

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

Version 2021					Introduction	Туре:	New Item		x	inal Version			Date:	6/23/	2024
		PRODUCT INFORM	ATION							SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Camber Pharmaceuticals, Inc.				Applica	ation:	ANDA	a. Temperatu	re – Indicat	e the USP tempe	rature range for t	his product.			
Application Number for NDA/ANI		ed device):	212788					a. romporata	Temperatu		Controlled Room		and 25 C (68'	° – 77° F)	
Medical Device Class, if applicab										0					
DUNS:	11-856-3719								Other Terr	perature Range F	Requirement				
Proprietary Name (If Applicable) a	nd Established Name:	Ranolazine Extended-Release Ta							(write	e in)					
Selling Unit NDC:	31722-669-60	Unit of Use NDC	3172	22-669-60	UPC:	331722669	9603		Notes						
UDI		CVX Code:			MVX Code:										
Description:	Ranolazine Extended-Release	Tablets 1000 mg									I to customers on i			No	
Is this product to be shipped to customers on dry ice? No															
Active Ingredient(s): Ranolazine b. Contact for temperature excursion questions:															
UDI for Additional Draduat Inform	-tion.							b. Contact for		re excursion que	estions:	Come Daiu			
URL for Additional Product Inform Address:	800 Centennial Ave, Suite 1	erpharma.com			Address 2:				Name: Number:			Soma Raju 732-529-042	2		
City:	Piscataway			State:	NJ	Zip: 08	8854		Group E-r	nail·		somaraju@h		۰ ۱	
Key Contact:	Customer Service			Email:	customerservice				0.0up = .			<u>bomanaja or</u>	010100000.0011	<u>-</u>	
Phone Number:	1-866-827-3647			Fax:	732-562-8788			c. Special reg	ulations fo	r product in any	states?			No	
Product Therapeutic Classification	n: Antianginal								Special re	turns requirement	s for this product?			No	
-															
	ADDITIONAL PROD	OUCT INFORMATION			PRODUCT	DESCRIPTI	ON INFORMATION	d. Store prod	uct (unit of	sale) upright?				No	
The product is?		Is the Product	Direct-Ship Only					1	Protect pr	oduct (unit of sa	le) from light?		i	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			5126.			1	Initial she	lf life at launch (i	f different):				Months
a product kit?	No				Strength:	100	00 mg								
if yes, list NDCs of		FDA Approval Status				F 11-	a sector de sector de d				ORDER INFORM	IATION			
component parts reverse numbered?	No				Dosage For		n coated, extended- ease tablet		Unit of Sa	lo		What is the	NDC selling	unit?	
co-licensed?	No	Allergens Present				Tele				Bottle		1 Bottle of 6		unit:	
latex-free?	Yes					Obl	long			Box/Carton			g. 1 Box of 10) Vials)	
preservative-free?	Yes	- A	Icohol		Product Sha	ape:				Ampule		(.		
correctional institution block?	No				Product Col	Blu	e			Glass		Minimum or	der quantity	?	Yes
opioid?	No				Froduct Col					Гube				L.	
Cannabinoid?	No	Country of Origin	India		Product Imp		oossed with 'R19' on one e and 'H' on the other side			/ial Liquid Sgl					
If Unit Dose, is item bar coded to u	init dose for					SIDE	e and H on the other side			/ial Liquid Multi		If Yes, how		ch package t	ype?
hospital scanning?		Is this product covered Trade Agreements Act								/ial Powder Sgl /ial Powder Multi			Each Inner/Carton/	/De els	
If Unit Dose, indicate NDC here:		Trade Agreements Act								Other: Write In			Case	Pack	
		FOR GENERIC DRUG P	PODUCTS						· · · · · ·	Strief. White in			Case		
		TOK GENERIC DROG P	NODUCI 3					-							
				Aut	thorized Generic	*If Authoriz	zed Generic, other			PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB					section fie	lds are not applicable	Rec. sell unit	to custome	er?		Rx billing u	nit to pharma	icv.	
II. Generic Equivalent to What Bran	nd?: Ranexa												Each	.,.	
							(Write-in, e.g. 1 Vial)				Gram				
	DRUC	SUPPLY CHAIN SECURITY ACT	(DSCSA) INFORMAT	ION									Milliliter		
		No.								1751					
Does supplier meet DSCSA definit Is product exempt from DSCSA?	non of manufacturer?	Yes No	GLN	ı:	0331722498975					TIEN	AND PACKING I	NFORMATION	1		
				_		_		1			D ¹	ene (110	4- \		
If yes, select exemption:			GCP	*:				1		Weight Lbs.		ons (US msm	,		Saleable #
Other exemption - Write in: Is product repackaged?		No	lí vo		iginal product pur	rchased		Item/Each:			Depth	Width	Height	(Cube)	Pieces
Is product sold by manufacturer's	exclusive distributor?	Yes		ct from m		Chaseu		nem/Each.		0.27	2.2	2.2	3.88	18.76	1
Has FDA granted waiver/exception		No			 e manufacturer fo	or repackag	ed product	Box/Carton/B	undle/						
If yes, attach documentation from		<u>.</u>	_					Inner Pack:							
								Case:		7.2	13.75	9.5	5	653.13	24
		GTIN AND HIBCC PRODUCT	INFORMATION												
Saleable Unit of Measure								Pallet:							
X Item/Each	Saleable Qua	ntity HIBCC		GTIN	N-14 31722669603		nit of Use GTIN-14 0331722669603								
Box/Carton/Bundle/Inner Pack				0033	51722003003		0001722003000		COST	INFORMATION			WHOLESALE	R USE ONL	Y:
X Case	24	_		2033	31722669607	_									
Pallet								Regular Cost				Vendor #:			
						_		Invoice Cost	(WAC) (\$)		\$28.05	Whsl. Code	#:		
								1	_			Fineline Co	de:		
						_		As of date:	5	5/1/2024					
								1							
<u> </u>				non bar-	d lattar BACKAC		ABEL AND PHOTO OF P			PARCORE		l			
*Please provide any additional info	ormation on page 2	Allach copy of SAFETY L	ATA SHEET (SUS) OF	non nazar			ABEL AND PHOTO OF P d Drop Ship Only.	RODUCT PACKA	Signature						
Flease provide any additional into	ormation on page 2.				See new p. 3 for	Designated	a brop snip Only.		Signature	•					

