

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014					Intro	oduction Type:		New Item		Final Version			Date:	2/4/	2019	
PRODUCT INFORMATION									SPECIAL HANDLING AND STORAGE REQUIREMENTS*							
Company Name: Camber Pharmaceuticals Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.									
Application Number for ND	DA/ANDA/BLA (drug); PMA/510(k)(med device):				206419			Tempera	Controlled Room - between 20 and 25 C (68° - 77° F							
DUNS:	82-667-4775								Other Te							
	able) and Established Name: Tolterodine Tartrate ER Capsules 4MG 30CT								(write in)							
Selling Unit NDC:					UPC: 331722608305' MVX Code:				In this product to be objected to sustamore on ice?							
UDI CVX Code:				WVA Code.				Is this product to be shipped to customers on ice? No						-		
Description: Capsule filling machine with size "3", imprinted with 'J' on cap and '105' on body.										Is this product to be shipped to customers on dry ice? No						
Active Ingredient(s): Tolterodone Tartrate									b. Contact for temperature excursion questions: Name: Soma Raiu							
URL for Additional Product Information: www.camberpharma.com							Number	732-529-0423								
Address:				Address 2:								maraju@heterousa.com				
City:	Piscataway			State:	NJ Zip : 08854											
Key Contact:	Customer Service			Email:	customerservice@camberpharma.com 732-562-8788			a.com	c. Special regulations	No No						
Phone Number:	732-529-0430			Fax: 732-562-8788					Special returns requirements for this product? No					-		
Product Therapeutic Classifi	cation:								d Store product (unit	of cala) upright?				No		
ADDITIONA	L PRODUCT INFORM	ATION	1		PRODUCT	DESCRIPTION	INFORM	ATION	d. Store product (unit of sale) upright? Protect product (unit of sale) from light? No							
Is the Product													Months			
a legend device?		No		0:	Í	2007				nelf life at launch (if o	different):			24	Months	
reverse numbered?	No			Size:		30CT			minute of the first that the state of the st							
co-licensed?	No			Strength:		4MG				0	RDER INFO	RMATION				
Is the Product	Direct-Ship Only			oog					1104 44 6	Nata .		What is the	NDC colling	unit?		
Is the Product	oduct Unit Dose			Dosage Form	:	Capsule			Unit of S	Bottle		1 box of 12 b		unitr		
				L				x	Box/Carton			g. 1 Box of 1	0 Vials)			
If Unit Dose, is item bar coded to unit dose for hospital scanning?			Product Shape: N/A				Ampule									
If Unit Dose NDC, indicate NDC here:			Todas onapoi					Glass		Minimum or	der quantity	?	Yes			
Country of Origin				Product Colo	Product Color: Blue					Tube Vial Liquid Sgl						
			Decident learner	Product Imprint: J / 105			Vial Liquid Multi If Yes, how many of which package type?					type?				
Is this product covered under the Trade Agreements Act (TAA)?			Product imprint: J/105			Vial Powder Sql Each										
]	Vial Power Multi			Inner/Carton	/Pack					
FOR GENERIC DRUG PRODUCTS										Other: Write In	1		Case			
			TOR SENERIO DROST RODUCTO								_					
Authorized Generic *If Authorized Generic, other section									PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating: AB			fields are not applicable				Rec. sell unit to customer?			Rx billing unit to pharmacy:						
II. Generic Equivalent to What Brand?: Detrol LA											Each					
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION									(Write-in, e.g. 1 Vial)				Gram Milliliter			
	DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION												wiiiiiter			
Does supplier meet DSCSA of	definition of manufact	urer?	Yes	GLN:					ITEM AND PACKING INFORMATION							
Is product exempt from DSC											D'					
If yes, select exemption: Other exemption - Write in:										Weight Lbs.	Depth	nsions (US m Height	width	Volume (Cube)	# Pieces:	
Is product repackaged?			No	If Yes, was origin	al product	purchased dir	rect		Item:		Бериі			(Oubc)		
Is product sold by manufactu	urer's exclusive distri			from mfr?		•		_		0.05		3	1.5	1		
Has FDA granted waiver/exc	eption/exemption for	product?	No	If yes, attach doc	umentatio	n from FDA.			Box/Carton/Bundle/	0.75	6.75	3	5	0.05	12	
			GTIN PRODUCT INFORMATION						Inner Pack:							
			Saleable						Case:	8	14	8.25	10.75	0.71	96	
			Level Unit			Qua	antity	GTIN-14	Pallet:						352	
Serialized?	Yes	х	Item	X 2D			1	00331722608305							352	
If not, when?		х	Box/Carton/Bundle/Inner Pack X	X 2D			2	10331722608302	UPC:	Case:						
Items aggregated?	gregated? Yes x Case x 2D Linear 96 30331722608306 Pallet 2D Linear							30331722608306	Carton:							
	2D Linear 2D L							COST	WHOLESALER USE ONLY:							
								Regular Cost	Vendor #:							
				2D	\Box	Linear			Invoice Cost (WAC) (\$)		\$100.00	Whsl. Code Fineline Co				
									Federal Excise Tax Pe As of date:	r unit of Sale	1	rineline Co	ue:			
												1				
		,	Attach copy of SAFETY DATA SHEET	(SDS) or non haz	ard letter, F	PACKAGE INSE	ERT, LABI	EL AND PHOTO OF PRO	DDUCT PACKAGING and B	ARCODE.						
*Please provide any addition	al information on pag		• •	•		v p. 3 for Desid			Signatu							



