

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014					Introduction	Туре:	Post Launch Change	е		Final Version			Date:	4/27	7/2017
			PRODUCT INFORMATION	ON						SPECIAL HANDL	ING AND STO	RAGE REQ	JIREMENTS'	*	
Company Name:	Camber Pharmaceuti	rals			Apr	plication:	ANDA	\neg i	a. Temperature – Indica	to the USP temper	aturo rango	or this prod	ıct		
Application Number for ND			:	204093					Temperature		atare range			en 20 and 25	5 C (68° – 77° F
DUNS:	82-667-4775								•	=					
Proprietary Name (If Applical		Montoluk	ast Sodium Chewable Tablets	4MC 20CT						nperature Range Re e in)	quirement				1
Selling Unit NDC:	31722-727-30	varie.	Individual Unit NDC:	31722-727-30	UPC:	3317227273	303		(WIII	e III)					_
UDI	NA NA		CVX Code:	01122 121 00	MVX Code:	NA	-		Is this pro	duct to be shipped to	customers o	n ice?		No	
Description:	Oval biography abono	d light pink to pink toblete	embossed with '112' on upper	r punch and III an lower		1000		=	•	duct to be shipped to				No	_
Description.	Ovai biconvex snaper	a, light pink to pink tablets	embossed with 112 on upper	i punchanu i on lower					is this pro	duct to be shipped to	J Customers C	ii diy ice :		INU	_
Active Ingredient(s):		Montelukast Sodium							b. Contact for temperat	ure excursion que	stions:				
									Name:			Soma Raju			
URL for Additional Product I		www.camberpharma.cor	n						Number: 732-529-0423						
Address:	1031 Centennial Avenue Address 2:							Group E-mail: somaraju@heterousa.com							
City:	Piscataway			State: Email:	NJ	Zip:	08854								
Key Contact: Phone Number:	Customer Service 732-529-0430			Fax:	customerservice@ 732-562-8788	<u> ecamberpham</u>	ia.com		c. Special regulations for product in any states? Special returns requirements for this product? No						_
Product Therapeutic Classifi				ı ax.	132-302-6166				Special returns requirements for this product?						
Product Therapeutic Classiii	ication.								d Store product (unit o	f cala) upriaht?				No	
ADDITIONA	AL PRODUCT INFORM	ATION		F	PRODUCT DESCRI	PTION INFOR	MATION		d. Store product (unit o	r sale) uprignt? roduct (unit of sale) from light?			No	_
				•						roduct (driit or said	., o ligiti.			24	
Is the Product a legend device?		No						 111	e. Shelf life:	If life at launch (if o	lifforont).			24	Months Months
reverse numbered?		No		Size:	30				illidai sile	ii iiie at iauncii (ii t	annerenty.				Months
co-licensed?		No		0						(ORDER INFO	RMATION			
Is the Product		Direct-Ship Only		Strength:	4 mg										
Is the Product		Unit of Use		Dosage Form:	Oral solid	l tablet			Unit of Sa				NDC selling	unit?	
										Bottle		1 box of 24			
If Unit Dose, is item bar code	ed to unit dose for hosp	ital scanning?						<u> </u>	х	Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
If Unit Dose NDC, indicate N	IDC horo:			Product Shape	e: oval					Ampule Glass		Minimum o	der quantity	.2	Yes
II Offit Dose NDC, indicate No	DO Here.									Tube		William Ci	uer quantity	•	163
Country of Origin		India		Product Color	: pink					Vial Liquid Sgl					
Is this product covered under	r the Trade Agreements	Act (TAA)2		Product Imprir	nt: 112'/'l'					Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
is this product covered under	Title Trade Agreements	No No		i roddot imprii	112/1					Vial Powder Sql			Each		
										Vial Power Multi			Inner/Carton	/Pack	
			FOR GENERIC DRUG PROD	DUCTS						Other: Write In	1	24	Case		
			FOR GENERIC DRUG PROD	00013											
				Autho	rized Generic	*If Authorized	d Generic, other secti	tion		PHAR	MACY ORDE	R / BILL UNI	Т		
I. Orange Book Rating:	AB					fields are no		_	Rec. sell unit to custom	or?		Dy hilling u	nit to pharm	2010	
II. Generic Equivalent to Wha		Singulair							Rec. sell unit to customer? Rx billing unit to pharmacy: Each						
conono Equivalent to Trin		9							(Write-in, e.g. 1 Vial)				Gram		
		DRUG SUPPI	LY CHAIN SECURITY ACT (DS	SCSA) INFORMATION					, , ,				Milliliter		
													='		
Does supplier meet DSCSA			Yes	GLN:						ITEM A	ND PACKING	INFORMATI	ON		
Is product exempt from DSC	CSA?		No								Dime	-: (IC		Values	
If yes, select exemption: Other exemption - Write in:							1			Weight Lbs.	Depth	sions (US m	Width	Volume (Cube)	# Pieces:
Is product repackaged?	•		No	If Yes, was origina	I product purchas	ed direct	_		Item:		Бери	Height		(Gubc)	1
Is product sold by manufact	turer's exclusive distr		No	from mfr?	p. oudot pui oi do	ou un oot		_		0.1		3	1.5		
Has FDA granted waiver/exc			No	If yes, attach docu	umentation from F	DA.			Box/Carton/Bundle/						
									Inner Pack:						
			GTIN PRODUCT INFORMA						Case:	2.3	10	4.25	6.75	0.166	24
				aleable Unit		O	CTINI 4.4	[]	Pallet:						
Serialized?	Yes	х	Item	VIII X 2D	Linear	Quantity	GTIN-14 00331722727303		Pallet:						4416
If not, when?	res	1 -	Box/Carton/Bundle/Inner Pack	2D 2D	Linear	- '	00331122121303		UPC:	Case:					1
Items aggregated?	Yes	x	Case	x x 2D	Linear	24	20331722727307			Carton:					
		-	Pallet	2D	Linear										
				2D	Linear				COST	NFORMATION			WHOLESAL	ER USE ONI	LY:
				2D	Linear			— Г							
				2D	Linear				Regular Cost			Vendor #:			
				2D	Linear				Invoice Cost (WAC) (\$) Federal Excise Tax Per	Unit of Sala	\$10.65	Whsl. Code Fineline Co			
[As of date:	OHIL OF SAIR	1	i illeline Co	uc.		
