

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

						Introduction 7	Type:	Post Launch Change	1	x Final Version			Date:	6/23/	2024
			PRODUCT INFORMAT	ION						SPECIAL HAND	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharmaceution	cale Inc				Applica	tion:	ANDA	a Tomporatuu	re - Indicate the USP tempe	raturo rango for t	hie product			
Application Number for NDA/AN			co).	20:	8213	Арриса	tion.	ANDA	a. remperatur	Temperature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applical		Jio(k)(illea devic		201	0210				-	remperature range	Controlled Hoom	20111001120	una 20 0 (00	,	
DUNS:	11-856-3719								1	Other Temperature Range I	Pequirement				
Proprietary Name (If Applicable) a		Roflum	nilast Tablets 250 mcg						1	(write in)	requirement				
Selling Unit NDC:	31722-676-36	. Itolium	Unit of Use NDC:			UPC:	3317226	676366	-	Notes					
UDI			CVX Code:			MVX Code:			1						
	Definition Tableto 20	F0							i	In this product to be objected				No	
Description:	Roflumilast Tablets 25	30 mcg								Is this product to be shipped Is this product to be shipped				No	
Active Ingredient(s):	Dr	oflumilast							-	is this product to be shipped	i to customers on a	ily ice:		140	
b. Contact for temperature excursion questions:															
URL for Additional Product Inforr	mation: wv	tion: www.camberpharma.com							Name: Soma Raju						
Address:	800 Centennial Ave, S					Address 2:		Number:			732-529-0423				
City:	Piscataway				NJ	Zip:	08854	Group E-mail: somaraju@heterousa.com			<u>n</u>				
Key Contact:	Customer Service				customerservice	@camber	pharma.com								
Phone Number:	1-866-827-3647				Fax:	732-562-8788			c. Special reg	ulations for product in any	states?			No	
Product Therapeutic Classificatio	n: Se	lective phosphodi	liesterase-4 enzyme inhibitor							Special returns requirement	s for this product?			No	
					_										
	ADDITIONA	AL PRODUCT INF	FORMATION			PRODUCT	DESCRIP	TION INFORMATION	d. Store produ	uct (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 Dose	,	0:	2	8 Unit-dose tablets	e. Shelf life:	,	,			24	Months
if yes, enter class #	1.12		Orphan Drug Status			Size:		1 x 28)		Initial shelf life at launch (if different):				Months
a product kit?	No	,	, •			0	2	50 mcg		,	•				
if yes, list NDCs of			FDA Approval Status			Strength:		-			ORDER INFORM	ATION			
component parts						Dosage For	m. T	ablet							
reverse numbered?	No)				Dosage 1 on				Unit of Sale Bottle		What is the			
co-licensed?		No Allergens Present								1 Carton of 2					
latex-free?	Ye		Gluten, Wheat,	. Corn. Alcoho	ol	Product Sha	Product Shape: Round, flat, bevel edged			x Box/Carton			g. 1 Box of 1) Vials)	
preservative-free?	Ye		, , , , , , , , , , , , , , , , , , , ,	, , , , , , , , , , , , , , , , , , ,						Ampule				_	
correctional institution block?	No					Product Col	lor:	Vhite to off white		Glass		Minimum o	der quantity	?	Yes
opioid? Cannabinoid?	No		Country of Origin	India			_	Debossed with 'H' on one		Tube					
	No	,	Country of Origin	India		Product Imp		ide and 'T' on the other		Vial Liquid Sgl		If Van haw		ah maakama	
If Unit Dose, is item bar coded to unhospital scanning?	Ye	20	Is this product covered ur	ador the		side and 1 on the other			Vial Liquid Multi If Yes, how many of Vial Powder Sgl 1 Each			Each	сп раскаде	type?	
If Unit Dose, indicate NDC here:		722-676-35	Trade Agreements Act (T		No					Vial Powder Multi			Inner/Carton	/Pack	
Il Ollit Dose, ilidicate NDC liere.	31	122-010-33	ITade Agreements Act (1	AA):	INU					Other: Write In			Case	rack	
			FOR GENERIC DRUG PRO	DUCTS					1	Guion Willoui			Odoo		
			TOR GENERIC DROGT RO	DUCIS											
					Aur	horized Ceneric	*If Autho	orized Generic other		PH	ARMACY ORDER	/ BILL UNIT			
	10				Au	thorized Generic		orized Generic, other	Boo sellowit		ARMACY ORDER				
I. Orange Book Rating:	AB				Au	thorized Generic		orized Generic, other fields are not applicable	Rec. sell unit	PH. to customer?	ARMACY ORDER	/ BILL UNIT		асу:	
