

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

						Introduction Type	Post Launch Change		x Final Version			Date:	6/23	
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	EMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN	IDA/BLA (drug); PM	A/510(k)(med device	ce):	20	4093				Temperature Range	Controlled Room -		and 25 C (68	s° – 77° F)	
Medical Device Class, if applica			·						-					
DUNS:	11-856-3719							-	Other Temperature Range	Requirement				
Proprietary Name (If Applicable)	and Established Nar	ne: Montel	lukast Sodium Chewable Ta	ablets 4 mg					(write in)					
Selling Unit NDC:	31722-727-30		Unit of Use NDC	:	31722-727-30		722727303		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Montelukast Sodiu	m Chewable Tablets	s 4 ma					T	Is this product to be shippe	d to customers on ic	e?		No	1
									Is this product to be shippe				No	
Active Ingredient(s):		Montelukast sodium	n, USP											
							b. Contact fo	r temperature excursion qu	estions:					
URL for Additional Product Inform		www.camberpharma	a.com						Name:		Soma Raju			
Address:	800 Centennial Av	e, Suite 1				Address 2:			Number:		732-529-042			
City:	Piscataway				State:		p: 08854	_	Group E-mail:		somaraju@h	eterousa.cor	<u>n</u>	
Key Contact:	Customer Service				Email:	customerservice@car	nberpharma.com			-1-10			NI.	1
Phone Number:	1-866-827-3647	1 1			Fax:	732-562-8788		c. Special reg	gulations for product in any				No	
Product Therapeutic Classification	on:	Leukotriene recepto	or antagonist (LTRA)						Special returns requirement	is for this product?			No	
	ADDITIO	NAL BRODUCT IN	FORMATION			PROBLICT DEC	ODIDTION INCODINATION							1
	ADDITIC	NAL PRODUCT IN				PRODUCT DES	CRIPTION INFORMATION	d. Store prod	duct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	Only				Protect product (unit of sa	ale) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	30 ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status						Initial shelf life at launch (if different):				Months
a product kit?		No	EDA 4			Strength:	4 mg			ORDER INFORM	ATION			
if yes, list NDCs of			FDA Approval Status				Chewable tablet			ORDER INFORM	ATION			
component parts reverse numbered?		No				Dosage Form:	Criewable tablet		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 30		unit.	
latex-free?		Yes					Oval, biconvex		Box/Carton		(Write-in, e.g		0 Vials)	
preservative-free?		Yes	G	luten		Product Shape:	,		Ampule		(,		
correctional institution block?		No				Product Color:	Light pink to pink,		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Color:	speckled		Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Debossed with 'I' on one side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for					r roudet imprint.	and '112' on the other side		Vial Liquid Multi		If Yes, how I		ch package	type?
hospital scanning?														
			Is this product covered						Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:			Is this product covered Trade Agreements Act (No				Vial Powder Multi			Inner/Cartor	/Pack	
			Trade Agreements Act ((TAA)?	No								/Pack	
				(TAA)?	No				Vial Powder Multi			Inner/Cartor	ı/Pack	
			Trade Agreements Act ((TAA)?					Vial Powder Multi Other: Write In	LA DILLA OVA DA STA		Inner/Cartor	ı/Pack	
If Unit Dose, indicate NDC here:			Trade Agreements Act ((TAA)?			Authorized Generic, other		Vial Powder Multi Other: Write In	IARMACY ORDER	/ BILL UNIT	Inner/Cartor Case		
If Unit Dose, indicate NDC here:	AB		Trade Agreements Act ((TAA)?			Authorized Generic, other titon fields are not applicable	Rec. sell unit	Vial Powder Multi Other: Write In	IARMACY ORDER		Inner/Cartor Case		
If Unit Dose, indicate NDC here:		Singulair	Trade Agreements Act ((TAA)?					Vial Powder Multi Other: Write In PH t to customer?	IARMACY ORDER	/ BILL UNIT	Inner/Cartor Case iit to pharma		
If Unit Dose, indicate NDC here:			Trade Agreements Act ((TAA)?	Auti			Rec. sell unit	Vial Powder Multi Other: Write In PH t to customer?	IARMACY ORDER	/ BILL UNIT	Inner/Cartor Case lit to pharma Each Gram		
If Unit Dose, indicate NDC here:			Trade Agreements Act ((TAA)?	Auti				Vial Powder Multi Other: Write In PH t to customer?	IARMACY ORDER	/ BILL UNIT	Inner/Cartor Case iit to pharma		
