

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

						Introduction [*]	Type: Post Launch Change	Э	x Final Version			Date:	6/6/2	2024	
			PRODUCT INFORMAT	ION					SPECIAL HAND	LING AND STOR	AGE REQUIF	REMENTS*			
Company Name: Camber Pharmaceuticals, Inc.					Applica	tion: ANDA	a. Temperatu	a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 203835									Controlled Room		and 25 C (68	3° – 77° F)			
Medical Device Class, if applicable:															
DUNS:	11-856-3719								Other Temperature Range R	equirement					
Proprietary Name (If Applicable) a	nd Established Nar	ne: Losart	tan Potassium Tablets, USP 5	50 mg					(write in)	•					
Selling Unit NDC:	31722-701-90		Unit of Use NDC:		31722-701-90	UPC:	331722701907		Notes						
UDI			CVX Code:			MVX Code:									
Description:	Losartan Potassium	Tablets, USP 50 m	mg						Is this product to be shipped	to customers on i	ce?		No		
Is this product to be shipped to customers on dry ice?									No						
Active Ingredient(s): Losartan potassium, USP															
b. Contact for temperature excursion questions:															
URL for Additional Product Inform								Name: Soma Ra							
Address:		entennial Ave, Suite 1				Address 2:						732-529-0423			
City:	Piscataway				State: Email:	NJ	Zip: 08854		Group E-mail:		somaraju@h	neterousa.com	<u>n</u>		
Key Contact:	Customer Service 1-866-827-3647				Fax:	732-562-8788	@camberpharma.com						N1-		
Phone Number:		Angiotensin II receptor blocker (ARB)			гах.	132-302-0100		c. Special reg	c. Special regulations for product in any states?				No		
Product Therapeutic Classification	n:	Angiotensin ii recep	ploi blocker (ARB)						Special returns requirements	s for this product?			No		
	ADDITIO	NAL PRODUCT INI	EORMATION			PPODUCT	DESCRIPTION INFORMATION	d Store prod	uct (unit of sale) upright?				No		
	ADDITIO	VALIRODOCTIN		D: . 01: 6		TRODUCTI	BESCHI HON IN ORMATION	u. Store prou	· · · · -						
The product is?	Г		Is the Product	Direct-Ship (Unit of Use	Uniy		90 ct	e. Shelf life:	Protect product (unit of sal	le) from light?			No		
a legend device?		No	Is the Product	Unit of Use		Size:	90 ct	e. Shelf life:	Initial shelf life at launch (if	different):			24	Months Months	
if yes, enter class # a product kit?		No	Orphan Drug Status				50 mg		illitiai Sileli ille at iaulicii (il	unierent).				WOILLIS	
if yes, list NDCs of		140	FDA Approval Status			Strength:	30 mg			ORDER INFORM	IATION				
component parts			. Ditrippioral olatao				Film coated tablet				-				
reverse numbered?		No				Dosage For	m:		Unit of Sale		What is the	NDC selling	unit?		
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 90) Tablets			
latex-free?		Yes	Lact	nsa		Product Sha	Oval		Box/Carton						
preservative-free?		Yes	Luci			1 Todact one			Ampule						
correctional institution block?		No				Product Col	White to off-white		Glass		Minimum o	rder quantity	y?	Yes	
opioid?		No	0				Debossed with 'I' on one side an		Tube						
Cannabinoid?		No	Country of Origin	India		Product Imp	orint: '6' on the other side with scorelin		Vial Liquid Sgl		W.V b			····	
If Unit Dose, is item bar coded to u hospital scanning?	init dose for		Is this product covered ur	odor the					Vial Liquid Multi Vial Powder Sgl		If Yes, how	Each	icn package	type?	
If Unit Dose, indicate NDC here:			Trade Agreements Act (T		No				Vial Powder Multi			Inner/Cartor	/Pack		
ii onit bose, indicate NBC fiere.	l.		Trade rigidements rici (1	701).	140				Other: Write In			Case	// ack		
			FOR GENERIC DRUG PRO	DUCTS					Culon Trino III			ouoo			
			TOR GENERIO BROOT RO	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,											
					Aut	horized Generic	*If Authorized Generic, other		PHA	RMACY ORDER	/ BILL UNIT				
I. Orange Book Rating:							section fields are not applicable	e Rec. sell unit					armacy.		
II. Generic Equivalent to What Bra	ΔR								to customer?		Ry hilling u	nit to nharm	Rx billing unit to pharmacy:		
II. Generic Equivalent to What Brand?:							occion noido dio noi applicabi		to customer?		Rx billing u				
conono Equitationi to Tinat Dia	AB and?:	Cozaar					coston notae are not approach				Rx billing u	Each			
and Salaria Equivalent to That Salaria			Y CHAIN SECURITY ACT (D	OSCSA) INFOR	RMATION		costion notes are not applicable	(Write-in, e.g.			Rx billing u				
	nd?:	DRUG SUPPL		OSCSA) INFOR			occion nota di Oriot apprication		1 Vial)			Each Gram Milliliter			
Does supplier meet DSCSA defini	nd?:	DRUG SUPPL	Yes	OSCSA) INFOR	RMATION GLN:	0331722498975	occion inside di Oriet application		1 Vial)	AND PACKING IN		Each Gram Milliliter			
	nd?:	DRUG SUPPL		DSCSA) INFOR	GLN:	0331722498975	от при		1 Vial)		FORMATION	Each Gram Milliliter			
Does supplier meet DSCSA defini	nd?:	DRUG SUPPL	Yes	DSCSA) INFOR		0331722498975	от подости подости подринали		1 Vial)			Each Gram Milliliter	Volume	Saleable #	
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	nd?:	DRUG SUPPL	Yes No	DSCSA) INFOR	GLN: GCP:			(Write-in, e.g.	1 Vial)		FORMATION	Each Gram Milliliter	Volume (Cube)	Saleable # Pieces	
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	nd?:	DRUG SUPPL	Yes No	OSCSA) INFOR	GLN: GCP: If yes, was or	ginal product	под пот под пот		1 Vial)	Dimensi	NFORMATION	Each Gram Milliliter			
