

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

Version 2021						Introduction Type	: New Item		x Final Version			Date:	6/24	1/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	IDLING AND STOR	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharmace	euticals, Inc.				Application	ANDA	a. Temperatu	re - Indicate the USP temp	erature range for t	this product.			
Application Number for NDA/AN			ce):	205	646		1	di romporato	Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applical														
DUNS:	11-856-3719							-	Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a		me: Tolvar	otan Tablets 30 mg					T	(write in)					
Selling Unit NDC:	31722-869-03		Unit of Use NDC:			UPC: 33	1722869034		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Tolvaptan Tablets	20 ma						-	la this product to be chippe	d to quotomoro on i	ioo?		No	1
Description.	Tolvapian Tableis	30 mg							Is this product to be shippe Is this product to be shippe				No	-
Active Ingredient(s):		Tolvaptan						+	is this product to be shippe	u to customers on	dry ice:		140	1
, tout o mg. outoni(o).		Torrapian						b. Contact fo	r temperature excursion qu	estions:				
URL for Additional Product Inform	nation:	www.camberpharm	a.com					1	Name:		Soma Raju			
Address:	800 Centennial Av	e, Suite 1				Address 2:		1	Number:		732-529-042	23		
City:	Piscataway				State:	NJ Z	p: 08854		Group E-mail:		somaraju@	neterousa.co	<u>m</u>	
Key Contact:	Customer Service				Email:	customerservice@ca	mberpharma.com							
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special reg	gulations for product in any	states?			No	1
Product Therapeutic Classification	n:	Selective vasopres	sin V ₂ -receptor antagonist						Special returns requiremen	ts for this product?			No	
	ADDITIO	NAL PRODUCT IN	FORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store prod	luct (unit of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship O	nlv				Protect product (unit of sa	ale) from light?			No	i
a legend device?		No	Is the Product	Unit Dose	,		10 ct	e. Shelf life:	r rotoot product (dime of or	,g			24	Months
if yes, enter class #		110	Orphan Drug Status			Size:	10 00	0. 0	Initial shelf life at launch (if different):				Months
a product kit?		No	O.p.ian Drug Glatag				30 mg		made onon mo de idanon (1
if yes, list NDCs of		1.10	FDA Approval Status			Strength:	3			ORDER INFOR	MATION			
component parts						B	Tablet							
reverse numbered?		No				Dosage Form:			Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						Bottle		1 Carton of 1	0 Unit Dose Ta	blets in (1x10)	Blister Pack
latex-free?		Yes	Dairy Lastes	e, Corn, Alcohol		Product Shape:	Round, bevel edged,		x Box/Carton		(Write-in, e	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	Daily, Lactos	e, Com, Alconor		Froduct Snape.	biconvex		Ampule					
correctional institution block?		No				Product Color:	Blue		Glass		Minimum o	rder quantity	<i>i</i> ?	Yes
opioid?		No				rioduct color.			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Debossed with 'H' on one side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u						oaaot iiipiiiti	and 'T10' on the other side		Vial Liquid Multi				ich package	type?
hospital scanning?		Yes	Is this product covered to						Vial Powder Sgl		24	Each		
If Unit Dose, indicate NDC here:		31722-869-31	Trade Agreements Act (TAA)?	No				Vial Powder Multi			Inner/Cartor	n/Pack	
								<u> </u>	Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
									D.	ARMACY ORDER	Y DULL LINUT			
					At		Authorized Generic, other ction fields are not applicable			IARMACY ORDER				
I. Orange Book Rating:	AB					56	ction fields are not applicable	Rec. sell unit	to customer?	-	Rx billing u	nit to pharm	acy:	
II. Generic Equivalent to What Bra	and?:	Samsca							410.0			Each		
		DRUG GURRI	LY CHAIN SECURITY ACT	(Dece A) INFOR	MATION			(Write-in, e.g	. 1 Vial)			Gram Milliliter		
		DRUG SUFFI	LT CHAIN SECURITT ACT	(DSCSA) INFOR	WATION							williller		
Does supplier meet DSCSA defini	ition of manufacture	ar?	Yes		GLN:	0331722498975			ITEN	AND PACKING I	NEORMATIO	N		
Is product exempt from DSCSA?	ition of manaractary		No		OLIV.	0001122430310						••		
If ves. select exemption:					GCP:					Dimene	ions (US msr	nte \	Volume	Saleable #
Other exemption - Write in:					GCF:			_	Weight Lbs.	Dimens	Width	•	(Cube)	Saleable #
Is product repackaged?			No		If you was a	riginal product purchas	hod book	Item/Each:		1		Height		
Is product repackaged:	s avelusiva distribu	tor?	Yes		direct from n		seu	itelli/Eacii.	0.05	4.6	1.1	1.82	9.21	1
Has FDA granted waiver/exception			No	_		ce manufacturer for re	packaged product	Box/Carton/E	Bundle/					
If yes, attach documentation fro		Judet.	110		i iovide soui	ce manaracturer for re	buckagea product	Inner Pack:	Junaic,					
,,								Case:						
		GTI	IN AND HIBCC PRODUCT I	NFORMATION					1.8	9.75	7.5	4.5	329.06	24
								Pallet:						
Saleable Unit of Measure	Sa	aleable Quantity	HIBCC		GTI	N-14	Unit of Use GTIN-14							
X Item/Each		1			003	31722869034								
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESAL	ER USE ONL	Y:
X Case		24			203	31722869038								
Pallet								Regular Cost			Vendor #:			
								Invoice Cost	(WAC) (\$)	\$1,200.00	Whsl. Code			
								11.	0/4/0000		Fineline Co	de:		
								As of date:	6/1/2022		-			
]-			4 1		- ·			<u> </u>			1			
			Attach copy of SAFETY D	ATA SHEET (SD:	 or non haza 	ird letter, PACKAGE INS	ERT, LABEL AND PHOTO OF	PRODUCT PACK						
*Please provide any additional inf							ignated Drop Ship Only.		Signature:					



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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	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?