

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

Version 2021						Introduction	Туре:	Post Launch Change		4 F	inal Version			Date:	10/19	9/2023
			PRODUCT INFORMA	TION							SPECIAL HAN	DLING AND STOR	AGE REQUIF	EMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA					ANDA	a. Temperature – Indicate the USP temperature range for this product.										
Application Number for NDA/ANDA/BLA (drug); PMA/510(K)(med device): 202682 a. Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)																
Medical Device Class, if applical														,		
DUNS:	11-856-3719									Other Tem	perature Range F	Requirement				
Proprietary Name (If Applicable) a	and Established Na	ame: Ator	moxetine Hydrochloride Capsul	les, USP 60 mg						(write		•				
Selling Unit NDC:	31722-718-30		Unit of Use NDC:		31722-718-30		331722	718301		Notes						
UDI			CVX Code:			MVX Code:										
Description:	Atomoxetine Hydr	rochloride Capsule:	s, USP 60 mg							Is this prod	luct to be shipped	to customers on id	e?		No	1
										Is this prod	luct to be shipped	to customers on d	ry ice?		No	
Active Ingredient(s):		Atomoxetine														
							b. Contact for temperature excursion questions:									
URL for Additional Product Inform Address:		www.camberphar				Address 2:			Name: Number:				Soma Raju 732-529-0423			
City:	Piscataway	Ave (and) 800 Cen	tennial Ave, Suite 1		State:	NJ	7in:	08854	Number: Group E-mail:						com	
Key Contact:	Customer Service	,			Email:			nberpharma.com	Group E-mail.			somaraju@heterousa.com				
Phone Number:	1-866-827-3647				Fax:		732-562-8788			gulations fo	product in any	states?			No	1
Product Therapeutic Classification		Selective norepir	nephrine reuptake inhibitor (SN	RI)						-		s for this product?			No	
l round morapound diagonicum	····			,						Opoolai rot	arrio roquiromoni	o tot ano product.				1
	ADDITIO	ONAL PRODUCT	INFORMATION			PRODUCT	DESCRIF	PTION INFORMATION	d. Store prod	duct (unit of	sale) upright?				No	1
The product is?			Is the Product	Direct-Ship 0	Only				01010		oduct (unit of sa	lo) from light?			No	1
a legend device?		No	Is the Product	Unit of Use	Striy		Г		e. Shelf life:	Frotect pr	oduct (unit or sa	ile) iroin light?			24	Months
if yes, enter class #		140	Orphan Drug Status			Size:	3	30 ct	c. onen me.	Initial she	f life at launch (i	if different):			2.7	Months
a product kit?		No				04		00								
if yes, list NDCs of			FDA Approval Status			Strength:		60 mg				ORDER INFORM	IATION			
component parts						Dosage For	m: H	Hard gelatin capsules								
reverse numbered?		No					··· [, gp		Unit of Sa			What is the		unit?	
co-licensed?		No	Allergens Present								sottle		1 Bottle of 30			
latex-free?		Yes				Product Sha	ape:	Capsule			lox/Carton		(Write-in, e.	j. 1 Box of 10) Vials)	
preservative-free? correctional institution block?		Yes No					-	Blue opaque cap and yellow	-		mpule Blass		Minimum or	dor augntity	2	Yes
opioid?		No				Product Col		opaque body			ube		William Of	uer quantity		163
Cannabinoid?		No	Country of Origin	India							ial Liquid Sql					
If Unit Dose, is item bar coded to u	unit dose for					Product Imp	orint:	'I' on cap and '109' on body		\ \	'ial Liquid Multi		If Yes, how	nany of whi	ch package	type?
hospital scanning?			Is this product covered u				_				ial Powder Sql		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (ΓAA)?	No						ial Power Multi			Inner/Carton	/Pack	
						4		Other: Write In			Case					
			FOR GENERIC DRUG PR	ODUCTS												
						thorized Generic	*16	orized Generic, other			DU	ARMACY ORDER	/ PILL LINIT			
				_	Au	monzed Generic		fields are not applicable	PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating: II. Generic Equivalent to What Brand?: Strattera				coolien noide are not applicable			Rec. sell unit to customer?				Rx billing unit to pharmacy:					
II. Generic Equivalent to What Brand?: Strattera							(Write-in, e.g. 1 Vial)			Gram						
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION					(Wille III, C.g	j. 1 viai)				Milliliter						
				,												
Does supplier meet DSCSA defini	nition of manufactur	rer?	Yes		GLN:	0331722000000					ITEM	I AND PACKING IN	IFORMATION			
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			iginal product			Item/Each:		0.08	1.50	1.50	2.50	5.63	1
Is product sold by manufacturer's			Yes	_		rect from mfr?						1.00	1.00	2.00	0.00	i i
Has FDA granted waiver/exception		roduct?	No		Provide sour	ce manufacturer fo	or repack	aged product	Box/Carton/i	Bundle/						
If yes, attach documentation fro	om FDA.								Case:							
		G	TIN AND HIBCC PRODUCT I	NEORMATION					Case:		2.35	9.65	6.75	4.00	260.44	24
			THE ARD THE COT INCEDED TO	NI OKMATION					Pallet:							
Saleable Unit of Measure	S	Saleable Quantity	HIBCC		GTII	N-14		Unit of Use GTIN-14								
X Item/Each		1			003	31722718301		00331722718301								
Box/Carton/Bundle/Inner Pack										COST	INFORMATION			VHOLESALI	ER USE ONL	_Y:
		24			203	31722718305										
X Case									Regular				Vendor #:			
X Case Pallet								J		(ALLA O) (A)		000	NAME - 1 O - 1			
							_		Invoice Cost	(WAC) (\$)		\$63.00	Whsl. Code			
									Invoice Cost	(WAC) (\$)		\$63.00	Whsl. Code Fineline Cod			
										(WAC) (\$)		\$63.00				
									Invoice Cost	(WAC) (\$)		\$63.00				
			Attach copy of SAFETY DA	ATA SHEET (SI	DS) or non haza	rd letter, PACKAGE	INSERT	, LABEL AND PHOTO OF P	Invoice Cost As of date:		BARCODE.	\$63.00				



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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HA	ZARD 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? No	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#: NCPDP#: NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments					
SP# ADD'L STORAGE INFORMATION	Registry: No Registry Program Contact Name: Phone: Comments					
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: 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	Special regulations or returns requirements for this					
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No	product in certain states? If so, which states? Other requirements? Comments?					
Comments:						
MISCELLANE	OUS 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 conficunt 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?