

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

Version 2021						Introduction Type:	Post Launch Change		x Final Version			Date:	11/19	9/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN	NDA/BLA (drug); PN	A/510(k)(med devi	ice):	202	682				Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applica			·					İ	-					
DUNS:	11-856-3719								Other Temperature Range	Requirement				
Proprietary Name (If Applicable)	and Established Na	me: Atom	oxetine Hydrochloride Capsu	lles, USP 40 mg				[	(write in)					
Selling Unit NDC:	31722-717-30		Unit of Use NDC	:	31722-717-30		722717304		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Atomoxetine Hydro	ochloride Capsules,	USP 40 mg					I	Is this product to be shippe	d to customers on i	ce?		No	1
	·								Is this product to be shippe				No	1
Active Ingredient(s):		Atomoxetine hydro	ochloride, USP											
								b. Contact fo	r temperature excursion qu	estions:				
URL for Additional Product Inform		www.camberpharn	na.com						Name:		Soma Raju			
Address:	800 Centennial Av	e, Suite 1			State:	Address 2: NJ Zip	00054		Number:		732-529-042			
City: Key Contact:	Piscataway Customer Service				Email:	customerservice@cam	: 08854		Group E-mail:		somaraju@r	neterousa.com	<u>11</u>	
Phone Number:	1-866-827-3647				Fax:	732-562-8788	<u>Бегрианна.соні</u>	c Special rea	gulations for product in any	states?			No	1
Product Therapeutic Classification		Selective norepine	phrine reuptake inhibitor (SN	JRI)				or opecial to	Special returns requirement				No	1
Troduct Therapeutic Glassification	o	Colocato Horopino	primio roupiano minibilor (or	,					opeciai returno requiremen	is for this product:			140	1
	ADDITIO	ONAL PRODUCT IN	NFORMATION			PRODUCT DESC	RIPTION INFORMATION	d. Store prod	duct (unit of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship Or	nly			11	Protect product (unit of sa	ale) from light?			No	i
a legend device?		No	Is the Product	Unit of Use	· · · ·		30 ct	e. Shelf life:	Protect product (unit of Sa	ile) iroin light?			24	Months
if yes, enter class #		110	Orphan Drug Status			Size:	50 61	C. Onen me.	Initial shelf life at launch (	if different):			24	Months
a product kit?		No	orpilari Drug otatuo			a	40 mg		muai onon mo at iaanon (					]
if yes, list NDCs of			FDA Approval Status			Strength:	Ü			ORDER INFORM	MATION			
component parts						Dosage Form:	Hard gelatin capsule							
reverse numbered?		No				Dosage Form.			Unit of Sale		What is the		unit?	
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 3			
latex-free?		Yes	Anima	Products		Product Shape:	Capsule		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes				•	Division and the second		Ampule					
correctional institution block? opioid?		No No				Product Color:	Blue opaque cap and blue opaque body		Glass Tube		Minimum o	der quantity	11	Yes
Cannabinoid?		No	Country of Origin	India			Imprinted with 'I' on cap		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for	140	country or origin	maia		Product Imprint:	and '108' on body		Vial Liquid Multi		If Yes, how	many of whi	ich package	type?
hospital scanning?	um 4000 101		Is this product covered	under the					Vial Powder Sql			Each	pg-	.,,,,,
If Unit Dose, indicate NDC here:			Trade Agreements Act	(TAA)?	No				Vial Powder Multi			Inner/Cartor	n/Pack	
									Other: Write In			Case		
			FOR GENERIC DRUG PF	RODUCTS										
											_			
					Aut		uthorized Generic, other		Pl	IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB					secti	ion fields are not applicable	Rec. sell unit	t to customer?		Rx billing u	nit to pharm	асу:	
II. Generic Equivalent to What Bra	and?:	Strattera										Each		
								(Write-in, e.g	ı. 1 Vial)			Gram		
		DRUG SUPP	LY CHAIN SECURITY ACT	(DSCSA) INFOR	MATION							Milliliter		
Does supplier meet DSCSA defin			Yes	_	GLN:	0331722498975			ITEN	I AND PACKING I	NEORMATIO	N .		
Is product exempt from DSCSA?		err	No	_	GLN:	0331722496975			IIEN	I AND FACKING I	NFORMATIO	<b>1</b>		
					000			1		Dim	ione (IIC	nto \	37-1	0-1
If yes, select exemption: Other exemption - Write in:					GCP:			1	Weight Lbs.		ions (US msn Width	•	Volume (Cube)	Saleable # Pieces
Is product repackaged?			No		If you was ari	ginal product purchase	.d	Item/Each:		Depth		Height		
Is product sold by manufacturer's	s exclusive distribu	tor?	Yes		direct from mf		su	item/Lacii.	0.08	1.55	1.55	2.55	6.13	1
Has FDA granted waiver/exception			No	_		· · e manufacturer for repa	ackaged product	Box/Carton/E	Bundle/					
If yes, attach documentation fro						•	<u> </u>	Inner Pack:						
								Case:	2.2	9.75	6.75	4	263.25	24
		GT	IN AND HIBCC PRODUCT	INFORMATION					2.2	3.73	0.73	-	200.20	24
11								Pallet:						
Saleable Unit of Measure	S	aleable Quantity	HIBCC		GTIN		Unit of Use GTIN-14							
X Item/Each		1			0033	1722717304	00331722717304		COST INFORMATION			WHOLESAL	ER USE ONL	V.
Box/Carton/Bundle/Inner Pack		24			2022	1722717308			COST INFORMATION			WHOLESAL	ER USE UNL	.T.
X Case Pallet		24			2033	11/22/1/300		Regular Cost	•		Vendor #:			
1 carrox								Invoice Cost		\$53.10	Whsl. Code	#:		
									(·····•) (Ψ)	φυσ. 10	Fineline Co			
								As of date:	12/1/2024			uc.		
								As of date:	12/1/2024			uc.		
												uc.		
			Attach copy of SAFETY D	ATA SHEET (SDS	S) or non hazar	d letter, PACKAGE INSE	RT, LABEL AND PHOTO OF F							



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

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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?	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:					



## **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 S	nip 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: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	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 Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order:  Drop Ship service fee billed with each order:		Overnight receipt available:  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, hospitals, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available:  PO Receipt Cut off time:  Phone: Fax: EDI:  Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess 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?
Miscellaneous Notes:		
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure? Is product order for restocking purposes?