

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

Version 2021						Introduction Type:	: Post Launch Change		x Final Version			Date:	11/19	9/2024
			PRODUCT INFORMA	TION					SPECIAL H	NDLING AND STOR	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 202682								Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)		
Medical Device Class, if applicable:														
DUNS:	11-856-3719								Other Temperature Rang	Requirement				
Proprietary Name (If Applicable) a	and Established Na	ame: Atom	oxetine Hydrochloride Capsu	iles, USP 100 m	g			I	(write in)					
Selling Unit NDC:	31722-720-30		Unit of Use NDC	:	31722-720-30		1722720304		Notes					
UDI			CVX Code:			MVX Code:								
Description: Atomoxetine Hydrochloride Capsules, USP 100 mg Is this product to be shipped to customers on ice? No									1					
									Is this product to be shipp				No	1
Active Ingredient(s): Atomoxetine hydrochloride, USP														
									r temperature excursion of	uestions:				
URL for Additional Product Inforn		www.camberpharn	na.com						Name:		Soma Raju			
Address:	800 Centennial A	ve, Suite 1			State:	Address 2:			Number:		732-529-042			
City: Key Contact:	Piscataway Customer Service				Email:	customerservice@car	p: 08854	Group E-mail: somaraju@heterousa.com						
Phone Number:	1-866-827-3647	-			Fax:	732-562-8788	nberpriamia.com	c Special re	gulations for product in a	v statos?			No	1
Product Therapeutic Classificatio		Selective norening	ephrine reuptake inhibitor (SN	IRI\	I ux.	702 302 0700		c. opeciai re	Special returns requirement	-			No	-
Trouder Therapeutic Classificatio	""-	Ocicotive norepine	primite reaptane initibilor (Or	iitij					opeciai returns requireme	into for tino product:			140	_
	ADDITI	ONAL PRODUCT I	NEORMATION			PRODUCT DESC	CRIPTION INFORMATION	I d Store proc	luct (unit of sale) upright?				No	1
	7,55			Direct-Ship C	Sml	1 1105001 5201		u. otore proc						1
The product is? a legend device?		No	Is the Product Is the Product	Unit of Use	riiy		30 ct	e. Shelf life:	Protect product (unit of	sale) from light?			No 24	Mantha
if yes, enter class #		INO	Orphan Drug Status	Offic of Ose		Size:	30 Ct	e. Shelf life:	Initial shelf life at launcl	(if different):			24	Months Months
a product kit?		No	Orphan Drug Status				100 mg		illiliai Sileli ille at iaulici	i (ii uiiierenii).				WOILLIS
if yes, list NDCs of		140	FDA Approval Status			Strength:	g			ORDER INFORM	MATION			
component parts						D F	Hard gelatin capsule							
reverse numbered?		No				Dosage Form:			Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present				-		x Bottle		1 Bottle of 3	0 capsules		
latex-free?		Yes	Animal	Products		Product Shape:	Capsule		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	7 111111111			oudot onapo.			Ampule					
correctional institution block?		No				Product Color:	Brown opaque cap and		Glass		Minimum o	rder quantity	/?	Yes
opioid?		No					Brown opaque body		Tube					
Cannabinoid?	and deep for	No	Country of Origin	India		Product Imprint:	Imprinted with 'I' on cap and '111' on body		Vial Liquid Sgl		K Vaa haw			
If Unit Dose, is item bar coded to unhospital scanning?	unit dose for		Is this product covered	under the			and III on body		Vial Liquid Mult Vial Powder Sq			Each	ich package	type?
If Unit Dose, indicate NDC here:			Trade Agreements Act (No				Vial Powder Mu		24	Inner/Cartor	n/Pack	
ii onii bose, indicate Nbo nere.			Trado Agroomonio Aori		140				Other: Write In	u		Case	I/I dok	
			FOR GENERIC DRUG PF	PODUCTS]		
					Autl	horized Generic *If /	Authorized Generic, other			PHARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						ction fields are not applicable	Rec. sell unit	t to customer?		Py hilling u	nit to pharm	acv.	
II. Generic Equivalent to What Bra		Strattera									ita billing u	Each	uoy.	
III Conono Equivalent to Tinat En								(Write-in, e.g	. 1 Vial)			Gram		
		DRUG SUPP	LY CHAIN SECURITY ACT	(DSCSA) INFOR	RMATION							Milliliter		
Does supplier meet DSCSA defini	ition of manufactu	rer?	Yes		GLN:	0331722498975			ITI	M AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No											
If yes, select exemption:					GCP:				Weight Lbs.		ions (US msn		Volume	Saleable #
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No	_		ginal product purchas	ed	Item/Each:	0.09	1.58	1.58	3.13	7.81	1
Is product sold by manufacturer's			Yes	_	direct from mf									
Has FDA granted waiver/exceptio		roduct?	No		Provide sourc	e manufacturer for rep	backaged product	Box/Carton/E	Bundle/					
If yes, attach documentation from	m FDA.							Case:						
		GT	IN AND HIBCC PRODUCT I	NEORMATION				Case.	2.55	9.75	6.75	4	263.25	24
		٥.	IN AND HIBOUT NODOUT	IN OKMATION				Pallet:			+			
Saleable Unit of Measure	5	Saleable Quantity	HIBCC		GTIN	I-14	Unit of Use GTIN-14	l l anota						
X Item/Each		1				1722720304	00331722720304							
Box/Carton/Bundle/Inner Pack									COST INFORMATIO	N		WHOLESAL	ER USE ONL	_Y:
x Case		24			2033	1722720308								
Pallet								Regular Cos			Vendor #:			
								Invoice Cost	(WAC) (\$)	\$57.38	Whsl. Code			
								H	12/1/2024		Fineline Co	de:		
	-							As of date:	12/1/2024		-			
								11						
1			Attach conv of SAFETV D	ATA SHEET (SP	S) or non hozor	d latter DACKAGE INC	ERT, LABEL AND PHOTO OF F	DEUDITICA DVCA	AGING and BARCODE		1			
*Please provide any additional inf	formation on page	2	, macin copy of SAFETT D	MA SHEET (SL	o, or non nazan		ignated Drop Ship Only.	NODOGI FACK	Signature:					
						p. o ioi Dea	2. 2. ap 2 2							



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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? No	SDS Hazard Classification						
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? 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	Hazardous Waste Identification						
e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	EPA Hazardous Waste Code: Waste Characteristics						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMS or REGISTRY RESTRICTIONS						
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#: NPI #:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments						
ADD'L STORAGE INFORMATION	Registry: Registry Program Contact Name: Comments No Phone:						
Is the Product							
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 CLASS OF TRADE RESTRICTION:	RETURN INSTRUCTIONS Contact tel. # if product received damaged: I-866-827-3647 Is product returnable for credit: Yes						
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: Restricted to hospital, clinics, and physician offices only: No	Special regulations or returns requirements for this product in certain states?						
Restricted from US territories? (explain in comments) No Comments:	If so, which states? Other requirements? Comments?						
MISCELLANE	DUS 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 S	nip Product	Standard Order Receipt and Processing
Purchase orders may be accepted by: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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 Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order:		Overnight receipt available: 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, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess 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?