

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

Version 2021						Introduction Type	e: Post Launch Change		x Final Version			Date:	5/23	3/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	RAGE REQUI	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						<u> </u>	Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)							
Medical Device Class, if applicable:														
DUNS:	11-856-3719							_	Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a	and Established Na	me: Mont	elukast Sodium Chewable Ta	blets 4 mg					(write in)					
Selling Unit NDC:	31722-727-90		Unit of Use NDC		31722-727-90		1722727907		Notes					
UDI			CVX Code:			MVX Code:								
Description: Montelukast Sodium Chewable Tablets 4 mg Is this product to be shipped to customers on ice? No									1					
									Is this product to be shippe				No	1
Active Ingredient(s): Montelukast sodium, USP														
								b. Contact fo	r temperature excursion qu	estions:				
URL for Additional Product Inforn		www.camberpharn	na.com		1			1	Name:		Soma Raju			
Address:	800 Centennial Av	/e, Suite 1			Ctata	Address 2:	00054	-	Number:		732-529-042			
City: Key Contact:	Piscataway Customer Service	State: NJ Email: cus			customerservice@ca	Cip: 08854	-	Group E-mail:		somarajuer	neterousa.co	<u>III.</u>		
Phone Number:	1-866-827-3647				732-562-8788	amberphama.com	c Special re	gulations for product in any	states?			No	1	
Product Therapeutic Classificatio		Leukotriene recep	tor antagonist (LTRA)					or openiar re	Special returns requirement				No	1
Troduct Therapeutic Glassificatio		Zounomono rocop	tor amagemen (21101)						opeciai retarris requiremen	s for ans product:			140	1
	ADDITIO	ONAL PRODUCT II	NFORMATION			PRODUCT DES	SCRIPTION INFORMATION	d. Store proc	duct (unit of sale) upright?				No	1
The meduation			Is the Product	Direct-Ship 0	Only					la) fram limbt?			No	i
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 #		INO	Orphan Drug Status	Offic of OSC		Size:	90 Ct	e. Sileli ille.	Initial shelf life at launch (if different):			24	Months
a product kit?		No	orpinan Drug otatao				4 mg		muai onon mo at iaanon (1
if yes, list NDCs of			FDA Approval Status			Strength:				ORDER INFORM	MATION			
component parts						Dosage Form:	Chewable tablet							
reverse numbered?		No				Dosage i oilii.			Unit of Sale		What is the		unit?	
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 9			
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 o	rder quantity	/?	Yes
opioid? Cannabinoid?		No	Country of Origin	India			Debossed with 'I' on one side		Tube					
If Unit Dose, is item bar coded to u	unit does for	No	Country of Origin	iliula		Product Imprint	and '112' on the other side		Vial Liquid Sgl Vial Liquid Multi		If Yes how	many of wh	ich package	type?
hospital scanning?	uriit dose ioi		Is this product covered	inder the					Vial Powder Sql			Each	icii package	type:
If Unit Dose, indicate NDC here:			Trade Agreements Act (No				Vial Powder Multi			Inner/Cartor	n/Pack	
				,					Other: Write In			Case		
			FOR GENERIC DRUG PF	ODUCTS										
					Aut	horized Generic *If	Authorized Generic, other		Pl	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB					se	ction fields are not applicable	Rec. sell unit	t to customer?		Rx billing u	nit to pharm	acv:	
II. Generic Equivalent to What Bra	and?:	Singulair						I		1		Each	,-	
								(Write-in, e.g	ı. 1 Vial)			Gram		
		DRUG SUPF	PLY CHAIN SECURITY ACT	(DSCSA) INFO	RMATION							Milliliter		
Does supplier meet DSCSA defini	ition of manufactur	er?	Yes	_	GLN:	0331722498975			ITEN	I AND PACKING II	NFORMATIO	N		
Is product exempt from DSCSA?			No					-						
If yes, select exemption:					GCP:				Weight Lbs.		ions (US msn	•	Volume	Saleable #
Other exemption - Write in:			NI-						g LD3.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No Yes	_		ginal product purcha	sed	Item/Each:	0.11	1.5	1.5	3	6.75	1
Is product sold by manufacturer's Has FDA granted waiver/exceptio			No	-	direct from mf	r ? e manufacturer for re	anackaged product	Box/Carton/E	Pundlo/					
If yes, attach documentation from		oduct?	140		Frovide Sourc	e manulacturer for re	epackageu product	Inner Pack:	oundle/					
ii yes, attacii accamentation noi	III I DA.							Case:						
		G1	TIN AND HIBCC PRODUCT I	NFORMATION				I I Gusoi	3.25	9.5	6.5	4	247	24
								Pallet:						
Saleable Unit of Measure	S	aleable Quantity	HIBCC		GTIN	I-14	Unit of Use GTIN-14							
X Item/Each		1			0033	1722727907	00331722727907							
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESAL	ER USE ONL	.Y:
X Case		24			2033	1722727901		11	_		l.,			
Pallet								Regular Cos			Vendor #:			
	-							Invoice Cost	(WAC) (\$)	\$30.95	Whsl. Code			
	-							As of date:	4/3/2017		Fineline Co	ue:		
	-							As of date:	7/3/2017		-			
l '			Attach copy of SAFETY D	ATA SHEET (SI	DS) or non hazar	d letter, PACKAGE IN	SERT, LABEL AND PHOTO OF F	PRODUCT PACK	AGING and BARCODE		-			
*Please provide any additional inf		•	, 0. 0 11 0.		-,		signated 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):	ODO Harrad Obrasidantas						
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	·						
	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.						



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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?