

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

Version 2021						Introduction Type	: New Item		x Final Version			Date:	6/24/	/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	IDLING AND STOR	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharmac	ceuticals, Inc.				Application	: ANDA	a. Temperatu	re - Indicate the USP tempe	erature range for t	his product.			
Application Number for NDA/AN			ce):	20	6419			i i i i i i i i i i i i i i i i i i i	Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applica			•					†						
DUNS:	11-856-3719							*	Other Temperature Range I	Requirement				
Proprietary Name (If Applicable)	and Established Na	ame: Toltero	odine Tartrate Extended-Rel	ease Capsules	2 mg			T	(write in)	·				
Selling Unit NDC:	31722-607-30		Unit of Use NDC		31722-607-30	UPC: 33	1722607308	Ī	Notes					
UDI			CVX Code:			MVX Code:		I						
Description:	Tolterodine Tartra	ate Extended-Release	Capsules 2 mg					ī	Is this product to be shipped	d to customers on i	ce?		No	1
									Is this product to be shipped				No	1
Active Ingredient(s):		Tolterodine tartrate,	, USP					†			•			
									r temperature excursion qu	estions:				
URL for Additional Product Inforr	mation:	www.camberpharma	a.com					I	Name:		Soma Raju			
Address:	800 Centennial A	ve, Suite 1				Address 2:			Number:		732-529-042			
City:	Piscataway				State:		ip: 08854		Group E-mail:		somaraju@h	neterousa.com	<u>n</u>	
Key Contact:	Customer Service	9			Email:	customerservice@ca	mberpharma.com							1
Phone Number:	1-866-827-3647				Fax:	732-562-8788		c. Special re	gulations for product in any				No	-
Product Therapeutic Classification	on:	Antimuscarinic							Special returns requirement	ts for this product?			No	_
	ADDITI	IONAL PROPUST IN	FORMATION			PROPUST DES	ODIDTICAL INFORMATION							7
	ADDITI	IONAL PRODUCT IN				PRODUCT DES	CRIPTION INFORMATION	d. Store prod	luct (unit of sale) upright?				No	_
The product is?			Is the Product	Direct-Ship C	Only				Protect product (unit of sa	ale) 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 (if different):				Months
a product kit?		No	EDA Ammerial Status			Strength:	2 mg			ORDER INFORM	AATION			
if yes, list NDCs of component parts			FDA Approval Status				Hard gelatin, extended-			ORDER INFORM	MATION			
reverse numbered?		No				Dosage Form:	release capsule		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 3			
latex-free?		Yes					Capsule		Box/Carton			g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	Alcoh	ol, Nuts		Product Shape:			Ampule		, , ,		,	
correctional institution block?	•	No				Product Color:	Blue green		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	unit dose for						and '104' on body		Vial Liquid Multi				ich package t	type?
hospital scanning?			Is this product covered						Vial Powder Sgl		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (IAA)?	No				Vial Powder Multi			Inner/Cartor	n/Pack	
								1	Other: Write In			Case		
			FOR GENERIC DRUG PF	ODUCIS										
						horized Generic *If	Authorized Generic, other		DL	IARMACY ORDER	/ DILL LINIT			
				_	Aut		ction fields are not applicable			IANMACT ONDER				
I. Orange Book Rating:	AB	D. r. III A				30	otion ricids are not applicable	Rec. sell uni	to customer?		Rx billing u		acy:	
II. Generic Equivalent to What Bra	and?:	Detrol LA						OM/site in a s	4 \/;el\			Each		
		DRIIG SHIPPI	Y CHAIN SECURITY ACT	(DSCSA) INFO	MATION			(Write-in, e.g	. i viai)			Gram Milliliter		
		DRUG SUFFE	ET CHAIN SECONITT ACT	(DOCOA) INI OI	MATION							wiiiiiitei		
Does supplier meet DSCSA defin	nition of manufactur	rer?	Yes		GLN:	0331722498975			ITEN	AND PACKING I	NFORMATIO	V		
Is product exempt from DSCSA?			No											
If ves. select exemption:					GCP:			il		Dimensi	ions (US msn	nts.)	Volume	Saleable #
Other exemption - Write in:					JUF .			1	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If ves, was ori	ginal product purcha	sed	Item/Each:		1				
Is product sold by manufacturer's	's exclusive distribu	utor?	Yes	_	direct from mi			, Edoil.	0.05	1.5	1.5	2.56	5.76	1
Has FDA granted waiver/exception			No	\neg		e manufacturer for re	packaged product	Box/Carton/E	Bundle/					
If yes, attach documentation fro	om FDA.							Inner Pack:						
								Case:	1.65	9.75	6.75	3.8	250.09	24
		GTI	N AND HIBCC PRODUCT	NFORMATION					1.00	5.70	0.70	0.0	200.00	2-7
								Pallet:						
Saleable Unit of Measure	S	Saleable Quantity	HIBCC		GTIN		Unit of Use GTIN-14							
X Item/Each		1			0033	1722607308	00331722607308	I — —	COST INFORMATION			WILOL EOM	ER USE ONL	٧.
Box/Carton/Bundle/Inner Pack		24			2000	1722607302			COST INFORMATION			WHOLESAL	ER USE ONL	1.6
		24			2033	11/2200/302		Regular Cos	•		Vendor #:			
X Case								Invoice Cost		\$20.00	Whsl. Code	#-		
X Case Pallet								I IIIVOICE COST	(**AU) (#)	\$∠0.00				
								As of date:	1/26/2024		Fineline Co			
								As of date:	1/26/2024					
								As of date:	1/26/2024					
			Attach copy of SAFETY D	ATA SHEET (SD	DS) or non hazar	d letter, PACKAGE INS	SERT, LABEL AND PHOTO OF I							



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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?