



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

Version 2021

Introduction Type:  Post Launch Change

Final Version

Date: 5/23/2024

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: <input type="text" value="Camber Pharmaceuticals, Inc."/>		Application: <input type="text" value="ANDA"/>		<b>a. Temperature – Indicate the USP temperature range for this product.</b>			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <input type="text" value="204093"/>				Temperature Range: <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>			
Medical Device Class, if applicable: <input type="text"/>				Other Temperature Range Requirement (write in): <input type="text"/>			
DUNS: <input type="text" value="11-856-3719"/>				Notes: <input type="text"/>			
Proprietary Name (If Applicable) and Established Name: <input type="text" value="Montelukast Sodium Chewable Tablets 4 mg"/>		Unit of Use NDC: <input type="text" value="31722-727-90"/>		UPC: <input type="text" value="33172272907"/>			
Selling Unit NDC: <input type="text"/>		CVX Code: <input type="text"/>		MVX Code: <input type="text"/>		Is this product to be shipped to customers on ice? <input type="checkbox"/> No	
UDI: <input type="text"/>						Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No	
Description: <input type="text" value="Montelukast Sodium Chewable Tablets 4 mg"/>				<b>b. Contact for temperature excursion questions:</b>			
Active Ingredient(s): <input type="text" value="Montelukast sodium, USP"/>				Name: <input type="text" value="Soma Raju"/>			
URL for Additional Product Information: <input type="text" value="www.camberpharma.com"/>				Number: <input type="text" value="732-529-0423"/>			
Address: <input type="text" value="800 Centennial Ave, Suite 1"/>		Address 2: <input type="text"/>		Group E-mail: <input type="text" value="somaraju@heterousa.com"/>			
City: <input type="text" value="Piscataway"/>		State: <input type="text" value="NJ"/>		Zip: <input type="text" value="08854"/>			
Key Contact: <input type="text" value="Customer Service"/>		Email: <input type="text" value="customerservice@camberpharma.com"/>					
Phone Number: <input type="text" value="1-866-827-3647"/>		Fax: <input type="text" value="732-562-8788"/>					
Product Therapeutic Classification: <input type="text" value="Leukotriene receptor antagonist (LTRA)"/>				<b>c. Special regulations for product in any states?</b>			
				Special returns requirements for this product? <input type="checkbox"/> No			
				<b>d. Store product (unit of sale) upright?</b>			
				Protect product (unit of sale) from light? <input type="checkbox"/> No			
				<b>e. Shelf life:</b>			
				Initial shelf life at launch (if different): <input type="text" value="24"/> Months			
ADDITIONAL PRODUCT INFORMATION				PRODUCT DESCRIPTION INFORMATION			
The product is a legend device? <input type="checkbox"/> No		Is the Product... Direct-Ship Only <input type="checkbox"/>		Size: <input type="text" value="90 ct"/>			
if yes, enter class # a product kit? <input type="checkbox"/> No		Is the Product... Unit of Use <input type="checkbox"/>		Strength: <input type="text" value="4 mg"/>			
if yes, list NDCs of component parts reverse numbered? <input type="checkbox"/>		Orphan Drug Status <input type="checkbox"/>		Dosage Form: <input type="text" value="Chewable tablet"/>			
co-licensed? <input type="checkbox"/> No		FDA Approval Status <input type="text"/>		Product Shape: <input type="text" value="Oval, biconvex"/>			
latex-free? <input type="checkbox"/> Yes		Allergens Present <input type="text" value="Gluten"/>		Product Color: <input type="text" value="Light pink to pink, speckled"/>			
preservative-free? <input type="checkbox"/> Yes		Country of Origin <input type="text" value="India"/>		Product Imprint: <input type="text" value="Debossed with '1' on one side and '112' on the other side"/>			
correctional institution block? <input type="checkbox"/> No		Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No					
opioid? <input type="checkbox"/> No							
Cannabinoid? <input type="checkbox"/> No							
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/>							
If Unit Dose, indicate NDC here: <input type="text"/>							