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	nd?: tion of manufacture	DRUG SUPPL	Yes No No Yes	DSCSA) INFOR	GLN: GCP: If yes, was or purchased di	ginal product		(Write-in, e.g.	1 Vial) Weight Lbs. 0.05	Dimensi Depth	IFORMATION ons (US msm Width	Each Gram Milliliter Ints.) Height	(Cube)	Pieces	
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception	nd?: tion of manufacture s exclusive distribut	DRUG SUPPL	Yes No	OSCSA) INFOR	GLN: GCP: If yes, was or purchased di	ginal product	or repackaged product	(Write-in, e.g.	1 Vial) Weight Lbs. 0.05	Dimensi Depth	IFORMATION ons (US msm Width	Each Gram Milliliter Ints.) Height	(Cube)	Pieces	
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Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from	nd?: tion of manufacture s exclusive distribut n/exemption for pro	DRUG SUPPL'er?	Yes No No Yes No		GLN: GCP: If yes, was or purchased di Provide source	ginal product rect from mfr? se manufacturer f		Item/Each: Box/Carton/B Inner Pack: Case:	Weight Lbs. 0.05 Sundle/ 1.8	Dimension Depth 1.5	ons (US msm Width 1.5	Each Gram Milliliter	(Cube) 6.75 280	Pieces 1 24	
Does supplier meet DSCSA definits product exempt from DSCSA? If yes, select exemption. Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from	nd?: tion of manufacture s exclusive distribut n/exemption for pro	DRUG SUPPL or? oor? oduct? GTIN leable Quantity	Yes No No Yes No No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or purchased di Provide source	iginal product ect from mfr? ee manufacturer f	or repackaged product Unit of Use GTIN-14	Item/Each: Box/Carton/B Inner Pack: Case:	Weight Lbs. 0.05	Dimension Depth 1.5	ons (US msm Width 1.5	Each Gram Milliliter	(Cube) 6.75	Pieces 1 24	
Does supplier meet DSCSA definits product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure x	nd?: tion of manufacture s exclusive distribut n/exemption for pro	DRUG SUPPL or? oor? oduct? GTIN leable Quantity	Yes No No Yes No No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or purchased di Provide source GTIN 0033	iginal product ect from mfr? ee manufacturer f	or repackaged product Unit of Use GTIN-14	Item/Each: Box/Carton/B Inner Pack: Case: Pallet:	Weight Lbs. 0.05 undle/ 1.8 COST INFORMATION	Dimension Depth 1.5	ons (US msm Width 1.5	Each Gram Milliliter	(Cube) 6.75 280	Pieces 1 24	
Does supplier meet DSCSA defini Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X tem/Each Box/Carton/Bundle/Inner Pack	nd?: tion of manufacture s exclusive distribut n/exemption for pro	DRUG SUPPL or? cor? bduct? GTIN leable Quantity 1	Yes No No Yes No No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or purchased di Provide source GTIN 0033	ginal product ect from mfr? ee manufacturer f	or repackaged product Unit of Use GTIN-14	ttem/Each: Box/Carton/B Inner Pack: Case: Pallet:	Weight Lbs. 0.05 Fundle/ 1.8 COST INFORMATION	Dimension Depth 1.5	Vendor #:	Each Gram Milliliter No. Height 3	(Cube) 6.75 280	Pieces 1 24	
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Does supplier meet DSCSA definits product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X term/Each Bow/Carton/Bundie/Inner Pack X Case	nd?: tion of manufacture s exclusive distribut n/exemption for pro	DRUG SUPPL or? cor? bduct? GTIN leable Quantity 1	Yes No No Yes No No AND HIBCC PRODUCT IN		GLN: GCP: If yes, was or purchased di Provide source GTIN 0033	ginal product ect from mfr? ee manufacturer f	or repackaged product Unit of Use GTIN-14	Item/Each: Box/Carton/B Inner Pack: Case: Pallet: Regular Cost Invoice Cost	Weight Lbs. 0.05 1.8 COST INFORMATION (WAC) (\$)	Dimension Depth 1.5	ons (US msm Width 1.5 7 Vendor #: Whsl. Code	Each Gram Milliliter Note: A second of the	(Cube) 6.75 280	Pieces 1 24	
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Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

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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 e. Inhalation Hazard?	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS
a. UN/Identification Number 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:
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments Registry: No
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone: Comments
Is the Product 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:	RETURN INSTRUCTIONS Contact tel. # if product received damaged: 1-866-827-3647
Schedule No. Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION:	Is product returnable for credit: URL/Link to returns policy: Yes
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	contact - customerservice@camberpharma.com
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?
Comments:	ii 30, wiiiori states: Ottier requirements: Ottiinients:
MISCELLANE	OUS 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 Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI b. Autofax Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time:
c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number:	Shipping lead time of PO: Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #: Name: Phone:	
Expedited Freight Charges 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, 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: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information 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?
Miscellaneous Notes:	
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? Is product order for restocking purposes?