

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

Version 2021						Introduction Type:	Post Launch Change		x Final Version			Date:	6/23	3/2024
			PRODUCT INFORMA	TION					SPECIAL HAI	IDLING AND STOR	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): 074737							Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)							
Medical Device Class, if applical								İ	· -					
DUNS:	11-856-3719							*	Other Temperature Range	Requirement	Excursions	permitted to 1	5°C to 30°C	(59° to 86°F)
Proprietary Name (If Applicable) a	ind Established Na	me: Capto	pril Tablets, USP 50 mg					[(write in)					
Selling Unit NDC:	31722-143-01		Unit of Use NDC:				722143011		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Captopril Tablets,	USP 50 mg						Ī	Is this product to be shippe	d to customers on i	ce?		No	1
									Is this product to be shippe				No	1
Active Ingredient(s):		Captopril, USP												
								b. Contact fo	r temperature excursion qu	estions:				
URL for Additional Product Inform		www.camberpharm	na.com						Name:		Soma Raju			
Address:	800 Centennial Av	ve, Suite 1			State:	Address 2: NJ Zip	00054		Number:		732-529-042			
City: Key Contact:	Piscataway Customer Service				Email:	customerservice@cam	bernharma.com	Group E-mail: somaraju@heterousa.com						
Phone Number:	1-866-827-3647	·			Fax:	732-562-8788	<u>Бегрианна.соні</u>	c Special rea	gulations for product in any	states?			No	1
Product Therapeutic Classification		Angiotensin I-conv	erting enzyme (ACE) inhibito	r	-			or opecial to	Special returns requiremen				No	1
Troduct Therapeatic Glassification		/ wighterion i conv	orang oneymo (102) minono	•					opeoiai returns requiremen	to for tillo product:			140	J
	ADDITI	ONAL PRODUCT IN	NFORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store prod	luct (unit of sale) upright?				No	1
The meduation			Is the Product	Direct-Ship C	nly					ala) fram limbt?			No	i
The product is? a legend device?		No	Is the Product	Neither	Jilly .		100 ct	e. Shelf life:	Protect product (unit of s	ale) from light?			24	Months
if yes, enter class #		INO	Orphan Drug Status	TACILICI		Size:	100 Ct	e. Sileli ille.	Initial shelf life at launch	(if different):			24	Months
a product kit?		No	o.p.ia D. ag otatao				50 mg		initial onon mo at launon	(a				,
if yes, list NDCs of			FDA Approval Status			Strength:	Ü			ORDER INFORM	MATION			
component parts						Dosage Form:	Uncoated tablet							
reverse numbered?		No				Dosage i oi iii.			Unit of Sale			NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 1			
latex-free?		Yes	Dairy, Lactose, Caseir		ol, Animal	Product Shape:	Capsule		Box/Carton		(Write-in, e.	.g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	Pro	ducts		•	Mile to a first tra		Ampule					V
correctional institution block? opioid?		No No				Product Color:	White to off white		Glass Tube		Wilnimum o	rder quantity	11	Yes
Cannabinoid?		No	Country of Origin	USA			Debossed with 'C' before the bisect and		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for	140	Country of Origin	00/1		Product Imprint:	'34' after the bisect on one side and plain on other side		Vial Liquid Multi		If Yes, how	many of whi	ich package	type?
hospital scanning?	4000 101		Is this product covered (under the			un oarer side		Vial Powder Sql			Each	pg-	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?	Yes				Vial Powder Mult			Inner/Cartor	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
					Au		uthorized Generic, other			HARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB					sect	ion fields are not applicable	Rec. sell unit	t to customer?	_	Rx billing u	nit to pharm	асу:	
II. Generic Equivalent to What Bra	nd?:	Capoten										Each		
		DRUG GURD	LV OUAIN OF OUR TV ACT	(DOOGA) INICO	MATION			(Write-in, e.g	. 1 Vial)			Gram		
		DRUG SUPP	LY CHAIN SECURITY ACT	(DSCSA) INFOR	RMATION							Milliliter		
Does supplier meet DSCSA defini	tion of manufactur	or?	Yes	_	GLN:	0331722498975			ITE	M AND PACKING II	NEORMATIO	N		
Is product exempt from DSCSA?	tion of manufactur		No	_	OLIV.	0001122400010						••		
If ves. select exemption:					GCP:			1		Dimonei	ions (US msn	nte \	Volume	Saleable #
Other exemption - Write in:					GCP:			1	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes was o	riginal product purchase	vd	Item/Each:						
Is product sold by manufacturer's	exclusive distribu	itor?	Yes		direct from n			inomy Euroni	0.1	1.75	1.75	3.5	10.72	1
Has FDA granted waiver/exception			No			ce manufacturer for repa	ackaged product	Box/Carton/E	Bundle/					
If yes, attach documentation from	m FDA.							Inner Pack:						
								Case:	2.65	11.25	7.5	4.25	358.59	24
		GT	IN AND HIBCC PRODUCT I	NFORMATION					2.00	11.20	7.0		000.00	
Onlankin Hait of Manager	_							Pallet:						
Saleable Unit of Measure	S	aleable Quantity	HIBCC			N-14	Unit of Use GTIN-14							
X Item/Each Box/Carton/Bundle/Inner Pack		1			003	31722143011			COST INFORMATION			WHOLESAL	ER USE ONL	γ.
X Case		24			103	31722143018			COST IN ORMATION			WIIOLLOAL	LK USL UNI	.1.
Pallet					100			Regular Cost	t		Vendor #:			
								Invoice Cost		\$148.80	Whsl. Code	#:		
								11			Fineline Co			
								As of date:	9/20/2021]			
μ								Ц			<u> </u>			
		_	Attach copy of SAFETY D.	ATA SHEET (SE	S) or non haza		RT, LABEL AND PHOTO OF F	PRODUCT PACK						
*Please provide any additional inf	ormation on nage	,					gnated Drop Ship Only.		Signature:					



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD 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 Corrosive Oxidizer 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:						



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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?