

## **Standard Pharmaceutical Product Information (Rx Product Only)**

© August 2014							Intro	oduction T	ype:	Pos	t Launch Change		Final Version			Date:	4/27	/2017
				PRODUCT INFORM	ATION								SPECIAL HANDL	ING AND ST	ORAGE REQ	UIREMENTS	*	
Company Name: Camber Pharmaceuticals Application: ANDA								a. Temperature – Indicate the USP temperature range for this product.										
Application Number for NDA	A/ANDA/BLA (drug);	PMA/510(k)(med	device):		20	4093						Temper	ature Range		Controlled F	oom – betwe	en 20 and 25	C (68° – 77° I
DUNS:	82-667-4775											Other T	emperature Range Re	quirement				
Proprietary Name (If Applicable) and Established Name: Montelukast Sodium Chewable Tablets 5MG 30CT						(write in)												
	31722-728-30			Individual Unit NDC:		31722-728-30		UPC:	33172272	28300								
UDI	NA			CVX Code:			MVX	Code:	NA			Is this p	roduct to be shipped to	o customers	on ice?		No	_
Description:	Round biconvex sha	ped, light pink to p	ink tablets	s embossed with '113' on	upper punch	and 'I' on lower						Is this p	roduct to be shipped to	o customers	on dry ice?		No	-
Active Ingredient(s):		Montelukast So	dium									b. Contact for temper Name:	ature excursion que	stions:	Soma Raju			
	RL for Additional Product Information: www.camberpharma.com							Numbe	r:		732-529-04							
Address:	1031 Centennial Avenue Address 2:								Group	E-mail:		somaraju@l	eterousa.coi	n				
City:	Piscataway     State:     NJ     Zip:     08854       Customer Service     Email:     customerservice@camberoharma.com																	
Key Contact: Phone Number:	Customer Service 732-529-0430				Email: customerservice@camberpharma.com Fax: 732-562-8788				c. Special regulations	returns requirements f		ct?		No No	-			
				1 dA. 132-302-0700				Opecial	returns requirements i		611		INU	-				
Product Therapeutic Classification: d. Store product (unit of sale) upright? No																		
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION								Protect product (unit of sale) from light? No										
Is the Product												e. Shelf life:	• •				24	Months
a legend device?			No			Cine		30					helf life at launch (if o	different):				Months
reverse numbered?		1	No		1	Size:		30					-					-
co-licensed?			No			Strength:		5 mg				ORDER INFORMATION						
Is the Product		Direct-Ship Onl	/			ouongun		o mg										
Is the Product		Unit of Use				Dosage Form	:	Oral solid	tablet			Unit of	Bottle		1 box of 24	NDC selling	unit?	
												x	Box/Carton			.g. 1 Box of 1	0 Vials)	
If Unit Dose, is item bar code	d to unit dose for hos	pital scanning?				<b>D</b>		a set				~	Ampule		(11110 111, 0	.g. 1 20x 01 1	o viaio)	
If Unit Dose NDC, indicate ND	DC here:					Product Shap	e:	oval					Glass		Minimum o	rder quantity	/?	Yes
						Product Color	r:	pink					Tube					
Country of Origin		India											Vial Liquid Sgl Vial Liquid Multi		K Vee herr			4.m.e.2
Is this product covered under the Trade Agreements Act (TAA)? No Product Imprint: 113//I'						Vial Liquid Multi If Yes, how many of which package type? Vial Powder Sql Each												
		-											Vial Power Multi			Inner/Cartor	/Pack	
													Other: Write In	-	24	Case		
				FOR GENERIC DRUG P	RODUCTS							_						
Authorized Generic *If Authorized Generic, other section								PHARMACY ORDER / BILL UNIT										
I. Orange Book Rating:	AB				1	, duit	011200 0011		fields are			Rec. sell unit to customer? Rx billing unit to pharmacy:						
II. Generic Equivalent to What		Singulair																
												(Write-in, e.g. 1 Vial)				Gram		
		DRU	g Suppl'	Y CHAIN SECURITY ACT	(DSCSA) IN	FORMATION										Milliliter		
Does supplier meet DSCSA definition of manufacturer? Yes GLN:									ITEM AND PACKING INFORMATION									
Is product exempt from DSC			N	No														
If yes, select exemption:					_								Weight Lbs.		nsions (US n		Volume	# Pieces:
Other exemption - Write in:				1					I. Passa	_				Depth	Height	Width	(Cube)	
Is product repackaged? Is product sold by manufactu	urar's avclusiva dist	ributor?	N	No		Yes, was origina om mfr?	ai product	purchase	a airect			ltem:	0.1		3	1.5		
Has FDA granted waiver/exce				No		yes, attach doc	umentatio	on from FD	DA.			Box/Carton/Bundle/						
5		· ·			-							Inner Pack:						
				GTIN PRODUCT INFOR								Case:	2.5	10	4.5	7	0.182	24
				Level	Saleable				Quantity	OT		Pallet:						
Serialized?	Yes	г	x	Item	Unit	<b>X</b> 2D		Linear	Quantity		N-14 31722728300	Pallet:						4416
If not, when?	103			Box/Carton/Bundle/Inner Pack		2D		Linear		000		UPC:	Case:					1
Items aggregated?	Yes		x	Case	x	<b>X</b> 2D		Linear	24	203	31722728304		Carton:					
	Pallet 2D Linear																	
		[				2D		Linear				COS	T INFORMATION			WHOLESAL	ER USE ON	LY:
		ŀ			$ \rightarrow $	2D		Linear				Regular Cost			Vonder #			
		ŀ				2D 2D		Linear Linear				Invoice Cost (WAC) (	¢)	\$10.6F	Vendor #: Whsl. Code	#-		
						Federal Excise Tax P		φ10.05	Fineline Co									
												As of date:	5000		1			
				Attach copy of SAFETY [	DATA SHEET	(SDS) or non ha						ODUCT PACKAGING and B						
*Please provide any addition	al information on pa	ige 2.					See nev	wp.3forE	Designated	Drop \$	Ship Only.	Signatu	ıre:					



