

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

Version 2021						Introduction Type	e: New Item		x Final Version			Date:	6/24	4/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STO	RAGE REQUIF	REMENTS*		
Company Name:	Camber Pharmac	euticals, Inc.				Application	: ANDA	a. Temperature	- Indicate the USP tempe	rature range for t	his product.			
Application Number for NDA/ANI			e):	20	6419				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) as	nd Established Na	me: Toltero	dine Tartrate Extended-Rele	ease Capsules	4 mg				(write in)	•				
Selling Unit NDC:	31722-608-30		Unit of Use NDC:		31722-608-30		1722608305	[]	Notes					
UDI			CVX Code:			MVX Code:								
Description:	Tolterodine Tartra	te Extended-Release	Capsules 4 mg					il i	Is this product to be shipped	to customers on	ce?		No	7
•									Is this product to be shipped				No	1
Active Ingredient(s):		Tolterodine tartrate,	USP											-
								b. Contact for t	emperature excursion que	estions:				
URL for Additional Product Inform		www.camberpharma	ı.com						Name:		Soma Raju			
Address:	800 Centennial Av	ve, Suite 1				Address 2:			Number:		732-529-042			
City:	Piscataway				State:		ip: 08854	Group E-mail: somaraju@heterousa.com						
Key Contact:	Customer Service 1-866-827-3647				Email:	customerservice@ca	mberpharma.com	c. Special regulations for product in any states?				NI.	7	
Phone Number:		A			Fax:	732-562-8788							No	-
Product Therapeutic Classification	1:	Antimuscarinic							Special returns requirement	s for this product?			No	
	ADDITI	ONAL PROPUST IN	CODMATION			PROBLICE DES	ACRIPTION INFORMATION							7
	ADDITIO	ONAL PRODUCT INF	-ORMATION			PRODUCT DES	CRIPTION INFORMATION	d. Store produc	ct (unit of sale) upright?				No	_
The product is?			Is the Product	Direct-Ship C	Only				Protect product (unit of sa	le) 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 #		1	Orphan Drug Status					'	Initial shelf life at launch (i	f different):				Months
a product kit?		No	EDA Ammerical Status			Strength:	4 mg			ORDER INFORI	MATION			
if yes, list NDCs of component parts			FDA Approval Status				Hard gelatin, extended-			OKDEK INFORI	MATION			
reverse numbered?		No				Dosage Form:	release capsule		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present				release superior	Ì	x Bottle		1 Bottle of 30			
latex-free?		Yes					Capsule		Box/Carton		(Write-in, e.		0 Vials)	
preservative-free?		Yes	Alcoh	ol, Nuts		Product Shape:	1.1		Ampule		, , , , ,		,	
correctional institution block?		No				Product Color:	Blue		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Froduct Color.			Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint	Imprinted with 'J' on cap		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for					oddot imprint	and '105' on body		Vial Liquid Multi				ch package	type?
hospital scanning?			Is this product covered u						Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act ((AA)?	No			-	Vial Powder Multi Other: Write In			Inner/Carton	/Pack	
				AD110T0				L	Other: write in			Case		
			FOR GENERIC DRUG PR	ODUCIS										
					Aut	horized Generic *If	Authorized Generic, other		PH	ARMACY ORDER	/ BILL LINIT			
	AD			_	Aut		ction fields are not applicable	Rec. sell unit to		AKIIIAOT OKDEN		to a l		
	AB	Detrol LA						Rec. sell unit to	o customer?	1	Rx billing ur		acy:	
II. Generic Equivalent to What Bran	na?:	Detroi LA						(Write-in, e.g. 1	Vial			Each Gram		
		DRUG SUPPL	Y CHAIN SECURITY ACT (DSCSA) INFO	RMATION			(vviite-iii, e.g. i	viai)			Milliliter		
												· · · · · · · · · · · · · · · · · · ·		
Does supplier meet DSCSA definit	ion of manufactur	rer?	Yes	T	GLN:	0331722498975			ITEN	I AND PACKING I	NFORMATION	١		
Is product exempt from DSCSA?			No											
If ves. select exemption:					GCP:			I		Dimens	ions (US msm	its.)	Volume	Saleable #
Other exemption - Write in:					- 2			'	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was ori	ginal product purcha	sed	Item/Each:	0.06	1		2.56	5.76	
Is product sold by manufacturer's	exclusive distribu	itor?	Yes		direct from mf				0.06	1.5	1.5	2.56	5.76	1
Has FDA granted waiver/exception	n/exemption for pr	oduct?	No		Provide source	e manufacturer for re	packaged product	Box/Carton/Bu	ndle/					
If yes, attach documentation from	n FDA.							Inner Pack:						
								Case:	1.8	9.75	6.75	3.8	250.09	24
		GTIN	N AND HIBCC PRODUCT II	NFORMATION							1			
Saleable Unit of Measure	_							Pallet:						
	S	Saleable Quantity	HIBCC		GTIN	I-14 1722608305	Unit of Use GTIN-14 00331722608305							
X Item/Each Box/Carton/Bundle/Inner Pack		1			0033	1722006305	00331722608305		COST INFORMATION		1	WHO! ESAL	ER USE ONL	ı v.
x Case		24			2033	1722608309			JOOT INFORMATION			IO-L-OAL	ER OOL ONL	
Pallet		24			2033	22000003		Regular Cost			Vendor #:			
	1							Invoice Cost (W	VAC) (\$)	\$20.00	Whsl. Code	#:		
	1									+==1.00	Fineline Cod			
								As of date:	1/26/2024					
											.1			
			Attach copy of SAFETY DA	ATA SHEET (SE	DS) or non hazar	d letter, PACKAGE INS	SERT, LABEL AND PHOTO OF F							



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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?