								- 1							
			Attach copy of SAFETY DATA	A SHEET (SDS) or non haz	ard letter, PACKAG	E INSERT. I A	BEL AND PHOTO OF	PRODU	UCT PACKAGING and BAR	RCODE.					



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL I	HAZARD CLASSIFICATION and TRANSPORTATION	
Is this product (check all that apply):		·
a. Cytotoxic?	SDS Hazard Classification	
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	ODO HAZARA GIAGGIRIGATORI	
Is the product a CA Prop 65 carcinogen?	Organic Corrosive	
Is the product a CA Prop 65 carcinogen?	Inorganic Oxidizer	
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard	
a Contact Haranda	A arread Class Identify NEDA Ctarage Levels	
c. Contact Hazard?	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?	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?	
Cargo	If Yes, is it managed with a pharmacy registry?	
Passenger & Cargo	Website URL:	
	Website ORL.	
Is this a reportable quantity? No		
RQ Threshold:	Comments / Details: (For example, iPledge program?)	
Is this a marine pollutant? No		
Is this product shipped utilizing an authorized DOT exception or Special Permit?		
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 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)
<u></u>	NPI #: No)
ADD'L STORAGE INFORMATION		
Is the Product	Comments	
Controlled Substance? No		
Controlled by State(s)?	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:	
N c c		
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:	If so, which states? Other requirements? Comments?	
Restricted from US territories? (explain in comments) No		
Comments:		
MISCELLAI	ANEOUS 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: a. EDI b. Autofax Yes No Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time: 2:30PM Eastern						
c. Fax d. Phone only No Phone No.:	Shipping lead time of PO: 24/48 Hours Days						
e. Supplier Web Site only No Site Address:	Ships same day for next day receipt: No						
Minimum Order Quantity: case pack	Ships for second day receipt: No						
Supplier's Customer Service Number: 732-529-0430 x466 x465 x467 x470	Ships regular ground for 3-10 days receipt: Yes						
Contracted 3PL company / contact #: Name: Phone:							
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing						
Expedited freight fees billed with each order: No No	Overnight receipt available: Yes						
Drop Ship service fee billed with each order: No No	PO Receipt cut off time: 2:30PM Eastern						
Drop Ship miscellaneous fees billed: No	Days of week overnight is available:						
Comments:	x Tuesday x Wednesday Thursday x Friday						
	Priority Overnight receipt available: Yes						
Class of Trade Restriction:	PO Receipt Cut off time: 2:30PM EST						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No	Saturday Overnight receipt available: No						
Restricted to retail pharmacy only: Yes	PO Receipt Cut off time:						
Restricted to hospital, clinics, and physician offices only: No	Order receipt method: No Phone #:						
Restricted from US territories? (explain in comments) No	Fax: Yes Fax #: 732-562-8788						
Comments:	EDI: Yes						
	Overnight Fees apply: Other fees apply: No						
Other Data Information Demoired to Decree DO							
Other Data Information Required to Process PO:	Return Instructions						
Patient Procedure Date: Physician Name:	Contact # if product is received damaged: Is product returnable for credit: Yes						
Physician/Clinic Phone #	URL/Link to returns policy:						
Physician State License #	Special regulations or returns requirements for this product in certain states? Yes						
Physician/Clinic DEA #:	If so, which states? Other requirements? Comments?						
Physician/Clinic Specialty:	·						
Miscellaneous Notes:							
	ADDITIONAL INFORMATION						
	Is product order for scheduled patient procedure?						
	Is product order for restocking purposes?						