

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

						Introduction 1	Гуре:	New Item		x Final Version			Date:	11/7	/2024
			PRODUCT INFORMAT	ION						SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharmaceuti	icals Inc				Applica	tion:	ANDA	a Temperatur	re - Indicate the USP temp	erature range for t	his product			
Application Number for NDA/AN			:e)·	20	09908	7.400.000		7.11271	u. remperatur	Temperature Range	Controlled Room		and 25 C (6	3° – 77° F)	
Medical Device Class, if applical													`		
DUNS:	11-856-3719								-	Other Temperature Range	Requirement	Excursions p	ermitted to 1	5-30°C (59-8	36°F)
Proprietary Name (If Applicable) a	and Established Name	e: Tadalat	fil Tablets, USP 2.5 mg		_				1	(write in)					,
Selling Unit NDC:	31722-643-30		Unit of Use NDC:		31722-643-30	UPC:	331722643306		1	Notes					
UDI			CVX Code:			MVX Code:									
Description:	Tadalafil Tablets, USI	P 2.5 ma							1	Is this product to be shippe	d to customers on i	ce?		No	1
•		ŭ								Is this product to be shippe				No	1
Active Ingredient(s):	Ta	adalafil, USP							1						
									b. Contact for	temperature excursion qu	estions:				
URL for Additional Product Inform		ww.camberpharm	a.com							Name:		Soma Raju			
Address:	800 Centennial Ave,	Suite 1			State:	Address 2:			-	Number:		732-529-042			
City:	Piscataway Customer Service				Email:	NJ	Zip: 08854		-	Group E-mail:		somaraju@h	ieterousa.coi	<u>n</u>	
Key Contact: Phone Number:	1-866-827-3647				Fax:	732-562-8788	@camberpharma	i.com	c Special reg	ulations for product in any	etatoe?			No	1
Product Therapeutic Classificatio		hosphodiesterase	5 (DDE5) inhibitor		l ux.	702 002 0700			c. opeciai regi	Special returns requiremen				No	
Froduct Therapeutic Classificatio	,,,,	liospriodiesterase	5 (FDE5) ITITIDITO							Special returns requiremen	is for this product?			INO	
	ADDITIONA	AL PRODUCT INF	ORMATION			PRODUCT	DESCRIPTION IN	FORMATION	d Store produ	uct (unit of sale) upright?				No	1
T	ADDITION	ALT RODGOT IN		Discret Ohio	Orto	TRODUCT	JEGGIUII TIGIV III	II OIIIIATION	u. Store prout]
The product is? a legend device?	Ne	_	Is the Product	Direct-Ship Unit of Use	Only		30 ct		e. Shelf life:	Protect product (unit of s	ale) from light?			No 24	Months
if yes, enter class #	IN	0	Orphan Drug Status	Offic Of Ose		Size:	30 61		e. Sileli ille.	Initial shelf life at launch	if different):			24	Months
a product kit?	Ne	0	Orphan Drug Otatus			_	2.5 mg			initial shell life at launon	ii diiiciciity.				Wonting
if yes, list NDCs of			FDA Approval Status			Strength:	2.0 mg				ORDER INFORM	IATION			
component parts						Dosage For	Film-coat	ted tablet							
reverse numbered?	Ne	0				Dosage For				Unit of Sale		What is the	NDC selling	unit?	
co-licensed?	Ne		Allergens Present							x Bottle		1 Bottle of 30			
latex-free?	Ye					Product Sha	Round, b	oiconvex		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?	Ye									Ampule				_	
correctional institution block?	Ne					Product Col	or: Blue			Glass		Minimum o	der quantit	y?	Yes
opioid? Cannabinoid?	N		Country of Origin	India			Debossed	with 'T18' on one		Tube Vial Liquid Sgl					
If Unit Dose, is item bar coded to u		0	Country of Origin	mula		Product Imp		I' on the other side		Vial Liquid Sgi		If Yes, how	many of wh	ich nackada	type?
hospital scanning?	uriit dose roi								1 1	viai Liquiu iviuiti				icii package	
			Is this product covered un	nder the						Vial Powder Sal		24	Fach		
If Unit Dose, indicate NDC here:			Is this product covered un Trade Agreements Act (T		No					Vial Powder Sgl Vial Powder Multi			Each Inner/Cartor	/Pack	
If Unit Dose, indicate NDC here:			Is this product covered ur Trade Agreements Act (T		No					Vial Powder Sgl Vial Powder Multi Other: Write In			Each Inner/Cartor Case	/Pack	
If Unit Dose, indicate NDC here:				AA)?	No					Vial Powder Multi			Inner/Cartor	/Pack	
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	AA)?	No					Vial Powder Multi			Inner/Cartor	n/Pack	
If Unit Dose, indicate NDC here:			Trade Agreements Act (T	AA)?		norized Generic	*If Authorized G	Seneric, other		Vial Powder Multi Other: Write In	ARMACY ORDER		Inner/Cartor	l/Pack	
	AB1		Trade Agreements Act (T	AA)?		norized Generic		Seneric, other re not applicable	Rec. sell unit	Vial Powder Multi Other: Write In	ARMACY ORDER	/ BILL UNIT	Inner/Cartor Case		
If Unit Dose, indicate NDC here: I. Orange Book Rating: II. Generic Equivalent to What Bra		ialis	Trade Agreements Act (T	AA)?		norized Generic			Rec. sell unit	Vial Powder Multi Other: Write In	ARMACY ORDER		Inner/Cartor Case		
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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 HAZ	ARD 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? 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? (if yes, answer a-e below and provide SDS)	SDS Hazard Classification X Organic Oxidizer Oxidizer Contact Hazard Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level: Is the product a NIOSH hazardous drug? If yes, indicate which:						
a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Hazardous Waste Identification 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?	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:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP# ADD'L STORAGE INFORMATION	Comments Registry: Registry Program Contact Name: Comments Phone:						
Is the Product	Comments						
Controlled Substance? Controlled Substance? Controlled Substance? Controlled Substance Code Listed Chemical (List I or II) No ARCOS Reportable? 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: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No Comments:	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?						
COHMITCHES.							
MISCELLANEC	DUS 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 for Designated Drop Ship Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI b. Autofax Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time:
c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number:	Shipping lead time of PO: Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Contracted 3PL company / contact #: Name: Phone:	
Expedited Freight Charges 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, 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: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information 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?
Miscellaneous Notes:	
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? Is product order for restocking purposes?