

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

Version 2021						Introduction Type:	Post Launch Change		x Final Version			Date:	5/23/	/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	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): 204093								Temperature Range	Controlled Room -		and 25 C (68	s° – 77° F)		
Medical Device Class, if applica									· -					
DUNS:	11-856-3719								Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) a	and Established Na	me: Monte	elukast Sodium Chewable Ta	blets 5 mg				I	(write in)					
Selling Unit NDC:	31722-728-90		Unit of Use NDC:	:	31722-728-90		722728904		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Montelukast Sodiu	ım Chewable Tablets	s 5 mg					T	Is this product to be shipped	to customers on id	e?		No	
									Is this product to be shipped				No	
Active Ingredient(s): Montelukast sodium, USP														
								b. Contact for	r temperature excursion que	estions:				
URL for Additional Product Inform		www.camberpharm	a.com		1				Name:		Soma Raju			
Address:	800 Centennial Av	e, Suite 1			States	Address 2:	00054		Number:		732-529-042			
City: Key Contact:	Piscataway Customer Service		State: NJ Zip: 08854 Email: customerservice@camberpharma.com					Group E-mail: somaraju@heterousa.com						
Phone Number:	1-866-827-3647				Fax:	732-562-8788	<u>Бегрианна.соні</u>	c Special rec	julations for product in any	states?			No	1
Product Therapeutic Classification		Leukotriene recepto	or antagonist (LTRA)		-			o. opoolai rog	Special returns requirement				No	
Troduct merapeane classification	o	Louitottione recepto	or amagoriiot (E1101)						Openiar returns requirement	3 for this product:			140	1
	ADDITIO	ONAL PRODUCT IN	IFORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store prod	uct (unit of sale) upright?				No	1
The medication			Is the Product	Direct-Ship (	Only					la) fram limbt?			No	1
The product is? a legend device?		No	Is the Product	Unit of Use	Jilly		90 ct	e. Shelf life:	Protect product (unit of sa	ile) from light?			24	Months
if yes, enter class #		INU	Orphan Drug Status	Offic of Ode		Size:	90 Ct	e. Sileli ille.	Initial shelf life at launch (	if different):			24	Months
a product kit?		No	orphan Drug Glatao				5 mg		minum onon mo ut munon (					
if yes, list NDCs of		1.14	FDA Approval Status			Strength:				ORDER INFORM	ATION			
component parts						Dosage Form:	Chewable tablet							
reverse numbered?		No				Dosage i oiii.			Unit of Sale		What is the		unit?	
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 90			
latex-free?		Yes	G	luten		Product Shape:	Oval, biconvex		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes							Ampule				_	
correctional institution block?		No				Product Color:	Light pink to pink, speckled		Glass		Minimum or	der quantity	?	Yes
opioid? Cannabinoid?		No	Country of Origin	India			Debossed with 'I' on one side		Tube Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit does for	No	Country of Origin	IIIuia		Product Imprint:	and '113' on the other side		Vial Liquid Sgi Vial Liquid Multi		If Yes, how i	many of whi	ch nackane i	tyne?
hospital scanning?	unit dose for		Is this product covered to	under the					Vial Powder Sql			Each	on package	урс.
If Unit Dose, indicate NDC here:			Trade Agreements Act (		No				Vial Powder Multi			Inner/Carton	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PR	RODUCTS										
											I			
					Autl		uthorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB					sect	ion fields are not applicable	Rec. sell unit	to customer?		Rx billing ur	it to pharma	acv:	
II. Generic Equivalent to What Bra	and?:	Singulair								1		Each	•	
-								(Write-in, e.g.	. 1 Vial)	4		Gram		
		DRUG SUPPL	LY CHAIN SECURITY ACT	(DSCSA) INFO	RMATION							Milliliter		
		_												
Does supplier meet DSCSA defin		er?	Yes No	_	GLN:	0331722498975			IIEN	I AND PACKING IN	IFORMATION			
Is product exempt from DSCSA?			INO					!						
If yes, select exemption:					GCP:							ts.)	Volume	Saleable #
1 -1									Weight Lbs.		ons (US msm		(Cube)	Pieces
Other exemption - Write in:			Ne						Weight Lbs.	Dimensi Depth	ons (US msm Width	Height		1
Is product repackaged?	'e avelueiva distribu	tor?	No Yes		If yes, was ori	ginal product purchase	ed	Item/Each:	Weight Lbs.		•	Height 3	6.75	
Is product repackaged? Is product sold by manufacturer's			Yes		If yes, was ori	r?			0.12	Depth	Width		6.75	
Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	on/exemption for pr				If yes, was ori			Box/Carton/B	0.12	Depth	Width		6.75	
Is product repackaged? Is product sold by manufacturer's	on/exemption for pr		Yes		If yes, was ori	r?			0.12 Sundle/	Depth 1.5	Width 1.5	3		24
Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio	on/exemption for pr	oduct?	Yes	NFORMATION	If yes, was ori	r?		Box/Carton/B	0.12	Depth	Width		6.75	24
Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro	on/exemption for pr	oduct?	Yes No	NFORMATION	If yes, was ori	r?		Box/Carton/B	0.12 Sundle/	Depth 1.5	Width 1.5	3		24
Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro  Saleable Unit of Measure	on/exemption for pr om FDA.	GTI aleable Quantity	Yes No	INFORMATION	If yes, was ori direct from mf Provide sourc	r? e manufacturer for rep	unit of Use GTIN-14	Box/Carton/B Inner Pack: Case:	0.12 Sundle/	Depth 1.5	Width 1.5	3		24
Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro  Saleable Unit of Measure  x Item/Each	on/exemption for pr om FDA.	oduct?	Yes No IN AND HIBCC PRODUCT I	NFORMATION	If yes, was ori direct from mf Provide sourc	r? e manufacturer for rep	ackaged product	Box/Carton/B Inner Pack: Case:	0.12 sundle/	Depth 1.5	Width 1.5 6.5	4	247	
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Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptio If yes, attach documentation fro  Saleable Unit of Measure  x   tem/Each   Bow/Carton/Bundle/Inner Pack   x   Case	on/exemption for pr om FDA.	GTI aleable Quantity	Yes No IN AND HIBCC PRODUCT I	INFORMATION	If yes, was origined from mf Provide source  GTIN 0033	r? e manufacturer for rep -14 1722728904	unit of Use GTIN-14	Box/Carton/B Inner Pack: Case: Pallet:  Regular Cost Invoice Cost	0.12  0.12  3.3  COST INFORMATION  (WAC) (\$)	Depth 1.5 9.5	Width 1.5 6.5 Vendor #: Whsl. Code	3  4  WHOLESALI	247	
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## **Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)**

#### Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply):						
a. Cytotoxic?	SDS Hazard Classification					
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?  No	x Organic Corrosive Inorganic Oxidizer					
Is the product a CA Prop 65 reproductive toxicant?  No  Does the product label bear a CA Prop 65 warning?  No	Inorganic Oxidizer Steroid/Androgen Contact Hazard					
boos the product laber bear a OAT Top 65 warning:	Gerout-Malageri Gonaca Malageri					
c. Contact Hazard?	Does the product have an Aerosol class? If yes, No					
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:					
(If yes, attach SDS with special instructions.)	NFPA Storage Level:					
e. Does the product contain DEHP?						
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug? No					
(if yes, answer a-e below and provide SDS)	If yes, indicate which:					
a. UN/Identification Number						
b. Proper Shipping Name						
c. DOT Hazard Class	Hazardous Waste Identification					
d. Packing Group e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics					
	1.11.11.11.11.11.11.11.11.11.11.11.11.1					
Is this product regulated for shipment by IATA?  (if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS					
a. UN/Identification Number						
b. Proper Shipping Name	Is there a REMS on this product?					
c. DOT Hazard Class	If Yes, is it managed with a pharmacy registry?					
d. Packing Group	Website URL:					
e. Inhalation Hazard?						
Is the product restricted for air shipment? If so, indicate restriction:	Med Guide Required No					
Passenger	Limited Distribution Requirement					
Cargo	Comments / Details: (For example, iPledge program?)					
Passenger & Cargo	2500					
Is this a reportable quantity? No RQ Threshold:	REMS: No REMS Program Manager Name: Phone:					
Is this a marine pollutant? No	REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively:					
Is this product shipped utilizing an authorized DOT exception or Special Permit?	Wholesale distributor support:					
No (if yes, identify method below)	Provider Name: DEA #:					
Limited Quantity	Site Enrollment Number assigned NCPDP#:					
Consumer Commodity, ORM-D	by Supplier: NPI #:					
Small Quantity (49 CFR 173.4) Special Permit; DOT-SP	Comments					
Special Provision (listed in Column 7 of 49 CFR 172.101);	Connents					
SP#	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)? No Listed Chemical (List I or II) No						
ARCOS Reportable? No If yes, indicate which:	Contact tel. # if product received damaged: 1-866-827-3647					
Schedule No. Is it a scheduled listed chemical product?: No	Is product returnable for credit:					
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes	contact - customerservice@camberpharma.com					
Restricted to retail pharmacy only:	Special regulations or returns requirements for this					
Restricted to hospital, clinics, and physician offices only:	product in certain states?					
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?					
Comments:						
MISCELLANE	OUS NOTES and/or Image of Product Barcode:					
People with Phenylketonuria: Montelukast sodium chewable tablets 5-mg (equivalent to 5-mg montelukast						
, and the state of	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,					



## **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 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?