

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

Version 2024						Introduction Type:	New Item	X	Final Version			Date:	3/30/	/2025
			PRODUCT INFORMAT	TION					SPECIAL HAND	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Camber Pharmac	euticals. Inc.				Application:	ANDA	a. Temperature – Indica	te the USP temper	rature range for th	is product.			
Application Number for NDA/ANI	DA/BLA: PMA/510	(k): 205499				NDA 505(b) Type:	NOT APPLICABLE			Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab						.,,,,,		ī l	5 .			`		
DUNS:	11-856-3719							Other Ter	nperature Range R	Requirement				
Proprietary Name (If Applicable) a	nd Established Na	ame: Olmesa	rtan Medoxomil Tablets, US	P 20 mg					te in)					
Selling Unit NDC:	31722-853-90		Unit of Use NDC:		31722-853-90	UPC: 331	722853903	Notes	,					
UDI			CVX Code:			MVX Code:		1						
Description:	Olmesartan Mede	xomil Tablets, USP 20	ma					le this pro	duct to be shipped	to customers on ic	62		No	1
Description.	Omicoartan wede	XOTTIII TUDICUS, COT 20	ilig							to customers on dr			No	
Active Ingredient(s):		Olmesartan medoxor	mil. USP								,			
. ,								b. Contact for temperat	ure excursion que	estions:				
URL for Additional Product Inform	ation:	www.camberpharma.	com					Name:			Soma Raju			
Address:	800 Centennial A	ve, Suite 1				Address 2:		Number:			732-529-042			
City:	Piscataway				State:		: 08854	Group E-	mail:		somaraju@h	eterousa.con	1	
Key Contact:	Customer Service	•			Email:	customerservice@cam	berpharma.com							,
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special regulations for					No	
Product Therapeutic Classification	1:	Angiotensin II receptor	or blocker (ARB)					Special re	eturns requirements	s for this product?			No	
								_						-
	ADDITI	ONAL PRODUCT INFO	ORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store product (unit o	f sale) upright?				No	
The product is?			Is the Product	Direct-Ship Or	nly			Protect p	roduct (unit of sal	le) from light?			No	1
a legend device?		No	Is the Product	Unit of Use		Size:	90 ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			Size.		Initial sh	elf life at launch (if	f different):				Months
a product kit?		No				Strength:	20 mg							
if yes, list NDCs of			FDA Approval Status			ou ongun				ORDER INFORM	ATION			
component parts						Dosage Form:	Film coated tablet							
reverse numbered?		No						Unit of S			What is the		unit?	
co-licensed?		No	Allergens Present						Bottle		1 Bottle of 9			
latex-free?		Yes	Dairy, Lactose, Cas	sein, Whey, Alc	ohol	Product Shape:	Round, biconvex		Box/Carton		(Write-in, e.	g. 1 Box of 10) Vials)	
preservative-free?		Yes					White to off white		Ampule		Minimum	dau aa	•	Van
correctional institution block? opioid?		No No				Product Color:	white to oil write		Glass Tube		Minimum or	der quantity	ſ	Yes
Cannabinoid?		No	Country of Origin	India			Debossed with 'H' on one side and		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for	140	Country or Origin	ilidia		Product Imprint:	'03' on the other side		Vial Liquid Multi		If Yes, how	many of whi	ch nackano	tvne?
hospital scanning?	THE GOSE TO		In this was don't account to									Each	cii package	type:
			Is this product covered un Trade Agreements Act (T.		No				Vial Powder Sgl Vial Powder Multi				/Pack	
If Unit Dose, indicate NDC here:			Trade Agreements Act (T		No				Vial Powder Sgl Vial Powder Multi Other: Write In			Inner/Carton Case	/Pack	
			Trade Agreements Act (Ta	AA)?	No				Vial Powder Multi			Inner/Carton	/Pack	
				AA)?	No				Vial Powder Multi			Inner/Carton	/Pack	
			Trade Agreements Act (Ta	AA)?		othorized Generic *If A	uthorized Generic, other		Vial Powder Multi Other: Write In	ARMACY ORDER		Inner/Carton	/Pack	
If Unit Dose, indicate NDC here:	AB		Trade Agreements Act (Ta	AA)?			uthorized Generic, other ion fields are not applicable		Vial Powder Multi Other: Write In	ARMACY ORDER	/ BILL UNIT	Inner/Carton Case		
		Benicar	Trade Agreements Act (Ta	AA)?					Vial Powder Multi Other: Write In	ARMACY ORDER		Inner/Carton Case		
If Unit Dose, indicate NDC here:		Benicar	Trade Agreements Act (T.	DDUCTS	Au			Rec. sell unit to custom (Write-in, e.g. 1 Vial)	Vial Powder Multi Other: Write In	ARMACY ORDER	/ BILL UNIT	Inner/Carton. Case nit to pharma Each Gram		
If Unit Dose, indicate NDC here:		Benicar	Trade Agreements Act (Ta	DDUCTS	Au			Rec. sell unit to custom	Vial Powder Multi Other: Write In	ARMACY ORDER	/ BILL UNIT	Inner/Carton Case nit to pharma Each		
