

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

Version 2021					Introduction 7	Туре:	New Item		x Final Vers	sion			Date:	4/18	3/2023	
PRODUCT INFORMATION							SPECIA	AL HAND	LING AND STOR	AGE REQUIREMENTS*						
Company Name:	Camber Pharmaceutic	cals, Inc.				Applica	tion:	ANDA	a. Temperatu	a. Temperature – Indicate the USP temperature range for this product.						
Application Number for NDA/AN			ice):	208	213				11	Temperature Rang		Controlled Room -		and 25 C (68	3° – 77° F)	
Medical Device Class, if applical	ble:															
DUNS:	82-677-4775									Other Temperature	Range R	equirement				
Proprietary Name (If Applicable) a		: Roflum	nilast Tablets 250mcg							(write in)						
Selling Unit NDC:	31722-676-32		Unit of Use NDC:			UPC:	3317226	676328	-	Notes						
UDI			CVX Code:			MVX Code:			-							
Description:	Roflumilast Tablets 25	50mcg								Is this product to be					No	
Is this product to be shipped to customers on dry ice?  No																
Active Ingredient(s):  Roflumilast  b. Contact for temperature excursion questions:																
URL for Additional Product Inforr	mation: ww	w.camberpharma	a.com						b. Contact for temperature excursion questions:  Name: Soma Raju							
Address:	1031 Centennial Ave (	and) 800 Centen	nnial Ave, Suite 1			Address 2:								732-529-0423		
City:	Piscataway				State:	NJ	Zip:	08854	Group E-mail: somaraju@heterousa.com							
Key Contact:	Customer Service				Email:	customerservice	@camber	rpharma.com							_	
Phone Number:	1-866-827-3647				Fax:	732-562-8788	32-562-8788			ulations for produc					No	
Product Therapeutic Classification	on: Se	lective Phosphod	diesterase-4 Enzyme Inhibito	rs						Special returns req	uirements	for this product?			No	
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION d. Store product (unit of sale) upright?											1					
	ADDITIONA	L PRODUCT IN				PRODUCTI	DESCRIP	TION INFORMATION	d. Store prod	uct (unit of sale) up	_				No	
The product is?	-		Is the Product	Direct-Ship C	inly		-			Protect product (u	ınit of sa	le) from light?			No	
a legend device?	No	•	Is the Product	Unit Dose		Size:		0 Unit-dose Tablets 2x10)	e. Shelf life:	1-101-1 -1-16 1161					24	Months
if yes, enter class # a product kit?	No		Orphan Drug Status							Initial shelf life at	iaunch (ii	rainerent):				Months
if yes, list NDCs of	INU		FDA Approval Status			Strength: 250mcg						ORDER INFORM	ATION			
component parts						B	Т	ablet								
reverse numbered?	No	,				Dosage Fori	m:		Unit of Sale				What is the NDC selling unit?			
co-licensed?	No Allergens Present							Bottle				1 carton of 20 Unit-dose tablets				
latex-free?	Ye		Gluten, wheat	, corn, alcohol		Product Shape: round, flat bevel edged tablets			1 Box/Carton (Write-in, e.g. 1 Box of 10 Vials)							
preservative-free?	Ye						ta			Ampule						V
correctional institution block? opioid?	No No					Product Col	lor:	white to off white		Glass Tube			Wilnimum o	rder quantity	y?	Yes
Cannabinoid?	No		Country of Origin	India			de	ebossed with 'H' on one side		Vial Liqui	d Sal					
If Unit Dose, is item bar coded to u			Country of Origin	maia		Product Imp	Product Imprint: and 'T' on the other side			Vial Liquid Multi If Yes, how many of which package ty			type?			
hospital scanning?	No		Is this product covered ur	nder the					Vial Powder Sql							
If Unit Dose, indicate NDC here:	317	722-676-31	Trade Agreements Act (T	AA)?	No				Vial Power Multi				Inner/Carton/Pack			
									]	Other: W	rite In			Case		
			FOR GENERIC DRUG PRO	DUCTS												
						orized Generic, other	PHARMACY ORDER / BILL UNIT									
I. Orange Book Rating:	AB					section fields are not applicable			Rec. sell unit to customer?			Rx billing unit to pharmacy:				
II. Generic Equivalent to What Bra	and?: Da	lliresp							and the state of t			Each				
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION						(Write-in, e.g. 1 Vial) Gram Milliliter										
DRUG SUFFET CHAIN SECURITY ACT (DSUSA) INFORMINATION																
Does supplier meet DSCSA defini	ition of manufacturer?		Yes		GLN:	0331722000000					ITEM .	AND PACKING IN	IFORMATIO	I		
Is product exempt from DSCSA?			No													
If yes, select exemption:					GCP:				1	Weigh	4160	Dimension	ons (US msn	nts.)	Volume	Saleable #
Other exemption - Write in:									1	weign	t LDS.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			iginal product			Item/Each:	0.0	04	4.5	1	2	9	1
Is product sold by manufacturer's			Yes	_		rect from mfr?		dd	D/2 : -			-				
Has FDA granted waiver/exception If yes, attach documentation fro		ict?	No		Provide sour	ce manufacturer f	or repack	raged product	Box/Carton/B Inner Pack:	undle/						
ir yes, attach documentation fro	III FDA.								Case:							-
		GTIN	N AND HIBCC PRODUCT IN	FORMATION					l Case.	11	.6	15	12	13	2340	231
									Pallet:							
Saleable Unit of Measure	Salea	ble Quantity	HIBCC		GTI	N-14		Unit of Use GTIN-14								
X Item/Each		1			003	31722676328										
Box/Carton/Bundle/Inner Pack								COST INFORMATION			WHOLESALER USE ONLY:					
X Case		231			203	31722676322										
Pallet	_								Regular Cost	(MAC) (\$)	-	6000.00	Vendor #: Whsl. Code	#-		
									Invoice Cost	(**AC) (\$)	-	\$232.60	Fineline Co			
									As of date:	4/17/2023	3		i memie co	uc.		
													1			
							_		1.1				1			
<u>-L</u>			Attach copy of SAFETY DAT	A SHEET (SDS	) or non hazar	d letter, PACKAGE	INSERT,	LABEL AND PHOTO OF	PRODUCT PACK	AGING and BARCOI	DE.					



