

Standard Pharmaceutical Product Information (Rx Product Only)

					Introduction Typ	be:	New Item		Final Version			Date:		
			PRODUCT INFORMATION	N					SPECIAL HANDL	ING AND STO	RAGE REQ	UIREMENTS	*	
Company Name:	Camber Pharmaceuti	cale			Applica	ation:	ANDA	a. Temperature – Indic	ata tha LICD tampar	roturo rongo i	or this prod	unt		
Application Number for ND) -	209908	Аррію	ation.	7111071		ture Range	rature range i			en 20 and 25	C (68° – 77° F
		minoro(k)(mea aevice)	<i>y</i> .	200000				-	=		- COTTLI CHICA T	oom bomo	011 20 4114 20	
DUNS:	82-667-4775		T						mperature Range Re	equirement				1
Proprietary Name (If Applical		Name: Tadalafil	Tablets 10MG 30CT		UPC: 33	31722645300		(wri	ite in)					1
Selling Unit NDC:	31722-645-30		Individual Unit NDC:			31722645300		1. 0.2			0			
UDI			CVX Code:		MVX Code:			: I	oduct to be shipped to				No	-
Description:	Capsule shape conca	ive punches embossed wi	ith 'H' on lower punch and 'T16' o	on upper punch.				Is this pro	oduct to be shipped to	to customers o	n dry ice?		No	_
Active Ingredient(s):		Tadalafil						b. Contact for tempera	ture excursion que	estions:				
l								Name:			Soma Raju	00		
URL for Additional Product In Address:				Address 2:			Number:			732-529-0423 somaraju@heterousa.com				
City:				n. 1000	0E4	Group E-mail: somaraju@heterousa.com								
Key Contact:	Customer Service				State: NJ Zip: 08854 Email: customerservice@camberpharma.com			c Special regulations	or product in any e	tates?			No	
Phone Number:	732-529-0430				Fax: 732-562-8788			c. Special regulations for product in any states? Special returns requirements for this product						
Product Therapeutic Classifi					102 002 0100			I oposiai i	otarrio roquiromonto i	ror and produc	•			-
Froduct Therapeutic Classiii	ication.							d Ctone mandries (rimit					NI-	
ADDITIONA	AL PRODUCT INFORM	ATION	1	DI	RODUCT DESCRIPTION	ON INFORMATI	TION	d. Store product (unit of	or sale) uprignt? product (unit of sale	a) from liabt?			No No	-
	AL FRODUCT IN ORM	ATION		r	RODOCT DESCRIPTION	ON IN ORMATI	TION	•	broduct (unit or Sale	e) iroin iigiit?			INU	7
Is the Product								e. Shelf life:						Months
a legend device?		No		Size:	30CT			Initial sh	elf life at launch (if o	different):				Months
reverse numbered?		No								ORDER INFOR	MATION			
co-licensed?		Direct-Ship Only		Strength:	10MG				Ţ	ORDER INFO	RIVIATION			
Is the Product Is the Product		Unit Dose						Unit of S	ala		What is the	NDC selling	unit?	
is the Floduct		OTHE DOSC		Dosage Form:	Tablet			Onit of 3	Bottle		1 box of 24		unik.	
								x	Box/Carton			g. 1 Box of 1	0 Vials)	
If Unit Dose, is item bar code	ed to unit dose for hosp	ital scanning?							Ampule		(,	
If Unit Dose NDC, indicate NI	DC here:			Product Shape:	: Capsule-shap	ped			Glass		Minimum o	rder quantity	/?	Yes
, , , , , , , , , , , , , , , , , , , ,				Product Color:	White				Tube					-
Country of Origin		India		Product Color:	vvnite				Vial Liquid Sgl					
Is this product covered under	r the Trade Agreements	Act (TAA)2		Product Imprint	t: T16 / H				Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
is this product covered under	tile frade Agreements	ACI (IAA):		i roduct imprim					Vial Powder Sql			Each		
<u> </u>]				'		Vial Power Multi		24	Inner/Cartor	√Pack	
					<u></u>				Vial Power Multi Other: Write In	_	24	Case	/Pack	
			FOR GENERIC DRUG PRODU	UCTS							24	4	/Pack	
			FOR GENERIC DRUG PRODU			KA III STATE			Other: Write In	BMACY ORDE		Case	/Pack	
			FOR GENERIC DRUG PRODU				eneric, other section		Other: Write In	RMACY ORDE	R/BILL UNI	Case		
I. Orange Book Rating:	AB	To a	FOR GENERIC DRUG PRODU			If Authorized Ge ields are not app		Rec. sell unit to custom	Other: Write In	RMACY ORDE	R/BILL UNI	Case T nit to pharm		
I. Orange Book Rating:		Cialis	FOR GENERIC DRUG PRODU						Other: Write In	RMACY ORDE	R/BILL UNI	Case T nit to pharm Each		
				Authori				Rec. sell unit to custor	Other: Write In	RMACY ORDE	R/BILL UNI	Case T nit to pharm Each Gram		
			FOR GENERIC DRUG PRODU	Authori					Other: Write In	RMACY ORDE	R/BILL UNI	Case T nit to pharm Each		
