

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

Version 2021						Introduction 1	Туре:	Post Launch Change		4 Final Version			Date:	6/1/	2024
			PRODUCT INFORMA	TION						SPECIAL HAN	IDLING AND STOP	AGE REQUI	REMENTS*		
Company Name:	Camber Pharmaceu	uticals. Inc.				Applica	ation:	ANDA	a. Temperature -	Indicate the USP temp	erature range for t	his product.			
Application Number for NDA/AN			e):	204	793					mperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicat	ble:								Î.						
DUNS:	11-856-3719								°	her Temperature Range	Requirement				
Proprietary Name (If Applicable) a		ne: Silodos	in Capsules 8 mg							(write in)					
Selling Unit NDC:	31722-636-30		Unit of Use NDC:		31722-636-30		331722	636308	N	otes					
UDI			CVX Code:			MVX Code:									
Description:	Silodosin Capsules	8 mg								this product to be shippe				No]
Is this product to be shipped to customers on dry ice? No															
Active Ingredient(s): Silodosin b. Contact for temperature excursion questions:															
URL for Additional Product Inform	ation:	www.camberpharma	com							nperature excursion qu ame:	estions:	Soma Raju			
Address:	800 Centennial Ave		<u></u>		1	Address 2:				umber:		732-529-042	3		
City:					State:		NJ Zip: 08854			Group E-mail:			eterousa.cor	n	
Key Contact:	Customer Service					ustomerservice@camberpharma.com							_		
Phone Number:	1-866-827-3647	I-866-827-3647 Fax:			Fax:	732-562-8788			c. Special regula	tions for product in any	states?			No	1
Product Therapeutic Classification	n: /	Alpha-1 adrenergic	eceptor antagonist						S	ecial returns requiremen	ts for this product?			No]
					1										1
	ADDITIO	NAL PRODUCT INF	ORMATION			PRODUCT	DESCRIP	PTION INFORMATION	d. Store product	(unit of sale) upright?				No]
The product is?			Is the Product	Direct-Ship O	nly				Pi	otect product (unit of sa	ale) from light?			No	1
a legend device?	1	No	Is the Product	Unit of Use		Size:	:	30 ct	e. Shelf life:		-			24	Months
if yes, enter class #			Orphan Drug Status			5126.			In	itial shelf life at launch ((if different):				Months
a product kit?	1	No				Strength:	8	8 mg							
if yes, list NDCs of			FDA Approval Status					Used as lather searched			ORDER INFORM	ATION			
component parts reverse numbered?		No				Dosage Form	m:	Hard gelatin capsule		nit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							x Bottle		1 Bottle of 3		unit.	
latex-free?		Yes	Allergens Tresent					Capsule		Box/Carton			g. 1 Box of 1) Vials)	
preservative-free?	1	Yes				Product Sha	ape:			Ampule		(,	5	,	
correctional institution block?	1	No				Product Col	lor:	White cap and white body		Glass		Minimum or	der quantity	?	Yes
opioid?		No				FIGURE CON				Tube					
Cannabinoid?		No	Country of Origin	India		Product Imp		Imprinted with 'H' on cap		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for						â	and 'S2' on body		Vial Liquid Multi		If Yes, how		ch package	type?
hospital scanning?	_		Is this product covered u Trade Agreements Act (N					Vial Powder Sgl Vial Powder Multi		24	Each	(De ele	
If Unit Dose, indicate NDC here:			Trade Agreements Act (IAA)?	No					Other: Write In			Inner/Carton Case	/Раск	
			FOR GENERIC DRUG PR	ODUCTS						Ouler. White hi			Case		
			TOR GENERIC DRUGTR	000013					-						
					Au	thorized Generic	*If Auth	orized Generic, other	PHARMACY ORDER / BILL UNIT						
I. Orange Book Rating:	AB							fields are not applicable	Rec. sell unit to				nit to pharm:	acv.	
II. Generic Equivalent to What Bran		Rapaflo							Rec. sell unit to customer? Rx billing unit to pharmacy: Each						
							(Write-in, e.g. 1 \	/ial)			Gram				
		DRUG SUPPL	Y CHAIN SECURITY ACT (DSCSA) INFOR	MATION								Milliliter		
				_		000180						FORMER			
Does supplier meet DSCSA definit	tion of manufacturer	r?	Yes	_	GLN:	0331722498975				ITEN	I AND PACKING I	NFORMATION	N		
Is product exempt from DSCSA?			UVI												
If yes, select exemption:	_				GCP:					Weight Lbs.		ons (US msm	-	Volume	Saleable #
Other exemption - Write in: Is product repackaged?	-		No		K	iniuni nundunt			Item/Each:		Depth	Width	Height	(Cube)	Pieces
Is product repackaged?	ovclusivo distributo	or2	Yes	_	direct from m	iginal product pur	rcnased		item/Each:	0.08	1.5	1.5	3	6.75	1
Has FDA granted waiver/exception			No	-		ce manufacturer fo	or repack	aged product	Box/Carton/Bun	dle/					
If yes, attach documentation from									Inner Pack:						
									Case:	2.3	9.5	6.5	4	247	24
		GTI	N AND HIBCC PRODUCT II	NFORMATION						2.5	3.5	0.0		247	24
					-				Pallet:						
Saleable Unit of Measure	Sal	leable Quantity	HIBCC			N-14		Unit of Use GTIN-14							
X Item/Each Box/Carton/Bundle/Inner Pack	_	1			0033	31722636308	-	00331722636308		COST INFORMATION			WHOLESALI		v .
Box/Carton/Bundle/Inner Pack	-	24			303	31722636309	-			- OKMATION			MICLEGAL	LK USE UNL	
Pallet	-	24			303		-		Regular Cost			Vendor #:			
									Invoice Cost (W/	AC) (\$)	\$30.00	Whsl. Code	#:		
												Fineline Co			
									As of date:	8/20/2020					
μ												ļ			
			Attach copy of SAFETY DA	ATA SHEET (SD	S) or non haza			, LABEL AND PHOTO OF F							
*Please provide any additional information on page 2. See new p. 3 for Designated Drop Ship Only. Signature:															

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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? 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 Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number No No No No No No No N	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No NFPA Storage Level: Is the product a NIOSH hazardous drug? Is the product a NIOSH hazardous drug? No If yes, indicate which: If yes, indicate which:							
a. On/definition for holder b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Code:							
(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? No 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) Special Permit; DOT-SP	REMS: No REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: DEA #: Provider Name: DEA #: Site Enrollment Number assigned NCPDP#: by Supplier: NPI #:							
Special Provision (listed in Column 7 of 49 CFR 172.101); SP#ADD'L STORAGE INFORMATION	No Registry Program Contact Name: Comments							
Is the Product Controlled Substance? Controlled Substance? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: Schedule No. Is it a scheduled listed chemical product?: No	RETURN INSTRUCTIONS Contact tel. # if product received damaged: 1-866-827-3647 Is product returnable for credit: Yes							
CLASS OF TRADE RESTRICTION: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes	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 Comments: No	Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?							
MISCELLANE	OUS 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?