

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

Version 2024					Introduction	ion Type:	New Item	x	Final Version			Date:	3/11/	/2025
			PRODUCT INFORMAT	ION					SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Camber Pharmaceuticals, Inc.				Арр	Application: ANDA a. Temperature – Indic			dicate the USP tempe	ate the USP temperature range for this product.				
Application Number for NDA/ANI	DA/BLA; PMA/510(k): 2144	67		NDA 505(b) T	ype:	NOT APPLICABLE		perature Range	Cold - between 2		– 46° F)		
Medical Device Class, if applicab														
	11-856-3719							Othe	r Temperature Range F	Requirement	Patients may store	e enalapril maleate o °F) for up to 60 days	ral solution at room	m temperature (20°
Proprietary Name (If Applicable) and		ne: Enala	april Maleate Oral Solution 1 mg						(write in)		heat.			-
	31722-020-15		Unit of Use NDC:	31722-02			020152	Note	s		*To be shipped methods (e.g. (to customers usi Cold Packs, Cold	ig proper cold st Storage Trucks)	torage shipping
UDI			CVX Code:		MVX Code	le:		1					storage maono)	
Description:	Enalapril Maleate C	Iral Solution 1 mg/	/mL						s product to be shipped				No]
								Is thi	s product to be shipped	d to customers on c	Iry ice?		No]
Active Ingredient(s):		Enalapril maleate,	USP											
UDL for Additional Draduat Inform		www.camberpharn						b. Contact for temp Nam	erature excursion que	estions:	Soma Raju			
URL for Additional Product Inform Address:	800 Centennial Ave		na.com		Address 2:			Num			732-529-042	23		
	Piscataway	, Suite i		Stat		Zip:	08854		ip E-mail:			neterousa.con	1	
	Customer Service			Ema		vice@camber			.p =				-	
Phone Number:	1-866-827-3647			Fax				c. Special regulatio	ons for product in any	states?		1	No	1
Product Therapeutic Classification	n:	Angiotensin conve	erting enzyme (ACE) inhibitor					Spec	ial returns requirement	s for this product?			No	1
		-							·					1
	ADDITIO	NAL PRODUCT I	NFORMATION		PRODU	ICT DESCRIP	TION INFORMATION	d. Store product (u	nit of sale) upright?			1	No	1
The product is?			Is the Product	Direct-Ship Only	1			1	ect product (unit of sa	le) from light?			No	1
a legend device?	[No	Is the Product	Unit of Use	0	1	50 mL	e. Shelf life:		, .			24	Months
if yes, enter class #			Orphan Drug Status		Size:				al shelf life at launch (if different):				Months
a product kit?		No			Strength	. 1	mg/mL							4
if yes, list NDCs of			FDA Approval Status		Strength					ORDER INFORM	IATION			
component parts					Dosage I	Form:	Clear, oral solution							
reverse numbered?		No							of Sale		-	NDC selling		
co-licensed?		No	Allergens Present				1/4	X	Bottle			50 mL Oral S		
latex-free? preservative-free?		Yes No			Product	Shape:	I/A		Box/Carton Ampule		(vvrite-in, e.	g. 1 Box of 10	viais)	
correctional institution block?		No				C	Colorless		Glass		Minimum o	rder quantity	,	Yes
opioid?		No			Product	Color:	0001633		Tube		Willing of the second s	der quantity		163
Cannabinoid?		No	Country of Origin	India			I/A		Vial Liquid Sql					
If Unit Dose, is item bar coded to u)g		Product	Imprint:			Vial Liquid Multi		If Yes, how	many of whi	ch package (type?
