

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

Version 2021						Introduction Type:	New Item		000 Final Version			Date:	2/22	2/2022
			PRODUCT INFORMA	TION					SPECIAL HA	ANDLING 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 Rang	e Requirement				
Proprietary Name (If Applicable) a		ıme: Lisino	pril Tablets 10mg 100ct						(write in)					
Selling Unit NDC:	31722-177-01		Unit of Use NDC:				722177016		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Oral Solid - tablet	round, pink, Upper:	E3 Lower: Plain					T	Is this product to be shipp	ed to customers on	ice?		No	1
									Is this product to be shipp	ed to customers on	dry ice?		No	
Active Ingredient(s):		Lisinopril												
NO. C. A. Miller B. Market and S. C.							b. Contact fo	or temperature excursion of	questions:					
URL for Additional Product Inform						Address 0			Name:		Soma Raju			
Address:	Piscataway	Ave (and) 800 Cente	nniai Ave, Suite 1		State:	Address 2: NJ Zii	o: 08854	-	Number: Group E-mail:		732-529-042	23 @heterousa		
City: Key Contact:	Customer Service				Email:		camberpharma.com	-	Group E-mail:		<u>somaraju</u> (	<u>wneterous</u>	a.com	
Phone Number:	1-866-827-3647	·			Fax:	732-562-8788	camperpharma.com	c Special re	gulations for product in a	nv states?			No	7
Product Therapeutic Classification								or opecial to	Special returns requireme		,		No	1
l rouge morapouno oracomouno	•••								opoola, rotamo roquirom	nito for tino product.			- 110	1
	ADDITI	ONAL PRODUCT IN	NFORMATION			PRODUCT DESC	CRIPTION INFORMATION	d. Store prod	duct (unit of sale) upright?				No	7
The product is?			Is the Product	Direct-Ship Or	nlv			1	Protect product (unit of				No	i
a legend device?		No	Is the Product	Neither	y		100ct	e. Shelf life:	Protect product (unit of	sale) Ironi light?			24	Months
if yes, enter class #		140	Orphan Drug Status			Size:	10001	c. onen me.	Initial shelf life at launcl	(if different):			2.7	Months
a product kit?		No					10mg			(				
if yes, list NDCs of			FDA Approval Status			Strength:	9			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		Minimum o	rder 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 of Origin	00/1		Product Imprint:	oppon to town in an		Vial Liquid Mult		If Yes, how	many of whi	ich package	type?
hospital scanning?	4000 101		Is this product covered u	under the					Vial Powder Sq			Each	pg-	.,,,,,
If Unit Dose, indicate NDC here:			Trade Agreements Act (	TAA)?					Vial Power Mult	i		Inner/Cartor	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
					Au		authorized Generic, other			PHARMACY 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	nd?:	Zestril										Each		
								(Write-in, e.g	g. 1 Vial)			Gram		
		DRUG SUPP	LY CHAIN SECURITY ACT	(DSCSA) INFORI	MATION							Milliliter		
Does supplier meet DSCSA defini	tion of manufactur	or?	Yes	_	GLN:	0331722000000			IT	EM AND PACKING	INFORMATIO	N		
Is product exempt from DSCSA?	tion of manufactur	GI:	No	_	GLIV.	0331722000000			•••	LIII AND I ACITING	IN OKMATIO	.,		
					CCD.					Dimene	sions (US msr	nte \	V-I	Calactic "
If yes, select exemption: Other exemption - Write in:					GCP:			_	Weight Lbs.	Dimens Depth	Width	nts.) Height	Volume (Cube)	Saleable # Pieces
Is product repackaged?			No		If yes was or	riginal product purchas	he	Item/Each:		Deptil			·	
Is product sold by manufacturer's	exclusive distribu	itor?	No		direct from m		Su	nem/Lucii.	0.1		1.625	3	0	1
Has FDA granted waiver/exception			No	_		ce manufacturer for rep	ackaged product	Box/Carton/	Bundle/				0	
If yes, attach documentation from	m FDA.							Inner Pack:					0	1
								Case:	2.55	10.5	7.25	4.5		24
		GT	IN AND HIBCC PRODUCT I	NFORMATION										
Saleable Unit of Measure	_							Pallet:					0	
	S	aleable Quantity	HIBCC			N-14	Unit of Use GTIN-14							
X Item/Each Box/Carton/Bundle/Inner Pack		1			003	31722177016			COST INFORMATIO	N		WHO! ESAL	ER USE ONL	γ
X Case		24			103	31722177013			OCCI IN CHIMATIO	•		WIIOLLOAL	ER OOL ON	
Pallet					.00			Regular Cos	t		Vendor #:			
								Invoice Cost	(WAC) (\$)	\$6.50	Whsl. Code	#:		
											Fineline Co	de:		
								As of date:						
μ								Щ						
		_	Attach copy of SAFETY D	ATA SHEET (SDS	S) or non haza		ERT, LABEL AND PHOTO OF	PRODUCT PACK						
*Please provide any additional inf	ormation on page	2.				See new p. 3 for Desi	gnated 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					
<ul> <li>b. CA Prop. 65 Carcinogen or Reproductive Toxicant?</li> <li>Is the product a CA Prop 65 carcinogen?</li> <li>Is the product a CA Prop 65 reproductive toxicant?</li> <li>Does the product label bear a CA Prop 65 warning?</li> </ul>	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	. Troc Couring or price in a com			
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:				



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

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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?				