

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

Version 2021					Introduction 1	Type: P	ost Launch Change		x Final Version			Date:	11/19	9/2024
		PRODUCT INFORM	ATION						SPECIAL HAN	IDLING AND STOP	RAGE REQUI	REMENTS*	*	
Company Name: Camber Pharmaceuticals, Inc. AN					ANDA	a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AND			204	4397					Temperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab		·												
DUNS:	11-856-3719							· (Other Temperature Range	Requirement				
Proprietary Name (If Applicable) an		Tolterodine Tartrate Tablets 2 mg						[(write in)					
5	31722-806-60	Unit of Use NDC	:	31722-806-60		3317228066	502	I	Notes					
UDI		CVX Code:			MVX Code:									
Description:	Tolterodine Tartrate Tablets 2	2 mg						[I	s this product to be shippe	d to customers on i	ice?		No	1
Is this product to be shipped to customers on dry ice? No]			
Active Ingredient(s): Tolterodine tartrate, USP														
	b. Contact for temperature excursion questions:													
URL for Additional Product Information Address:	800 Centennial Ave, Suite 1	berpharma.com			Address 2:				Name:		Soma Raju 732-529-042	2		
City:	Piscataway			State:	NJ	Zip: 088	54		Number: Group E-mail:		somaraju@he			
	Customer Service			Email:	customerservice			`			<u>somaraja (em</u>	<u></u>		
Phone Number:	1-866-827-3647			Fax:	732-562-8788			c. Special regu	lations for product in any	states?			No	1
Product Therapeutic Classification		c receptor antagonist							Special returns requiremen				No	
														_
	ADDITIONAL PRC	DUCT INFORMATION			PRODUCT	DESCRIPTIO	N INFORMATION	d. Store produc	d. Store product (unit of sale) upright? No					
The product is?		Is the Product	Direct-Ship C	Dnly				-	Protect product (unit of sa	ale) from light?			No	1
a legend device?	No	Is the Product	Unit of Use			60 ct		e. Shelf life:		,			24	Months
if yes, enter class #		Orphan Drug Status			Size:	20 01			nitial shelf life at launch (if different):				Months
a product kit?	No				Strength:	2 mg								4
if yes, list NDCs of		FDA Approval Status			Suengui.					ORDER INFORM	MATION			
component parts					Dosage For	m: Film-	coated tablet							
reverse numbered?	No							L L	Unit of Sale			NDC selling	unit?	
co-licensed?	No	Allergens Present				D	d block	_	x Bottle		1 Bottle of 6		0 \ (' - 1 -)	
latex-free? preservative-free?	Yes				Product Sha	ape: Rour	nd, biconvex	-	Box/Carton Ampule		(vvrite-in, e.	g. 1 Box of 1	u viais)	
correctional institution block?	No					White	•	-	Glass		Minimum o	der quantity	2	Yes
opioid?	No				Product Col	or:		-	Tube		Minimum O	aci quantity	•	103
Cannabinoid?	No	Country of Origin	India		Bertert		sed with 'J' on one side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to un	nit dose for				Product Imp	and '1	58' on the other side	_	Vial Liquid Multi		If Yes, how	many of whi	ch package i	type?
hospital scanning?		Is this product covered							Vial Powder Sgl		24	Each		
If Unit Dose, indicate NDC here:		Trade Agreements Act	(TAA)?	No					Vial Powder Multi			Inner/Carton	/Pack	
								L	Other: Write In			Case		
		FOR GENERIC DRUG PI	RODUCTS											
								PHARMACY ORDER / BILL UNIT						
				Au	thorized Generic		d Generic, other			IARMACY ORDER				
I. Orange Book Rating: AB						section fields are not applicable Rec. sell unit to custome			o customer?	······································				
II. Generic Equivalent to What Bran	nd?: Detrol								1 <i>0</i> - 1)			Each Gram		
	ופח	IG SUPPLY CHAIN SECURITY ACT						(Write-in, e.g. 1	viai)			Milliliter		
	DIK			MATION								winniter		
Does supplier meet DSCSA definit	tion of manufacturer?	Yes		GLN:	0331722498975				ITEN	I AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?		No												
If yes, select exemption:				GCP:						Dimensi	ions (US msn	nts.)	Volume	Saleable #
Other exemption - Write in:								1	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?		No		If yes, was or	iginal product pur	chased		Item/Each:	0.05	1	1.5	2.5	5.63	1
Is product sold by manufacturer's	exclusive distributor?	Yes		direct from m					0.05	1.5	1.5	2.5	5.63	1
Has FDA granted waiver/exception		No		Provide sour	ce manufacturer fo	or repackaged	d product	Box/Carton/Bu	ndle/					
If yes, attach documentation from	n FDA.							Inner Pack:						
		GTIN AND HIBCC PRODUCT	NEORMATION					Case:	1.7	9.5	6.5	3.75	231.56	24
		GTIN AND HIBCC PRODUCT	INFORMATION					Pallet:						
Saleable Unit of Measure	Saleable Qu	antity HIBCC		CTI	N-14	Uni	t of Use GTIN-14	Fallet:						
X Item/Each					31722806602		31722806602	L						
Box/Carton/Bundle/Inner Pack									WHOLESALER USE ONLY:					
				31722806606	1722806606			COST INFORMATION Regular Cost						
						_		Invoice Cost (W	VAC) (\$)	\$20.00	Whsl. Code			
11	-					_			40/4/0004		Fineline Co	de:		
						-		As of date:	12/1/2021					
											1			
μ											1			
*Plasso provido enviendation - Luc	armation on page 2	Attach copy of SAFETY D	ATA SHEET (SE	or non haza (در										
*Please provide any additional info	ormation on page 2.				See new p. 3 for	Designated	Drop Ship Only.	:	Signature:					

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

	nated Drop Ship Only Products, Please Use Page 3						
MATERIAL	HAZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply): a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? C. Contact Hazard? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? No	x Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No NFPA Storage Level: Image: Contact Hazard						
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 c. DOT Hazard Class d. Packing Group	Is the product a NIOSH hazardous drug? If yes, indicate which: Hazardous Waste Identification						
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics						
Is this product regulated for shipment by IATA? No (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? Is the product restricted for air shipment? If so, indicate restriction: No	REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? No Website URL: No Med Guide Required No						
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) Special Provision (listed in Column 7 of 49 CFR 172.101);	Limited Distribution Requirement Comments / Details: (For example, iPledge program?) REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: Comments						
SP#	Registry: No						
ADD'L STORAGE INFORMATION Is the Product	Registry Program Contact Name: Phone: Comments						
Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) No	RETURN INSTRUCTIONS						
Controlled by State(s)? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: If yes, indicate which: Schedule No. Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy: contact - customerservice@camberpharma.com						
Restricted to retail pharmacy only: No Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No	Special regulations or returns requirements for this product in certain states? No If so, which states? Comments?						
Comments:							
MISCELLA	NEOUS NOTES and/or Image of Product Barcode:						



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Version 2021 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 b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	Purchase order daily receipt cut off time by supplier Cut off time: 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 Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available: Image: Comparison of the co
Class of Trade Restriction:	PO Receipt Cut off time:
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: PO Receipt Cut off time: Order receipt method: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?