

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

© August 2014						Introductio	n Type:	New Item	00	Final Version			Date:	9/30/	/2020
			PRODUCT IN	ORMATION						SPECIAL HANDL	ING AND ST	ORAGE REQ	UIREMENTS	*	
Company Name:	Camber Pharmaceuti	cals				Α	pplication:		a. Temperature – Indic	ate the USP temper	ature range f	or this prod	ict.		
Application Number for ND					2475				Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F						
DUNS:	826774775								Other Te	emperature Range Re	equirement				
Proprietary Name (If Applica		Name: ZA	FIRLUKAST TABLETS 2	DMG 60CT						rite in)	squironioni				1
Selling Unit NDC:	31722-008-60		Individual Un			UPC	33172200	8600	, i	,					-
UDI			CVX Code			MVX Code:			Is this p	roduct to be shipped	to customers	on ice?		No	
Description: White to off-white, tablet pressed with 8.00mm, round shaped, bevel concave punches, embossed with 'V' on lower punch and '17' on upper punch with corresponding dyes.							Is this product to be shipped to customers on dry ice? No								
Active Ingredient(s):	concepting ayou.	Zafirlukast							b. Contact for tempera	ture excursion ques	stions:	Soma Raju			
URL for Additional Product I	nformation.	www.camberpharm	ma com						Name: Number			732-529-04	3		
Address:	1031 Centennial Avenue			Address 2:			Group E			somaraju@heterousa.com					
City:	Piscataway			State: NJ Zip: 08854											
Key Contact:	Customer Service			Email: customerservice@camberpharma.com			c. Special regulations					No	_		
Phone Number:	732-529-0430			Fax: 732-562-8788			Special returns requirements for this product? No					_			
Product Therapeutic Classif	ication:														
	AL PRODUCT INFORM				550	DUCT DESCR			d. Store product (unit					No	-
	AL PRODUCT INFORM	IATION		_	PRC	DUCT DESCR	RIPTION INFO	ORMATION		product (unit of sale	e) from light?	,		Yes	
Is the Product									e. Shelf life:					24	Months
a legend device?		Na	<u> </u>		Size:	60			Initial sl	helf life at launch (if	afferent):				Months
reverse numbered? co-licensed?		No No									ORDER INFO	RMATION			
Is the Product		Direct-Ship Only	<u> </u>		Strength:	20MG						AHON			
Is the Product		Neither			Decese Fermi	Tablet			Unit of S	Sale		What is the	NDC selling	unit?	
					Dosage Form:	Tablet				Bottle		1 box of 24			
If Unit Dose, is item bar code	ed to unit dose for hose	oital scanning?							x	Box/Carton		(Write-in, e	g. 1 Box of 1	0 Vials)	
		No	)		Product Shape:	Round				Ampule					
If Unit Dose NDC, indicate N	DC here:									Glass Tube		Minimum o	rder quantity	r?	
Country of Origin		India			Product Color:	White t	o off-white			Vial Liquid Sgl					
Is this product covered unde	r the Trade Agreement	s Act (TAA)2			Product Imprint:	17 / V				Vial Liquid Multi		If Yes, how	many of wh	ich package	type?
is this product covered unde	The Trade Agreement	No	<u> </u>		i roudet imprint.	, •				Vial Powder Sql			Each		
										Vial Power Multi		24	Inner/Carton	/Pack	
			FOR GENERIC DF							Other: Write In	-		Case		
			T OK CENERIO DI	00110000010											
					X Authoriz	ed Generic	*If Authori:	zed Generic, other section		PHAR	MACY ORDE	R / BILL UN	Т		
I. Orange Book Rating: AB				fields are not applicable				Rec. sell unit to custor	mer?		Rx billing u	nit to pharm	acv:		
II. Generic Equivalent to What		Accolate							Rec. sell unit to customer? Rx billing unit to pharmacy:						
									(Write-in, e.g. 1 Vial)				Gram		
		DRUG SI	UPPLY CHAIN SECURIT	Y ACT (DSCSA) INI	FORMATION								Milliliter		
									-						
Does supplier meet DSCSA Is product exempt from DSC		turer?	Yes No	G	LN: 0	331722000000	)			ITEM A	ND PACKING	INFORMAT	ION		
Is product exempt from DSC If yes, select exemption:	5A?		INU								Dimo	nsions (US n	emte )	Volume	
Other exemption - Write in:										Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:
Is product repackaged?			No	lf	Yes, was original	product purch	ased direct		Item:	0.4	2 opui	-		( • • • • )	
Is product sold by manufact			Yes	fr	om mfr?					0.1		3.4	1.5		1
Has FDA granted waiver/exc	eption/exemption for	product?	No	lf	yes, attach docum	entation from	FDA.		Box/Carton/Bundle/						
			CTINERRODUCE						Inner Pack:						
			GTIN PRODUCT	Saleable					Case:	2.45	10	4.5	7		24
			Level	Unit			Quantity	GTIN-14	Pallet:						
Serialized?	Yes		<b>x</b> Item		<b>X</b> 2D	Linear	1	00331722008600							194
If not, when?		]	Box/Carton/Bundle/Inne	r Pack	2D	Linear			UPC:	Case:	203317220	08604			·
Items aggregated?			X Case	x	<b>X</b> 2D	Linear	24	20331722008604		Carton:					
			Pallet		2D	Linear									
					2D	Linear			COST	INFORMATION			WHOLESAL	ER USE ONL	LT:
					2D 2D	Linear Linear			Regular Cost			Vendor #:	1		
					2D 2D	Linear			Invoice Cost (WAC) (\$	<b>)</b>	\$73.34	Whsl. Code	#·		
						Linder			Federal Excise Tax Pe		φr 0.04	Fineline Co			
									As of date:			1			
			Attach copy of SAFE	TY DATA SHEET (S	SDS) or non hazard	letter, PACKA	GE INSERT, L	ABEL AND PHOTO OF PF	RODUCT PACKAGING and I	BARCODE.					
*Please provide any addition	nal information on pag	ge 2.			s	ee new p. 3 fo	or Designated	l Drop Ship Only.	Signatu	re:					