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra	and?:	DRUG SUPPL	Trade Agreements Act (FOR GENERIC DRUG PR	(TAA)?	Aut	sec			Vial Powder Multi Other: Write In Plant to customer?		/ BILL UNIT Rx billing ur	Inner/Cartor Case lit to pharm Each Gram Milliliter		
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra	and?:	DRUG SUPPL	Trade Agreements Act ((TAA)?	Auti				Vial Powder Multi Other: Write In Plant to customer?	IARMACY ORDER	/ BILL UNIT Rx billing ur	Inner/Cartor Case lit to pharm Each Gram Milliliter		
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA?	and?:	DRUG SUPPL	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT Yes	(TAA)?	Auti RMATION GLN:	sec			Vial Powder Multi Other: Write In Plant to customer?	I AND PACKING IN	/ BILL UNIT Rx billing ur	Inner/Cartor Case iit to pharm Each Gram Milliliter	acy:	Salastia
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption:	and?:	DRUG SUPPL	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT Yes	(TAA)?	Aut	sec			Vial Powder Multi Other: Write In Plant to customer?	I AND PACKING IN Dimensio	/ BILL UNIT Rx billing ur IFORMATION Ons (US msm	Inner/Cartor Case Lit to pharm Each Gram Milliliter	acy:	Saleable #
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	and?:	DRUG SUPPL	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT Yes No	(TAA)?	Aution GLN: GCP:	0331722498975	tion fields are not applicable	(Write-in, e.g	Vial Powder Multi Other: Write In PH t to customer? 1 1 Vial) ITEL Weight Lbs.	I AND PACKING IN Dimensie Depth	/ BILL UNIT Rx billing un IFORMATION Ons (US msm Width	Inner/Cartor Case lit to pharm Each Gram Milliliter ts.) Height	Volume	Pieces
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra Does supplier meet DSCSA defin Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	and?: ition of manufacture	DRUG SUPPL	Trade Agreements Act (FOR GENERIC DRUG PR LY CHAIN SECURITY ACT Yes	(TAA)?	Aution GLN: GCP:	0331722498975	tion fields are not applicable		Vial Powder Multi Other: Write In Pt t to customer?	I AND PACKING IN Dimensio	/ BILL UNIT Rx billing ur IFORMATION Ons (US msm	Inner/Cartor Case Lit to pharm Each Gram Milliliter	acy:	
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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 H.	AZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply):							
a. Cytotoxic?	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	x Organic Corrosive						
Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? No	x Organic Corrosive Inorganic Oxidizer						
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard						
boos the product laber bear a OAT Top 65 warming:	Storial Analogon Storial Trazard						
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						
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	Latina PENO at this analysis						
b. Proper Shipping Name c. DOT Hazard Class	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry?						
d. Packing Group	in res, is in harraged with a pharmacy registry? Website URL:						
e. Inhalation Hazard?	Wedshie Green						
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	- Samuel Control of the Control of t						
Is this a reportable quantity? No	REMS: No						
RQ Threshold:	REMS Program Manager Name: Phone:						
Is this a marine pollutant? No	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 Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments						
SP#	Registry: No						
SF#	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Comments						
Is the Product							
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS						
Controlled by State(s)? No Listed Chemical (List I or II)							
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: No	Control and the control and th						
	Special regulations or returns requirements for this product in certain states?						
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No	product in certain states? If so, which states? Other requirements? Comments?						
	n so, milen excess. Other requirements: Outriments:						
Comments:							
	EOUS NOTES and/or Image of Product Barcode:						
People with Phenylketonuria: Montelukast sodium chewable tablets 4-mg (equivalent to 4-mg monteluka	st) contain 0.672 mg of phenylalanine.						



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?