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For Designated Drop Ship Only Products, Please Use Page 3

MA	TERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply): a. Cytotoxic?	No	SD	S Hazard Classification					
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	140		o Hazara Glassification					
Is the product a CA Prop 65 carcinogen?	No	x 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	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:	No					
d. Does this product require special clean-up instructions?  (If yes, attach SDS with special instructions.)	No	NFPA Storage Level:						
e. Does the product contain DEHP?	No	NFFA Storage Level.						
•								
Is this product regulated for shipment by DOT?	No	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		Hazardous Wasta Identification						
c. DOT Hazard Class		Hazardous Waste Identification						
d. Packing Group e. Inhalation Hazard?	No	EPA Hazardous Waste Code:	Waste Characteristics					
		LFA Hazardous Wasie Code.	waste Characteristics					
Is this product regulated for shipment by IATA?	No	DEMO	DEGICTOV DEGEDICATIONS					
(if yes, answer a-e below and provide SDS)		REMS of	REGISTRY RESTRICTIONS					
a. UN/Identification Number		to those a DEMO on this was due to	No					
b. Proper Shipping Name c. DOT Hazard Class		Is there a REMS on this product?	No					
d. Packing Group		If Yes, is it managed with a pharmacy registry? Website URL:						
e. Inhalation Hazard?	No	Website OIL.						
			N					
Is the product restricted for air shipment? If so, indicate restriction:	No	Med Guide Required	No					
Passenger Cargo		Limited Distribution Requirement Comments / Details: (For example, iPledge program?)						
Passenger & Cargo		Comments / Details. (For example, ir ledge program:)						
		DEMO.	N <sub>2</sub>					
Is this a reportable quantity? No RQ Threshold:		REMS:  REMS Program Manager Name:	No					
Is this a marine pollutant? No		Supplier Manages REMS registry exclusively:	Phone:					
Is this a manne politicant: NO Second 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		Comments						
Special Provision (listed in Column 7 of 49 CFR 172.101);								
SP#		Registry:	No					
		Registry Program Contact Name:	Phone:					
ADD'L STORAGE INFORMATION		Comments						
Is the Product								
Controlled Substance? No Controlled Substance Code		RE	TURN INSTRUCTIONS					
Controlled by State(s)? No Listed Chemical (List I or II)	No							
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:	Yes					
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 - customerse	ervice@camberpharma.com					
Restricted to retail pharmacy only:	No	Special regulations or returns requirements for this						
Restricted to hospital, clinics, and physician offices only:	No	product in certain states?	No					
Restricted from US territories? (explain in comments)	No	If so, which states? Other requirements? Comments?						
Comments:		San						
Continents.								
MI	SCELLANEO	US NOTES and/or Image of Product Barcode:						



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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?