I. Orange Book Rating: II. Generic Equivalent to What Bra		aliresp			Au	thorized Generic				to customer?	ARMACY ORDER		Each	асу:	
		aliresp	CHAIN SECURITY ACT (C	DSCSA) INFOR		thorized Generic			Rec. sell unit (Write-in, e.g.	to customer?	ARMACY ORDER		Each Gram	асу:	
		aliresp	Y CHAIN SECURITY ACT (D	DSCSA) INFOR		thorized Generic				to customer?	ARMACY ORDER		Each	acy:	
II. Generic Equivalent to What Bra	and?: Da	aliresp DRUG SUPPLY	Y CHAIN SECURITY ACT (D	DSCSA) INFOR		0331722498975	section			to customer?	ARMACY ORDER	Rx billing u	Each Gram Milliliter	acy:	
II. Generic Equivalent to What Bra	and?: Da	aliresp DRUG SUPPLY	·	DSCSA) INFOR	RMATION		section			to customer?]	Rx billing u	Each Gram Milliliter	асу:	
II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA?	and?: Da	aliresp DRUG SUPPLY	Yes	DSCSA) INFOR	RMATION GLN:		section			to customer? 1 Vial) ПЕМ	AND PACKING IN	Rx billing u	Each Gram Milliliter		Saleable #
II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption:	and?: Da	aliresp DRUG SUPPLY	Yes	OSCSA) INFOR	RMATION		section			to customer?	AND PACKING IN	Rx billing under the state of t	Each Gram Milliliter	Volume	Saleable #
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II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	and?: Da	aliresp DRUG SUPPLY	Yes No	DSCSA) INFOR	GLN: GCP: If yes, was or	0331722498975	section			to customer? 1 Vial) ПЕМ	AND PACKING IN	Rx billing under the state of t	Each Gram Milliliter	Volume	
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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 HA	ZARD 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? Is the product a CA Prop 65 reproductive toxicant? No Does the product label bear a CA Prop 65 warning? No	x Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard					
c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP?	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:					
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name	Is the product a NIOSH hazardous drug? If yes, indicate which:					
c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics					
Is this product regulated for shipment by IATA?						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:					
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)					
Is this a reportable quantity? No RQ Threshold: Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit? No (if yes, identify method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4)	REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: NO Phone: DEA #: NCPDP#: NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Registry: No					
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone: Comments					
Is the Product Controlled Substance? Controlled Substance Code Controlled by State(s)? ARCOS Reportable? No If yes, indicate which: Schedule No. Is it a scheduled listed chemical product?: No	RETURN INSTRUCTIONS Contact tel. # if product received damaged: Is product returnable for credit: Yes					
CLASS OF TRADE RESTRICTION:	Is product returnable for credit: URL/Link to returns policy: Yes					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: No	contact - customerservice@camberpharma.com Special regulations or returns requirements for this product in certain states? No					
Restricted from US territories? (explain in comments) No Comments:	If so, which states? Other requirements? Comments?					
MISCELLANE	OUS NOTES and/or Image of Product Barcode:					



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 Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI b. Autofax Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time:
c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number:	Shipping lead time of PO: Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
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:	Overnight receipt available:
Drop Ship service fee billed with each order:	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, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to Process 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?