

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

Version 2021						Introduction 1	Гуре:	Post Launch Change		4 Final Version			Date:	6/1/2	/2024
			PRODUCT INFORMA	TION						SPECIAL HAN	IDLING AND STOP	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharmaceutica	ls. Inc.				Applica	tion:	ANDA	a. Temperature -	Indicate the USP temp	erature range for t	his product.			
Application Number for NDA/AN			e):	204	1793					nperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicat															
DUNS:	11-856-3719								Oth	er Temperature Range	Requirement				
Proprietary Name (If Applicable) a	nd Established Name:	Silodos	in Capsules 4 mg						[(write in)					
Selling Unit NDC:	31722-635-30		Unit of Use NDC:	-	31722-635-30		33172263	5301	Not	es					
UDI			CVX Code:			MVX Code:									
Description:	Silodosin Capsules 4 m	g							ls t	nis product to be shippe	d to customers on i	ce?		No	1
									ls t	nis product to be shippe	d to customers on o	dry ice?		No	
Active Ingredient(s):	Active Ingredient(s): Silodosin														
										perature excursion qu	estions:				
URL for Additional Product Inform Address:	800 Centennial Ave, Su	.camberpharma	.com		1	Address 2:			Nai			Soma Raju 732-529-042	2		
City:	Piscataway	ite i			State:	NJ	Zip: 08	8854		nber: oup E-mail:			is ieterousa.cor	0	
Key Contact:	Customer Service				Email:	customerservice				up E mail.		Somaraja en	101010030.001	<u>u</u>	
Phone Number:	1-866-827-3647				Fax:	732-562-8788			c. Special regulat	ons for product in any	states?			No	
Product Therapeutic Classification	n: Alph	a-1 adrenergic r	eceptor antagonist		1					cial returns requiremen				No	1
•					1						•				_
	ADDITIONAL	PRODUCT INF				PRODUCT	DESCRIPTI	ION INFORMATION	d. Store product (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship O	nly					tect product (unit of sa	ale) from light?			No	1
a legend device?	No		Is the Product	Unit of Use	· ·	0.	30	ct	e. Shelf life:	p. ou aot (unit of Se	,			24	Months
if yes, enter class #	110		Orphan Drug Status			Size:				ial shelf life at launch (if different):				Months
a product kit?	No					Strength:	4 m	ng							-
if yes, list NDCs of			FDA Approval Status			Strength.					ORDER INFORM	IATION			
component parts						Dosage Form	n: Hai	rd gelatin capsule							
reverse numbered?	No		All			-				t of Sale			NDC selling	unit?	
co-licensed? latex-free?	No		Allergens Present				Co	psule		x Bottle Box/Carton		1 Bottle of 3	g. 1 Box of 1) \/iolo)	
preservative-free?	Yes					Product Sha	pe:	psule		Ampule		(write-iii, e.	g. 1 Dox 01 1	5 viais)	
correctional institution block?	No						Wh	nite cap and white body		Glass		Minimum o	der quantity	?	Yes
opioid?	No					Product Cole	or:			Tube			,		
Cannabinoid?	No		Country of Origin	India		Product Imp		printed with 'H' on cap		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for					rioductimp	and	d 'S1' on body		Vial Liquid Multi		If Yes, how		ch package	type?
hospital scanning?			Is this product covered u							Vial Powder Sgl		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (AA)?	No					Vial Powder Multi			Inner/Carton	/Pack	
			FOR GENERIC DRUG PR				_			Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCIS					_						
					Δι	thorized Generic	*If Authori	zed Generic, other		PI	ARMACY ORDER				
L Oran an Datak Dation	AB				7.0	chonzed Ochene		elds are not applicable	Rec. sell unit to c						
I. Orange Book Rating: II. Generic Equivalent to What Bran		aflo							Rec. sen unit to c	ustomer ?		RX billing u	nit to pharma Each	acy:	
II. Generic Equivalent to what Bra	itap	ano							(Write-in, e.g. 1 Vi	al)			Gram		
-		DRUG SUPPLY	Y CHAIN SECURITY ACT (DSCSA) INFOR	MATION				(, e.g				Milliliter		
				_								-			
Does supplier meet DSCSA definit	tion of manufacturer?		Yes		GLN:	0331722498975				ITEN	AND PACKING I	NFORMATIO	١		
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:					Weight Lbs.		ions (US msn	-	Volume	Saleable #
Other exemption - Write in:							_			Weight Ebs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No	_		iginal product pur	chased		Item/Each:	0.05	1.5	1.5	3	6.75	1
Is product sold by manufacturer's Has FDA granted waiver/exception			Yes No	_	direct from m	tr? ce manufacturer fo			Box/Carton/Bund	a/					
If yes, attach documentation from			NO		FIOVICE SOURCE		пераскау	jeu product	Inner Pack:						
in yes, attach documentation nor	III DA.								Case:						
		GTIN	I AND HIBCC PRODUCT II	NFORMATION						1.75	9.5	6.5	4	247	24
									Pallet:						
Saleable Unit of Measure	Saleab	le Quantity	HIBCC			N-14		Init of Use GTIN-14							
X Item/Each		1			003	31722635301	00	0331722635301							
Box/Carton/Bundle/Inner Pack							-			COST INFORMATION			WHOLESAL	ER USE ONL	LY:
X Case		24			3033	31722635302	-		Barrular Caat			Vandard			
Pallet							-		Regular Cost Invoice Cost (WA	(\$)	¢20.00	Vendor #: Whsl. Code	#-		
									Invoice Cost (WA	~) (¥)	\$30.00	Fineline Co			
									As of date:	8/20/2020					
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haza	rd letter, PACKAGE	INSERT, L	ABEL AND PHOTO OF F	PRODUCT PACKAGIN	G and BARCODE.		<u> </u>			

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Version 2021 For Designa	ted Drop Ship Only Products, Please Use Page 3						
MATERIAL HA	ZARD 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?