

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

Version 2021						Introduction	Туре:	Post Launch Change	X	Final Version			Date:	11/19	9/2024	
			PRODUCT INFORMA	TION						SPECIAL HAN	IDLING AND STOP	RAGE REQUI	REMENTS*			
Company Name:	Camber Pharmaceuticals.	Inc.				Applica	ation:	ANDA	a. Temperature – Indic	ate the USP temp	erature range for t	his product.				
Application Number for NDA/AN			e):	202	2682					ature Range	Controlled Room		and 25 C (68	° – 77° F)		
Medical Device Class, if applicat		~							· ·	0						
DUNS:	11-856-3719								Other Te	emperature Range I	Requirement					
Proprietary Name (If Applicable) a		Atomo	xetine Hydrochloride Capsul						(w	rite in)						
Selling Unit NDC:	31722-718-30		Unit of Use NDC:		31722-718-30		33172271	8301	Notes							
UDI			CVX Code:			MVX Code:										
Description:	Atomoxetine Hydrochloride	e Capsules, l	JSP 60 mg							roduct to be shipped				No		
Is this product to be shipped to customers on dry ice? No																
Active Ingredient(s): Atomoxetine hydrochloride, USP																
								b. Contact for temperature excursion questions:								
URL for Additional Product Inform Address:		mberpharma	a.com		1	Address 2:			Name: Number			Soma Raju 732-529-042	2			
City:	800 Centennial Ave, Suite 1 Piscataway State:				NJ Zip: 08854			Group E-mail:			.s ieterousa.cor	n				
Key Contact:	Customer Service					sustomerservice@camberpharma.com			- man.		Somaraja en	101010030.001	<u>.</u>			
Phone Number:	1-866-827-3647				732-562-8788			c. Special regulations	for product in any	states?			No	1		
Product Therapeutic Classification	n: Selecti	ve norepinep	hrine reuptake inhibitor (SN	RI)	1				Special returns requirements for this produc				? No			
•					1					•	•				1	
	ADDITIONAL P	RODUCT INF	FORMATION			PRODUCT	DESCRIPT	ION INFORMATION	d. Store product (unit	of sale) upright?				No	1	
The product is?			Is the Product	Direct-Ship C	Inly				1	product (unit of sa	ale) from light?			No	i	
a legend device?	No		Is the Product	Unit of Use			30	ct	e. Shelf life:	product (unit of oc	,			24	Months	
if yes, enter class #			Orphan Drug Status			Size:				helf life at launch (if different):				Months	
a product kit?	No					Strength:	60	mg							-	
if yes, list NDCs of			FDA Approval Status			ou chgan.					ORDER INFORM	MATION				
component parts						Dosage For	m: Ha	rd gelatin capsule								
reverse numbered?	No		All			_			Unit of	-		What is the 1 Bottle of 3		unit?		
co-licensed? latex-free?	No Yes		Allergens Present				Ca	psule	X	Bottle Box/Carton			g. 1 Box of 1) (iale)		
preservative-free?	Yes	_	Animal	Products		Product Sha	ape:	ipsule		Ampule		(write-iii, e.	g. 1 Dox 01 1	5 viais)		
correctional institution block?	No					De la col	Blu	ue opaque cap and		Glass		Minimum or	der quantity	?	Yes	
opioid?	No					Product Col		llow body		Tube						
Cannabinoid?	No		Country of Origin	India		Product Imp		printed with 'I' on cap		Vial Liquid Sgl						
If Unit Dose, is item bar coded to u	unit dose for					i roudet imp	an an	d '109' on body		Vial Liquid Multi				ch package t	type?	
hospital scanning?			Is this product covered u							Vial Powder Sgl		24	Each			
If Unit Dose, indicate NDC here:			Trade Agreements Act (IAA)?	No					Vial Powder Multi Other: Write In			Inner/Carton	/Pack		
			FOR GENERIC DRUG PR	ODUCTO						Other: white in			Case			
			FOR GENERIC DRUG PR	ODUCIS												
					Au	thorized Generic	*If Authori	ized Generic, other	PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating:	AB			_				elds are not applicable	Rec. sell unit to custo				nit to pharm	ev:		
I. Grange book nating: No II. Generate Equivalent to What Brand?: Strattera						Rec. sell unit to customer? Rx billing unit to pharmacy:										
		-							(Write-in, e.g. 1 Vial)				Gram			
	D	RUG SUPPL	Y CHAIN SECURITY ACT (DSCSA) INFOR	MATION								Milliliter			
Does supplier meet DSCSA definit	tion of manufacturer?		Yes	_	GLN:	0331722498975				ITEN	I AND PACKING I	NFORMATION	N			
Is product exempt from DSCSA?			No						1							
If yes, select exemption:					GCP:					Weight Lbs.		ions (US msm	,	Volume	Saleable #	
Other exemption - Write in:			No								Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?	avaluaiva diatrikutar2			_		riginal product pur	rchased		Item/Each:	0.08	1.55	1.55	2.55	6.13	1	
Is product sold by manufacturer's Has FDA granted waiver/exception			Yes	-	direct from m	ce manufacturer fo	or ronackar	and product	Box/Carton/Bundle/							
If yes, attach documentation from					Trovide Sour		orrepuertag	jeu product	Inner Pack:							
									Case:	0.05	0.75	0.75	4	000.05	24	
		GTI	N AND HIBCC PRODUCT I	NFORMATION						2.25	9.75	6.75	4	263.25	24	
									Pallet:							
Saleable Unit of Measure	Saleable	Quantity	HIBCC			N-14		Init of Use GTIN-14								
X Item/Each	1		00331722718301 00331722718301						WHOLESALER USE ONLY:							
Box/Carton/Bundle/Inner Pack						04700740005	_		COS	T INFORMATION			WHOLESAL	ER USE ONL	.Y:	
X Case Pallet	24				203	31722718305	-		Regular Cost			Vendor #:				
r and							-		Invoice Cost (WAC) (\$	1	\$53.10	Whsl. Code	#-			
	-						-			,	φυυ.10	Fineline Co				
							-		As of date:	12/1/2024						
												1				
									[]							
			Attach copy of SAFETY DA	ATA SHEET (SD	S) or non haza											
	ormation on page 2.					See new p. 3 for	r Designate	d Drop Ship Only.	Signatu	re:						

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Version 2021 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? 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? 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 Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) a. UN/Identification Number No No No No No No No N	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No NFPA Storage Level: Is the product a NIOSH hazardous drug? Is the product a NIOSH hazardous drug? No If yes, indicate which: If yes, indicate which:						
a. On/definition for holder b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? Is this product regulated for shipment by IATA? No	Hazardous Waste Identification EPA Hazardous Waste Code: Waste Code:						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? No 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) Special Permit; DOT-SP	REMS: No REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: DEA #: Provider Name: DEA #: Site Enrollment Number assigned NCPDP#: by Supplier: NPI #:						
Special Provision (listed in Column 7 of 49 CFR 172.101); SP#ADD'L STORAGE INFORMATION	No Registry Program Contact Name: Comments						
Is the Product Controlled Substance? Controlled Substance? No Listed Chemical (List I or II) No ARCOS Reportable? No If yes, indicate which: Schedule No. Is it a scheduled listed chemical product?: No	RETURN INSTRUCTIONS Contact tel. # if product received damaged: 1-866-827-3647 Is product returnable for credit: Yes						
CLASS OF TRADE RESTRICTION: 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: No Restricted to hospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No Comments: No	Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments?						
MISCELLANE	OUS NOTES and/or Image of Product Barcode:						



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

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?