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: <input type="text" value="AB"/>		Authorized Generic <input type="checkbox"/>		*If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: <input type="text" value="Singulair"/>							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes		GLN: <input type="text" value="0331722498975"/>					
Is product exempt from DSCSA? <input type="checkbox"/> No		GCP: <input type="text"/>					
If yes, select exemption: <input type="text"/>		If yes, was original product purchased direct from mfr? <input type="checkbox"/>					
Other exemption - Write in: <input type="text"/>		Provide source manufacturer for repackaged product <input type="text"/>					
Is product repackaged? <input type="checkbox"/> No							
Is product sold by manufacturer's exclusive distributor? <input type="checkbox"/> Yes							
Has FDA granted waiver/exception/exemption for product? <input type="checkbox"/> No							
If yes, attach documentation from FDA. <input type="text"/>							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure		Saleable Quantity		HIBCC		GTIN-14	
<input checked="" type="checkbox"/> Item/Each		<input type="text" value="1"/>				<input type="text" value="00331722727907"/>	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack							
<input checked="" type="checkbox"/> Case		<input type="text" value="24"/>				<input type="text" value="20331722727901"/>	
<input type="checkbox"/> Pallet							
						Unit of Use GTIN-14 <input type="text" value="00331722727907"/>	
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost <input type="text"/>		Invoice Cost (WAC) (\$) <input type="text" value="\$30.95"/>		Vendor #: <input type="text"/>		Whsl. Code #: <input type="text"/>	
As of date: <input type="text" value="4/3/2017"/>				Fineline Code: <input type="text"/>			
ORDER INFORMATION							
Unit of Sale		What is the NDC selling unit?					
<input checked="" type="checkbox"/> Bottle		<input type="text" value="1 Bottle of 90 Tablets"/>					
<input type="checkbox"/> Box/ Carton		(Write-in, e.g. 1 Box of 10 Vials)					
<input type="checkbox"/> Ampule							
<input type="checkbox"/> Glass		Minimum order quantity? <input type="checkbox"/> Yes					
<input type="checkbox"/> Tube							
<input type="checkbox"/> Vial Liquid Sgl		If Yes, how many of which package type?					
<input type="checkbox"/> Vial Liquid Multi		<input type="text" value="24"/> Each					
<input type="checkbox"/> Vial Powder Sgl		<input type="text"/>					
<input type="checkbox"/> Vial Powder Multi		Inner/ Carton/ Pack					
<input type="checkbox"/> Other: Write In		Case					
PHARMACY ORDER / BILL UNIT							
Rec. sell unit to customer? <input type="text"/>		Rx billing unit to pharmacy:					
(Write-in, e.g. 1 Vial)		<input type="checkbox"/> Each					
		<input type="checkbox"/> Gram					
		<input type="checkbox"/> Milliliter					
ITEM AND PACKING INFORMATION							
		Weight Lbs.		Dimensions (US msmts.)		Volume	
				Depth		Saleable #	
				Width		Pieces	
				Height			
Item/Each:		<input type="text" value="0.11"/>		<input type="text" value="1.5"/>		<input type="text" value="1.5"/>	
Box/ Carton/ Bundle/ Inner Pack:		<input type="text"/>		<input type="text"/>		<input type="text"/>	
Case:		<input type="text" value="3.25"/>		<input type="text" value="9.5"/>		<input type="text" value="6.75"/>	
Pallet:		<input type="text"/>		<input type="text"/>		<input type="text" value="24"/>	

\*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

See new p. 3 for Designated Drop Ship Only.

Signature:

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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#

### 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:

### SDS Hazard Classification

Organic  Corrosive  
 Inorganic  Oxidizer  
 Steroid/Androgen  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?  No  
 Website URL:

Med Guide Required  No  
 Limited Distribution Requirement  No  
 Comments / Details: (For example, iPledge program?)

**REMS:**  No

REMS Program Manager Name:  Phone:

Supplier Manages REMS registry exclusively:  No  
 Wholesale distributor support:  No  
 Provider Name:  DEA #:

Site Enrollment Number assigned by Supplier:  NCPDP#:   
 NPI #:

Comments:

**Registry:**  No

Registry Program Contact Name:  Phone:

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:

People with Phenylketonuria: Montelukast sodium chewable tablets 4-mg (equivalent to 4-mg montelukast) contain 0.672 mg of phenylalanine.

