



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

Version 2021 Introduction Type:  New Item  Final Version Date: 11/26/2024

**PRODUCT INFORMATION**

Company Name: Camber Pharmaceuticals, Inc. Application: ANDA  
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 210914  
 Medical Device Class, if applicable:  
 DUNS: 11-856-3719  
 Proprietary Name (If Applicable) and Established Name: Levocetirizine Dihydrochloride Oral Solution 2.5 mg/5 mL (0.5 mg/mL)  
 Selling Unit NDC: 31722-659-31 Unit of Use NDC: 31722-659-31 UPC: 331722659314  
 UDI CVX Code: MVX Code:  
 Description: Levocetirizine Dihydrochloride Oral Solution 2.5 mg/5 mL (0.5 mg/mL)  
 Active Ingredient(s): Levocetirizine dihydrochloride, USP  
 URL for Additional Product Information: [www.camberpharma.com](http://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](mailto:customerservice@camberpharma.com)  
 Phone Number: 1-866-827-3647 Fax: 732-562-8788  
 Product Therapeutic Classification: Histamine H<sub>1</sub>-receptor antagonist

**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: Excursions permitted to 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](mailto:somaraju@heterousa.com)

c. Special regulations for product in any states?  
 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:  
 Initial shelf life at launch (if different): 24 Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device? if yes, enter class #	<input type="checkbox"/> No	Is the Product... Is the Product... Orphan Drug Status	Direct-Ship Only <input type="checkbox"/> Unit of Use <input type="checkbox"/>
a product kit? if yes, list NDCs of component parts reverse numbered?	<input type="checkbox"/> No	FDA Approval Status	Size: 148 mL
co-licensed? latex-free? preservative-free? correctional institution block? opioid? Cannabinoid?	<input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> No <input type="checkbox"/> No	Allergens Present	Strength: 2.5 mg/5 mL (0.5 mg/mL)
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>	Country of Origin: India	Dosage Form: Clear, oral solution
If Unit Dose, indicate NDC here:	<input type="checkbox"/>	Is this product covered under the Trade Agreements Act (TAA)?	Product Shape: NA Product Color: Colorless Product Imprint: N/A

**ORDER INFORMATION**

Unit of Sale:  Bottle  
 Box/Carton  
 Ampule  
 Glass  
 Tube  
 Vial Liquid Sgl  
 Vial Liquid Multi  
 Vial Powder Sgl  
 Vial Powder Multi  
 Other: Write In

What is the NDC selling unit?  
 1 Bottle of 148 mL Oral Solution  
 (Write-in, e.g. 1 Box of 10 Vials)

Minimum order quantity?  Yes

If Yes, how many of which package type?  
 20 Each  
 Inner/ Carton/ Pack  
 Case

**FOR GENERIC DRUG PRODUCTS**

I. Orange Book Rating: AA  
 II. Generic Equivalent to What Brand?: Xyzal  
 Authorized Generic \*If Authorized Generic, other section fields are not applicable

**PHARMACY ORDER / BILL UNIT**

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

**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

**ITEM AND PACKING INFORMATION**

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.5	2.2	2.2	5.8	28.07	1
Box/Carton/Bundle/ Inner Pack:						
Case:	10.75	11.4	9.5	6.6	714.78	20
Pallet:						

**GTIN AND HIBCC PRODUCT INFORMATION**

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00331722659314	00331722659314
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	20		30331722659315	
<input type="checkbox"/> Pallet				

**COST INFORMATION**

Regular Cost  
 Invoice Cost (WAC) (\$) \$45.00  
 As of date: 9/23/2019

**WHOLESALE USE ONLY:**  
 Vendor #:  
 Whsl. Code #:  
 Finline Code:



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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

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?  No

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?  No

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

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:   
 Site Enrollment Number assigned by Supplier:

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:



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

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI <input type="checkbox"/> b. Autofax <input type="checkbox"/> c. Fax <input type="checkbox"/> d. Phone only <input type="checkbox"/> e. Supplier Web Site only <input type="checkbox"/> Minimum Order Quantity: <input type="text"/> Supplier's Customer Service Number: <input type="text"/> Contracted 3PL company / contact #: <input type="text"/> Name: <input type="text"/> Phone: <input type="text"/> Fax Number: <input type="text"/> Fax Number: <input type="text"/> Phone No.: <input type="text"/> Site Address: <input type="text"/>	<b>Purchase order daily receipt cut off time by supplier</b> Cut off time: <input type="text"/> Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> Ships for second day receipt: <input type="checkbox"/> Ships regular ground for 3-10 days receipt: <input type="checkbox"/>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: <input type="text"/> Drop Ship service fee billed with each order: <input type="text"/> Drop Ship miscellaneous fees billed: <input type="text"/> Comments: <input type="text"/>	<b>Overnight receipt available:</b> <input type="checkbox"/> PO Receipt cut off time: <input type="text"/> Days of week overnight is available: <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday <b>Priority Overnight receipt available:</b> <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> <b>Saturday Overnight receipt available:</b> <input type="checkbox"/> PO Receipt Cut off time: <input type="text"/> Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/> Fax: <input type="text"/> Fax #: <input type="text"/> EDI: <input type="text"/> Overnight Fees apply: <input type="checkbox"/> Other fees apply: <input type="checkbox"/>
Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Restricted to retail pharmacy only: <input type="checkbox"/> Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> Restricted from US territories? (explain in comments) <input type="checkbox"/> Comments: <input type="text"/>	
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/>	Contact # if product is received damaged: <input type="text"/> Is product returnable for credit: <input type="checkbox"/> URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> If so, which states? Other requirements? Comments? <input type="text"/>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<input type="text"/>	Is product order for scheduled patient procedure? <input type="checkbox"/> Is product order for restocking purposes? <input type="checkbox"/>