

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

Version 2024							Introduction 7	Туре:	New Item		x Final Version			Date:	11/7/	2024
				PRODUCT INFORMAT	TION						SPECIAL HAN	IDLING AND STOR	AGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application:						ANDA	a. Temperature – Indicate the USP temperature range for this product.									
Application Number for NDA/AN			213014				NDA 505(b) Type		NOT APPLICABLE		Temperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applical											· -					
DUNS:	11-856-3719									`	Other Temperature Range	Requirement	AFTER RECONS	FITUTION: Store be	elow 30°C (86°F) or	in refrigerator at
Proprietary Name (If Applicable) a		ame:	Sildenafil for	r Oral Suspension 10 m	ng/mL						(write in)		2°C to 8°C (36°F to days after reconst		ze. Discard any un	used portion 60
Selling Unit NDC:	31722-136-31			Unit of Use NDC:			UPC:	33172	2136310		Notes					
UDI				CVX Code:			MVX Code:									
Description:	Sildenafil for Oral	Suspension 1	0 mg/mL								Is this product to be shippe	d to customers on i	ce?		No	
											Is this product to be shippe	d to customers on o	Iry ice?		No	
Active Ingredient(s):		Sildenafil cit	rate, USP													
URI for Additional Product Information: www.cambembarma.com									b. Contact for	temperature excursion qu	estions:	O D-'				
URL for Additional Product Inform Address:	800 Centennial Ave, Suite 1			Address 2:				Name: Number:		Soma Raju 732-529-042	2					
City:	Piscataway	ave, oute i			State:	State: NJ Zip: 08854							somaraju@heterousa.com			
Key Contact:	Customer Service	;e			Email:	-	e@camberpharma.com		Stroup E-Ilian.							
Phone Number:	1-866-827-3647				Fax: 732-562-8788				c. Special regulations for product in any states?			No			7	
Product Therapeutic Classification	n:	Phosphodies	sterase-5 (PD	E-5) inhibitor				Special returns requirements for th				ts for this product?	duct? No			
			,	•		I					.,					
	ADDITI	IONAL PRODU	UCT INFORM	IATION			PRODUCT	DESCRI	IPTION INFORMATION	d. Store product (unit of sale) upright?						
The product is?			ls	the Product	Direct-Ship O	nly					Protect product (unit of sa	ale) from light?			No	
a legend device?		No		the Product	Neither		Size:		112 mL following	e. Shelf life:	. ,	. •			24	Months
if yes, enter class #			Oı	rphan Drug Status			Size.		reconstitution		Initial shelf life at launch (	if different):				Months
a product kit?		Yes					Strength:		10 mg/mL following							
if yes, list NDCs of			FE	DA Approval Status					reconstitution			ORDER INFORM	IATION			
component parts reverse numbered?		INI.					Dosage Fori		Crystalline powder for oral suspension		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No No	Δ1	lergens Present					suspension		x Bottle		1 Bottle of 1			nension
latex-free?		Yes							N/A		Box/Carton			g. 1 Box of 10		ochion
preservative-free?		No		Gluten, Corn, S	ugar, and Whea	at	Product Sha	ape:			Ampule		,,	,	,	
correctional institution block?		No	_				Product Col	lor:	White to off-white		x Glass		Minimum or	der quantity	?	Yes
opioid?		No					Froduct Cor	ю.			Tube				'	
Cannabinoid?		No	Co	ountry of Origin	India		Product Imp	orint:	N/A		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for										Vial Liquid Multi				ch package t	type?
hospital scanning? If Unit Dose, indicate NDC here:				this product covered u ade Agreements Act (T	nder the	Yes					Vial Powder Sgl Vial Powder Multi		1	Each Inner/Carton	/Dook	
II Offit Dose, indicate NDC fiere.			- 11	ade Agreements Act (1	AA):	162					Other: Write In			Case	/Fack	
			FOR	GENERIC DRUG PR	ODUCTS											
				OZNZNIO DINOGRA	5555.5											
						Au	uthorized Generic	*If Autl	horized Generic, other		Pł	IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB							section	n fields are not applicable	Rec. sell unit to customer? Rx billing unit to pharmacy:						
II. Generic Equivalent to What Brand?: Revatio for Oral Suspension							Each									
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORM								(Write-in, e.g.				Gram				
		DRUG	SUPPLY CH	AIN SECURITY ACT (	DSCSA) INFOR	MATION				HCPCS J-Cod	le:	1		Milliliter		
Does supplier meet DSCSA defini	tion of manufactur	rer?		Yes	_	GLN:	0331722498975				ITEN	M AND PACKING I	NEORMATIO	J		
Is product exempt from DSCSA?	tion of manadacta		N		-	OLIV.	0001122430313							•		
If yes, select exemption:						GCP:						Dimonei	ons (US msn	nts )	Volume	Saleable #
Other exemption - Write in:											Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			N	0		If yes, was o	riginal product pur	rchased		Item/Each:	0.35		2			1
Is product sold by manufacturer's	exclusive distribu	utor?		Yes		direct from n					0.35	2.8	2	5.25	29.40	1
Has FDA granted waiver/exception		roduct?		No		Provide sour	ce manufacturer fo	or repac	kaged product	Box/Carton/B	undle/					
If yes, attach documentation from	m FDA.									Inner Pack:						
			CTINI ANI	D HIBCC PRODUCT IN	JEORMATION					Case:	5.05	9.25	9.25	7.25	620.33	12
			GTIN ANI	D HIBCC PRODUCT II	NFORMATION					Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)	Saleable	н	BCC		GTI	IN-14		Unit of Use GTIN-14	r allet.						
	3(*)	Quantity	• • • • • • • • • • • • • • • • • • • •	-		5				-						
x Item/Each	N	1				003	331722136310									
Box/Carton/Bundle/Inner Pack											COST INFORMATION			WHOLESALE	ER USE ONL	Y:
X Case	N	12				203	331722136314			<u> </u>						
Pallet								_		Regular Cost	M(AC) (\$)	£400.00	Vendor #:	ш.		
			-							Invoice Cost (	VVAC) (P)	\$120.00	Whsl. Code Fineline Co			
										As of date:	6/1/2022		. mome ou			
													ĺ			
			Attac	ch copy of SAFETY DA	TA SHEET (SD	S) or non haza			T, LABEL AND PHOTO OF P	RODUCT PACKA	GING and BARCODE.	·				
*Please provide any additional inf		•					C 2 f	- D:	ated Dron Shin Only		Cianatura					



