

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

Version 2021						Introduction Ty	/pe:	New Item		x Final V	ersion			Date:	3/22/	/2024
			PRODUCT INFORMA	TION						SPE	CIAL HAND	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.										
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 216841							Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)									
Medical Device Class, if applical			·							•	-					
DUNS:	11-856-3719									Other Temperatu	ure Range R	equirement				
Proprietary Name (If Applicable) a	nd Established Na	ame: Rufina	amide Oral Suspension 40 m	ng/mL						(write in)						
Selling Unit NDC:	31722-688-46		Unit of Use NDC:		31722-688-46		331722688468			Notes						
UDI			CVX Code:			MVX Code:										
Description: Rufinamide Oral Suspension 40 mg/mL Is this product to be shipped to customers on ice? No								1								
									to customers on di			No				
Active Ingredient(s):	Active Ingredient(s): Rufinamide, USP															
						b. Contact fo	or temperature exc	cursion que								
URL for Additional Product Inforn		www.camberpharma			1					Name:			Soma Raju			
Address:		Ave (and) 800 Center	nnial Ave, Suite 1		State:	Address 2:	7: 0005			Number:			732-529-042		_	
City: Key Contact:	Piscataway Customer Service	۵			Email:	customerservice@	Zip: 08854		Group E-mail: somaraju@heterousa.com							
Phone Number:	1-866-827-3647	<u> </u>			Fax:	732-562-8788	camberphann	2.00111	c Special re	gulations for prod	luct in any	states?			No	1
Product Therapeutic Classificatio		Anticonvulsant			-				or openiar re		-	for this product?			No	1
l rouge morapouno oracomouno	•••									Openial retains i	oquiromonic	ror and product.				1
	ADDIT	IONAL PRODUCT IN	FORMATION			PRODUCT DE	ESCRIPTION	NFORMATION	d. Store proc	duct (unit of sale)	upright?				Yes	1
The product is?			Is the Product	Direct-Ship (Only					Protect product		a) from light?			No	1
a legend device?		No	Is the Product	Unit of Use	Stilly		460 mL		e. Shelf life:	Frotect product	(unit or sai	e) irom ngmr			24	Months
if yes, enter class #		140	Orphan Drug Status			Size:	400 1112		C. Onen me.	Initial shelf life	at launch (if	different):			2.7	Months
a product kit?		No					40 mg/r	nL				,-				,
if yes, list NDCs of			FDA Approval Status			Strength:						ORDER INFORM	ATION			
component parts						Dosage Form:	Oral Su	spension								
reverse numbered?		No				Doougo : o	•			Unit of Sale			What is the			
co-licensed?		No	Allergens Present							x Bottle			1 Bottle of 4			
latex-free?		Yes	Ale	cohol		Product Shape	e: N/A			Box/Ca			(Write-in, e.	g. 1 Box of 10	0 Vials)	
preservative-free? correctional institution block?		No No					White			Ampule	В		Minimum or	dor augntitu		Yes
opioid?		No				Product Color	r: VVIIILE			Tube			William Or	uer quaritity	•	162
Cannabinoid?		No	Country of Origin	India			N/A				quid Sgl					
If Unit Dose, is item bar coded to u	unit dose for	110	,g			Product Impri	int:				quid Multi		If Yes, how	many of whi	ch package t	type?
hospital scanning?			Is this product covered of	under the							wder Sql			Each		•
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?	No					Vial Po	wer Multi			Inner/Carton	/Pack	
										Other:	Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS												
					Aut		*If Authorized				PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						section fields a	re not applicable	Rec. sell unit	t to customer?			Rx billing u		acy:	
II. Generic Equivalent to What Bra	nd?:	Banzel												Each		
		DDIIC CUDD	Y CHAIN SECURITY ACT	(Decea) INFO	DMATION				(Write-in, e.g	j. 1 Vial)				Gram Milliliter		
		DRUG SUFFI	T CHAIN SECURITY ACT	(DSCSA) INFO	RMATION									wiiiiiter		
Does supplier meet DSCSA defini	tion of manufactu	rer?	Yes	_	GLN:	0331722000000					ITEM	AND PACKING IN	IFORMATION			
Is product exempt from DSCSA?			No		02.11	0001122000000										
If ves. select exemption:					GCP:							Dimensio	ons (US msm	its)	Volume	Saleable #
Other exemption - Write in:					GUF.					Wei	ght Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If ves. was ori	ginal product purch	hased		Item/Each:			•				
Is product sold by manufacturer's	exclusive distribi	utor?	Yes		direct from mi						1.36	4	3.4	7.5	102	1
Has FDA granted waiver/exceptio	n/exemption for p	roduct?	No		Provide source	e manufacturer for	repackaged p	roduct	Box/Carton/E	Bundle/						
If yes, attach documentation from	m FDA.								Inner Pack:							
									Case:		18.15	16.5	10.75	8.5	1,507.69	12
		GT	N AND HIBCC PRODUCT I	NFORMATION											.,	
Saleable Unit of Measure									Pallet:							
X Item/Each		Saleable Quantity	HIBCC		GTIN	I-14 1722688468		TUse GTIN-14 722688468								
X Item/Each Box/Carton/Bundle/Inner Pack					0033	1122000400	00331	122000400		COST INFO	RMATION			NHOLESAL	ER USE ONL	Y:
X Case		12			2033	1722688462				333 3.						
Pallet		· <u>-</u>			2500				Regular Cos	t			Vendor #:			
									Invoice Cost	(WAC) (\$)		\$375.00	Whsl. Code	#:		
													Fineline Co			
									As of date:	3/18/20	024					
													1			
μ									Ц				<u> </u>			
		_	Attach copy of SAFETY D	ATA SHEET (SI	DS) or non hazar				PRODUCT PACK		ODE.					
*Please provide any additional inf	ormation on page	2.				See new p. 3 for D	Jesignated Dr	op Ship Only.		Signature:						



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION							
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	SDS Hazard Classification						
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? No	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)	REMS or REGISTRY RESTRICTIONS						
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	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: Phone: DEA #: NCPDP#: NCPDP#: NPI #:						
Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments Registry: No						
5F#	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	Comments						
Is the Product Controlled Substance? Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No	RETURN INSTRUCTIONS						
ARCOS Reportable? No If yes, indicate which: Schedule No. Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: Is product returnable for credit: 1-866-827-3647 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 - customerservice@camberpharma.com						
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?						
Comments:							
MISCELLAN	EOUS NOTES and/or Image of Product Barcode:						
Rufinamide oral suspension liquid is supplied in a polyethylene terephthalate (PET) bottle with child-resi adapter. Replace cap securely after opening. The cap fits properly in place when the adapter is in place	stant closure. The oral suspension is packaged with a dispenser set which contains two 20 mL calibrated oral dosing syringes and an . Use within 90 days of first opening the bottle, then discard any remainder.						



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FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop S	nip 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:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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 Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order:		Overnight receipt available: 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, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess 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?