

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

Version 2021					Introduction T	Гуре:	Post Launch Change		4 Final Version		1	Date:	10/19	/2023
		PRODUCT INF	ORMATION						SPECIAL HAN	DLING AND STOR	AGE REQUIR	EMENTS*		
Company Name: Camber Pharmaceuticals. Inc.					Applicat	Application: ANDA		a. Temperatu	e – Indicate the USP temp	erature range for t	his product.			
Application Number for NDA/AND			20	2682				ui romporata	Temperature Range	Controlled Room -	- between 20 a	and 25 C (68°	' – 77° F)	
Medical Device Class, if applicable:														
DUNS:	11-856-3719								Other Temperature Range	Requirement				
Proprietary Name (If Applicable) an	nd Established Name:	Atomoxetine Hydrochloride	Capsules, USP 25 mg	1					(write in)	•				
	31722-716-30	Unit of Use		31722-716-30		331722	2716307		Notes					
UDI		CVX Cod	:		MVX Code:									
Description:	Atomoxetine Hydrochloride	Capsules, USP 25 mg							Is this product to be shippe	d to customers on id	ce?	[No	1
••••	,	3							Is this product to be shippe				No	1
Active Ingredient(s):	Atomoxe	etine										L		
								b. Contact for	temperature excursion qu	estions:				
	RL 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			
	Piscataway			State:	NJ	· ·			Group E-mail:			somaraju@heterousa.com		
	Customer Service			Email:	customerservice@camberpharma.com 732-562-8788			- Owner is the model is a second set in some start and				r	N	1
	1-866-827-3647	a according to the second data in hit		Fax:	132-302-0100	2-302-0700			c. Special regulations for product in any states? No				1	
Product Therapeutic Classification	Selective	e norepinephrine reuptake inhibi	or (SNRI)						Special returns requiremen	s for this product?			No	i -
					PRODUCT	DECON	DTION INFORMATION	1.01				1	N	1
	ADDITIONAL PRO	ODUCT INFORMATION	-		PRODUCTI	DESCRIP	PTION INFORMATION	a. Store prode	uct (unit of sale) upright?				No	
The product is?		Is the Product	Direct-Ship	Only		-			Protect product (unit of sa	le) from light?			No	1
a legend device?	No	Is the Product	Unit of Use		Size:	:	30 ct	e. Shelf life:					24	Months
if yes, enter class #		Orphan Drug Sta	tus			-		-	Initial shelf life at launch (if different):		ļ		Months
a product kit? if yes, list NDCs of	No	FDA Approval S	otuc		Strength:	1	25 mg			ORDER INFORM				
component parts		PDA Approvar S	atus			ŀ				ORDER INFORM	IATION			
reverse numbered?	No				Dosage Form	m: I	Hard gelatin capsules		Unit of Sale		What is the M	NDC selling	unit?	
co-licensed?	No	Allergens Prese	nt			-	1		x Bottle		1 Bottle of 30			
latex-free?	Yes				Desition Of a		0		Box/Carton		(Write-in, e.g		Vials)	
preservative-free?	Yes				Product Sha	ipe:	Capsule		Ampule					
correctional institution block?	No				Product Cold	or: 1	Blue opaque cap and white		Glass		Minimum or	der quantity	? [Yes
opioid?	No				FIGULE	ог. (opaque body		Tube				L.	
Cannabinoid?	No	Country of Origin	India		Product Imp	rint-	'l' on cap and '107' on body		Vial Liquid Sgl					
If Unit Dose, is item bar coded to un	nit dose for						r en eap and ter en bedy		Vial Liquid Multi		If Yes, how n		ch package t	ype?
hospital scanning?		Is this product co						Vial Powder Sql 24 Each						
If Unit Dose, indicate NDC here:		Trade Agreement	s Act (TAA)?	No					Vial Power Multi Other: Write In			Inner/Carton/ Case	Pack	
									Other: write in			Case		
		FOR GENERIC DR	UG PRODUCTS					-						
				A	thorized Generic	*If Auth	norized Generic, other		DI	ARMACY ORDER				
	10			Au	Infolized Generic		fields are not applicable	Bee celling		ARMAGTORDER				
I. Orange Book Railing.							Rx billing unit to pharmacy:							
II. Generic Equivalent to What Brand?: Strattera								(Write-in, e.g. 1 Vial) Each						
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION (Vinte-in, e.g. 1 Viai) Gram Millitier														
												Willing		
Does supplier meet DSCSA definit	ion of manufacturer?	Yes		GLN:	0331722000000				ITEN	AND PACKING I	FORMATION			
Is product exempt from DSCSA?		No												
If yes, select exemption:				GCP:						Dimensi	ons (US msm	ts.)	Volume	Saleable #
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?		No		If yes, was or	riginal product			Item/Each:	0.00				. ,	
Is product sold by manufacturer's	exclusive distributor?	Yes			rect from mfr?				0.06	1.50	1.50	2.50	5.63	1
Has FDA granted waiver/exception	/exemption for product?	No		Provide sour	ce manufacturer fo	or repack	kaged product	Box/Carton/B	undle/					
If yes, attach documentation from	n FDA.							Inner Pack:						
								Case:	2.00	9.65	6.75	4.00	260.44	24
		GTIN AND HIBCC PRO	OUCT INFORMATION											¹
Saleable Unit of Measure	0.1			0.71				Pallet:						
X Item/Each	Saleable Q	Quantity HIBCC			N-14 31722716307		Unit of Use GTIN-14 00331722716307							[]
X Item/Each Box/Carton/Bundle/Inner Pack	1			003	51722710307		00331722710307		COST INFORMATION		v	VHOLESALE	R USE ONL	Y:
X Case	24			203	31722716301	-			SOOT IN ORMATION			MOLLOALL		
Pallet	24			200	01722710001			Regular			Vendor #:	1		
								Invoice Cost (WAC) (\$)	\$55.00	Whsl. Code #	¥:		
										\$00.00	Fineline Cod			
						1		As of date:			1	l		
											1			
						_								
		Attach copy of SAF	TY DATA SHEET (S	DS) or non haza	rd letter, PACKAGE	INSERT	F, LABEL AND PHOTO OF P	RODUCT PACKA	GING and BARCODE.					
*Please provide any additional info	ormation on page 2.						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?