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

#### Version 2024

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?	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?							
Is the product a CA Prop 65 carcinogen?	x Organic Corrosive						
Is the product a CA Prop 65 reproductive toxicant?	Inorganic Oxidizer						
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard						
c. Contact Hazard?	Does the product have an Aerosol class? If yes, No						
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:						
(If yes, attach SDS with special instructions.)	NFPA Storage Level:						
e. Does the product contain DEHP?							
Is this product regulated for shipment by DOT?	Is the product a NIOSH hazardous drug?						
(if yes, answer a-e below and provide SDS)	If yes, indicate which:						
a. UN/Identification Number	ii yes, indicate which.						
b. Proper Shipping Name							
c. DOT Hazard Class	Hazardous Waste Identification						
d. Packing Group							
e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics						
, ,	REMS or REGISTRY RESTRICTIONS						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMOUT REGISTRY RESTRICTIONS						
	Is there a REMS on this product?						
b. Proper Shipping Name c. DOT Hazard Class	If Yes, is it managed with a pharmacy registry?						
d. Packing Group	Website URL:						
e. Inhalation Hazard?	Website UKL.						
Is the product restricted for air shipment? If so, indicate restriction:	Med Guide Required No						
Passenger	Limited Distribution Requirement						
Cargo	Comments / Details: (For example, iPledge program?)						
Passenger & Cargo							
Is this a reportable quantity? No	REMS: No						
RQ Threshold:	REMS Program Manager Name: Phone:						
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:						
Is this product shipped utilizing an authorized DOT exception or Special Permit?	Wholesale distributor support:						
No (if yes, identify method below)	Provider Name: DEA #:						
Limited Quantity	Site Enrollment Number assigned NCPDP#:						
Consumer Commodity, ORM-D	by Supplier: NPI #:						
Small Quantity (49 CFR 173.4)	Comments						
Special Permit; DOT-SP	Comments						
Special Provision (listed in Column 7 of 49 CFR 172.101);							
SP#	Registry: No						
ADDII CTODAGE INFORMATION	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	Comments						
Is the Product							
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS						
Controlled by State(s)? No Listed Chemical (List I or II) No							
ARCOS Reportable? No If yes, indicate which:	Contact tel. # if product received damaged: 1-866-827-3647						
Schedule No. Is it a scheduled listed chemical product?: No	Is product returnable for credit:						
CLASS OF TRADE RESTRICTION:	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 product in certain states?						
Restricted to hospital, clinics, and physician offices only:  No	INU						
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?						
Comments:							
MISCELLANEO	DUS NOTES and/or Image of Product Barcode:						



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

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#### 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:  PO Receipt cut off time:  Days of week overnight is available:  Monday Tuesday Wednesday Thursday Friday						
	Priority Overnight receipt available:						
Class of Trade Restriction:  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:	PO Receipt Cut off time:  Saturday Overnight receipt available: PO Receipt Cut off time: Phone: 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:  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 states? If so, which states? Other requirements? Comments?						
	ADDITIONAL INFORMATION						
	Is product order for scheduled patient procedure? Is product order for restocking purposes?						