Cost | |
| Invoice Cost (WAC) ($) | $30.00 |
| As of date: | 3/15/2021 |

## WHOLESALER USE ONLY:

| | |
|---|---|
| Vendor #: | |
| Whsl. Code #: | |
| 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:

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

**Version 2021**

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) | No |
| a. UN/Identification Number | |
| b. Proper Shipping Name | |
| c. DOT Hazard Class | |
| d. Packing Group | |
| e. Inhalation Hazard? | |
| Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) | No |
| a. UN/Identification Number | |
| b. Proper Shipping Name | |
| c. DOT Hazard Class | |
| d. Packing Group | |
| e. Inhalation Hazard? | |
| 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? | 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)
- [ ] Special Permit; DOT-SP
- [ ] Special Provision (listed in Column 7 of 49 CFR 172.101);

SP#

### SDS Hazard Classification

- [x] 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 | | | |

### 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:

### 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:

Release DATE

# 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 Drop Ship Product

Purchase orders may be accepted by:

a. EDI
b. Autofax — Fax Number:
c. Fax — Fax Number:
d. Phone only — Phone No.:
e. Supplier Web Site only — Site Address:

Minimum Order Quantity:
Supplier's Customer Service Number:
Contracted 3PL company / contact #: Name:
Phone:

## Standard Order Receipt and Processing

**Purchase order daily receipt cut off time by supplier**
Cut off time:

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 Designated Drop Ship Fees:

Expedited freight fees billed with each order:
Drop Ship service fee billed with each order:
Drop Ship miscellaneous fees billed:
Comments:

## Overnight and Priority Overnight PO Processing

**Overnight receipt available:**
PO Receipt cut off time:
Days of week overnight is available:
Monday
Tuesday
Wednesday
Thursday
Friday

**Priority Overnight receipt available:**
PO Receipt Cut off time:

**Saturday Overnight receipt available:**
PO Receipt Cut off time:

Order receipt method: Phone: Phone #:
Fax: Fax #:
EDI:

Overnight Fees apply:
Other fees apply:

## Class of Trade Restriction:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices
Restricted to retail pharmacy only:
Restricted to hospital, clinics, and physician offices only:
Restricted from US territories? (explain in comments)
Comments:

## Other Data Information Required to Process PO:

Patient Procedure Date:
Physician Name:
Physician/Clinic Phone #
Physician State License #
Physician/Clinic DEA #:
Physician/Clinic Specialty:

## Return Instructions

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?