

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

Version 2021						Introduction Ty	rpe: Post La	aunch Change		x Final Version			Date:	11/19	9/2024
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STOR	AGE REQUIF	EMENTS*		
Company Name:	Camber Pharmac	euticals Inc				Applicati	on:	ANDA	a Temperatu	re - Indicate the USP tempe	rature range for th	nis product			
Application Number for NDA/AN			ce):	20	14397	1 44			d. remperate	Temperature Range	Controlled Room -		and 25 C (68	° – 77° F)	
Medical Device Class, if applical									†						
DUNS:	11-856-3719								1	Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) a	and Established N	ame: Tolter	odine Tartrate Tablets 1 mg						Ţ	(write in)					
Selling Unit NDC:	31722-805-60		Unit of Use NDC:		31722-805-60	UPC:	331722805605		1	Notes					
UDI			CVX Code:			MVX Code:			I						
Description:	Tolterodine Tartra	ate Tablets 1 mg							ī	Is this product to be shipped	to customers on ic	e?		No	1
										Is this product to be shipped				No	
Active Ingredient(s): Tolterodine tartrate, USP							†			•			_		
							b. Contact fo	r temperature excursion que	estions:						
URL for Additional Product Inform		www.camberpharm	a.com						I	Name:		Soma Raju			
Address:	800 Centennial A	ve, Suite 1				Address 2:				Number:		732-529-042			
City:	Piscataway				<b>Zip</b> : 08854		Group E-mail: somaraju@heterousa.com								
Key Contact:	Customer Service	9			Email:	customerservice@	camberpharma.co	<u>om</u>							7
Phone Number:	1-866-827-3647				Fax:	732-562-8788			c. Special reg	gulations for product in any				No	-
Product Therapeutic Classification	on:	Muscarinic recepto	r antagonist							Special returns requirement	s for this product?			No	
	4.5.5.17		EARLIA TIAN												-
	ADDIII	ONAL PRODUCT IN				PRODUCT D	ESCRIPTION INF	ORMATION	d. Store prod	luct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship (	Only					Protect product (unit of sa	le) from light?			No	
a legend device?		No	Is the Product	Unit of Use		Size:	60 ct		e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status							Initial shelf life at launch (i	if different):				Months
a product kit?		No	FD 4 4			Strength:	1 mg				ORDER INFORM	ATION			
if yes, list NDCs of component parts			FDA Approval Status				Film-coate	d toblet			ORDER INFORM	ATION			
reverse numbered?		No				Dosage Form	Fillif-coate	u tablet		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							x Bottle		1 Bottle of 60			
latex-free?		Yes	7 morgano i rocom				Round, bic	convex		Box/Carton		(Write-in, e.g		) Vials)	
preservative-free?		Yes				Product Shap	e:			Ampule		(	,	,	
correctional institution block?		No				Product Colo	Pale yellow	N		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Colo				Tube					
Cannabinoid?		No	Country of Origin	India		Product Impri		th 'J' on one side		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for					1 roduct impir	nt: and '157' on the	the other side		Vial Liquid Multi		If Yes, how		ch package	type?
hospital scanning?			Is this product covered u							Vial Powder Sgl			Each		
If Unit Dose, indicate NDC here:															
			Trade Agreements Act (1	ΓAA)?	No					Vial Powder Multi			Inner/Carton	/Pack	
					No				<u>]</u>	Vial Powder Multi Other: Write In			Inner/Carton Case	/Pack	
			FOR GENERIC DRUG PR		No									/Pack	
						horizod Conorio	*If A the sine of Con	and albert		Other: Write In	ADMACY ODDED			/Pack	
						horized Generic	*If Authorized Ger			Other: Write In	ARMACY ORDER	/ BILL UNIT	Case		
I. Orange Book Rating:	AB	Date				horized Generic	*If Authorized Ger section fields are		Rec. sell unit	Other: Write In	ARMACY ORDER		Case		
		Detrol				horized Generic				Other: Write In  PH to customer?	ARMACY ORDER	/ BILL UNIT	Case  nit to pharma Each		
I. Orange Book Rating:			FOR GENERIC DRUG PR	ODUCTS	Aut	horized Generic			Rec. sell unit	Other: Write In  PH to customer?	ARMACY ORDER	/ BILL UNIT	nit to pharma Each Gram		
I. Orange Book Rating:				ODUCTS	Aut	horized Generic				Other: Write In  PH to customer?	ARMACY ORDER	/ BILL UNIT	Case  nit to pharma Each		
I. Orange Book Rating:	and?:	DRUG SUPPI	FOR GENERIC DRUG PR	ODUCTS	Aut	horized Generic				Other: Write In  PH  to customer?  1 Vial)	ARMACY ORDER	/ BILL UNIT	case  iit to pharma Each Gram Milliliter		
I. Orange Book Rating: II. Generic Equivalent to What Bra	and?:	DRUG SUPPI	FOR GENERIC DRUG PR	ODUCTS	Aut					Other: Write In  PH  to customer?  1 Vial)		/ BILL UNIT	case  iit to pharma Each Gram Milliliter		
I. Orange Book Rating: II. Generic Equivalent to What Bra  Does supplier meet DSCSA defini Is product exempt from DSCSA?	and?:	DRUG SUPPI	FOR GENERIC DRUG PR  LY CHAIN SECURITY ACT (	ODUCTS	Aut RMATION GLN:					Other: Write In  PH to customer? . 1 Vial)	I AND PACKING IN	/ BILL UNIT  Rx billing ur	Case  iit to pharma Each Gram Milliliter	acy:	Saleable #
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## **Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)**

#### Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL	HAZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic? 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? Does the product label bear a CA Prop 65 warning?	SDS Hazard Classification  x Organic Corrosive Oxidizer Inorganic Oxidizer 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?  Is this product regulated for shipment by DOT?	identify NFPA Storage Level: NFPA Storage Level:  Is the product a NIOSH hazardous drug?  No					
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class	If yes, indicate which:  Hazardous Waste Identification					
d. Packing Group e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics					
Is this product regulated for shipment by IATA?						
(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?	REMS or REGISTRY RESTRICTIONS  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#:  NCPDP#:  NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments  Registry:  No					
<del></del>	Registry Program Contact Name: Phone:					
ADD'L STORAGE INFORMATION	Comments					
Is the Product Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS					
Controlled by State(s)?  ARCOS Reportable?  Schedule No.  No  Listed Chemical (List I or II)  If yes, indicate which:  Is it a scheduled listed chemical product?:  No  CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged:  1-866-827-3647  Yes					
	URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Ye	contact - customerservice@camberpharma.com					
Restricted to retail pharmacy only:	Special regulations or returns requirements for this					
Restricted to hospital, clinics, and physician offices only:  Restricted from US territories? (explain in comments)  No.						
Comments:						
MISCELL	NEOUS NOTES and/or Image of Product Barcode:					



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

#### Version 2021

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

Order Method fo	r Designated Drop Ship 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:	Fax Number: Fax Number: Phone No.: Site Address:	Shipping lead time of PO:  Hours  Days  Ships same day for next day receipt: Ships for second day receipt:
F	Name: Phone:	Ships regular ground for 3-10 days receipt:
Expedited Freight Charg	ges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:		Overnight receipt available:
Drop Ship service fee billed with each order:		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 only: Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician of Restricted from US territories? (explain in conficulty) Comments:	offices only:	Saturday Overnight receipt available:  PO Receipt Cut off time: Phone: Fax: EDI:  Overnight Fees apply: Other fees apply:
Other Data Infor	rmation Required to Process 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?
Mis	scellaneous Notes:	
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure? Is product order for restocking purposes?