

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

Version 2024						Introduction 1	ype: New Item		x Fina	al Version			Date:	5/30/	/2025	
PRODUCT INFORMATION						SPECIAL HANDLING AND STORAGE REQUIREMENTS*										
Company Name:	Camber Pharmace	euticals, Inc.				Applica	tion: ANDA	a. Temperat	a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/AN	IDA/BLA; PMA/510(k): 205	499			NDA 505(b) Type:	NOT APPLICABLE		Temperature		Controlled Room -		and 25 C (68	° – 77° F)		
Medical Device Class, if applical	ble:															
DUNS:	11-856-3719									rature Range I	Requirement					
Proprietary Name (If Applicable) a		me: Olm	nesartan Medoxomil Tablets, US	P 5 mg					(write in	1)						
Selling Unit NDC:	31722-852-30		Unit of Use NDC:		31722-852-30		331722852302		Notes							
UDI			CVX Code:			MVX Code:										
Description:	Olmesartan Medox	comil Tablets, USI	P 5 mg						Is this produc	t to be shipped	d to customers on ic	e?		No		
									Is this produc	t to be shipped	d to customers on d	ry ice?		No		
Active Ingredient(s): Olmesartan medoxomil, USP																
URL for Additional Product Inforn	URL for Additional Product Information: www.camberpharma.com						b. Contact for temperature excursion questions: Name: Soma Raju									
Address:	800 Centennial Av		ma.com			Address 2:			Name: Number:			732-529-042	23			
City:	Piscataway	o, cano i			State:	NJ	Zip: 08854				somaraju@heterousa.com					
Key Contact:	Customer Service				Email:	customerservice(©camberpharma.com							_		
Phone Number:	1-866-827-3647				Fax:	732-562-8788	32-562-8788 c. Spec			roduct in any	states?			No	No	
Product Therapeutic Classificatio	on:	Angiotensin II red	ceptor blocker (ARB)						Special return	ns requirement	ts for this product?			No		
-										-	•				1	
	ADDITIO	DNAL PRODUCT	INFORMATION			PRODUCT	DESCRIPTION INFORMATION	d. Store pro	duct (unit of sa	le) upright?				No		
The product is?			Is the Product	Direct-Ship (Only			- []	Protect prod	uct (unit of sa	ale) from light?			No	1	
a legend device?		No	Is the Product	Unit of Use		Size:	30 ct	e. Shelf life:						24	Months	
if yes, enter class #			Orphan Drug Status			Size.			Initial shelf li	ife at launch (if different):				Months	
a product kit?		No				Strength:	5 mg									
if yes, list NDCs of			FDA Approval Status								ORDER INFORM	ATION				
component parts reverse numbered?		ls.				Dosage Forn	n: Film coated tablet		Unit of Sale			\A/la a4 !a 4la a	NDC selling			
co-licensed?		No No	Allergens Present						x Bott	tlo		1 Bottle of 3		unit?		
latex-free?		Yes					Round, biconvex			/Carton			g. 1 Box of 10) Viale)		
preservative-free?		Yes	Dairy, Lactose, Ca	sein, Whey, Al	cohol	Product Sha	pe:		Amı			(**************************************	.g. 1 Dox of 10	o viaio)		
correctional institution block?		No				Burnel Oct	Yellow		Gla			Minimum o	rder quantity	?	Yes	
opioid?		No				Product Cole	or:		Tub	e				'		
Cannabinoid?		No	Country of Origin	India		Product Imp	Debossed with 'H' on one side and '01' on the other side	d		l Liquid Sgl						
If Unit Dose, is item bar coded to u	unit dose for					Froductilip	1111C. Of the other side			l Liquid Multi			many of whi	ch package t	type?	
hospital scanning?			Is this product covered u		-					Powder Sgl		24	Each			
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	AA)?	No					Powder Multi er: Write In			Inner/Carton	/Pack		
			FOR GENERIC DRUG PR	DUIGTO					Oth	er: write in			Case			
			FOR GENERIC DRUG PR	DDUCIS												
					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	Rec. sell unit to customer? Rx billing unit to pharmacy:							
II. Generic Equivalent to What Bra		Benicar						Tice. sen un	Each			ıcy.				
The second Equitation to This Statuti								(Write-in, e.g. 1 Vial) Gram								
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION HCPCS J-Code:								Milliliter								
				_												
Does supplier meet DSCSA defini	ition of manufacture	er?	Yes	_	GLN:	0331722498975				ITEN	AND PACKING IN	IFORMATIO	N			
Is product exempt from DSCSA?			No													
If yes, select exemption:					GCP:				v	Weight Lbs.		ons (US msn		Volume	Saleable #	
Other exemption - Write in:			M.					_		J . =	Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?		12	No Yes	-		riginal product pur	chased	Item/Each:		0.05	1.5	1.5	2.5	5.63	1	
Is product sold by manufacturer's Has FDA granted waiver/exceptio			No.	+	direct from m		r repackaged product	Box/Carton/	/Rundle/							
If yes, attach documentation from		Juuci:			riovide soul	ce manufacturer re	repackaged product	Inner Pack:	Dullale							
,								Case:					4.05	070.05		
		G	TIN AND HIBCC PRODUCT I	IFORMATION						1.8	10	6.5	4.25	276.25	24	
								Pallet:								
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GTI	N-14	Unit of Use GTIN-14									
		Quantity			200		00001700050000									
x Item/Each Box/Carton/Bundle/Inner Pack	N	1			003	31722852302	00331722852302		COSTUN	FORMATION			WHOLESALE	ED LIGE ONL	V·	
Box/Carton/Bundle/Inner Pack X Case	N	24			203	31722852306	-		COST IN	OKWATION			WHOLESALI	LK USE UNL		
X Case Pallet	IN	24			203	01122002000	-	Regular Cos	et			Vendor #:				
							1	Invoice Cos			\$3.39	Whsl. Code	#:			
							1	11			72.00	Fineline Co				
								As of date:	5/14	4/2025						
												I				
					_											
*Please provide any additional inf	f		Attach copy of SAFETY DA	TA SHEET (SI	OS) or non haza		INSERT, LABEL AND PHOTO	OF PRODUCT PACE	KAGING and BA	RCODE.						



