

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

Version 2024						Introduction Ty	rpe: Post Launch Change		x Final Version			Date:	11/19	9/2024
			PRODUCT INFORMAT	ION					SPECIAL HA	NDLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharmac	ceuticals, Inc.				Application	on: ANDA	a. Temperatur	e - Indicate the USP temp	perature range for t	his product.			
Application Number for NDA/ANI	DA/BLA; PMA/510	O(k): 214790				NDA 505(b) Type:	NOT APPLICABLE		Temperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicable:														
DUNS:	11-856-3719							_	Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a		ame: Sertralir	ne Hydrochloride Tablets, US	SP 50 mg (base	)				(write in)					
Selling Unit NDC:	31722-146-05		Unit of Use NDC:				331722146050		Notes					
UDI			CVX Code:			MVX Code:		1						
Description:	Sertraline Hydroc	hloride Tablets, USP 5	0 mg (base)						Is this product to be shippe	ed to customers on i	ce?		No	
									Is this product to be shippe	ed to customers on o	Iry ice?		No	
Active Ingredient(s):		Sertraline hydrochlor	ide, USP					11		_				
URL for Additional Product Information: www.camberpharma.com								b. Contact for	temperature excursion q	uestions:	Soma Raju			
Address:	800 Centennial A		COM			Address 2:		+	Name: Number:		732-529-042	3		
City:	Piscataway	ve, Suite 1  Address 2:  State: NJ					<b>Zip:</b> 08854	-	Group E-mail: somaraju@heterousa.com					
Key Contact:	Customer Service	9			Email:	customerservice@	camberpharma.com		o.oup 2 man.				-	
Phone Number:	1-866-827-3647				Fax:	732-562-8788	· ·	c. Special reg	ulations for product in an	y states?			No	
Product Therapeutic Classification	1:	Selective serotonin re	euptake inhibitor (SSRI)					_	Special returns requiremen	nts for this product?			No	
	ADDITI	IONAL PRODUCT INF	ORMATION			PRODUCT D	ESCRIPTION INFORMATION	d. Store produ	ct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship Or	nly			11	Protect product (unit of s	sale) from light?			No	ĺ
a legend device?		No	Is the Product	Neither	-	Size:	500 ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status			Size:			Initial shelf life at launch	(if different):				Months
a product kit?		No				Strength:	50 mg							
if yes, list NDCs of			FDA Approval Status							ORDER INFORM	IATION			
component parts						Dosage Form	Film coated tablet		Unit of Sale		What is the	NDC aallina	:42	
reverse numbered? co-licensed?		No No	Allergens Present						x Bottle		1 Bottle of 50		unitr	
latex-free?		Yes					Modified capsule		Box/Carton			g. 1 Box of 10	) Vials)	
preservative-free?		Yes	Corn, Alcoho	l, Sugar, Dye		Product Shap	e:		Ampule		(	,		
correctional institution block?		No				Product Color	Blue		Glass		Minimum or	der quantity	?	Yes
opioid?		No				Froduct Color			Tube					
Cannabinoid?		No	Country of Origin	USA		Product Impri	One side debossed with 'T' and '50' with functional score line in between and		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for						plain on the other side		Vial Liquid Multi		If Yes, how		ch package	type?
hospital scanning?			Is this product covered un Trade Agreements Act (Tr		Yes				Vial Powder Sgl Vial Powder Muli	,		Each	/DI-	
If Unit Dose, indicate NDC here:			Trade Agreements Act (17	AA)?	Yes				Other: Write In	II .		Inner/Carton Case	Раск	
			FOR GENERIC DRUG PRO	DUCTE				<u> </u>	Other. Write III			Case		
			FOR GENERIC DRUG FRO	DUCIS										
				Ī	Au	thorized Generic	*If Authorized Generic, other		Р	HARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB			т '			section fields are not applicable	Rec. sell unit			Rx billing ur	it to phorms	.01	
II. Generic Equivalent to What Bran		Zoloft		1				Tree. Sen unit	io customer.		IXX billing u	Each	icy.	
Conone Equivalent to Tinat Drai								(Write-in, e.g.	1 Vial)			Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (D	SCSA) INFORI	MATION			HCPCS J-Cod	e:			Milliliter		
Does supplier meet DSCSA definit	ion of manufactu	rer?	Yes		GLN:	0331722498975			ITE	M AND PACKING I	NFORMATION			
Is product exempt from DSCSA?			No											
If yes, select exemption:					GCP:				Weight Lbs.		ons (US msm		Volume	Saleable #
Other exemption - Write in:									g	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?		10	No Yes		If yes, was or direct from m	iginal product purcl	nased	Item/Each:	0.22	2.2	2.2	3.9	18.88	1
Is product sold by manufacturer's Has FDA granted waiver/exception			No	-			repackaged product	Box/Carton/Bi	undlo/	_				
If yes, attach documentation from		Toduct?	140	1	Frovide Source	Le manulacturer for	repackaged product	Inner Pack:	undie/					
yoo, attaon accamentation non								Case:						
		GTIN	AND HIBCC PRODUCT IN	FORMATION					5.7	14.5	10.25	4.75	705.97	24
								Pallet:						
Saleable Unit of Measure	RFID tag(Y/N)		HIBCC		GTII	N-14	Unit of Use GTIN-14							
		Quantity												
X Item/Each	N	1			0033	31722146050			COST INFORMATION			WHOLESALE	D LISE ON	v
Box/Carton/Bundle/Inner Pack  X Case	N	24			103	31722146057			COST INFORMATION		1	MIOLESALI	IN USE UNL	.1.
Pallet	IN	2-7			103			Regular Cost			Vendor #:			
								Invoice Cost (	WAC) (\$)	\$42.75	-	#:		
								ll `			Fineline Cod	le:		
								As of date:	7/23/2021			'		
								11						
			Attach copy of SAFETY DAT	TA SHEET (SDS	S) or non haza		NSERT, LABEL AND PHOTO OF	PRODUCT PACKA						
*Please provide any additional info	ormation on page	Z.				See new p. 3 for D	Designated Drop Ship Only.		Signature:					



