

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

Version 2024						Introduction	Type: New Item		x Fin	al Version			Date:	10/22	2/2025
			PRODUCT INFORMA	TION					:	SPECIAL HAN	IDLING AND STOR	AGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA							a. Temperat	a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/ANDA/BLA; PMA/510(k): 214467 NDA 505(b) Type: NOT APPLICABLE Temperature Range Cold – between 2 and 8 C (36° – 46° F)															
Medical Device Class, if applical															
DUNS:	11-856-3719									rature Range F	Requirement	Patients may stor	e enalapril maleate °F) for up to 60 days	oral solution at room	n temperature (20°
Proprietary Name (If Applicable) a	and Established Na 31722-020-15	ame:	Enalapril Maleate Oral Solution 1 Unit of Use NDC:		31722-020-15				(write in	1)		heat.			
Selling Unit NDC: UDI	31722-020-15		CVX Code:		31722-020-15	UPC: MVX Code:	331722020152		Notes			methods (e.g. 0	to customers us Cold Packs, Cold	ng proper cold si Storage Trucks)	torage snipping
-						III VX Gode.									1
								d to customers on it d to customers on d			No No				
Active Ingredient(s): Enalapril maleate, USP								is this produc	or to be shipped	u to customers on c	ily ice:		NO	J	
b. Contact for temperature excursion questions:															
URL for Additional Product Inforn		www.camberp	pharma.com						Name:			Soma Raju			
Address:		300 Centennial Ave, Suite 1			Ctata	Address 2: ate: NJ Zip: 08854			Number:				732-529-0423		
City: Key Contact:	Piscataway  Customer Service	<u> </u>			State: Email:	-	@camberpharma.com		Group E-mail: somaraju@heterousa.com						
Phone Number:	1-866-827-3647	9			Fax:	732-562-8788	<u>@camberpriama.com</u>	c. Special re	c. Special regulations for product in any states?						1
Product Therapeutic Classificatio		Angiotensin o	converting enzyme (ACE) inhibitor								ts for this product?			No No	
l round morapound diagonicans		g	g, (,						opoolal rotal	no roquironioni	to for the product.				1
	ADDITI	IONAL PRODU	ICT INFORMATION			PRODUCT	DESCRIPTION INFORMATION	d. Store pro	duct (unit of sa	le) upright?				No	1
The product is?			Is the Product	Direct-Ship	Only				Protect prod	luct (unit of sa	ale) from light?			No	ĺ
a legend device?		No	Is the Product	Unit of Use	-	Size:	150 mL	e. Shelf life:		•	, ,			24	Months
if yes, enter class #			Orphan Drug Status			Size.			Initial shelf I	ife at launch (	if different):				Months
a product kit?		No				Strength:	1 mg/mL				ORDER INFORM	MATION			
if yes, list NDCs of component parts			FDA Approval Status				Clear, oral solution				ORDER INFORM	IATION			
reverse numbered?		No				Dosage For	m:		Unit of Sale			What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bot	tle		1 Bottle of 1	50 mL Oral S	olution	
latex-free?		Yes				Product Sha	N/A			k/Carton		(Write-in, e.	.g. 1 Box of 1	) Vials)	
preservative-free?		No				1.00000.0.0				pule				_	
correctional institution block? opioid?		No No				Product Col	or: Colorless		Gla Tub			Minimum o	rder quantity	?	Yes
Cannabinoid?		No	Country of Origin	India			N/A			l Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for		Country or Origin			Product Imp	orint:			l Liquid Multi		If Yes, how	many of whi	ch package t	type?
hospital scanning?			Is this product covered							l Powder Sgl			Each		•
If Unit Dose, indicate NDC here:			Trade Agreements Act (	TAA)?	No					l Powder Multi			Inner/Carton	/Pack	
									Oth	er: Write In			Case		
			FOR GENERIC DRUG PF	ODUCTS											
					Au	thorized Generic	*If Authorized Generic, other			PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						section fields are not applicab	le Rec. sell un	it to customer?	,		Rx hilling u	nit to pharma	acv.	
	Seneric Equivalent to What Brand?: Epaned				1100.00	Each					,.				
-								(Write-in, e.	g. 1 Vial)		_		Gram		
		DRUG S	SUPPLY CHAIN SECURITY ACT	(DSCSA) INFO	RMATION			HCPCS J-C	ode:				Milliliter		
Does supplier meet DSCSA defini	tion of manufactu	ror?	Yes		GLN:	0843368117603				ITEN	AND PACKING I	NEORMATIO	N		
Is product exempt from DSCSA?			No		02	0010000111000							•		
If yes, select exemption:					GCP:						Dimensi	ons (US msr	nts.)	Volume	Saleable #
Other exemption - Write in:									'	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			iginal product pur	chased	Item/Each:		0.5	2.4	2.4	5.2	29.95	1
Is product sold by manufacturer's			Yes	_	direct from m					0.0	2.7		J.2	20.00	'
Has FDA granted waiver/exception If yes, attach documentation from		roduct?	No		Provide sour	ce manufacturer f	or repackaged product	Box/Carton	Bundle/						
ii yes, attacii documentation iroi	III FDA.							Case:							
			GTIN AND HIBCC PRODUCT	NFORMATION						6.4	10.1	7.9	6.4	510.66	12
								Pallet:							
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GTI	N-14	Unit of Use GTIN-14								
	N	Quantity			002	31722020152	00331722020152								
x Item/Each Box/Carton/Bundle/Inner Pack	N	1			003	31122020132	00331722020132		COST_IN	FORMATION			WHOLESAL	R USE ONL	Y:
X Case	N	12			203	31722020156									
Pallet								Regular Co				Vendor #:			
								Invoice Cos	t (WAC) (\$)		\$269.36	Whsl. Code			
								A	404	1/2024		Fineline Co	de:		
								As of date:	12/	1/2024		1			
•			Attach copy of SAFETY D	ATA SHEET (SI	DS) or non haza	rd letter, PACKAGE	INSERT, LABEL AND PHOTO	OF PRODUCT PACE	KAGING and BA	RCODE.		•			
ī	ormation on page	_		,	-		Designated Drop Ship Only								



### **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 HAZARD CLASSIFICATION and TRANSPORTATION							
Is this product (check all that apply): a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	SDS Hazard Classification						
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?  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?  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	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)	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:  NO  DEA #: NCPDP#: NCPDP#: NPI #:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments  Registry:  No						
3F#	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	Comments						
Is the Product  Controlled Substance?  Controlled Substance Code  Controlled by State(s)?  No  Listed Chemical (List I or II)  No	RETURN INSTRUCTIONS						
ARCOS Reportable?  Schedule No.  If yes, indicate which: Is it a scheduled listed chemical product?:  No  CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged:  Is product returnable for credit:  URL/Link to returns policy:  1-866-827-3647  Yes  URL/Link to returns policy:						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes	contact - customerservice@camberpharma.com						
Restricted to retail pharmacy only:  No	Special regulations or returns requirements for this						
Restricted to hospital, clinics, and physician offices only:  No Restricted from US territories? (explain in comments)  No	product in certain states?  If so, which states? Other requirements? Comments?						
Comments:							
	EOUS NOTES and/or Image of Product Barcode:						
Patients may store Enalapril Maleate Oral Solution at room temperature (20° to 25°C/ 68° to 77°F). If sto	red at room temperature, discard after 60 days.						



## **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 Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier
a. EDI		Cut off time:
b. Autofax	Fax Number:	
c. Fax	Fax Number:	Shipping lead time of PO: Hours Days
d. Phone only	Phone No.:	
e. Supplier Web Site only	Site Address:	Ships same day for next day receipt:
Minimum Order Quantity:		Ships for second day receipt:
Supplier's Customer Service Number:		Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #:	Name:	
	Phone:	
Expedited Freight Cha	arges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each orde	er:	Overnight receipt available:
Drop Ship service fee billed with each orde	er:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed:		Days of week overnight is available: Monday
Comments:		Tuesday
		Wednesday
		Thursday
		Friday
		Priority Overnight receipt available:
Cla	ss of Trade Restriction:	PO Receipt Cut off time:
Restricted to retail pharmacy only:	harmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:  PO Receipt Cut off time:
Restricted to retail priarriacy only.  Restricted to hospital, clinics, and physiciar	n offices only:	Phone: Phone #:
Restricted from US territories? (explain in c	-	Order receipt method: Fax: Fax #:
Comments:	oninions)	EDI:
		Overnight Fees apply:
		Other fees apply:
Other Data Inf	formation Required to Process PO:	Return Instructions
Patient Procedure Date:	1	Contact # if product is received damaged:
Physician Name:		Is product returnable for credit:
Physician/Clinic Phone #		URL/Link to returns policy:
Physician State License #		ONE Ellik to retains policy.
Physician/Clinic DEA #:		Special regulations or returns requirements for this product in certain states?
Physician/Clinic Specialty:		If so, which states? Other requirements? Comments?
	Miscellaneous Notes:	·
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure?
		Is product order for restocking purposes?