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

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For Designated Drop Ship Only Products, Please Use Page 3

MA	TERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION				
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	No	SC	S 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 No No	x Organic Inorganic 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?	No No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level:	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	No	Is the product a NIOSH hazardous drug? If yes, indicate which:	No			
c. DOT Hazard Class d. Packing Group		Haza EPA Hazardous Waste Code:	rdous Waste Identification			
e. Inhalation Hazard? Is this product regulated for shipment by IATA?	No	EFA Hazardous Waste Code.		Waste Characteristics		
(if yes, answer a-e below and provide SDS)		REMS o	r 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:	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?)	No			
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);		Comments				
SP#		Registry: Registry Program Contact Name:	No	Phone:		
ADD'L STORAGE INFORMATION		Comments		Thoric.		
Is the Product Controlled Substance? Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II)	No	RI	ETURN INSTRUCTIONS			
ARCOS Reportable? Schedule No. If yes, indicate which: Is it a scheduled listed chemical product?:	No	Contact tel. # if product received damaged: Is product returnable for credit:	1-866-827-3647 Yes			
CLASS OF TRADE RESTRICTION:		URL/Link to returns policy:				
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes	contact - customerse	rvice@camberpharma.com			
Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only:	No No	Special regulations or returns requirements for this product in certain states?				
Restricted from US territories? (explain in comments) Comments:	No	If so, which states? Other requirements? Comments?				
MI	SCELLANEC	US 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.

Purchase order ally receipt cut off time by supplier a. EDI b. Autofax C. Fax Fax Number: C. Fax d. Phone only Phone only Supplier Veb Sile only Supplier Veb S	Order Method	for Designated Drop Ship Product	Standard Order Receipt and Processing				
b. Autofax c. Fax d. Phone only e. Supplier Web Site only e. Supplier Web Site only supplier Subserver Service Number: Contracted 3PL company / contact #: Name: Phone Phone Phone Phone Phone Site Address Ships aame day for next day receipt: Ships regular ground for 3-10 days receipt: S	Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier				
d. Phone only e. Supplier Web Site only Site Address: Supplier Soustomer Service Number: Contracted 3PL company / contact # Name: Phone No. Expedited freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee billed: Drop Ship service fee billed: Drop Ship service fee billed: Drop Ship service fee billed with each order: Drop Ship service fee billed: Drop Ship ser	a. EDI		Cut off time:				
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