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bran	nd?:	Benicar DRUG SUPPLY	Trade Agreements Act (T. FOR GENERIC DRUG PRO CHAIN SECURITY ACT (D.)	DDUCTS DSCSA) INFOR	Au	sect		Rec. sell unit to custom (Write-in, e.g. 1 Vial)	Vial Powder Multi Other: Write In PH/		/ BILL UNIT Rx billing u	Inner/Carton Case nit to pharma Each Gram Milliliter		
If Unit Dose, indicate NDC here: 1. Orange Book Rating: II. Generic Equivalent to What Bran	nd?:	Benicar DRUG SUPPLY	Trade Agreements Act (T. FOR GENERIC DRUG PRO CHAIN SECURITY ACT (E.) Yes	DDUCTS DSCSA) INFOR	Au			Rec. sell unit to custom (Write-in, e.g. 1 Vial)	Vial Powder Multi Other: Write In PH/	ARMACY ORDER	/ BILL UNIT Rx billing u	Inner/Carton Case nit to pharma Each Gram Milliliter		
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If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Braid Does supplier meet DSCSA definities product exempt from DSCSA? If yes, select exemption:	nd?:	Benicar DRUG SUPPLY	Trade Agreements Act (T. FOR GENERIC DRUG PRO CHAIN SECURITY ACT (E.) Yes	DDUCTS DSCSA) INFOR	Au	sect		Rec. sell unit to custom (Write-in, e.g. 1 Vial)	Vial Powder Multi Other: Write In PHA er?	AND PACKING IN	/ BILL UNIT Rx billing un	Inner/Carton Case nit to pharma Each Gram Milliliter	ecy:	Saleable #
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Braid Does supplier meet DSCSA definities product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	nd?:	Benicar DRUG SUPPLY	Trade Agreements Act (T. FOR GENERIC DRUG PRO CHAIN SECURITY ACT (E. Yes No	DDUCTS DSCSA) INFOR	MATION GLN: GCP:	sect		Rec. sell unit to custom (Write-in, e.g. 1 Vial) HCPCS J-Code:	Vial Powder Multi Other: Write In PH/	AND PACKING IN	/ BILL UNIT Rx billing un	Inner/Carton Case nit to pharma Each Gram Milliliter	асу:	Saleable # Pieces
If Unit Dose, indicate NDC here: 1. Orange Book Rating: II. Generic Equivalent to What Brail Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	nd?: ion of manufactu	DRUG SUPPLY	Trade Agreements Act (T. FOR GENERIC DRUG PRO CHAIN SECURITY ACT (E. Yes No	DDUCTS DSCSA) INFOR	MATION GLN: GCP: If yes, was or	0331722498975		Rec. sell unit to custom (Write-in, e.g. 1 Vial)	Vial Powder Multi Other: Write In PHA er?	AND PACKING IN	/ BILL UNIT Rx billing un	Inner/Carton Case nit to pharma Each Gram Milliliter	ecy:	
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If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Brain Br	ion of manufacture exclusive distribution for professional content of the content	Benicar DRUG SUPPLY rer? tor?	Trade Agreements Act (T. FOR GENERIC DRUG PRO CHAIN SECURITY ACT (E. Yes No	DDUCTS DDUCTS DSCSA) INFOR	MATION GLN: GCP: If yes, was or purchased di	0331722498975	ion fields are not applicable	Rec. sell unit to custom (Write-in, e.g. 1 Vial) HCPCS J-Code: Item/Each: Box/Carton/Bundle/	Vial Powder Multi Other: Write In PH/ er? ITEM Weight Lbs.	AND PACKING IN Dimensic Depth	/ BILL UNIT Rx billing un FORMATION Ons (US msm Width	Inner/Carton Case hit to pharma Each Gram Milliliter hts.) Height	Volume (Cube)	Pieces
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If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Brain Br	ion of manufacture exclusive distribution for professional content of the content	Benicar DRUG SUPPLY rer? tor? oduct?	Trade Agreements Act (T. FOR GENERIC DRUG PRO CHAIN SECURITY ACT (E. Yes No No Yes	DDUCTS DDSCSA) INFOR	MATION GLN: GCP: If yes, was or purchased di	0331722498975 riginal product rect from mfr?	ion fields are not applicable	Rec. sell unit to custom (Write-in, e.g. 1 Vial) HCPCS J-Code: Item/Each: Box/Carton/Bundle/	Vial Powder Multi Other: Write In PH/ er? ITEM Weight Lbs.	AND PACKING IN Dimensic Depth	/ BILL UNIT Rx billing un FORMATION Ons (US msm Width	Inner/Carton Case hit to pharma Each Gram Milliliter hts.) Height	Volume (Cube)	Pieces
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Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2024

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	Waste Characteristics
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	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?	No	
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:		



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

Version 2024

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
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