



# 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*	
<b>Company Name:</b> Camber Pharmaceuticals, Inc. <b>Application:</b> ANDA <b>Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):</b> 204093 <b>Medical Device Class, if applicable:</b> _____ <b>DUNS:</b> 11-856-3719 <b>Proprietary Name (If Applicable) and Established Name:</b> Montelukast Sodium Chewable Tablets 5 mg <b>Selling Unit NDC:</b> 31722-728-90 <b>Unit of Use NDC:</b> 31722-728-90 <b>UPC:</b> 331722728904 <b>UDI:</b> _____ <b>CVX Code:</b> _____ <b>MXV Code:</b> _____ <b>Description:</b> Montelukast Sodium Chewable Tablets 5 mg <b>Active Ingredient(s):</b> Montelukast sodium, USP <b>URL for Additional Product Information:</b> <a href="http://www.camberpharma.com">www.camberpharma.com</a> <b>Address:</b> 800 Centennial Ave, Suite 1 <b>Address 2:</b> _____ <b>City:</b> Piscataway <b>State:</b> NJ <b>Zip:</b> 08854 <b>Key Contact:</b> Customer Service <b>Email:</b> <a href="mailto:customerservice@camberpharma.com">customerservice@camberpharma.com</a> <b>Phone Number:</b> 1-866-827-3647 <b>Fax:</b> 732-562-8788 <b>Product Therapeutic Classification:</b> Leukotriene receptor antagonist (LTRA)		<b>a. Temperature – Indicate the USP temperature range for this product.</b> <b>Temperature Range:</b> <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>  <b>Other Temperature Range Requirement (write in):</b> _____ <b>Notes:</b> _____  Is this product to be shipped to customers on ice? <input type="checkbox"/> No Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No  <b>b. Contact for temperature excursion questions:</b> <b>Name:</b> Soma Raju <b>Number:</b> 732-529-0423 <b>Group E-mail:</b> <a href="mailto:somaraju@heterousa.com">somaraju@heterousa.com</a>  <b>c. Special regulations for product in any states?</b> <input type="checkbox"/> No Special returns requirements for this product? <input type="checkbox"/> No  <b>d. Store product (unit of sale) upright?</b> <input type="checkbox"/> No <b>Protect product (unit of sale) from light?</b> <input type="checkbox"/> No  <b>e. Shelf life:</b> <input type="text" value="24"/> Months <b>Initial shelf life at launch (if different):</b> <input type="text" value="24"/> Months	
ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
<b>The product is?</b> a legend device? <input type="checkbox"/> No if yes, enter class # _____ a product kit? <input type="checkbox"/> No if yes, list NDCs of component parts reverse numbered? _____ co-licensed? <input type="checkbox"/> No latex-free? <input type="checkbox"/> Yes preservative-free? <input type="checkbox"/> Yes correctional institution block? <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: _____		<b>Is the Product... Direct-Ship Only</b> <input type="checkbox"/> <b>Is the Product... Unit of Use</b> <input type="checkbox"/> <b>Orphan Drug Status</b> <input type="checkbox"/>  <b>FDA Approval Status</b> _____  <b>Allergens Present</b> <input type="checkbox"/> Gluten  <b>Country of Origin</b> <input type="text" value="India"/>  <b>Is this product covered under the Trade Agreements Act (TAA)?</b> <input type="checkbox"/> No	
		<b>Size:</b> <input type="text" value="90 ct"/>  <b>Strength:</b> <input type="text" value="5 mg"/>  <b>Dosage Form:</b> <input type="text" value="Chewable tablet"/>  <b>Product Shape:</b> <input type="text" value="Oval, biconvex"/>  <b>Product Color:</b> <input type="text" value="Light pink to pink, speckled"/>  <b>Product Imprint:</b> <input type="text" value="Debossed with '1' on one side and '113' on the other side"/>	
FOR GENERIC DRUG PRODUCTS			
<b>I. Orange Book Rating:</b> <input type="text" value="AB"/> <input type="checkbox"/> Authorized Generic      *If Authorized Generic, other section fields are not applicable <b>II. Generic Equivalent to What Brand?:</b> <input type="text" value="Singulair"/>			
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION			
<b>Does supplier meet DSCSA definition of manufacturer?</b> <input type="checkbox"/> Yes <b>Is product exempt from DSCSA?</b> <input type="checkbox"/> No <b>If yes, select exemption:</b> _____ <b>Other exemption - Write in:</b> _____ <b>Is product repackaged?</b> <input type="checkbox"/> No <b>Is product sold by manufacturer's exclusive distributor?</b> <input type="checkbox"/> Yes <b>Has FDA granted waiver/exception/exemption for product?</b> <input type="checkbox"/> No <b>If yes, attach documentation from FDA.</b> _____		<b>GLN:</b> <input type="text" value="00331722498975"/>  <b>GCP:</b> _____  <b>If yes, was original product purchased direct from mfr?</b> <input type="checkbox"/> _____ <b>Provide source manufacturer for repackaged product</b> _____	
