

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 HAI	IDLING AND STOR	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharmac	euticals, Inc.				Application:	ANDA	a. Temperati	ure - Indicate the USP temp	erature range for t	his product.			
Application Number for NDA/AN			ce):	075	903			- an remperate	Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applicable:														
DUNS:	82-677-4775							_	Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a		ame: Lisino	pril Tablets 20mg 100ct					T	(write in)					
Selling Unit NDC:	31722-178-01		Unit of Use NDC:			UPC: 331	722178013		Notes					
UDI			CVX Code:			MVX Code:								
Description:														
Description.	Oral Solid - tablet	, rouria, rea, opper.	E4 LOWEI. FIAIII						Is this product to be shippe				No	-
Active Ingredient(s):		Lisinopril						+	is this product to be shippe	d to customers on	uly ice:		140	_
Active ingredient(s).							b Contact fo	or temperature excursion qu	estions:					
URL for Additional Product Inform	nation:							- Di Comactio	Name:		Soma Raju			
Address:		Ave (and) 800 Cente	nnial Ave. Suite 1			Address 2:		1	Number:		732-529-042	23		
City:	Piscataway	. , ,			State:		p: 08854		Group E-mail:			@heterous	a.com	
Key Contact:	Customer Service	Э			Email:		camberpharma.com		•					
Phone Number:	1-866-827-3647				Fax:	732-562-8788	<u> </u>	c. Special re	gulations for product in any	states?			No	1
Product Therapeutic Classification	on:								Special returns requiremen	ts for this product?			No	1
· ·					l									_
	ADDITI	IONAL PRODUCT IN	NFORMATION			PRODUCT DESC	CRIPTION INFORMATION	d. Store product (unit of sale) upright?					7	
The product is?			Is the Product	Direct-Ship O	nlv			71	Protect product (unit of s	ale) from light?			No	í
a legend device?		No	Is the Product	Neither	,		100ct	e. Shelf life:	r rotect product (dilit or s	aie) iroin ngiit:			24	Months
if yes, enter class #		INO	Orphan Drug Status	11010101		Size:	10001	e. onen me.	Initial shelf life at launch	(if different):				Months
a product kit?		No	Orphan Drug Otatus				20mg		initial shell life at launen	(ii diricicity.				_ inoning
if yes, list NDCs of		110	FDA Approval Status			Strength:	g			ORDER INFOR	MATION			
component parts			.,,			1	Oral Solid - Tablet							
reverse numbered?		No				Dosage Form:			Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 bottle of 1	00 tablets		
latex-free?		Yes				Duadust Chana	Round		Box/Carton			.g. 1 Box of 1	0 Vials)	
preservative-free?		Yes				Product Shape:			Ampule			-		
correctional institution block?		No				Product Color:	Red		Glass		Minimum o	rder quantity	/?	Yes
opioid?		No				Froduct Color.			Tube					
Cannabinoid?		No	Country of Origin	USA		Product Imprint:	Upper: E4 Lower: Plain		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for					r roudet imprint.			Vial Liquid Multi				ich package	type?
hospital scanning?			Is this product covered to						Vial Powder Sql		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?					Vial Power Multi			Inner/Cartor	n/Pack	
]	Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
									_					
					Au		Authorized Generic, other			HARMACY ORDER	/ 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	асу:	
II. Generic Equivalent to What Bra	and?:	Zestril										Each		
		DRUG GURD	LY CHAIN SECURITY ACT	(DOOOA) INFOR	MATION			(Write-in, e.g	g. 1 Vial)			Gram		
		DRUG SUPP	LY CHAIN SECURITY ACT	(DSCSA) INFOR	MATION							Milliliter		
Does supplier meet DSCSA defini	ition of manufactu	ror?	Yes	_	GLN:	0331722000000			ITE	M AND PACKING I	NEORMATIO	N		
Is product exempt from DSCSA?			No	+	OLIN.	0501722000000						•		
								=		Dim	: /IIC #:	\		
If yes, select exemption:					GCP:			_	Weight Lbs.		ions (US msn		Volume (Cube)	Saleable # Pieces
Other exemption - Write in: Is product repackaged?			No		If you was -	riginal product much	od	Item/Each:	-	Depth	Width	Height	<u> </u>	
Is product repackaged? Is product sold by manufacturer's	e avelueiva dietrib	utor?	No		If yes, was of direct from n	riginal product purchas	eu	item/Each:	0.1		1.625	3	0	1
Has FDA granted waiver/exception			No	_		or r ce manufacturer for rep	nackaged product	Box/Carton/i	Rundle/					
If yes, attach documentation from		- Counci:	140		r rovide sour	ce manuracturer for rep	backageu product	Inner Pack:	Dullule/				0	
you, attaon accumentation no								Case:						
		GT	IN AND HIBCC PRODUCT I	NFORMATION				I Gussi	2.4	10.25	7.25	4.5		24
								Pallet:					_	
Saleable Unit of Measure	5	Saleable Quantity	HIBCC		GTI	N-14	Unit of Use GTIN-14						0	
X Item/Each		1				31722178013								
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESAL	ER USE ONL	LY:
X Case		24			103	31722178010								
Pallet	_							Regular Cos			Vendor #:			
								Invoice Cost	(WAC) (\$)	\$7.50	Whsl. Code			
								11			Fineline Co	de:		
								As of date:						
								11						
μ														
			Attach copy of SAFETY D	ATA SHEET (SD	S) or non haza		ERT, LABEL AND PHOTO OF	PRODUCT PACK						
*Please provide any additional inf	formation on page	2.				See new p. 3 for Des	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?	No No	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 fo	r Designated Drop Ship 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:	Fax Number: Fax Number: Phone No.: Site Address:	Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt:				
F	Name: Phone:	Ships regular ground for 3-10 days receipt:				
Expedited Freight Charg	ges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing				
Expedited freight fees billed with each order:		Overnight receipt available:				
Drop Ship service fee billed with each order:		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 only: Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician of Restricted from US territories? (explain in conficulty) Comments:	offices only:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:				
Other Data Infor	rmation Required to Process 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?				
Mis	scellaneous Notes:					
		ADDITIONAL INFORMATION				
		Is product order for scheduled patient procedure? Is product order for restocking purposes?				