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): **SDS Hazard Classification** a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Organic Corrosive No Is the product a CA Prop 65 reproductive toxicant? Inorganic Oxidizer Does the product label bear a CA Prop 65 warning? Steroid/Androgen Contact Hazard c. Contact Hazard? No Aerosol Class; Identify NFPA Storage Level: d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) Is the product a NIOSH hazardous drug? e. Does the product contain DEHP? No If yes, indicate which: Is this product regulated for shipment by DOT or IATA? No (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name **Hazardous Waste Identification** c. DOT Hazard Class EPA Hazardous Waste Code: d. Packing Group e. Inhalation Hazard? REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: Passenger Is there a REMS on this product? Cargo If Yes, is it managed with a pharmacy registry? Passenger & Cargo Website URL: Is this a reportable quantity? RQ Threshold: Comments / Details: (For example, iPledge program?) Is this a marine pollutant? Nο Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) REMS: Limited Quantity **REMS Program Manager Name:** Phone: Consumer Commodity, ORM-D Supplier Manages REMS registry exclusively: No Small Quantity (49 CFR 173.4) Wholesale distributor support: No Special Permit; DOT-SP Provider Name: Special Provision (listed in Column 7 of 49 CFR 172.101); Site Enrollment Number assigned DEA #: No by Supplier: No SP# PCPDP #: NPI#: No ADD'L STORAGE INFORMATION Is the Product.. Comments Controlled Substance? No Controlled by State(s)? No Registry: ARCOS Reportable? No Registry Program Contact Name: Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code Listed Chemical (List I or II) No RETURN INSTRUCTIONS If ves. indicate which: 732-529-0430 Is it a scheduled listed chemical product?: No Contact tel. # if product received damaged: CLASS OF TRADE RESTRICTION: Is product returnable for credit: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No URL/Link to returns policy: contact - customerservice@camberpharma.com Restricted to retail pharmacy only: Yes Special regulations or returns requirements for this product in certain states? No Restricted to hospital, clinics, and physician offices only: No If so, which states? Other requirements? Comments? Restricted from US territories? (explain in comments) No Comments: MISCELLANEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Page 3)

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

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing							
Purchase orders may be accepted by: a. EDI Yes	Purchase order daily receipt cut off time by supplier Cut off time: 2:30PM Eastern							
b. Autofax No Fax Number: c. Fax Yes Fax Number: 732-562-8788 d. Phone only No Phone No.:	Shipping lead time of PO: 24/48 Hours Days							
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	Ships same day for next day receipt: Ships for second day receipt: No Ships regular ground for 3-10 days receipt: Yes							
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing							
Expedited freight fees billed with each order: No	Overnight receipt available: Yes							
Drop Ship service fee billed with each order: No	PO Receipt cut off time: 2:30PM Eastern							
Drop Ship miscellaneous fees billed: Comments:	Days of week overnight is available: x X Tuesday Wednesday Thursday Friday							
	Priority Overnight receipt available: Yes							
Class of Trade Restriction:	PO Receipt Cut off time: 2:30PM EST							
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Saturday Overnight receipt available: No PO Receipt Cut off time: Phone: Yes Phone #: Fax #: 732-562-8788 Overnight Fees apply: Yes Yes No							
Other Data Information Required to Process PO:	Return Instructions							
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician/Clinic DEA #: Physician/Clinic Specialty: Miscellaneous Notes:	Contact # if product is received damaged: Is product returnable for credit: Ves URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?							
	ADDITIONAL INFORMATION							
	Is product order for scheduled patient procedure? Is product order for restocking purposes? No							