

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

Version 2021						Introduction Type:	New Item		000 Final Version			Date:	2/22	/2022
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STO	RAGE REQUI	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): 075903 Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)														
Medical Device Class, if applicable:														
DUNS:	82-677-4775							_	Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a		ame: Lisino	pril Tablets 10mg 1000ct						(write in)					
Selling Unit NDC:	31722-177-10		Unit of Use NDC:				722177108		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Oral Solid - tablet	, round, pink, Upper:	E3 Lower: Plain					T	Is this product to be shipped	to customers on	ice?		No	
									Is this product to be shipped	to customers on	dry ice?		No	
Active Ingredient(s):		Lisinopril												
							b. Contact fo	r temperature excursion qu	estions:					
URL for Additional Product Inforn		A (l) 000 O l	and all Arra Code 4			A ddunan Or		-	Name:		Soma Raju	10		
Address:	Piscataway	Ave (and) 800 Cente	nniai Ave, Suite 1		State:	Address 2: NJ Zii	o: 08854	-	Number: Group E-mail:		732-529-042	ು Dheterousa	. com	
City: Key Contact:	Customer Service	<u> </u>			Email:		camberpharma.com	-	Group E-mail:		Somaraju	<u>vneterousa</u>	a.com	
Phone Number:	1-866-827-3647	•			Fax:	732-562-8788	camberpharma.com	c Special re	gulations for product in any	states?			No	1
Product Therapeutic Classificatio								or observer to	Special returns requirement				No	1
l rouge morapouno oracomouno									opoolal rotarrio roquirorriorr	o for ano product.			- 110	1
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION d. Store product (unit of sale) upright?											No	1		
The product is?			Is the Product	Direct-Ship Or	dv			1	Protect product (unit of sa	lo) from light?			No	1
a legend device?		No	Is the Product	Neither	y		1000ct	e. Shelf life:	Frotect product (unit of Sa	ile) iroin light?			24	Months
if yes, enter class #		140	Orphan Drug Status	110111101		Size:	100000	c. Onen me.	Initial shelf life at launch (if different).			2.4	Months
a product kit?		No				a	10mg							
if yes, list NDCs of			FDA Approval Status			Strength:				ORDER INFOR	MATION			
component parts						Dosage Form:	Oral Solid - Tablet							
reverse numbered?		No				Dosage Form.			Unit of Sale			NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 bottle of 1			
latex-free?		Yes				Product Shape:	Round		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes					Pink		Ampule					
correctional institution block? opioid?		No No				Product Color:	PINK		Glass Tube		Wilnimum o	der quantity	11	Yes
Cannabinoid?		No	Country of Origin	USA			Upper: E3 Lower: Plain		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for	140	country or origin	00/1		Product Imprint:	oppor. Lo Lonor: 1 idiri		Vial Liquid Multi		If Yes. how	many of whi	ich package	type?
hospital scanning?	unii 4000 101		Is this product covered u	inder the					Vial Powder Sql			Each	pg-	-51
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?					Vial Power Multi			Inner/Cartor	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
											_			
					Au		Authorized Generic, other		Pl	ARMACY ORDER	R / BILL UNIT			
I. Orange Book Rating:	AB					sec	tion fields are not applicable	Rec. sell uni	t to customer?		Rx billing u	nit to pharm	acy:	
II. Generic Equivalent to What Bra	and?:	Zestril										Each		
								(Write-in, e.g	ı. 1 Vial)			Gram		
		DRUG SUPP	LY CHAIN SECURITY ACT	(DSCSA) INFORI	MATION							Milliliter		
Does supplier meet DSCSA defini	ition of manufactur	ror?	Yes	_	GLN:	0331722000000		1	ITEN	I AND PACKING I	INFORMATIO	V		
Is product exempt from DSCSA?	ition of manufactur	err	No	-	GLIN.	0331722000000			II EN	I AND I ACKING	IN ORMATIO	•		
					CCD.					Dime	ions (US msn	nte \	V-I	Calastite #
If yes, select exemption: Other exemption - Write in:					GCP:			1	Weight Lbs.	Dimens Depth	Width	nts.) Height	Volume (Cube)	Saleable # Pieces
Is product repackaged?			No		f vas was or	iginal product purchas	ad	Item/Each:		Deptii			·	
Is product sold by manufacturer's	s exclusive distribu	utor?	No		direct from m			item/Lucii.	0.6		3	5.5	0	1
Has FDA granted waiver/exceptio			No	_		ce manufacturer for rep	ackaged product	Box/Carton/i	Bundle/				0	
If yes, attach documentation from	m FDA.							Inner Pack:					0	
								Case:	7.3	12	9.25	6	0	12
		GT	IN AND HIBCC PRODUCT I	NFORMATION					7.0		0.20			
Onlands Hair of Manager	_							Pallet:					0	
Saleable Unit of Measure	S	Saleable Quantity	HIBCC			N-14	Unit of Use GTIN-14							
X Item/Each Box/Carton/Bundle/Inner Pack		1			003	31722177108			COST INFORMATION			WHOLESAL	ER USE ONL	٧٠
X Case		12			103	31722177105			3031 INI ORMATION			MHOLLSAL	ER OSE ONL	
Pallet		12			103	522177100		Regular Cos	t		Vendor #:			
								Invoice Cost		\$65.00	Whsl. Code	#:		
								11		723.00	Fineline Co			
								As of date:						
								11			1			
1								Ц						
			Attach copy of SAFETY DA	ATA SHEET (SDS) or non haza		ERT, LABEL AND PHOTO OF	PRODUCT PACK						
*Please provide any additional inf	formation on page	2.				See new p. 3 for Desi	ignated Drop Ship Only.		Signature:					



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For Designated Drop Ship Only Products, Please Use Page 3

M.F	TERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION				
Is this product (check all that apply): a. Cytotoxic?	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? Does the product label bear a CA Prop 65 warning? 	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	No	Is the product a NIOSH hazardous drug? If yes, indicate which:	No			
c. DOT Hazard Class d. Packing Group		Hazardous Waste Identification				
e. Inhalation Hazard?	No	EPA Hazardous Waste Code:		Waste Characteristics		
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)	No	REMS of	REGISTRY RESTRICTIONS			
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	No	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:	No			
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	No	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)				
Is this a reportable quantity? RQ Threshold: Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit? (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);	Comments					
SP#		Registry: Registry Program Contact Name:	No	Phone:		
ADD'L STORAGE INFORMATION		Comments		· ·		
Is the Product Controlled Substance? Controlled Substance Code Controlled by State(s)? ARCOS Reportable? No Listed Chemical (List I or II) If yes, indicate which:	No	RI Contact tel. # if product received damaged:	1-866-827-3647			
Schedule No. Is it a scheduled listed chemical product?: CLASS OF TRADE RESTRICTION:		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:	rvice@camberpharma.com			
Restricted to retail pharmacy only:	No	Special regulations or returns requirements for this				
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)	No No	product in certain states? If so, which states? Other requirements? Comments?				
Comments:						
М	ISCELLANEC	UUS 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?				