## **Standard Pharmaceutical Product Information (Page 2)**

For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

le this preduct (sheel, all that apply).								
Is this product (check all that apply): a. Cytotoxic? No	SDS Hazard Classification							
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?								
Is the product a CA Prop 65 carcinogen? No	Organic Corrosive							
Is the product a CA Prop 65 reproductive toxicant?	Ovidizer							
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard							
c. Contact Hazard? No	Aerosol Class; Identify NFPA Storage Level:							
d. Does this product require special clean-up instructions? No								
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug?							
e. Does the product contain DEHP? No	If yes, indicate which:							
Is this product regulated for shipment by DOT or IATA? No								
(if yes, answer a-e below and provide SDS)								
a. UN/Identification Number								
b. Proper Shipping Name	Hazardous Waste Identification							
c. DOT Hazard Class	EPA Hazardous Waste Code: NA							
d. Packing Group								
e. Inhalation Hazard?								
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS							
Passenger	Is there a REMS on this product? No							
Cargo	If Yes, is it managed with a pharmacy registry?							
Passenger & Cargo	Website URL:							
Is this a reportable quantity? No RQ Threshold:	Comments / Details: (For example, iPledge program?)							
Is this a marine pollutant? No	Comments / Details. (For example, inledge program?)							
Is this a manne political is a manne political is the pol								
No (if yes, identify method below)	REMS:							
Limited Quantity	REMS Program Manager Name: Phone:							
Consumer Commodity, ORM-D	Supplier Manages REMS registry exclusively: No							
Small Quantity (49 CFR 173.4)	Wholesale distributor support: No							
Special Permit; DOT-SP	Provider Name:							
Special Provision (listed in Column 7 of 49 CFR 172.101);	Site Enrollment Number assigned DEA #: No							
SP#	by Supplier: PCPDP #: No							
	NPI#: No							
ADD'L STORAGE INFORMATION	· · · · · · · · · · · · · · · · · · ·							
Is the Product	Comments							
Controlled Substance? No								
Controlled by State(s)? No	Registry: No							
ARCOS Reportable? No	Registry Program Contact Name: Phone:							
Schedule No. (inc. N for non-narcotic)	Comments							
Controlled Substance Code								
Listed Chemical (List I or II) No	RETURN INSTRUCTIONS							
If yes, indicate which:								
Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: 732-529-0430							
CLASS OF TRADE RESTRICTION:	Is product returnable for credit: Yes							
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No	URL/Link to returns policy: contact - customerservice@camberpharma.com							
Restricted to retail pharmacy only: Yes	Special regulations or returns requirements for this product in certain states? No							
Restricted to hospital, clinics, and physician offices only: No	If so, which states? Other requirements? Comments?							
Restricted from US territories? (explain in comments) No								
Comments:								
oommonia.								
MISCELLA	NEOUS NOTES and/or Image of Product Barcode:							



## **Standard Pharmaceutical Product Information (Page 3)**

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						
Purchase orders may be accepted by:   Autofax   Yes     b. Autofax   No   Fax Number:     c. Fax   Yes   Fax Number:     d. Phone only   No   Phone No.:     e. Supplier Web Site only   No   Site Address:     Minimum Order Quantity:   case pack   732-529-0430 x466 x465 x467 x470     Contracted 3PL company / contact #:   Name:   Phone:	Purchase order daily receipt cut off time by supplier     Cut off time:   2:30PM   Eastern     Shipping lead time of PO:   24/48   Hours   Days     Ships same day for next day receipt:   No   No     Ships for second day receipt:   No   No     Ships regular ground for 3-10 days receipt:   Yes						
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing						
Expedited freight fees billed with each order:   No     Drop Ship service fee billed with each order:   No     Drop Ship miscellaneous fees billed:   No     Comments:   Image: No     Comments:   Image: No     Class of Trade Restriction:     No     Restricted to retail pharmacy, hospitals, clinics and physician offices     No   Yes     Restricted to hospital, clinics, and physician offices only:   No     Restricted from US territories? (explain in comments)   No	Overnight receipt available:   Yes     PO Receipt cut off time:   2:30PM   Eastern     Days of week overnight is available:   X   Monday     X   Tuesday   Wednesday     X   Thursday   Friday     Priority Overnight receipt available:   Yes     PO Receipt Cut off time:   2:30PM EST     Saturday Overnight receipt available:   No     PO Receipt Cut off time:   No     Order receipt method:   Phone:   No     Fax:   Yes   Fax #:						
Comments:	rax. res rax #. res   EDI: Yes   Overnight Fees apply: Yes   Other fees apply: No						
Other Data Information Required to Process PO:	Return Instructions						
Patient Procedure Date:	Contact # if product is received damaged:   732-529-0430     Is product returnable for credit:   Yes     URL/Link to returns policy:						
	ADDITIONAL INFORMATION						