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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 HAZ	ZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply): a. Cytotoxic? 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? 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 Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No NFPA Storage Level: Is the product a NIOSH hazardous drug? If yes, indicate which: No						
b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics						
Is this product regulated to shipment by IATA? NO (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? No If Yes, is it managed with a pharmacy registry? No Website URL: Image: Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2"Colspan="						
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) Special Permit; DOT-SP Special Pervision (listed in Column 7 of 49 CFR 172.101);	REMS: No REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: Provider Name: Provider Name: DEA #: Site Enrollment Number assigned NCPDP#: by Supplier: NPI #:						
SP#	Registry: No						
ADD'L STORAGE INFORMATION Is the Product	Registry Program Contact Name: Phone: Comments						
Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: Is it a scheduled listed chemical product?: No Schedule No. CLASS OF TRADE RESTRICTION: CLASS OF TRADE RESTRICTION: Controlled Substance Code Controlled Substance Code	RETURN INSTRUCTIONS Contact tel. # if product received damaged: 1-866-827-3647 Is product returnable for credit: Yes						
	URL/Link to returns policy: customerserv						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes Restricted to retail pharmacy only: No Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No Comments:	Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?						
	DUS NOTES and/or Image of Product Barcode:						
	Soo Norte analor 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 c. Fax d. Phone only e. Supplier Web Site on 31722-669-60 Site Address: Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days 31722-669-60 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: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available: Image: Constraint of time: PO Receipt cut off time: Image: Constraint of time: Days of week overnight is available: Monday Tuesday Image: Constraint of the time: Wednesday Thursday Friday Friday
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: Order receipt method: Phone: Phone: Phone #: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?