

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

Version 2021						Introduction Type	e: Post Launch Change		x Final Version			Date:	11/19	9/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name:	Camber Pharmac	euticals, Inc.				Application	: ANDA	a. Temperature	e - Indicate the USP tempe	rature range for the	his product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 202682				2682				Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)						
Medical Device Class, if applicable:														
DUNS:	11-856-3719							·	Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) as	nd Established Na	ame: Ato	moxetine Hydrochloride Capsu	les, USP 25 mg					(write in)	·				
Selling Unit NDC:	31722-716-30		Unit of Use NDC:		31722-716-30	UPC: 33	31722716307		Notes					
UDI			CVX Code:			MVX Code:								
Description: Atomoxetine Hydrochloride Capsules, USP 25 mg Is this product to be shipped to customers on ice? No								1						
	,		-,9						Is this product to be shipped				No	
Active Ingredient(s): Atomoxetine hydrochloride, USP									•			_		
							b. Contact for	temperature excursion que	estions:					
URL for Additional Product Inform		www.camberpha	rma.com						Name:		Soma Raju			
Address:		ennial Ave, Suite 1			Address 2:				Number:		732-529-042			
City:	Piscataway				State:		ip: 08854		Group E-mail:		somaraju@h	eterousa.cor	<u>n</u>	
Key Contact:					Email:	customerservice@ca	amberpharma.com							7
Phone Number:	1-866-827-3647			5.1	Fax:	732-562-8788		c. Special regulations for product in any states?					No	-
Product Therapeutic Classification	1:	Selective norepir	nephrine reuptake inhibitor (SN	RI)					Special returns requirement	s for this product?			No	
														-
	ADDITI	ONAL PRODUCT	INFORMATION			PRODUCT DES	SCRIPTION INFORMATION	d. Store produ	ct (unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship 0	Only				Protect product (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			0.20.			Initial shelf life at launch (i	f different):				Months
a product kit?		No				Strength:	25 mg							
if yes, list NDCs of			FDA Approval Status							ORDER INFORM	IATION			
component parts		1.1				Dosage Form:	Hard gelatin capsule		Helicat Oak		\A/h-a4 in 4h-a	NDC aalliaa		
reverse numbered?		No	Allermana Dresent					Г	Unit of Sale		What is the		unit?	
co-licensed? latex-free?		No Yes	Allergens Present				Capsule	-	x Bottle Box/Carton		1 Bottle of 30	g. 1 Box of 1	0 Viole)	
preservative-free?		Yes	Animal	Products		Product Shape:	Capsule		Ampule		(vviite-iii, e.	y. 1 bux 01 11	J Viais)	
correctional institution block?		No					Opaque blue cap and		Glass		Minimum or	der auantity	2	Yes
opioid?		No				Product Color:	white opaque body		Tube		Million Or	uci quantity	•	103
Cannabinoid?		No	Country of Origin	India			Imprinted with 'I' on can		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for		, 3			Product Imprint	and '107' on body		Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
hospital scanning?			Is this product covered u	inder the					Vial Powder Sgl			Each		•
If Unit Dose, indicate NDC here:			Trade Agreements Act (ГАА)?	No				Vial Powder Multi			Inner/Carton	/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
					Auth		Authorized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB					SE	ection fields are not applicable	Rec. sell unit t	o customer?		Rx billing ur	nit to pharma	acv:	
II. Generic Equivalent to What Bran	nd?:	Strattera								1		Each		
-								(Write-in, e.g.	1 Vial)			Gram		
		DRUG SUP	PLY CHAIN SECURITY ACT (DSCSA) INFO	RMATION							Milliliter		
				_										
Does supplier meet DSCSA definit	ion of manufactur	rer?	Yes		GLN:	0331722498975			ITEN	AND PACKING IN	NFORMATION	1		
Is product exempt from DSCSA?			No											
If yes, select exemption:					GCP:				Weight Lbs.	Dimensi	ons (US msm	ıts.)	Volume	Saleable #
Other exemption - Write in:									weight LDS.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			ginal product purcha	sed	Item/Each:	0.07	1.55	1.55	2.55	6.13	1
Is product sold by manufacturer's			Yes		direct from mf						1.00	2.00	0.10	·
Has FDA granted waiver/exception		roduct?	No		Provide source	e manufacturer for re	epackaged product	Box/Carton/Bu	indle/					
If yes, attach documentation from	n FDA.							Inner Pack:						
			TIN AND HIBCC PRODUCT I	NEODMATION				Case:	2.1	9.75	6.75	4	263.25	24
			TIN AND HIBCC PRODUCT I	NFORMATION				Pallet:						
Saleable Unit of Measure		Saleable Quantity	HIBCC		GTIN	14	Unit of Use GTIN-14	Pallet:						
x Item/Each	3	1	HIBCC			1722716307	00331722716307							
	Box/Carton/Bundle/Inner Pack				3033	00331722716307			COST INFORMATION		WHOLESALER USE ONLY:			
X Case		24			2033	1722716301								
Pallet					1 2.00			Regular Cost			Vendor #:			
								Invoice Cost (\	WAC) (\$)	\$48.83	Whsl. Code	#:		
								`			Fineline Cod			
								As of date:	12/1/2024					
1											ļ			
			Attach copy of SAFETY DA	ATA SHEET (SI	OS) or non hazard		SERT, LABEL AND PHOTO OF P	RODUCT PACKA	GING and BARCODE.					
	rmation on page	2				See new n 2 for De	signated 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? 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 fo	r Designated Drop Ship 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:	Fax Number: Fax Number: Phone No.: Site Address:	Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt:					
F	Name: Phone:	Ships regular ground for 3-10 days receipt:					
Expedited Freight Charg	ges 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 only: Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician of Restricted from US territories? (explain in conficulty) Comments:	offices only:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:					
Other Data Infor	rmation Required to Process 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?					
Mis	scellaneous Notes:						
		ADDITIONAL INFORMATION					
		Is product order for scheduled patient procedure? Is product order for restocking purposes?					