

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

| Version 2021 | | | | | | Introduction Type: | : Post Launch Change | | x Final Version | | | Date: | 11/20 | 0/2024 |
|--|---------------------|---------------------------------|--------------------------------|---------------|------------------|---|---------------------------------|---|--------------------------------|---------------------|--------------------------|---------------|-------------|------------|
| | | | PRODUCT INFORMA | TION | | | | | SPECIAL HAN | DLING AND STOR | RAGE REQUI | 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): 091264 | | | | | | | Temperature Range | Controlled Room | | and 25 C (68 | 3° – 77° F) | | | |
| Medical Device Class, if applica | | | | | | | | İ | | | | | | |
| DUNS: | 11-856-3719 | | | | | | | | Other Temperature Range I | Requirement | | | | |
| Proprietary Name (If Applicable) a | | me: Levoc | cetirizine Dihydrochloride Tal | | | | | I | (write in) | | | | | |
| Selling Unit NDC: | 31722-551-90 | | Unit of Use NDC | | 31722-551-90 | | 1722551908 | | Notes | | | | | |
| UDI | | | CVX Code: | | | MVX Code: | | 1 | | | | | | |
| Description: | Levocetirizine Dihy | drochloride Tablets | 5 mg | | | | | Ţ | Is this product to be shipped | d to customers on i | ce? | | No |] |
| | | | | | | | | | Is this product to be shipped | d to customers on o | dry ice? | | No | |
| Active Ingredient(s): | | Levocetirizine dihy | drochloride, USP | | | | | | | | | | | |
| UDI for Additional Bradesis Inform | | | | | | | | b. Contact fo | r temperature excursion qu | estions: | 0 D - ' | | | |
| URL for Additional Product Inform Address: | 800 Centennial Av | www.camberpharm | na.com | | 1 | Address 2: | | - | Name: Number: | | Soma Raju 732-529-042 | 22 | | |
| City: | Piscataway | e, Suite i | | | State: | | p: 08854 | | Group E-mail: | | | eterousa.com | m | |
| Key Contact: | Customer Service | | | | Email: | customerservice@car | | | Group L-mail. | | <u>somaraju@i</u> | ieterousa.coi | Ш | |
| Phone Number: | 1-866-827-3647 | | | | Fax: | 732-562-8788 | | c. Special reg | gulations for product in any | states? | | | No | 7 |
| Product Therapeutic Classification | on: | Histamine H ₁ -recep | ptor antagonist | | | | | | Special returns requirement | | | | No | 1 |
| | | | | | _ | | | | -, | | | | | 1 |
| | ADDITIO | NAL PRODUCT IN | NFORMATION | | | PRODUCT DESC | CRIPTION INFORMATION | d. Store prod | luct (unit of sale) upright? | | | | No | 7 |
| The product is? | | | Is the Product | Direct-Ship (| Only | | | 11 | Protect product (unit of sa | ale) from light? | | | No | ī |
| a legend device? | | No | Is the Product | Unit of Use | | | 90 ct | e. Shelf life: | r rotoot product (dilit or ot | , | | | 24 | Months |
| if yes, enter class # | | | Orphan Drug Status | | | Size: | | | Initial shelf life at launch (| if different): | | | | Months |
| a product kit? | | No | | | | Strength: | 5 mg | | | | | | | |
| if yes, list NDCs of | | | FDA Approval Status | | | ou chigan. | | | | ORDER INFORM | MATION | | | |
| component parts | | | | | | Dosage Form: | Film coated tablet | | | | | | | |
| reverse numbered? | | No | All | | | - | | | Unit of Sale | | What is the | | unit? | |
| co-licensed? latex-free? | | No Yes | Allergens Present | | | | Scored, round, biconvex | | x Bottle Box/Carton | | 1 Bottle of 9 | g. 1 Box of 1 | 0 Viole) | |
| preservative-free? | | Yes | Dairy, Lac | tose, Casein | | Product Shape: | Scored, Tourid, Diconvex | | Ampule | | (Wille-III, e. | g. I box of i | o viais) | |
| correctional institution block? | • | No | | | | | White | | Glass | | Minimum or | rder quantity | /? | Yes |
| opioid? | | No | | | | Product Color: | | | Tube | | | | | |
| Cannabinoid? | | No | Country of Origin | India | | Product Imprint: | Debossed with '161' on one side | | Vial Liquid Sgl | | | | | |
| If Unit Dose, is item bar coded to | unit dose for | | | | | Product imprint. | and 'H' on other side | | Vial Liquid Multi | | | | ich package | type? |
| hospital scanning? | | | Is this product covered | | | | | | Vial Powder Sgl | | 24 | Each | | |
| If Unit Dose, indicate NDC here: | | | Trade Agreements Act (| TAA)? | No | | | | Vial Powder Multi | | | Inner/Cartor | n/Pack | |
| | | | | | | | | <u>l </u> | Other: Write In | | | Case | | |
| | | | FOR GENERIC DRUG PF | ODUCIS | | | | | | | | | | |
| | | | | | Aut | horized Generic *If / | Authorized Generic, other | | DI- | IARMACY ORDER | / BILL LINIT | | | |
| L Common Book Book on | AB | | | _ | Aut | | ction fields are not applicable | Boo call unit | to customer? | ARMAOT ORDER | | | | |
| I. Orange Book Rating: II. Generic Equivalent to What Bra | | Xyzal | | | | | | Rec. sen unit | to customer : | 1 | Rx billing u | Each | acy: | |
| II. Generic Equivalent to What Bra | anu r. | Луга | | | | | | (Write-in, e.g | 1 Vial) | | | Gram | | |
| | | DRUG SUPP | LY CHAIN SECURITY ACT | (DSCSA) INFO | RMATION | | | (************************************** | | | | Milliliter | | |
| | | | | | | | | | | | | | | |
| Does supplier meet DSCSA defin | | er? | Yes | | GLN: | 0331722498975 | | | ITEN | I AND PACKING II | NFORMATIO | N | | |
| Is product exempt from DSCSA? | • | | No | | | | | | | | | | | |
| If yes, select exemption: | | | | | GCP: | | |] [| Weight Lbs. | | ions (US msn | | Volume | Saleable # |
| Other exemption - Write in: | | | | | | | | | weight LDS. | Depth | Width | Height | (Cube) | Pieces |
| Is product repackaged? | | | No | _ | | ginal product purchas | sed | Item/Each: | 0.07 | 1.56 | 1.56 | 3.13 | 7.62 | 1 |
| Is product sold by manufacturer's | | | Yes No | - | direct from mi | | analismad was do | Dev/0 | | | | | | |
| Has FDA granted waiver/exception If yes, attach documentation fro | | bauct? | INO | | Provide source | e manufacturer for rep | раскадей ргодист | Box/Carton/E | Sunale/ | | | | | |
| ii yes, attacii documentation no | JIII I DA. | | | | | | | Case: | | | - | | | |
| | | GT | IN AND HIBCC PRODUCT I | NFORMATION | | | | I Cusc. | 2.1 | 9.75 | 7.00 | 4 | 290.06 | 24 |
| | | | | | | | | Pallet: | | | | | | |
| Saleable Unit of Measure | Sa | aleable Quantity | HIBCC | | GTIN | I-14 | Unit of Use GTIN-14 | | | | | | | |
| X Item/Each | | 1 | | | 0033 | 1722551908 | 00331722551908 | | | | | | | |
| Box/Carton/Bundle/Inner Pack | | | | | | | | | COST INFORMATION | | | WHOLESAL | ER USE ONL | _Y: |
| X Case | | 24 | | | 2033 | 1722551902 | | | | | Vand# | | | |
| Pallet | | | | | | | | Regular Cost Invoice Cost | | 040.00 | Vendor #: Whsl. Code | #. | | |
| 111 | | | | | | | | IIIVOICE COST | (**AC) (\$) | \$10.00 | Fineline Co | | | |
| | | | | | | | | 1.1 | | | | | | |
| | | | | | | | | As of date: | 12/1/2024 | | | | | |
| | | | | | | | | As of date: | 12/1/2024 | | | | | |
| | | | | | | | | As of date: | 12/1/2024 | | | | | |
| | | | Attach copy of SAFETY D | ATA SHEET (SI | OS) or non hazar | d letter, PACKAGE INS | ERT, LABEL AND PHOTO OF F | | | | | | | |