hospital scanning?			Is this product covered un						Vial Powder Sgl		12	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (TA	AA)? No					Vial Powder Multi			Inner/Carton	Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PRO	DUCTS										
					1				DU					
					Authorized Generi		prized Generic, other fields are not applicable	PHARMACY ORDER						
	AB					Section	neius are not applicable	Rec. sell unit to cus	stomer?		Rx billing u	nit to pharma	cy:	
II. Generic Equivalent to What Bran	nd?:	Epaned										Each		
			PLY CHAIN SECURITY ACT (D					(Write-in, e.g. 1 Vial HCPCS J-Code:	l)			Gram Milliliter		
		DR00 S0FF		SCSA) IN ORMATION				HCFC3 J-Code.		1		winniter		
Does supplier meet DSCSA definit	tion of manufacture	r?	Yes	GLN:	08433681176	603		1	ITEN	AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No	-										
If yes, select exemption:			INO											Saleable #
ii yes, select exemption.				CCP:						Dimonsi		ute)	Volumo	Pieces
Other exemption - Write in:				GCP:]	Weight Lbs.		ons (US msn	-	Volume (Cube)	
Other exemption - Write in: Is product repackaged?			No		as original product	purchased		Item/Each:		Depth	ons (US msn Width	Height	(Cube)	
Is product repackaged?	exclusive distribut	אר?			as original product	purchased		Item/Each:	Weight Lbs.		ons (US msn	-		1
			No	lf yes, w direct fro		-	aged product	Item/Each: Box/Carton/Bundle	0.5	Depth	ons (US msn Width	Height	(Cube)	1
Is product repackaged? Is product sold by manufacturer's	n/exemption for pro		No Yes	lf yes, w direct fro	om mfr?	-	aged product		0.5	Depth	ons (US msn Width	Height	(Cube)	1
Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior	n/exemption for pro	duct?	No Yes No	If yes, w direct fro Provide	om mfr?	-	aged product	Box/Carton/Bundle	0.5	Depth 2.4	ons (US msn Width 2.4	Height 5.2	(Cube) 29.95	
Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior	n/exemption for pro	duct?	No Yes	If yes, w direct fro Provide	om mfr?	-	aged product	Box/Carton/Bundle Inner Pack: Case:	0.5	Depth	ons (US msn Width	Height	(Cube)	1
Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from	n/exemption for pro n FDA.	oduct?	No Yes No TIN AND HIBCC PRODUCT IN	If yes, w direct fro Provide	om mfr? source manufacture	-		Box/Carton/Bundle Inner Pack:	0.5	Depth 2.4	ons (US msn Width 2.4	Height 5.2	(Cube) 29.95	
Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior	n/exemption for pro n FDA. RFID tag(Y/N)	duct? GT Saleable	No Yes No	If yes, w direct fro Provide	om mfr?	-	aged product Unit of Use GTIN-14	Box/Carton/Bundle Inner Pack: Case:	0.5	Depth 2.4	ons (US msn Width 2.4	Height 5.2	(Cube) 29.95	
Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exceptior If yes, attach documentation from Saleable Unit of Measure	n/exemption for pro n FDA. RFID tag(Y/N)	duct? GT Saleable Quantity	No Yes No TIN AND HIBCC PRODUCT IN	If yes, w direct fro Provide	GTIN-14	er for repack	Unit of Use GTIN-14	Box/Carton/Bundle Inner Pack: Case:	0.5	Depth 2.4	ons (US msn Width 2.4	Height 5.2	(Cube) 29.95	
Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure	n/exemption for pro n FDA. RFID tag(Y/N)	duct? GT Saleable	No Yes No TIN AND HIBCC PRODUCT IN	If yes, w direct fro Provide	om mfr? source manufacture	er for repack		Box/Carton/Bundle Inner Pack: Case: Pallet:	0.5 / 6.4	Depth 2.4	ons (US msn Width 2.4 7.9	Height 5.2 6.4	(Cube) 29.95 510.66	12
Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure	n/exemption for pro n FDA. RFID tag(Y/N)	duct? GT Saleable Quantity 1	No Yes No TIN AND HIBCC PRODUCT IN	If yes, w direct fro Provide	om mfr? source manufacture GTIN-14 00331722020152	er for repack	Unit of Use GTIN-14	Box/Carton/Bundle Inner Pack: Case: Pallet:	0.5	Depth 2.4	ons (US msn Width 2.4 7.9	Height 5.2	(Cube) 29.95 510.66	12
Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Cartor/Bundle/Inner Pack X Case	n/exemption for pro n FDA. RFID tag(Y/N)	duct? GT Saleable Quantity	No Yes No TIN AND HIBCC PRODUCT IN	If yes, w direct fro Provide	GTIN-14	er for repack	Unit of Use GTIN-14	Box/Carton/Bundle Inner Pack: Case: Pallet:	0.5 / 6.4	Depth 2.4	Vidth 2.4 7.9	Height 5.2 6.4	(Cube) 29.95 510.66	12
Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure	n/exemption for pro n FDA. RFID tag(Y/N)	duct? GT Saleable Quantity 1	No Yes No TIN AND HIBCC PRODUCT IN	If yes, w direct fro Provide	om mfr? source manufacture GTIN-14 00331722020152	er for repack	Unit of Use GTIN-14	Box/Carton/Bundle Inner Pack: Case: Pallet:	0.5 6.4 COST INFORMATION	Depth 2.4 10.1	Vidth 2.4 7.9 Vendor #:	Height 5.2 6.4 WHOLESALE	(Cube) 29.95 510.66	12
Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Cartor/Bundle/Inner Pack X Case	n/exemption for pro n FDA. RFID tag(Y/N)	duct? GT Saleable Quantity 1	No Yes No TIN AND HIBCC PRODUCT IN	If yes, w direct fro Provide	om mfr? source manufacture GTIN-14 00331722020152	er for repack	Unit of Use GTIN-14	Box/Carton/Bundle Inner Pack: Case: Pallet: Regular Cost	0.5 / 6.4 COST INFORMATION	Depth 2.4 10.1	Vidth 2.4 7.9	Height 5.2 6.4 WHOLESALE	(Cube) 29.95 510.66	12
Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Cartor/Bundle/Inner Pack X Case	n/exemption for pro n FDA. RFID tag(Y/N)	duct? GT Saleable Quantity 1	No Yes No TIN AND HIBCC PRODUCT IN	If yes, w direct fro Provide	om mfr? source manufacture GTIN-14 00331722020152	er for repack	Unit of Use GTIN-14	Box/Carton/Bundle Inner Pack: Case: Pallet: Regular Cost	0.5 6.4 COST INFORMATION	Depth 2.4 10.1	Vendor #:	Height 5.2 6.4 WHOLESALE	(Cube) 29.95 510.66	12
Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Cartor/Bundle/Inner Pack X Case	n/exemption for pro n FDA. RFID tag(Y/N)	duct? GT Saleable Quantity 1	No Yes No TIN AND HIBCC PRODUCT IN	If yes, w direct fro Provide	om mfr? source manufacture GTIN-14 00331722020152	er for repack	Unit of Use GTIN-14	Box/Carton/Bundle Inner Pack: Case: Pallet: Regular Cost Invoice Cost (WAC)	0.5 / 6.4 COST INFORMATION	Depth 2.4 10.1	Vendor #:	Height 5.2 6.4 WHOLESALE	(Cube) 29.95 510.66	12
Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Cartor/Bundle/Inner Pack X Case	n/exemption for pro n FDA. RFID tag(Y/N)	duct? GT Saleable Quantity 1	No Yes No TIN AND HIBCC PRODUCT IN HIBCC	FORMATION	GTIN-14 00331722020152 20331722020156	er for repack:	Unit of Use GTIN-14 00331722020152	Box/Carton/Bundle Inner Pack: Case: Pallet: Regular Cost Invoice Cost (WAC) As of date:	0.5 / 6.4 COST INFORMATION (\$) (12/1/2024	Depth 2.4 10.1	Vendor #:	Height 5.2 6.4 WHOLESALE	(Cube) 29.95 510.66	12
Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Cartor/Bundle/Inner Pack X Case Pallet	Vexemption for pro n FDA.	CT Saleable Quantity 1 12	No Yes No TIN AND HIBCC PRODUCT IN	FORMATION	GTIN-14 00331722020152 20331722020156 hazard letter, PACK/	AGE INSERT,	Unit of Use GTIN-14 00331722020152 LABEL AND PHOTO OF F	Box/Carton/Bundle Inner Pack: Case: Pallet: Regular Cost Invoice Cost (WAC) As of date: PRODUCT PACKAGING	0.5 / 6.4 COST INFORMATION 0 (\$) 12/1/2024 and BARCODE.	Depth 2.4 10.1	Vendor #:	Height 5.2 6.4 WHOLESALE	(Cube) 29.95 510.66	12
Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack X Case	Vexemption for pro n FDA.	CT Saleable Quantity 1 12	No Yes No TIN AND HIBCC PRODUCT IN HIBCC	FORMATION	GTIN-14 00331722020152 20331722020156 hazard letter, PACK/	AGE INSERT,	Unit of Use GTIN-14 00331722020152	Box/Carton/Bundle Inner Pack: Case: Pallet: Regular Cost Invoice Cost (WAC) As of date: PRODUCT PACKAGING	0.5 / 6.4 COST INFORMATION (\$) (12/1/2024	Depth 2.4 10.1	Vendor #:	Height 5.2 6.4 WHOLESALE	(Cube) 29.95 510.66	12

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

	ted Drop Ship Only Products, Please Use Page 3
MATERIAL HA	ZARD CLASSIFICATION and TRANSPORTATION
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? 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 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	x Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No NFPA Storage Level: Image: Contact Hazard Is the product a NIOSH hazardous drug? No If yes, indicate which: No
c. DOT Hazard Class	Hazardous Waste Identification
d. Packing Group e. Inhalation Hazard?	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/dentification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? Website URL:
Is the product restricted for air shipment? If so, indicate restriction: No Passenger Cargo Passenger & Cargo	Med Guide Required No Limited Distribution Requirement Image: 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) Special Permit; DOT-SP Special Pervision (listed in Column 7 of 49 CFR 172.101);	REMS: No REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: DEA #: Provider Name: DEA #: Site Enrollment Number assigned NCPDP#: by Supplier: NPI #:
SP#	Registry: No
ADD'L STORAGE INFORMATION	Registry Program Contact Name: Phone: Comments
Is the Product	RETURN INSTRUCTIONS
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: No Schedule No. Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: 1-866-827-3647 Is product returnable for credit: Yes URL/Link to returns policy: Ves
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	contact - customerservice@camberpharma.com
No resultation: select YEs if sold to retail pharmacy, nospitals, clinics and physician offices res Restricted to retail pharmacy only: No Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No Comments: No	Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?
MISCELLANE	OUS 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 store	ad at room temperature, discard after 60 days.



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

Version 2024	FOR DESIGNATED DROP SHIP PRODUCT ONLY - if r	ot a designated drop ship, do not complete.				
Order Method for Des	signated Drop Ship Product	Standard Order Receipt and Processing				
Purchase orders may be accepted by: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name Phone Expedited Freight Charges o		Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Da Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt: Overnight and Priority Overnight PO Processing	ays			
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:		Days of week overnight is available: Monday				
Comments:	s only:	Days of week overnight is available: Tuesday Tuesday Wednessi Priority Overnight receipt available: Friday PO Receipt Cut off time: PO Receipt Cut off time: Order receipt method: Phone: Fax: EDI: Overnight Fees apply: Policity	/ day			
Other Data Informati	ion 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?				
Miscell	aneous Notes:					
		ADDITIONAL INFORMATION				
		Is product order for scheduled patient procedure? Is product order for restocking purposes?				