

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

					Introduction 1	Type: Post Launch Change		x Final Version			Date:	6/23/	/2024
			PRODUCT INFORMA	TION				SPECIAL HAN	DLING AND STOR	AGE REQUIF	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA					a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/ANI			a):	204343		<u> </u>		emperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab								,					
DUNS:	11-856-3719						Ot	ther Temperature Range	Requirement				
Proprietary Name (If Applicable) a	nd Established Name	: Duloxet	tine Delayed-Release Caps					(write in)	•				
Selling Unit NDC:	31722-583-30		Unit of Use NDC:	31722-583-		331722583308	No	otes					
UDI			CVX Code:		MVX Code:								
Description:	Duloxetine Delayed-R	Release Capsules.	USP 60 mg				ls	this product to be shippe	d to customers on i	ce?		No	
		,	g					this product to be shippe				No	
Active Ingredient(s):	Dι	uloxetine hydrochlo	oride, USP							•			
							b. Contact for ter	mperature excursion qu	estions:				
URL for Additional Product Inform	ation: ww	ww.camberpharma.	.com				Na	ame:		Soma Raju			
Address:	800 Centennial Ave, S	Suite 1			Address 2:			umber:		732-529-042			
City:	Piscataway			State:		Zip: 08854	Gı	roup E-mail:		somaraju@h	eterousa.cor	<u>n</u>	
Key Contact:	Customer Service			Email:		@camberpharma.com							
Phone Number:	1-866-827-3647			Fax:	732-562-8788			tions for product in any				No	
Product Therapeutic Classification	n: Se	elective serotonin &	& norepinephrine reuptake	inhibitor (SNRI)			Sp	pecial returns requiremen	ts for this product?			No	
							_						
	ADDITION	AL PRODUCT INF	ORMATION		PRODUCT	DESCRIPTION INFORMATION	d. Store product	(unit of sale) upright?				No	
The product is?	_		Is the Product	Direct-Ship Only			Pr	otect product (unit of sa	ale) from light?			No	
a legend device?	No	ن ا	Is the Product	Unit of Use	Size:	30 ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status		0.20.		Ini	itial shelf life at launch (	if different):				Months
a product kit?	No	)			Strength:	60 mg							
if yes, list NDCs of			FDA Approval Status						ORDER INFORM	IATION			
component parts					Dosage Forn	m: Hard gelatin, delayed-				M/hat ia tha	NDCIII	:42	
reverse numbered?	No		Allannana Duanant			release capsule		nit of Sale		What is the		unit?	
co-licensed? latex-free?	No Ye		Allergens Present			Capsule		x Bottle Box/Carton		1 Bottle of 30 (Write-in, e.g		) \/iolo\	
preservative-free?	Ye		Corn, Alc	cohol, Sugar	Product Sha	pe: Capsule		Ampule		(vviite-iii, e.	g. 1 BOX 01 10	) viais)	
correctional institution block?	No					Opaque blue cap and	-	Glass		Minimum or	der auantity	2	Yes
opioid?	No				Product Cole	opaque green body		Tube		Million Or	aci quantity	•	103
Cannabinoid?	No		Country of Origin	India		'H' on can and '192' on		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u			, ,		Product Imp	body .		Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
hospital scanning?			Is this product covered u	under the			'II	Vial Powder Sgl		24	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (	TAA)? No				Vial Powder Multi			Inner/Carton	/Pack	
			<u> </u>					Other: Write In			Case		
			FOR GENERIC DRUG PR	RODUCTS						1			
										-			
					Authorized Generic	*If Authorized Generic, other		PH	IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB					section fields are not applicable	Rec. sell unit to	customer?		Rx billing ur	it to pharma	acy:	
II. Generic Equivalent to What Brai	nd?: Cy	mbalta							T .			•	
•	_	ymbalta									Each		
							(Write-in, e.g. 1 \	/ial)	1		Each Gram		
			Y CHAIN SECURITY ACT	(DSCSA) INFORMATION			(Write-in, e.g. 1 \	/ial)	1				
		DRUG SUPPLY					(Write-in, e.g. 1 \		1		Gram Milliliter		
Does supplier meet DSCSA definit	ion of manufacturer?	DRUG SUPPLY	Yes	(DSCSA) INFORMATION	0331722498975		(Write-in, e.g. 1 \		I AND PACKING I		Gram Milliliter		
Does supplier meet DSCSA definit Is product exempt from DSCSA?	tion of manufacturer?	DRUG SUPPLY			0331722498975		(Write-in, e.g. 1 V		I AND PACKING II		Gram Milliliter		
	tion of manufacturer?	DRUG SUPPLY	Yes		0331722498975		(Write-in, e.g. 1 \	ITEN			Gram Milliliter	Volume	Saleable #
Is product exempt from DSCSA?  If yes, select exemption:  Other exemption - Write in:	tion of manufacturer?	DRUG SUPPLY	Yes No	GLN:	0331722498975					NFORMATION	Gram Milliliter	Volume (Cube)	Saleable #
Is product exempt from DSCSA?  If yes, select exemption:  Other exemption - Write in: Is product repackaged?		DRUG SUPPLY	Yes No	GLN:	0331722498975	chased	(Write-in, e.g. 1 \	Weight Lbs.	Dimensi Depth	NFORMATION ons (US msm Width	Gram Milliliter ts.) Height	(Cube)	Pieces
Is product exempt from DSCSA?  If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	exclusive distributor	DRUG SUPPLY	Yes No No Yes	GLN:  GCP:  If yes, was direct from	original product pure		Item/Each:	Weight Lbs.	Dimensi	NFORMATION	Gram Milliliter		
Is product exempt from DSCSA?  If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception	exclusive distributor?	DRUG SUPPLY	Yes No	GLN:  GCP:  If yes, was direct from	original product pure	chased or repackaged product	Item/Each: Box/Carton/Bund	Weight Lbs.	Dimensi Depth	NFORMATION ons (US msm Width	Gram Milliliter ts.) Height	(Cube)	Pieces
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## **Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)**

#### Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL	HAZARD CLASSIFICATION and TRANSPORTATION				
Is this product (check all that apply):  a. Cytotoxic?  b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	SDS Hazard Classification				
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 e. Inhalation Hazard?	Hazardous Waste Identification  EPA Hazardous Waste Code:  Waste Characteristics				
Is this product regulated for shipment by IATA?	LEATIAZATUOUS WASTE COUE.				
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS				
a. UN/Identification Number 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#	Registry:  Registry Program Contact Name:  Phone:				
ADD'L STORAGE INFORMATION	Comments				
Is the Product  Controlled Substance?  Controlled Substance Code  Controlled by State(s)?  No  Listed Chemical (List I or II)  No	RETURN INSTRUCTIONS				
ARCOS Reportable?  Schedule No.  If yes, indicate which:  Is it a scheduled listed chemical product?:  No	Contact tel. # if product received damaged:  Is product returnable for credit:  Yes				
CLASS OF TRADE RESTRICTION:	URL/Link to returns policy:				
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Restricted to retail pharmacy only:  No	contact - customerservice@camberpharma.com				
Restricted to retail pharmacy only:  Restricted to hospital, clinics, and physician offices only:  Restricted from US territories? (explain in comments)  No	Special regulations or returns requirements for this product in certain states?  If so, which states? Other requirements? Comments?				
Comments:	The state of the s				
MISCELLA	NEOUS 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 Process	sing		
Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier			
a. EDI		Cut off time:			
b. Autofax	Fax Number:				
c. Fax	Fax Number:	Shipping lead time of PO: Hours	Days		
d. Phone only	Phone No.:				
e. Supplier Web Site only	Site Address:	Ships same day for next day receipt:			
Minimum Order Quantity:		Ships for second day receipt:			
Supplier's Customer Service Number:		Ships regular ground for 3-10 days receipt:			
Contracted 3PL company / contact #:	Name:				
	Phone:				
Expedited Freight Cha	rges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Pro	cessing		
Expedited freight fees billed with each orde	er:	Overnight receipt available:			
Drop Ship service fee billed with each orde	r:	PO Receipt cut off time:			
Drop Ship miscellaneous fees billed:		Days of week overnight is available:	Monday		
Comments:		,	Tuesday		
			Wednesday		
			Thursday		
			Friday		
		Priority Overnight receipt available:			
Cla	ss of Trade Restriction:	PO Receipt Cut off time:			
No restriction: Select VES if sold to retail of	narmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:			
Restricted to retail pharmacy only:	larmacy, nospitals, clinics and physician offices	PO Receipt Cut off time:			
Restricted to hospital, clinics, and physician	o offices only:	Phone: Phone #			
Restricted from US territories? (explain in c		Order receipt method: Fax: Fax #:			
Comments:		EDI:			
		Overnight Fees apply:			
		Other fees apply:			
Other Data Inf	ormation Required to Process PO:	Return Instructions			
Patient Procedure Date:		Contact # if product is received damaged:			
Physician Name:		Is product returnable for credit:			
Physician/Clinic Phone #		URL/Link to returns policy:			
Physician State License #					
Physician/Clinic DEA #:		Special regulations or returns requirements for this product in certa	ain states?		
Physician/Clinic Specialty:		If so, which states? Other requirements? Comments?			
	Miscellaneous Notes:				
		ADDITIONAL INFORMATION			
		Is product order for scheduled patient procedure?			
		Is product order for restocking purposes?			
		13 product order for restocking purposes:			