



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

Version 2024

Introduction Type: Post Launch Change

Final Version

Date: 8/11/2024

PRODUCT INFORMATION	
Company Name:	Camber Pharmaceuticals, Inc.
Application Number for NDA/ANDA/BLA; PMA/510(k):	202843
Medical Device Class, if applicable:	
DUNS:	11-856-3719
Proprietary Name (If Applicable) and Established Name:	Montelukast Sodium Tablets 10 mg (base)
Selling Unit NDC:	31722-726-30
Unit of Use NDC:	31722-726-30
UPC:	331722726306
CVX Code:	
MVX Code:	
Description:	Montelukast Sodium Tablets 10 mg (base)
Active Ingredient(s):	Montelukast sodium, USP
URL for Additional Product Information:	www.camberpharma.com
Address:	800 Centennial Ave, Suite 1
City:	Piscataway
Key Contact:	Customer Service
Phone Number:	1-866-827-3647
Product Therapeutic Classification:	Leukotriene receptor antagonist

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	Temperature Range: <input type="text"/> Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	<input type="text"/>
Notes	<input type="text"/>
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. Contact for temperature excursion questions:	Name: <input type="text"/> Soma Raju
	Number: <input type="text"/> 732-529-0423
	Group E-mail: <input type="text"/> somaraju@heterousa.com
c. Special regulations for product in any states?	<input type="checkbox"/> No
Special returns requirements for this product?	<input type="checkbox"/> No
d. Store product (unit of sale) upright?	<input type="checkbox"/> No
Protect product (unit of sale) from light?	<input type="checkbox"/> No
e. Shelf life:	<input type="text"/> 24 Months
Initial shelf life at launch (if different):	<input type="text"/> Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?		Is the Product... Direct-Ship Only	Size:
a legend device?	<input type="checkbox"/> No	Is the Product... Unit of Use	30 ct
if yes, enter class #		Orphan Drug Status	Strength:
a product kit?	<input type="checkbox"/> No	FDA Approval Status	10 mg
if yes, list NDCs of component parts		Allergens Present	Dosage Form:
reverse numbered?	<input type="checkbox"/> No	Country of Origin	Film-coated tablet
co-licensed?	<input type="checkbox"/> No	India	Product Shape:
latex-free?	<input type="checkbox"/> Yes	Is this product covered under the Trade Agreements Act (TAA)?	Rounded square
preservative-free?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Product Color:
correctional institution block?	<input type="checkbox"/> No		Beige
opioid?	<input type="checkbox"/> No		Product Imprint:
Cannabinoid?	<input type="checkbox"/> No		Debossed with '1' on one side and '114' on the other side
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"/>		

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text"/> 1 Bottle of 30 Tablets
<input type="checkbox"/> Box/ Carton	<input type="text"/> (Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	Minimum order quantity? <input type="checkbox"/> Yes
<input type="checkbox"/> Glass	
<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"/> 24 Each
<input type="checkbox"/> Vial Powder Sgl	<input type="text"/> Inner/ Carton/Pack
<input type="checkbox"/> Vial Powder Multi	<input type="text"/> Case
<input type="checkbox"/> Other: Write In	

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text"/> AB
II. Generic Equivalent to What Brand?:	<input type="text"/> Singulair
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text"/>	<input type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
HCPCS J-Code:	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="checkbox"/> Yes
Is product exempt from DSCSA?	<input type="checkbox"/> No
If yes, select exemption:	<input type="text"/>
Other exemption - Write in:	
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.	
GLN:	<input type="text"/> 0331722498975
GCP:	<input type="text"/>
If yes, was original product purchased direct from mfr?	<input type="checkbox"/>
Provide source manufacturer for repackaged product	<input type="text"/>

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/ Carton/ Bundle/ Inner Pack:	0.07	1.5	1.5	2.5	5.63	1
Case:	2.15	10	6.75	4.25	286.88	24
Pallet:						

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14
<input checked="" type="checkbox"/> Item/Each	N	1		00331722726306
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	N	24		20331722726300
<input type="checkbox"/> Pallet				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text"/>	Vendor #:	<input type="text"/>
Invoice Cost (WAC) (\$)	<input type="text"/> \$7.00	Whsl. Code #:	<input type="text"/>
As of date:	<input type="text"/> 4/3/2017	Fineline Code:	<input type="text"/>

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:

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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: 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:

