

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

						Introduction Type:	New Item		Final Version			Date:	8/6/2	2021
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharmac	euticals, Inc.				Application:	ANDA	a Temperatu	ure - Indicate the USP temp	erature range for the	is product			
Application Number for NDA/AN			ce):	20564	46			di romporato	Temperature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applica									·			`		
DUNS:	82-667-4775							-	Other Temperature Range	Requirement				
Proprietary Name (If Applicable)		ame: Tolvar	ptan Tablet 30mg 10ct					T	(write in)					
Selling Unit NDC:	31722-869-03		Unit of Use NDC:			UPC: 3317	22869034	1	Notes					
UDI			CVX Code:			MVX Code:		1						
Description.	Oral Calid Tablet	Davind abone blue		م الله طنتينا المما	laccon accorde	T10 an unner nunch un	4b	-	la thia anadust ta ha ahisaa	d 40 0	-2		No	1
Description:	Oral Solid Tablet,	Round snape, blue, t	bevel Concave punches emi	bossed with in on i	lower purion a	x 110 on upper punch wi	in corresponding dies		Is this product to be shippe Is this product to be shippe				No	
Active Ingredient(s):		Tolvaptan						-	is this product to be shippe	a to customers on a	y ice?		INO	1
Active ingredient(s).		Tolvapian						h Contact fo	or temperature excursion qu	actions:				
URL for Additional Product Infor	nation:	www.camberpha	arma com					b. Contact to	Name:	estions.	Soma Raju			
Address:	800 Centennial Av		arma.com			Address 2:		+	Number:		732-529-042	3		
City:	Piscataway				State:		08854	-	Group E-mail:		somaraju@		com	
Key Contact:	Customer Service	2			Email:	customerservice@c		-	5.5up 2a		<u>somaraja e</u>	eneter oust		
Phone Number:	1-866-827-3647				Fax:	732-562-8788	<u>amperpharmateem</u>	c. Special red	gulations for product in any	states?			No	1
Product Therapeutic Classification	n.								Special returns requiremen				No	
. Todast morapouno oracomouni									opeoidi rotarrio roquirorriori	o for ano product.				1
	ADDITI	ONAL PRODUCT IN	FORMATION			PRODUCT DESC	RIPTION INFORMATION	d Store prod	duct (unit of sale) upright?				No	1
	7,55111	J		Discort Ohio Out		1 1105001 5200		u. otore proc]
The product is?			Is the Product	Direct-Ship Only	У			11	Protect product (unit of sa	ile) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	10ct	e. Shelf life:					24	Months
if yes, enter class #		I.	Orphan Drug Status				20		Initial shelf life at launch (if different):			24	Months
a product kit?		No	FDA Ammanual Status			Strength:	30mg			ORDER INFORM	ATION			
if yes, list NDCs of			FDA Approval Status				Oral Solid - Tablet			OKDEK INFORM	ATION			
component parts reverse numbered?		Ne				Dosage Form:	Oral Solid - Tablet		Unit of Sale		What is the	NDC calling	unit?	
co-licensed?		No No	Allergens Present						Bottle		1 blister pacl			
latex-free?		Yes	Allergens Fresent				Round		x Box/Carton			g. 1 Box of 1		
preservative-free?		Yes				Product Shape:	Rodrid		Ampule		(vviite iii, e.,	g. 1 DOX 01 1	o viais)	
correctional institution block?		No					Blue		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Color:	Dide		Tube			uci quaitity	•	103
Cannabinoid?		No	Country of Origin	India			Upper: 'T10' Lower: 'H'		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for	110	,g			Product Imprint:			Vial Liquid Multi		If Yes, how	manv of whi	ch package	tvpe?
hospital scanning?	XIII. G000 101	No	Is this product covered u	under the					Vial Powder Sql			Each	pg	.,,,,
If Unit Dose, indicate NDC here:			Trade Agreements Act (10				Vial Power Multi			Inner/Carton	/Pack	
			_ `	,					Other: Write In			Case		
			FOR GENERIC DRUG PR	RODUCTS										
					Aut	horized Generic *If A	uthorized Generic, other		Pł	IARMACY ORDER	/ BILL UNIT			
L Ones de Barte de	AB			_										
I. Orange Book Rating:				_		secti	on fields are not applicable	Poo cell unit					acy:	
II. Generic Equivalent to What Bra		Samasa				secti	on fields are not applicable	Rec. sell unit	t to customer?	1	Rx billing u		•	
		Samsca				secti	on fields are not applicable		t to customer?			Each	•	
			V CHAIN SECURITY ACT	(DSCSA) INFORM	IATION	secti	on fields are not applicable	Rec. sell unit	t to customer?			Each Gram	•	
			LY CHAIN SECURITY ACT ((DSCSA) INFORM.	IATION	secti	on fields are not applicable		t to customer?			Each	·	
Does supplier meet DSCSA defin	and?:	DRUG SUPPL					on fields are not applicable		t to customer? j. 1 Vial)	AND PACKING IN	Rx billing u	Each Gram Milliliter		
Does supplier meet DSCSA defin	and?:	DRUG SUPPL	LY CHAIN SECURITY ACT (Yes No		IATION	secti	on fields are not applicable		t to customer? j. 1 Vial)	I AND PACKING IN	Rx billing u	Each Gram Milliliter	•	
Is product exempt from DSCSA?	and?:	DRUG SUPPL	Yes	G	GLN:		on fields are not applicable		t to customer? j. 1 Vial)		Rx billing un	Each Gram Milliliter		Salaskie "
Is product exempt from DSCSA? If yes, select exemption:	and?:	DRUG SUPPL	Yes	G			on fields are not applicable		t to customer? j. 1 Vial)	Dimensi	Rx billing un	Each Gram Milliliter	Volume	Saleable #
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	and?:	DRUG SUPPL	Yes No	G G	GLN: GCP:	031722000000		(Write-in, e.g	t to customer? j. 1 Vial) Weight Lbs.	Dimensi Depth	Rx billing un FORMATION Ons (US msm Width	Each Gram Milliliter		Pieces
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	and?: ition of manufactur	DRUG SUPPL	Yes No	G If	GLN: GCP: f yes, was or	031722000000			t to customer? j. 1 Vial) ITEN	Dimensi	Rx billing un	Each Gram Milliliter	Volume	
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer.	and?: ition of manufactur	DRUG SUPPL	Yes No No	G G If di	GLN: GCP: f yes, was or lirect from m	031722000000 lginal product purchase	d	(Write-in, e.g	t to customer? j. 1 Vial) Weight Lbs. 0.05	Dimensi Depth	Rx billing un FORMATION Ons (US msm Width	Each Gram Milliliter	Volume	Pieces
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Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer, Has FDA granted waiver/exception	and?: ition of manufactur s exclusive distribu on/exemption for pr m FDA.	DRUG SUPPL	Yes No No No No	G G If di P	GLN: GCP: f yes, was or lirect from m	031722000000 iginal product purchase fr? ee manufacturer for repa	d	(Write-in, e.g	t to customer? g. 1 Vial) Weight Lbs. 0.05 Bundle/	Dimensi Depth 4.625	Rx billing un	Each Gram Milliliter Ints.) Height	Volume	Pieces 1
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer' Has FDA granted waiver/exceptic If yes, attach documentation fro	and?: ition of manufactur s exclusive distribu on/exemption for pr m FDA.	DRUG SUPPL	Yes No No No No No No	G G If di P	GLN: f yes, was or firect from m Provide source GTII	031722000000 iginal product purchase fr? ee manufacturer for repa	d lickaged product	(Write-in, e.g	t to customer? g. 1 Vial) Weight Lbs. 0.05 Bundle/	Dimensi Depth 4.625	Rx billing under the second of	Each Gram Milliliter Ltts.) Height 2	Volume (Cube)	Pieces 1 24
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Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer. Has FDA granted waiver/exceptic If yes, attach documentation fro Saleable Unit of Measure X them/Each Bow/Cartor/Bundle/Inner Pack X Case	and?: ition of manufactur s exclusive distribu on/exemption for pr m FDA.	DRUG SUPPL rer? utor? roduct? GTI Saleable Quantity	Yes No No No No No No	G G If di P	GLN: GCP: f yes, was or lirect from m rovide source GTIII 0033	031722000000 Iginal product purchase fir? se manufacturer for repairs.	d lickaged product	(Write-in, e.g	t to customer? g. 1 Vial) Weight Lbs. 0.05 Bundle/ 1.4 COST INFORMATION t	Dimensi Depth 4.625 9.75	Rx billing under the state of t	Each Gram Milliliter Its.) Height 2 4.75	Volume (Cube)	Pieces 1 24
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Version 2021

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? 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?	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					
(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					
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? No Controlled Substance Code	RETURN INSTRUCTIONS				
Controlled by State(s)? ARCOS Reportable? No If yes, indicate which: Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged: 1-866-827-3647				
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Ye					
Restricted to retail pharmacy only:	·				
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No	product in certain states?				
Comments:					
MISCELL	ANEOUS NOTES and/or Image of Product Barcode:				



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

Version 2021

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated D	Orop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier
a. EDI		Cut off time:
	x Number:	
	x Number:	Shipping lead time of PO: Hours Days
	one No.:	China cama day far nayt day receipts
e. Supplier Web Site only Site Minimum Order Quantity:	e Address:	Ships same day for next day receipt: Ships for second day receipt:
Supplier's Customer Service Number:		Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #: Name:		Ships regular ground for 5-10 days receipt.
Phone:		
Expedited Freight Charges or Other De	esignated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
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:		Tuesday
		Wednesday
		Thursday
		Friday
		Priority Overnight receipt available:
Class of Trade Restr	riction:	PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals	c clinics and physician offices	Saturday Overnight receipt available:
Restricted to retail pharmacy only:	s, clinics and physician onices	PO Receipt Cut off time:
Restricted to hospital, clinics, and physician offices only:		Phone: Phone #:
Restricted from US territories? (explain in comments)		Order receipt method: Fax: Fax #:
Comments:		EDI:
		Overnight Fees apply:
		Other fees apply:
Other Data Information Require	ed to Process PO:	Return Instructions
Patient Procedure Date:		Contact # if product is received damaged:
Physician Name:		Is product returnable for credit:
Physician/Clinic Phone #		URL/Link to returns policy:
Physician State License #		
Physician/Clinic DEA #:		Special regulations or returns requirements for this product in certain states?
Physician/Clinic Specialty:		If so, which states? Other requirements? Comments?
Miscellaneous No	otes:	
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure?
		Is product order for restocking purposes?