## HDA

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

	nated Drop Ship Only Products, Please Use Page 3 HAZARD CLASSIFICATION and TRANSPORTATION						
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? No	Inorganic Oxidizer						
Does the product label bear a CA Prop 65 warning? No	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? No						
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:						
d. Packing Group							
e. Inhalation Hazard? No							
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?)						
	Comments / Details. (For example, in redge program: )						
Is this product shipped utilizing an authorized DOT exception or Special Permit?							
(if yes, identify method below)	REMS: No						
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 #:						
SP#	by Supplier: PCPDP #:						
	NPI#:						
ADD'L STORAGE INFORMATION	NE 177.						
Is the Product	Comments						
	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?:	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: No	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:							
MISCELLA	NEOUS NOTES and/or Image of Product Barcode:						



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

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if r	
Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by:         a. EDI         b. Autofax         c. Fax         d. Phone only         e. Supplier Web Site only         Minimum Order Quantity:         Supplier's Customer Service Number:         Contracted 3PL company / contact #:         Name:         Phone:	Purchase order daily receipt cut off time by supplier         Cut off time:       Eastern         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 Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:         Drop Ship service fee billed with each order:         Drop Ship miscellaneous fees billed:         Comments:	Overnight receipt available:       Eastern         PO Receipt cut off time:       Monday         Days of week overnight is available:       Monday         Tuesday       Wednesday         Thursday       Friday         Priority Overnight receipt available:       PO Receipt Cut off time:         PO Receipt Cut off time:       PO Receipt Cut off time:         Order receipt method:       Phone:         Fax:       EDI:         Overnight Fees apply:       Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure?