

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

Version 2021						Introduction Ty	/pe:	New Item]	x Final Version			Date:	3/20/	/2024
			PRODUCT INFORMA	TION						SPECIAL HAN	IDLING AND STOR	AGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						ANDA	a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN			e):	20-	4792		-		ai romporato	Temperature Range	Controlled Room -		and 25 C (68	3° – 77° F)	
Medical Device Class, if applica		, , , , , , , , , , , , , , , , , , ,	,						†						
DUNS:	11-856-3719								1	Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a	and Established N	ame: Fesote	rodine Fumarate Extended-	Release Tablets	8 mg				Ţ	(write in)					
Selling Unit NDC:	31722-034-30		Unit of Use NDC:		31722-034-30	UPC:	33172203430	12	Î	Notes					
UDI			CVX Code:			MVX Code:									
Description:	Fesoterodine Fur	marate Extended-Rele	ase Tablets 8 mg						T	Is this product to be shipped	d to customers on id	ce?		No	1
•			, , ,							Is this product to be shippe	d to customers on d	ry ice?		No	
Active Ingredient(s): Fesoterodine Fumarate							Î						•		
							b. Contact fo	r temperature excursion qu	estions:						
URL for Additional Product Inform		www.camberpharma.								Name:		Soma Raju			
Address:		Ave (and) 800 Centen	nial Ave, Suite 1			Address 2:				Number:		732-529-042			
City:	Piscataway Customer Service	•			State: Email:	NJ	Zip: 0885			Group E-mail:		somaraju@r	eterousa.cor	<u>n</u>	
Key Contact: Phone Number:	1-866-827-3647	е			Fax:	customerservice@ 732-562-8788	Camperphani	ia.com	c Special rea	gulations for product in any	ctatec?			No	1
Product Therapeutic Classification		Antimuscarinic			l ux.	702 002 0700			c. opeciai re	Special returns requirement				No	
Froduct Therapeutic Classification	on.	Anumuscannic								Special returns requiremen	is for this product?			NO	J
	ADDIT	IONAL PRODUCT INI	FORMATION			PRODUCT D	ESCRIPTION	INFORMATION	d Store prod	luct (unit of sale) upright?				No	1
	7.55			Diseast Chin C	Amilia.	T NODOO! D			u. otore proc]
The product is? a legend device?		No	Is the Product	Direct-Ship C Unit of Use	ліу		30 ct		e. Shelf life:	Protect product (unit of sa	ale) from light?			No 24	Months
if yes, enter class #		INO	Orphan Drug Status	Offit of Ose		Size:	30 61		e. Shelf life:	Initial shelf life at launch (if different).			24	Months
a product kit?		No	Orphian Drug Status				8 mg			minual shell life at launch (ii dillerelli).				Wionins
if yes, list NDCs of		INO	FDA Approval Status			Strength:	0g				ORDER INFORM	IATION			
component parts						Danama Farmi	Film c	pated tablet							
reverse numbered?		No				Dosage Form:	•			Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							x Bottle		1 Bottle of 3			
latex-free?		Yes		Soy		Product Shap	e: Oval,	oiconvex		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes								Ampule					
correctional institution block?		No				Product Color	r: Blue			Glass		Minimum or	der quantity	/?	Yes
opioid? Cannabinoid?		No	Country of Origin	India			Dahaa	sed with 'H' on one		Tube					
If Unit Dose, is item bar coded to	unit done for	No	Country of Origin	india		Product Impri		nd 'F7' on the other		Vial Liquid Sgl Vial Liquid Multi		If Voc. how	many of whi	ich package t	tvno?
hospital scanning?	unit dose for		Is this product covered u	inder the			side a	nd 17 on the other		Vial Powder Sql			Each	icii package i	type:
If Unit Dose, indicate NDC here:			Trade Agreements Act (No					Vial Power Multi		2.7	Inner/Carton	/Pack	
			,	,						Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS					-						
					Au	thorized Generic	*If Authorized	Generic, other		Pl	HARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						section fields	are not applicable	Rec. sell unit	to customer?		Rx billing u	nit to pharma	acv:	
II. Generic Equivalent to What Bra	and?:	Toviaz		_					I				Each		
•									(Write-in, e.g	. 1 Vial)	_		Gram		
		DRUG SUPPL	Y CHAIN SECURITY ACT	(DSCSA) INFOR	RMATION								Milliliter		
				_											
Does supplier meet DSCSA defin		irer?	Yes	_	GLN:	0331722000000				ITEN	M AND PACKING IN	NFORMATION	N		
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:]	Weight Lbs.		ons (US msm	-	Volume	Saleable #
Other exemption - Write in:			No								Depth	Width	Height	(Cube)	Pieces
Is product repackaged? Is product sold by manufacturer's	a avaluatus diatelle		Yes	_	If yes, was or direct from m	iginal product purch	nased		Item/Each:	0.1	1.56	1.56	3.13	7.62	1
Has FDA granted waiver/exception			No	-		rr r ce manufacturer for	ronackagod	product	Box/Carton/E	Rundle/					
If yes, attach documentation fro		Toduct:	140		r rovide source	se manufacturer for	гераскадец	product	Inner Pack:	Juliule/					
yoo, attaon accamontation no									Case:						
		GTII	N AND HIBCC PRODUCT I	NFORMATION					1	2.8	9.75	6.75	4	263.25	24
									Pallet:						
Saleable Unit of Measure	9	Saleable Quantity	HIBCC			N-14		of Use GTIN-14							
X Item/Each		1			003	31722034302	0033	1722034302							
										COST INFORMATION			WHOLESALI	ER USE ONL	Υ:
Box/Carton/Bundle/Inner Pack		24			203	31722034306						Vendor #:			
X Case									Regular Cost						
					-						040.00		#.		
X Case									Invoice Cost		\$40.00	Whsl. Code			
X Case									Invoice Cost	(WAC) (\$)	\$40.00				
X Case											\$40.00	Whsl. Code			
X Case									Invoice Cost	(WAC) (\$)	\$40.00	Whsl. Code			
X Case			Attach copy of SAFETY D	ATA SHEET (SD	S) or non haza	rd letter, PACKAGE I	NSERT, LAB	EL AND PHOTO OF F	As of date:	(WAC) (\$) 3/14/2024	\$40.00	Whsl. Code			



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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? No	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#: NCPDP#: NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments					
SP# ADD'L STORAGE INFORMATION	Registry: No Registry Program Contact Name: Phone: Comments					
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: Is product returnable for credit: URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	contact - customerservice@camberpharma.com					
Restricted to retail pharmacy only: No	Special regulations or returns requirements for this					
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No	product in certain states? If so, which states? Other requirements? Comments?					
Comments:						
MISCELLANE	OUS 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?