GTIN AND HIBCC PRODUCT INFORMATION			
<b>Saleable Unit of Measure</b> <input checked="" type="checkbox"/> Item/Each <input type="checkbox"/> Box/Carton/Bundle/Inner Pack <input checked="" type="checkbox"/> Case <input type="checkbox"/> Pallet		<b>Saleable Quantity</b> <input type="text" value="1"/>  <input type="text" value="24"/>  <b>HIBCC</b> _____  <b>GTIN-14</b> <input type="text" value="00331722728904"/> <input type="text" value="20331722728908"/>  <b>Unit of Use GTIN-14</b> <input type="text" value="00331722728904"/>	
COST INFORMATION		WHOLESALE USE ONLY:	
<b>Regular Cost</b> _____ <b>Invoice Cost (WAC) (\$)</b> <input type="text" value="\$30.95"/>  <b>As of date:</b> <input type="text" value="4/3/2017"/>		<b>Vendor #:</b> _____ <b>Whsl. Code #:</b> _____ <b>Fineline Code:</b> _____	

\*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: \_\_\_\_\_

Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION									
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? <input type="checkbox"/> No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant?            Is the product a CA Prop 65 carcinogen? <input type="checkbox"/> No            Is the product a CA Prop 65 reproductive toxicant? <input type="checkbox"/> No            Does the product label bear a CA Prop 65 warning? <input type="checkbox"/> No</p> <p>c. Contact Hazard? <input type="checkbox"/> No</p> <p>d. Does this product require special clean-up instructions?            (If yes, attach SDS with special instructions.) <input type="checkbox"/> No</p> <p>e. Does the product contain DEHP? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by DOT?            (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is this product regulated for shipment by IATA?            (if yes, answer a-e below and provide SDS) <input type="checkbox"/> No</p> <p>a. UN/Identification Number <input type="text"/></p> <p>b. Proper Shipping Name <input type="text"/></p> <p>c. DOT Hazard Class <input type="text"/></p> <p>d. Packing Group <input type="text"/></p> <p>e. Inhalation Hazard? <input type="checkbox"/> No</p> <p>Is the product restricted for air shipment? If so, indicate restriction: <input type="checkbox"/> No</p> <p><input type="checkbox"/> Passenger  <input type="checkbox"/> Cargo  <input type="checkbox"/> Passenger &amp; Cargo</p> <p>Is this a reportable quantity? <input type="checkbox"/> No            RQ Threshold: <input type="text"/></p> <p>Is this a marine pollutant? <input type="checkbox"/> No</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit?  <input type="checkbox"/> No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity  <input type="checkbox"/> Consumer Commodity, ORM-D  <input type="checkbox"/> Small Quantity (49 CFR 173.4)  <input type="checkbox"/> Special Permit; DOT-SP  <input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101);            SP# <input type="text"/></p>	<div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">SDS Hazard Classification</div> <table style="width:100%; border: 1px solid black;"> <tr> <td><input checked="" type="checkbox"/> Organic</td> <td><input type="checkbox"/> Corrosive</td> </tr> <tr> <td><input type="checkbox"/> Inorganic</td> <td><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td><input type="checkbox"/> Steroid/Androgen</td> <td><input type="checkbox"/> Contact Hazard</td> </tr> </table> <p>Does the product have an Aerosol class? If yes, identify NFPA Storage Level: <input type="checkbox"/> No            NFPA Storage Level: <input type="text"/></p> <p>Is the product a NIOSH hazardous drug? <input type="checkbox"/> No            If yes, indicate which: <input type="text"/></p>	<input checked="" type="checkbox"/> Organic	<input type="checkbox"/> Corrosive	<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer	<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard		
<input checked="" type="checkbox"/> Organic	<input type="checkbox"/> Corrosive								
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer								
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard								
Hazardous Waste Identification									
<table style="width:100%; border: 1px solid black;"> <tr> <td style="border: 1px solid black;">EPA Hazardous Waste Code: <input type="text"/></td> <td style="border: 1px solid black;">Waste Characteristics <input type="text"/></td> </tr> </table>		EPA Hazardous Waste Code: <input type="text"/>	Waste Characteristics <input type="text"/>						