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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? 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? Does the product label bear a CA Prop 65 warning? | SDS Hazard Classification x Organic Corrosive 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? Is this product regulated for shipment by DOT? | identify NFPA Storage Level: NFPA Storage Level: Is the product a NIOSH hazardous drug? No | | | | | |
| (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class | If yes, indicate which: Hazardous Waste Identification | | | | | |
| d. Packing Group e. Inhalation Hazard? | EPA Hazardous Waste Code: Waste Characteristics | | | | | |
| Is this product regulated for shipment by IATA? | | | | | | |
| (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? | REMS or REGISTRY RESTRICTIONS 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); SP# | Comments Registry: No | | | | | |
| | Registry Program Contact Name: Phone: | | | | | |
| ADD'L STORAGE INFORMATION | Comments | | | | | |
| Is the Product Controlled Substance? No Controlled Substance Code | RETURN INSTRUCTIONS | | | | | |
| Controlled by State(s)? ARCOS Reportable? Schedule No. No Listed Chemical (List I or II) If yes, indicate which: Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION: | Contact tel. # if product received damaged: 1-866-827-3647 Yes | | | | | |
| | URL/Link to returns policy: | | | | | |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Ye | contact - customerservice@camberpharma.com | | | | | |
| Restricted to retail pharmacy only: | 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: | | | | | | |
| MISCELL | NEOUS 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? |