

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

Version 2021						Introduction Typ	pe: New Item		x Final Version			Date:	6/23	3/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STO	RAGE REQUIP	REMENTS*		
Company Name:	Camber Pharmac	euticals, Inc.				Applicatio	n: ANDA	a. Temperatu	re - Indicate the USP temp	erature range for t	his product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 212788				2788			Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)							
Medical Device Class, if applicable:														
DUNS:	11-856-3719								Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a	nd Established Na	ame: R	anolazine Extended-Release Tab	lets 500 mg				T	(write in)	•				
Selling Unit NDC:	31722-668-60		Unit of Use NDC:		31722-668-60	UPC: 3	31722668606		Notes					
UDI			CVX Code:			MVX Code:								
Description: Ranolazine Extended-Release Tablets 500 mg Is this product to be shipped to customers on ice? No								1						
			g						Is this product to be shippe				No	1
Active Ingredient(s):		Ranolazine									•			4
							b. Contact fo	r temperature excursion qu	estions:					
URL for Additional Product Inform		www.camberph	arma.com						Name:		Soma Raju			
Address:	800 Centennial Av	ve, Suite 1				Address 2:			Number:		732-529-042			
City:	Piscataway				State:		<b>Zip</b> : 08854		Group E-mail: somaraju@heterousa.com					
Key Contact:	Customer Service Email:				customerservice@d	camberpharma.com						7		
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regulations for product in any states?					No	-
Product Therapeutic Classification	1:	Antianginal							Special returns requirement	ts for this product?			No	
								_						-
	ADDITI	ONAL PRODUC	T INFORMATION			PRODUCT DE	SCRIPTION INFORMATION	d. Store prod	luct (unit of sale) upright?				No	_
The product is?			Is the Product	Direct-Ship (	Only				Protect product (unit of sa	ile) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	60 ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			0.20.			Initial shelf life at launch (	if different):				Months
a product kit?		No				Strength:	500 mg							
if yes, list NDCs of			FDA Approval Status							ORDER INFORI	MATION			
component parts		la.				Dosage Form:	Film coated, extended-		Helica Contr		\M/ls a4 ia 4ls a	NDC a allian		
reverse numbered?		No	Allannana Brasant				release tablet		Unit of Sale		What is the		unit?	
co-licensed? latex-free?		No Yes	Allergens Present				Oblong	1	x Bottle Box/Carton		1 Bottle of 60	g. 1 Box of 1	O \/iolo\	
preservative-free?		Yes	Ald	ohol		Product Shape	e: Oblong		Ampule		(vviite-iii, e.	y. 1 bux 01 1	U Viais)	
correctional institution block?		No					Blue	-	Glass		Minimum or	der auantity	12	Yes
opioid?		No				Product Color:	Blac		Tube		Million O	uci quaintity	•	103
Cannabinoid?		No	Country of Origin	India			Debossed with 'R18' on one		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for		, ,			Product Imprir	side and 'H' on the other side		Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
hospital scanning?			Is this product covered u	inder the				1	Vial Powder Sgl		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (	ГАА)?	No				Vial Powder Multi			Inner/Cartor	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
					Aut		If Authorized Generic, other		Ph	IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB					S	ection fields are not applicable	Rec. sell unit	to customer?		Rx billing u	nit to pharm	асу:	
II. Generic Equivalent to What Brai	nd?:	Ranexa										Each	-	
								(Write-in, e.g	. 1 Vial)	_		Gram		
		DRUG SU	IPPLY CHAIN SECURITY ACT (	DSCSA) INFO	RMATION							Milliliter		
				_										
Does supplier meet DSCSA definit	ion of manufactur	rer?	Yes No	_	GLN:	0331722498975			IIEN	I AND PACKING I	NFORMATIO	N .		
Is product exempt from DSCSA?			NO											
If yes, select exemption:					GCP:				Weight Lbs.		ions (US msm	•	Volume	Saleable #
Other exemption - Write in:									rreigin LDS.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No	_		ginal product purch	ased	Item/Each:	0.16	1.65	1.65	3.39	9.23	1
Is product sold by manufacturer's			Yes No	_	direct from mf			- 10 . 1						
Has FDA granted waiver/exception		roduct?	INO		Provide sourc	e manuracturer for i	repackaged product	Box/Carton/E	sunale/					
If yes, attach documentation from	II FDA.							Case:						
			GTIN AND HIBCC PRODUCT I	NEORMATION				Case.	4.36	11.5	7.9	4.25	386.11	24
			5					Pallet:						
Saleable Unit of Measure	S	Saleable Quantity	HIBCC		GTIN	I-14	Unit of Use GTIN-14							
X Item/Each	_	1				1722668606	00331722668606							
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESAL	ER USE ONL	LY:
X Case		24			2033	1722668600								
Pallet	_							Regular Cost	t		Vendor #:			
								Invoice Cost	(WAC) (\$)	\$17.50	Whsl. Code			
								11	=///000		Fineline Co	de:		
								As of date:	5/1/2024					
1							10557 1 1551 1115 BUILTER							
			Attach copy of SAFETY DA	ATA SHEET (SI	טכ) or non hazar		NSERT, LABEL AND PHOTO OF	PRODUCT PACK	AGING and BARCODE. Signature:					
*Please provide any additional info		•					esignated Drop Ship Only.							



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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?  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	Hazardous Waste Identification						
e. Inhalation Hazard?  Is this product regulated for shipment by IATA?  No	EPA Hazardous Waste Code: Waste Characteristics						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMS or REGISTRY RESTRICTIONS						
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:  DEA #:  NCPDP#:  NPI #:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments						
ADD'L STORAGE INFORMATION	Registry:  Registry Program Contact Name:  Comments  No  Phone:						
Is the Product							
Controlled Substance Code Controlled by State(s)? ARCOS Reportable? Schedule No.  No Controlled Substance Code Listed Chemical (List I or II) No If yes, indicate which: Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION:	RETURN INSTRUCTIONS  Contact tel. # if product received damaged:  I-866-827-3647  Is product returnable for credit:  Yes						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes	URL/Link to returns policy:  contact - customerservice@camberpharma.com						
Restricted to retail pharmacy only:  Restricted to hospital, clinics, and physician offices only:  No	Special regulations or returns requirements for this product in certain states?						
Restricted from US territories? (explain in comments)  No  Comments:	If so, which states? Other requirements? Comments?						
MISCELLANE	DUS 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 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?