EPA Hazardous Waste Code: <input type="text"/>	Waste Characteristics <input type="text"/>								
REMS or REGISTRY RESTRICTIONS									
<p>Is there a REMS on this product? <input type="checkbox"/> No            If Yes, is it managed with a pharmacy registry?            Website URL: <input type="text"/></p> <p>Med Guide Required <input type="checkbox"/> No            Limited Distribution Requirement <input type="checkbox"/> No            Comments / Details: (For example, iPledge program?) <input type="text"/></p> <p><b>REMS:</b> <input type="checkbox"/> No</p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="checkbox"/> No            Wholesale distributor support: <input type="text"/></p> <p>Provider Name: <input type="text"/> DEA #: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/> NCPDP#: <input type="text"/> NPI #: <input type="text"/></p> <p>Comments <input type="text"/></p> <p><b>Registry:</b> <input type="checkbox"/> No</p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments <input type="text"/></p>									
RETURN INSTRUCTIONS									
<p>Contact tel. # if product received damaged: <input type="text" value="1-866-827-3647"/></p> <p>Is product returnable for credit: <input type="checkbox"/> Yes</p> <p>URL/Link to returns policy: <input type="text" value="contact - customerservice@camberpharma.com"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> No</p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>									
ADD'L STORAGE INFORMATION									
<p>Is the Product...</p> <table style="width:100%;"> <tr> <td>Controlled Substance? <input type="checkbox"/> No</td> <td>Controlled Substance Code <input type="text"/></td> </tr> <tr> <td>Controlled by State(s)? <input type="checkbox"/> No</td> <td>Listed Chemical (List I or II) <input type="checkbox"/> No</td> </tr> <tr> <td>ARCOS Reportable? <input type="checkbox"/> No</td> <td>If yes, indicate which: <input type="text"/></td> </tr> <tr> <td>Schedule No. <input type="text"/></td> <td>Is it a scheduled listed chemical product?: <input type="checkbox"/> No</td> </tr> </table>		Controlled Substance? <input type="checkbox"/> No	Controlled Substance Code <input type="text"/>	Controlled by State(s)? <input type="checkbox"/> No	Listed Chemical (List I or II) <input type="checkbox"/> No	ARCOS Reportable? <input type="checkbox"/> No	If yes, indicate which: <input type="text"/>	Schedule No. <input type="text"/>	Is it a scheduled listed chemical product?: <input type="checkbox"/> No
Controlled Substance? <input type="checkbox"/> No	Controlled Substance Code <input type="text"/>								
Controlled by State(s)? <input type="checkbox"/> No	Listed Chemical (List I or II) <input type="checkbox"/> No								
ARCOS Reportable? <input type="checkbox"/> No	If yes, indicate which: <input type="text"/>								
Schedule No. <input type="text"/>	Is it a scheduled listed chemical product?: <input type="checkbox"/> No								
CLASS OF TRADE RESTRICTION:									
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes</p> <p>Restricted to retail pharmacy only: <input type="checkbox"/> No</p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No</p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/> No</p> <p>Comments: <input type="text"/></p>									
MISCELLANEOUS NOTES and/or Image of Product Barcode:									
<p>People with Phenylketonuria: Montelukast sodium chewable tablets 5-mg (equivalent to 5-mg montelukast) contain 0.84 mg of phenylalanine.</p> <p><input type="text"/></p>									



# 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	Standard Order Receipt and Processing
<p>Purchase orders may be accepted by:</p> <ul style="list-style-type: none"> <li>a. EDI <input type="checkbox"/></li> <li>b. Autofax <input type="checkbox"/></li> <li>c. Fax <input type="checkbox"/></li> <li>d. Phone only <input type="checkbox"/></li> <li>e. Supplier Web Site only <input type="checkbox"/></li> </ul> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Monday</li> <li><input type="checkbox"/> Tuesday</li> <li><input type="checkbox"/> Wednesday</li> <li><input type="checkbox"/> Thursday</li> <li><input type="checkbox"/> Friday</li> </ul> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>	
Other Data Information Required to Process PO:	Return Instructions
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<p><input type="text"/></p>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>