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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?	SDS Hazard Classification						
Is the product a CA Prop 65 carcinogen?  Is the product a CA Prop 65 reproductive toxicant?  No  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?	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  NFPA Storage Level:						
Is this product regulated for shipment by DOT?  (if yes, answer a-e below and provide SDS)  a. UN/Identification Number  b. Proper Shipping Name	Is the product a NIOSH hazardous drug?  If yes, indicate which:						
c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	Hazardous Waste Identification  EPA Hazardous Waste Code:  Waste Characteristics						
ls this product regulated for shipment by IATA?	EFA Hazaiuous waste Code.						
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS						
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: No Phone:  DEA #: NCPDP#: NCPDP#: NPI #:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments  Registry:  No						
	Registry Program Contact Name: Phone:						
ADD'L STORAGE INFORMATION	Comments						
Is the Product  Controlled Substance?  Controlled Substance Code  Controlled by State(s)?  ARCOS Reportable?  Schedule No.  No  Controlled Substance Code  Listed Chemical (List I or II)  No  If yes, indicate which:  Is it a scheduled listed chemical product?:  No	RETURN INSTRUCTIONS  Contact tel. # if product received damaged:  Is product returnable for credit:  Yes						
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:  Restricted to hospital, clinics, and physician offices only:  No Restricted from US territories? (explain in comments)  No	Special regulations or returns requirements for this product in certain states?  If so, which states? Other requirements? Comments?						
Comments:							
MISCELLAN	EOUS NOTES and/or Image of Product Barcode:						



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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  Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time:
c. Fax d. Phone only Phone No.:	Shipping lead time of PO: Hours Days
e. Supplier Web Site only  Minimum Order Quantity:  Supplier's Customer Service Number:  Contracted 3PL company / contact #:  Name: Phone:	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:	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/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?