

## **Standard Pharmaceutical Product Information (Rx Product Only)**

© August 2014					Introduction Type:	New Item		Final Version			Date:	2/4/	2019		
			PRODUCT INFORMATION					SPECIAL HANDL	ING AND STO	RAGE REQI	JIREMENTS	*			
Company Name:	Camber Pharmaceuti	cale			Application	on: ANDA	a Tomporaturo – India	ato the USD temper	aturo rango fo	r this produ	ct				
	Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):			206419	206419			a. Temperature – Indicate the USP temperature range Temperature Range				Controlled Room – between 20 and 25 C (68° – 77°			
* *					00413			=	•	CONT. C. ICC.		311 20 and 20	0 (00 11		
DUNS:	82-667-4775	. l=	T					emperature Range Re	quirement				7		
Proprietary Name (If Applica Selling Unit NDC:	31722-607-30	Name:   Tolterodi	ine Tartrate Capsules 2MG 30CT Individual Unit NDC:	1	UPC:  3317	722607308'	- (w	rite in)					]		
UDI	31722-007-30				MVX Code:	22007306	la shia a			-:2		No			
				MYX Gode.			roduct to be shipped t					-			
Description: Capsule filling machine with size "4", imprinted with 'J' on cap and '104' on body.							Is this product to be shipped to customers on dry ice?  No						-		
Andrea In our director		Tallers Bar Tastaria													
Active Ingredient(s): Tolterodine Tartrate							b. Contact for temperature excursion questions:  Name:			Soma Raju					
URL for Additional Product Information: www.camberpharma.com							Number:			732-529-0423					
Address:	1031 Centennial Avenue				Address 2:			-mail:			eterousa.cor	n			
City:	Piscataway State: NJ Zip: 08854						1								
Key Contact:	Customer Service			Email:	customerservice@camb	erpharma.com	c. Special regulations for product in any states?								
Phone Number:	732-529-0430			Fax:	732-562-8788		Special	for this produc	uct? No						
Product Therapeutic Classifi	ication:						•								
_							d. Store product (unit	of sale) upright?				No			
ADDITIONA	AL PRODUCT INFORM	IATION	1		PRODUCT DESCRIPTION	INFORMATION		product (unit of sale	) from light?			No	•		
Is the Product			1				e. Shelf life:					24	Months		
a legend device?		No			****			helf life at launch (if	different):				Months		
reverse numbered?				Size:	30CT			,	,						
co-licensed?		No		Strength: 2MG				C	RDER INFOR	MATION					
Is the Product		Direct-Ship Only		Strength.	ZIVIG										
Is the Product		Unit Dose		Dosage Form	n: Capsule		Unit of	-			NDC selling	unit?			
								Bottle		1 box of 12 b					
If Unit Dose, is item bar code	ed to unit dose for hosp	ital scanning?					x	Box/Carton		(Write-in, e.	g. 1 Box of 1	) Vials)			
KIND Deer NDO Jediene N	IDO 1	-		Product Shap	oe: N/A		Ampule Glass Minimum order quantity? Yes								
If Unit Dose NDC, indicate N	IDC nere:							Glass Tube		Minimum or	der quantity	,	Yes		
Country of Origin		India		Product Colo	r: Blue-Green			Vial Liquid Sgl							
11							Vial Liquid Sgi Vial Liquid Multi If Yes, how many of which package type?								
Is this product covered under	er the Trade Agreement	s Act (TAA)?		Product Impr	int: J / 104		Vial Powder Sql Each								
								Vial Power Multi		12	Inner/Carton	/Pack			
			•				<b>'</b> 1	Other: Write In			Case				
			FOR GENERIC DRUG PRODUC	CTS											
								•							
				Auth		uthorized Generic, other section	PHARMACY ORDER / BILL UNIT								
I. Orange Book Rating:	AB				fields	s are not applicable	Rec. sell unit to customer?			Rx billing unit to pharmacy:					
II. Generic Equivalent to Wha	at Brand?:	Detrol LA					Each								
		DRUG GUDDI	V OLIAIN OF OUR TV A OT (DOO)	AN INCODINATION			(Write-in, e.g. 1 Vial)				Gram				
		DRUG SUPPL	LY CHAIN SECURITY ACT (DSCS	SA) INFORMATION							Milliliter				
Doos supplier most DSCSA	definition of manufact	uror?	Yes								- ·				
Is product exempt from DSC	exempt from DSCSA? No							ITEM AI	ND PACKING	INFORMATI					
If yes, select exemption:								ITEM A	ND PACKING	INFORMATI	ON				
			No	GLN:								Volume	# Pieces:		
Other exemption - Write in:	:		No	GLN:				ITEM Al		sions (US m		Volume (Cube)			
Other exemption - Write in: Is product repackaged?	:		No No		nal product purchased dire	ect	Item:	Weight Lbs.	Dimen	sions (US m Height	smts.) Width				
					nal product purchased dire	ect	Item:		Dimen	sions (US m	smts.)				
Is product repackaged?	urer's exclusive distri	butor?	No	If Yes, was origin	nal product purchased dire	ect	Box/Carton/Bundle/	Weight Lbs.	Dimen Depth	sions (US m Height	width	(Cube)	12		
Is product repackaged? Is product sold by manufactor	urer's exclusive distri	butor?	No No No	If Yes, was origin from mfr? If yes, attach doc		esct	Box/Carton/Bundle/ Inner Pack:	Weight Lbs.	Dimen	sions (US m Height	smts.) Width		12		
Is product repackaged? Is product sold by manufactor	urer's exclusive distri	butor?	No No No GTIN PRODUCT INFORMATIO	If Yes, was origin from mfr? If yes, attach doc		ect	Box/Carton/Bundle/	Weight Lbs.	Dimen Depth	sions (US m Height	width	(Cube)	12 96		
Is product repackaged? Is product sold by manufactor	urer's exclusive distri	butor?	No No No STIN PRODUCT INFORMATIC Salea	If Yes, was origin from mfr? If yes, attach doc ON	cumentation from FDA.		Box/Carton/Bundle/ Inner Pack: Case:	Weight Lbs. 0.05 0.7	Dimen Depth	sions (US m Height 3	width 1.5	(Cube) 0.05			
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## **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