

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

Version 2021						Introduction	Туре:	Post Launch Change		4	Final Version			Date:	10/19	9/2023	
			PRODUCT INFORMA	TION							SPECIAL HAN	DLING AND STOR	AGE REQUIR	EMENTS*			
Company Name:	Company Name: Camber Pharmaceuticals. Inc.				Application: ANDA			a. Temperature – Indicate the USP temperature range for t				his product.					
Application Number for NDA/AN		., .	e):	203	2682				ui remperati		ure Range	Controlled Room -	- between 20 a	and 25 C (68	° – 77° F)		
Medical Device Class, if applical			,								J. J						
DUNS:	11-856-3719									Other Ter	nperature Range F	Requirement					
Proprietary Name (If Applicable) a	nd Established Name:	Atomox	ketine Hydrochloride Capsu	les, USP 100 m	g					(writ	e in)	•					
Selling Unit NDC:	31722-720-30		Unit of Use NDC:		31722-720-30	UPC:	331722	2720304		Notes							
UDI			CVX Code:			MVX Code:											
Description:	Atomoxetine Hydrochlor	ide Capsules. U	JSP 100 mg							Is this pro	duct to be shipped	I to customers on id	e?		No	1	
Is this product to be shipped to customers on dy ice? No								1									
Active Ingredient(s): Atomoxetine																	
b. Contact for temperature excursion questions:																	
URL for Additional Product Information: www.camberpharma.com							Name: Soma Raju										
Address:	1031 Centennial Ave (and) 800 Centennial Ave, Suite 1					Address 2:			Number:				732-529-0423				
City:	Piscataway				State:	NJ				Group E-mail:				somaraju@heterousa.com			
Key Contact:							customerservice@camberpharma.com									1	
Phone Number:					732-562-8788	732-562-8788			c. Special regulations for product in any states?				No				
Product Therapeutic Classificatio	n: Selec	ctive norepineph	hrine reuptake inhibitor (SN	RI)						Special re	turns requirement	s for this product?			No	1	
																1	
	ADDITIONAL	PRODUCT INF	ORMATION			PRODUCT	DESCRI	PTION INFORMATION	d. Store proc	duct (unit of	sale) upright?				No		
The product is?			Is the Product	Direct-Ship C	Dnly		_			Protect p	roduct (unit of sa	le) from light?			No		
a legend device?	No		Is the Product	Unit of Use		Size:		30 ct	e. Shelf life:						24	Months	
if yes, enter class #			Orphan Drug Status			5126.		50 61		Initial she	elf life at launch (i	f different):				Months	
a product kit?	No					Strength:		100 mg									
if yes, list NDCs of			FDA Approval Status			ouongun		loo ng				ORDER INFORM	IATION				
component parts						Dosage For	m:	Hard gelatin capsules									
reverse numbered?	No					-	L		_	Unit of Sa			What is the I		unit?		
co-licensed?	No		Allergens Present				г		_		Bottle		1 Bottle of 30				
latex-free?	Yes					Product Sha	ape:	Capsule			Box/Carton		(Write-in, e.g	I. 1 Box of 10	Vials)		
preservative-free? correctional institution block?	Yes						-	Draum anagua aon and	-		Ampule Glass		Minimum en			Yes	
opioid?	No					Product Col		Brown opaque cap and Brown opaque body			Tube		Minimum or	der quantity	ſ	res	
Cannabinoid?	No		Country of Origin	India			-		-		Vial Liquid Sgl						
If Unit Dose, is item bar coded to u			obuility of origin	India		Product Imp	print:	'l' on cap and '111' on body			Vial Liquid Multi		If Yes, how r	nany of whi	h nackage t	type?	
hospital scanning?			Is this product covered u	under the			L		-		Vial Powder Sql			Each	in puonago i	JP0 ·	
If Unit Dose, indicate NDC here:			Trade Agreements Act (No				Vial Power Multi			Pack					
				,							Other: Write In			Case			
-			FOR GENERIC DRUG PR	ODUCTS													
										L							
					Au	thorized Generic	*If Auth	norized Generic, other			PH	ARMACY ORDER	/ BILL UNIT				
I. Orange Book Rating:	AB						section	fields are not applicable	Rec. sell uni	t to custom	er?		Rx billing un	it to pharma	cv:		
I. Generic Equivalent to What Brand?: Strattera								Each									
									(Write-in, e.g. 1 Vial) Gram								
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION Milliliter																	
Does supplier meet DSCSA defini	tion of manufacturer?		Yes	_	GLN:	0331722000000					ITEM	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:			No									Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?				_		riginal product			Item/Each:		0.10	1.75	1.75	2.50	7.66	1	
Is product sold by manufacturer's Has FDA granted waiver/exception		2	Yes No			irect from mfr? ce manufacturer fo	or ronact	kaged product	Box/Carton/	Bundlo/							
If yes, attach documentation from		r	NO		Flovide Soul		orrepace	kageu product	Inner Pack:	bunule/							
in yes, attach documentation not									Case:								
		GTIN	N AND HIBCC PRODUCT I	NFORMATION							2.80	11.00	7.50	4.00	330.00	24	
									Pallet:								
Saleable Unit of Measure	Saleabl	e Quantity	HIBCC		GTI	N-14		Unit of Use GTIN-14									
X Item/Each		1			003	31722720304		00331722720304	-								
Box/Carton/Bundle/Inner Pack								COST	INFORMATION		٧	VHOLESALE	R USE ONL	Y:			
X Case		24			203	31722720308											
Pallet	_								Regular				Vendor #:				
					_		_		Invoice Cost	(WAC) (\$)		\$71.00	Whsl. Code				
							_		1.				Fineline Cod	e:			
							_		As of date:	L							
μ													I				
*Please provide any additional inf			Attach copy of SAFETY DA	ATA SHEET (SD	or non haza			T, LABEL AND PHOTO OF P	KODUCT PACK								
						See new p. 3 for	r Designa	ated Drop Ship Only.		Signature	:						

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

·	nated Drop Ship Only Products, Please Use Page 3						
MATERIAL H	HAZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply): a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No Is the product a CA Prop 65 reproductive toxicant? No Does the product label bear a CA Prop 65 warning? C. Contact Hazard? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? No	x Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No NFPA Storage Level: Image: Contact Hazard						
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 c. DOT Hazard Class	Is the product a NIOSH hazardous drug? No If yes, indicate which: Hazardous Waste Identification						
d. Packing Group e. Inhalation Hazard?	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	REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? No						
c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? Is the product restricted for air shipment? If so, indicate restriction: Passenger	If Yes, is it managed with a pharmacy registry? Website URL: Med Guide Required Limited Distribution Requirement						
Cargo Passenger & Cargo Is this a reportable quantity? No RQ Threshold:	REMS: No REMS Program Manager Name: Phone:						
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)	Supplier Manages REMS registry exclusively:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments						
ADD'L STORAGE INFORMATION	Registry: No Registry Program Contact Name: Phone: Comments						
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: Image: Control of the state of	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: No 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? No If so, which states? Other requirements? Comments?						
Comments:							
MISCELLAN	IEOUS NOTES and/or Image of Product Barcode:						



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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 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: Image: Comparison of the co
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: Order receipt method: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?