

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014 Introduction Type: New Item								Final Version Date:						
PRODUCT INFORMATION								SPECIAL HANDLING AND STORAGE REQUIREMENTS*						
Company Name:	Camber Pharmaceuticals				Application: ANDA			a. Temperature – Indicate the USP temperature range for this product.						
Application Number for ND	, •, , ,			204993	204993			Temperature Range			Controlled Room - between 20 and 25 C (68° - 77° F			
DUNS:	826774775							Other Temperature Range Requirement						
Proprietary Name (If Application		Name: Rufinam	ide Tablet 400mg 120ct					(wr	ite in)					
Selling Unit NDC:	31722-599-12		Individual Unit NDC:			PC: 331722599	122							
UDI			CVX Code:		MVX Cod	ie:		Is this pr	oduct to be shipped	to customers	on ice?		No	
Description:	Is this product to be shipped to customers on dry ice?													
Corresponding dies. Active Ingredient(s): Rufinamide							b. Contact for temperature excursion questions:							
							Name:			Soma Raju				
URL for Additional Product Information: www.camberpharma.com Address: 1031 Centennial Avenue				Address 2:						732-529-0423 somaraju@heterousa.com				
City:	1031 Centennial Avenue Piscataway			State	State: NJ Zip: 08854			Group E	-maii:		somaraju@i	ieterousa.co	TI	
Key Contact:	Customer Service				Email: customerservice@camberpharma.com Fax: 732-562-8788			c. Special regulations	for product in any s	states?			No	
Phone Number:	732-529-0430							Special returns requirements for this product? No						
Product Therapeutic Classification:								<u></u>						
d. Store product (unit of sale) upright? No														
ADDITIONA	AL PRODUCT INFORM	IATION			PRODUCT DESCRIPTION INFORMATION			Protect product (unit of sale) from light?						
Is the Product								e. Shelf life: 24 Months				Months		
a legend device?		No		Size: 120			Initial shelf life at launch (if different):						Months	
reverse numbered?	<u>No</u>						ORDER INFORMATION							
co-licensed? Is the Product		No Direct-Ship Only		Strength:	Strength: 400mg					ORDER INFOR	RWATION			
Is the Product		Neither						Unit of S	iale		What is the	NDC selling	unit?	
lo mo r roudom	is the Floudet			Dosage For	Dosage Form: Oral Solid - Tablet			Unit of Sale What is the NDC selling unit? x Bottle 1 bottle of 120 tablets						
If Unit Dose, is item bar coded to unit dose for hospital scanning?								Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)		
NO				Product Sh	Product Shape: Oblong				Ampule				_	.,
If Unit Dose NDC, indicate NDC here:								 	Glass Tube		Minimum o	rder quantity	1?	Yes
Country of Origin		India		Product Co	lor: Pink				Vial Liquid Sgl					
Is this product covered under the Trade Agreements Act (TAA)?				Product Im	Product Imprint: Upper: 'R and 8' Lower: 'H'			Vial Liquid Multi If Yes, how many of which package type?						
No No				· · · · · · · · · · · · · · · · · · ·				Vial Powder Sql		12	Each			
								J	Vial Power Multi Other: Write In			Inner/Carton Case	/Pack	
		Other, write in			Case									
				Αι	thorized Generic		ed Generic, other section	PHARMACY ORDER / BILL UNIT						
I. Orange Book Rating: AB				fields are not applicable			Rec. sell unit to customer?			Rx billing unit to pharmacy:				
II. Generic Equivalent to What Brand?: Banzel							OMORA III - A A MI-II				Each			
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION								(Write-in, e.g. 1 Vial)				Gram Milliliter		
		DIGG COLLE	TOTALL DESCRIPTION	oca, ini onimation								Williame		
Does supplier meet DSCSA			Yes	GLN:	03317220000	000			ITEM A	IND PACKING	INFORMAT	ION		
Is product exempt from DSC														
If yes, select exemption: Other exemption - Write in:	,						_		Weight Lbs.	Dimer	nsions (US m Height	smts.) Width	Volume (Cube)	# Pieces:
Is product repackaged?	•		No	If Yes, was orio	ginal product pur	rchased direct		Item:	0.5	Бериі			(Oubc)	
Is product sold by manufactu	urer's exclusive distri	butor?	No	from mfr?	, p				0.5		5	2.5		1
Has FDA granted waiver/exc	eption/exemption for	product?	No	If yes, attach d	ocumentation fro	om FDA.		Box/Carton/Bundle/						
1			GTIN PRODUCT INFORMAT	ION				Inner Pack:						
				leabl				Case:	7.3	12	7.5	9		12
				Unit		Quantity	GTIN-14	Pallet:						
Serialized?	Yes	Х	Item	X 2D	Linea	ır 1	00331722599122							
If not, when?		l	Box/Carton/Bundle/Inner Pack	2D	Linea			UPC:	Case:					
Items aggregated?								Carton:						
	Pallet 2D Linear 2D Linear						COST	INFORMATION			WHOLESAL	ER USE ONL	Y:	
				2D	Linea									
				2D	Linea	ır		Regular Cost			Vendor #:			
				2D	Linea	ır		Invoice Cost (WAC) (\$)		\$1,026.32				
								Federal Excise Tax Per	Unit of Sale		Fineline Co	de:		
								As of date:			-			
		Α.	ttach copy of SAFETY DATA S	HEET (SDS) or no= 5	azard letter DACI	(ACE INSERT 1	AREL AND DHOTO OF DD	ODLICT BYCKYCING * 1	RAPCODE		<u> </u>			
*Please provide any addition	nal information on page		macricopy of SAFETT DATAS	TILL I (SDS) OF HOTE IS		AGE INSERT, LA		Signatur						



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): a. Cytotoxic? SDS Hazard Classification No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No X Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? Inorganic Oxidizer No Does the product label bear a CA Prop 65 warning? No Steroid/Androgen Contact Hazard c Contact Hazard? Nο 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? 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 Hazardous Waste Identification b. Proper Shipping Name c. DOT Hazard Class EPA Hazardous Waste Code: d. Packing Group e. Inhalation Hazard? No REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: 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? 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? (if yes, identify method below) REMS: Limited Quantity REMS Program Manager Name: Phone: Consumer Commodity, ORM-D Supplier Manages REMS registry exclusively: Small Quantity (49 CFR 173.4) Wholesale distributor support: Special Permit: DOT-SP Provider Name: Special Provision (listed in Column 7 of 49 CFR 172.101); Site Enrollment Number assigned DEA #: by Supplier: PCPDP #: NPI#: ADD'L STORAGE INFORMATION Is the Product... Comments Controlled Substance? No Controlled by State(s)? No Registry: ARCOS Reportable? No Registry Program Contact Name: Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code Listed Chemical (List I or II) No RETURN INSTRUCTIONS If yes, indicate which: 732-529-0430 Is it a scheduled listed chemical product?: No Contact tel. # if product received damaged: **CLASS OF TRADE RESTRICTION:** Is product returnable for credit: contact - customerservice@camberpharma.com No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes URL/Link to returns policy: No 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: No If so, which states? Other requirements? Comments? Restricted from US territories? (explain in comments) No Comments: MISCELLANEOUS 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	Purchase order daily receipt cut off time by supplier Cut off time: Eastern						
b. Autofax c. Fax d. Phone only Fax Number: Phone No.:	Shipping lead time of PO: Hours Days						
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	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:	Overnight receipt available:						
Drop Ship service fee billed with each order:	PO Receipt cut off time: Eastern						
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/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?						