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Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL H	HAZARD CLASSIFICATION and TRANSPORTATION	
Is this product (check all that apply):		,
a. Cytotoxic?	SDS Hazard Classification	
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	ODO HAZARA GRADANIONI	
Is the product a CA Prop 65 carcinogen?	Organic Corrosive	
Is the product a CA Prop 65 carcinogen?	Inorganic Oxidizer	
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard	
- O-st-st-H10	Associated Characteristic NETPA Characteristics	
c. Contact Hazard?	Aerosol Class; Identify NFPA Storage Level:	
d. Does this product require special clean-up instructions? No		
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug?	
e. Does the product contain DEHP?	If yes, indicate which:	
Is this product regulated for shipment by DOT or IATA?		
(if yes, answer a-e below and provide SDS)		
a. UN/Identification Number		
b. Proper Shipping Name	Hazardous Waste Identification	
c. DOT Hazard Class	EPA Hazardous Waste Code:	
d. Packing Group		
e. Inhalation Hazard?		
	DELIA DEGLETA DESTRUCTIONA	
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS	
Passenger	Is there a REMS on this product?	
Cargo	If Yes, is it managed with a pharmacy registry?	
Passenger & Cargo	Website URL:	
Is this a reportable quantity? No		
RQ Threshold:	Comments / Details: (For example, iPledge program?)	
Is this a marine pollutant?		
Is this product shipped utilizing an authorized DOT exception or Special Permit?		
No (if yes, identify method below)	REMS:	
Limited Quantity	REMS Program Manager Name: Phone:	
Consumer Commodity, ORM-D	Supplier Manages REMS registry exclusively: No	
Small Quantity (49 CFR 173.4)	Wholesale distributor support: No	
Special Permit; DOT-SP	Provider Name:	
Special Provision (listed in Column 7 of 49 CFR 172.101);	Site Enrollment Number assigned DEA #: No	
SP#	by Supplier: PCPDP #: No	
01 #		
ADD'L STORAGE INFORMATION	NPI #: No	
Is the Product	Comments	
	Comments	
	Pariety, No.	
Controlled by State(s)? ARCOS Reportable? No	Registry: No	
·	Registry Program Contact Name: Phone:	
Schedule No. (inc. N for non-narcotic)	Comments	
Controlled Substance Code	RETURN INSTRUCTIONS	
Listed Chemical (List I or II) No	RETURN INSTRUCTIONS	
If yes, indicate which:		
Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: 732-529-0430	
CLASS OF TRADE RESTRICTION:	Is product returnable for credit:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	URL/Link to returns policy: contact - customerservice@camberpharma.com	
Restricted to retail pharmacy only: Yes	Special regulations or returns requirements for this product in certain states?	
Restricted to hospital, clinics, and physician offices only:	If so, which states? Other requirements? Comments?	
Restricted from US territories? (explain in comments) No		
Comments:		
Comments.		
MISCELLAN	NEOUS NOTES and/or Image of Product Barcode:	



Standard Pharmaceutical Product Information (Page 3)

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: Case pack Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone: Yes Fax Number: 732-562-8788 No Phone No.: No Site Address: 732-529-0430 x466 x465 x467 x470 Name: Phone:	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:	Eastern Days No No Yes			
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Process				
Expedited freight fees billed with each order: No	Overnight receipt available:	Yes			
Drop Ship service fee billed with each order: No		Eastern			
Drop Ship miscellaneous fees billed: Comments:		x Monday x Tuesday x Wednesday x Thursday Friday			
	Priority Overnight receipt available:	Yes			
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) No Comments:	EDI: Yes Overnight Fees apply: Yes Other fees apply: No	2:30PM EST No 732-562-8788			
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: Miscellaneous Notes:	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 s If so, which states? Other requirements? Comments?	732-529-0430 Yes states? Yes			
	ADDITIONAL INFORMATION				
	Is product order for scheduled patient procedure? Is product order for restocking purposes?	No No			