

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

Version 2021						Introduction Typ	pe: New Item		x Final Version			Date:	6/23	/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOF	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharmac	euticals, Inc.				Applicatio	n: ANDA	a. Temperatur	e - Indicate the USP tempe	erature range for t	nis product.			
Application Number for NDA/ANI			vice):	21	3812		1	· · · · · · · · · · · · · · · · · ·	Temperature Range	Controlled Room		and 25 C (68	s° – 77° F)	
Medical Device Class, if applicab		. , ,	•						,					
DUNS:	11-856-3719							_	Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) a	nd Established Na	ame: Eple	erenone Tablets 50 mg					T	(write in)	•				
Selling Unit NDC:	31722-050-30		Unit of Use NDC:		31722-050-30		31722050302		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Eplerenone Table	ets 50 ma						T	Is this product to be shipped	d to customers on i	:e?		No	1
		g							Is this product to be shipped				No	1
Active Ingredient(s):		Eplerenone						1			•			
							b. Contact for	temperature excursion que	estions:					
URL for Additional Product Inform		www.camberphar	ma.com						Name:		Soma Raju			
Address:	800 Centennial A	ve, Suite 1				Address 2:			Number:		732-529-042			
City:	Piscataway				State:		<b>Zip</b> : 08854	Group E-mail: somaraju@heterousa.com			<u>n</u>			
Key Contact:	1-866-827-3647				customerservice@c	camberpharma.com	c. Special regulations for product in any states?					NI.	1	
Phone Number:		0.1			Fax:	732-562-8788							No	-
Product Therapeutic Classification	n:	Selective aldoste	rone receptor antagonist antih	pertensive					Special returns requirement	s for this product?			No	_
	A DDITI	IONIAL PROPUST	INFORMATION			PROBLICE DE	COORDINATION INCORMATION	<b>-</b>						7
	ADDITI	ONAL PRODUCT	INFORMATION			PRODUCT DE	SCRIPTION INFORMATION	d. Store produ	ict (unit of sale) upright?				No	_
The product is?			Is the Product	Direct-Ship C	Only				Protect product (unit of sa	ile) from light?			No	
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						Initial shelf life at launch (	if different):				Months
a product kit?		No	FD4 4			Strength:	50 mg			ORDER INFORM	ATION			
if yes, list NDCs of			FDA Approval Status				Film coated tablet			ORDER INFORK	IATION			
component parts reverse numbered?		No				Dosage Form:	Fill Coated tablet		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 30			
latex-free?		Yes					Round, biconvex		Box/Carton		(Write-in, e.g		0 Vials)	
preservative-free?		Yes	Dairy, Lac	tose, Casein		Product Shape	r:		Ampule		, , , ,	,	,	
correctional institution block?		No				Product Color:	Light yellow		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Color:			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprir	Debossed with 'V' on one side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for					r roduct imprii	and '67' on the other side		Vial Liquid Multi		If Yes, how		ch package	type?
hospital scanning?			Is this product covered u						Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (	ГАА)?	No				Vial Powder Multi			Inner/Carton	/Pack	
								<u> </u>	Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
									BU	ARMACY ORDER	/ DULL LINUT			
				_	Auti		If Authorized Generic, other section fields are not applicable			ARMACY ORDER				
	AB					s	ection neids are not applicable	Rec. sell unit t	to customer?	-	Rx billing ur		acy:	
II. Generic Equivalent to What Brai	nd?:	Inspra							4.1.0.10			Each		
		DRIIG SUB	PLY CHAIN SECURITY ACT	DSCSA) INFO	MATION			(Write-in, e.g.	1 Viai)			Gram Milliliter		
		DRUG SUP	PLT CHAIN SECURITY ACT	DSCSA) INFO	RMATION							Milliliter		
Does supplier meet DSCSA definit	tion of manufactur	ror?	Yes	_	GLN:	0331722498975			ITEN	I AND PACKING II	NEORMATION			
Is product exempt from DSCSA?	ion or manaracta		No	_	OLIV.	0001722400070				. ,		-		
If ves. select exemption:					GCP:					Dimensi	ons (US msm	to \	Volume	Saleable #
other exemption - Write in:					GCP:				Weight Lbs.	Depth	Width		(Cube)	Pieces
Is product repackaged?			No		If you was ori	ginal product purch	acad	Item/Each:				Height	I .	
Is product sold by manufacturer's	exclusive distribu	utor?	Yes		direct from mf		uscu	item/Lucii.	0.07	1.57	1.57	3.13	7.72	1
Has FDA granted waiver/exception			No	7			repackaged product	Box/Carton/Bu	ındle/					
If yes, attach documentation from							, , ,	Inner Pack:						
-								Case:	1.95	10	6.75	4.25	286.88	24
				VFORMATION					1.95	10	6.75	4.25	200.00	24
		G	TIN AND HIBCC PRODUCT I											
								Pallet:						
Saleable Unit of Measure	S	Saleable Quantity	HIBCC		GTIN		Unit of Use GTIN-14	Pallet:						
X Item/Each	Ş					I-14 1722050302	Unit of Use GTIN-14 00331722050302	Pallet:	COST INFORMATION			AULOL ES AL	ED LICE OF	ν.
X Item/Each Box/Carton/Bundle/Inner Pack	S	Saleable Quantity			0033	1722050302		Pallet:	COST INFORMATION		\	WHOLESAL	ER USE ONL	Y:
X   Item/Each   Box/Carton/Bundle/Inner Pack   X   Case	S	Saleable Quantity			0033				COST INFORMATION			WHOLESAL	ER USE ONL	.Y:
X Item/Each Box/Carton/Bundle/Inner Pack	s	Saleable Quantity			0033	1722050302		Regular Cost		\$25.00	Vendor #:		ER USE ONL	.Y:
X   Item/Each   Box/Carton/Bundle/Inner Pack   X   Case	s	Saleable Quantity			0033	1722050302				\$25.00	Vendor #: Whsl. Code	#:	ER USE ONL	LY:
X   Item/Each   Box/Carton/Bundle/Inner Pack   X   Case	5	Saleable Quantity			0033	1722050302		Regular Cost Invoice Cost (		\$25.00	Vendor #:	#:	ER USE ONL	Y:
X   Item/Each   Box/Carton/Bundle/Inner Pack   X   Case	5	Saleable Quantity			0033	1722050302		Regular Cost	WAC) (\$)	\$25.00	Vendor #: Whsl. Code	#:	ER USE ONL	.Y:
X   Item/Each   Box/Carton/Bundle/Inner Pack   X   Case	S	Saleable Quantity			0033	1722050302		Regular Cost Invoice Cost (	WAC) (\$)	\$25.00	Vendor #: Whsl. Code	#:	ER USE ONL	LY:
X   Item/Each   Box/Carton/Bundle/Inner Pack   X   Case	S	Saleable Quantity	HIBCC		3033	1722050302 1722050303		Regular Cost Invoice Cost (I	WAC) (\$) [8/28/2023	\$25.00	Vendor #: Whsl. Code	#:	ER USE ONL	.Y:



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HA	ZARD 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 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?