

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

						Introduction Ty	pe: New Item		x Final Version			Date:	6/23/	/2024	
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	EMENTS*			
Company Name: Camber Pharmaceuticals, Inc.					Application	n: ANDA	a. Temperat	a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/AN			e):	075	5903				Temperature Range	Controlled Room -		and 25 C (68	, – 77° F)		
Medical Device Class, if applica	ble:								-						
DUNS:	11-856-3719								Other Temperature Range	Requirement	Protect from	freezing and	excessive he	at	
Proprietary Name (If Applicable) a		ame: Lisinop	ril Tablets, USP 2.5 mg						(write in)						
Selling Unit NDC:	31722-172-05		Unit of Use NDC:				331722172059		Notes						
UDI			CVX Code:			MVX Code:									
Description:	Lisinopril Tablets,	USP 2.5 mg							Is this product to be shippe	d to customers on ic	:e?		No	1	
									Is this product to be shippe	d to customers on d	ry ice?		No	1	
Active Ingredient(s):		Lisinopril, USP													
URL for Additional Product Information: www.camberpharma.com							b. Contact fo	b. Contact for temperature excursion questions: Name: Soma Raiu							
Address:	800 Centennial A	www.camberpharma	<u>.com</u>		1	Address 2:			Name: Number:		Soma Raju 732-529-042	9			
City:	Piscataway	7e, Suite 1			State:		Zip: 08854		Group E-mail:		somaraju@h		1		
Key Contact:					camberpharma.com		Group E maii.		<u>somaraja e r</u>	CtCrOusu.com	1				
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special re	gulations for product in any	states?			No	1	
Product Therapeutic Classification	n:	Angiotensin converti	ing enzyme (ACE) inhibitor		1				Special returns requirement				No	1	
		- U	5 , (,		1				.,					1	
	ADDITI	IONAL PRODUCT INF	ORMATION			PRODUCT DE	SCRIPTION INFORMATION	d. Store pro	duct (unit of sale) upright?				No	1	
The product is?			Is the Product	Direct-Ship C	Only				Protect product (unit of sa	ile) from liaht?			No	1	
a legend device?		No	Is the Product	Neither		Size:	500 ct	e. Shelf life:		,			24	Months	
if yes, enter class #			Orphan Drug Status			Size:			Initial shelf life at launch (if different):				Months	
a product kit?		No				Strength:	2.5 mg					'			
if yes, list NDCs of			FDA Approval Status			ou ongun				ORDER INFORM	ATION				
component parts						Dosage Form:	Tablet				Maria - 1 - 11 - 1	UDO III			
reverse numbered? co-licensed?		No	Allannana Drasant						Unit of Sale x Bottle		What is the 1 Bottle of 5		unit?		
latex-free?		No Yes	Allergens Present				Round, flat faced,		Box/Carton			j. 1 Box of 10) \/iale\		
preservative-free?		Yes	С	orn		Product Shape	beveled edge		Ampule		(**************************************	g. 1 DOX 01 10	viais)		
correctional institution block?		No					White		Glass		Minimum or	der quantity	?	Yes	
opioid?		No				Product Color:			Tube						
Cannabinoid?		No	Country of Origin	USA		Product Imprir	Debossed with 'E 1' on one side		Vial Liquid Sgl						
If Unit Dose, is item bar coded to	unit dose for					r roduct imprii	and plain on the other side		Vial Liquid Multi				ch package t	rype?	
hospital scanning?			Is this product covered u						Vial Powder Sgl			Each			
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?	Yes				Vial Powder Multi			Inner/Carton	Pack		
									Other: Write In			Case			
			FOR GENERIC DRUG PR	ODUCIS											
										PHARMACY ORDER / BILL UNIT					
L Common Book Bodinson															
				_	/10		If Authorized Generic, other section fields are not applicable	Pag call uni		ARMACY ORDER					
I. Orange Book Rating:	AB	Zostril			710		section fields are not applicable	Rec. sell uni	it to customer?	ARMACY ORDER	Rx billing u		су:		
II. Generic Equivalent to What Bra		Zestril			7.0				it to customer?	ARMACY ORDER		Each	icy:		
			Y CHAIN SECURITY ACT ((DSCSA) INFOR				Rec. sell uni	it to customer?	ARMACY ORDER			icy:		
			Y CHAIN SECURITY ACT ((DSCSA) INFOR					it to customer? g. 1 Vial)		Rx billing u	Each Gram Milliliter	ncy:		
II. Generic Equivalent to What Bra	ind?:	DRUG SUPPLY	Yes	(DSCSA) INFOR					it to customer? g. 1 Vial)	I AND PACKING IN	Rx billing u	Each Gram Milliliter	ncy:		
II. Generic Equivalent to What Bra	ind?:	DRUG SUPPLY		(DSCSA) INFOR	RMATION				it to customer? g. 1 Vial)		Rx billing u	Each Gram Milliliter	acy:		
II. Generic Equivalent to What Bra	ind?:	DRUG SUPPLY	Yes	(DSCSA) INFOR	RMATION				it to customer? g. 1 Vial) ITEN	I AND PACKING IN	Rx billing u	Each Gram Milliliter	Volume	Saleable #	
II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	ınd?:	DRUG SUPPLY	Yes No	(DSCSA) INFOR	RMATION GLN: GCP:	0331722498975	section fields are not applicable	(Write-in, e.g	it to customer? g. 1 Vial)	I AND PACKING IN	Rx billing u	Each Gram Milliliter		Saleable # Pieces	
II. Generic Equivalent to What Bra Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	nd?:	DRUG SUPPLY	Yes No	(DSCSA) INFOR	GLN: GCP: If yes, was or	0331722498975	section fields are not applicable		it to customer? g. 1 Vial) ITEN	I AND PACKING IN	Rx billing under the second se	Each Gram Milliliter	Volume		
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Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HA	ZARD 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:				



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 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?