

Standard Pharmaceutical Product Information (Rx Product Only)

					Intr	oduction Type:	Post Launch Change		Final Version			Date:	4/12	2/2017
			PRODUCT INFORMA	ATION					SPECIAL HANDL	ING AND ST	ORAGE REQ	UIREMENTS'	ŧ	
Company Name:	Camber Pharmaceuti	cals				Application:	ANDA	a. Temperature – Indio	cate the USP temper	ature range	for this prod	uct.		
Application Number for NDA	A/ANDA/BLA (drug);	PMA/510(k)(med device)):	204343					ature Range				en 20 and 25	5 C (68° – 77° F
	82-667-4775							Other Te	emperature Range Re	auirement				
Proprietary Name (If Applicat	ble) and Established	Name: Duloxetin	e Delayed Release Capsul	les 60MG 30CT					rite in)					1
	31722-583-30		Individual Unit NDC:	31722-58		UPC: 331722	583305	, i i i i i i i i i i i i i i i i i i i						-
UDI	NA		CVX Code:		MVX	X Code: NA		Is this pr	roduct to be shipped to	o customers o	on ice?		No	_
Description:	Opaque green/opaqu	e blue capsules imprinted	with 'H'/'192'					Is this pr	roduct to be shipped to	o customers o	on dry ice?		No	_
Active Ingredient(s):		Duloxetine						b. Contact for tempera	ature excursion que	stions:				
								Name:			Soma Raju			
URL for Additional Product In		www.camberpharma.com	n			-		Number			732-529-042			
	1031 Centennial Ave	nue		State	Addres		00054	Group E	E-mail:		somaraju@r	eterousa.cor	n	
City: Key Contact:	Piscataway State: NJ Zip: 08854 Customer Service Email: customerservice@camberpharma.com					c. Special regulations	for product in any s	tates?			No			
Phone Number:	732-529-0430				Fax: 732-562-8788				returns requirements f		ct?		No	-
Product Therapeutic Classifie	ication:							-						-
								d. Store product (unit	of sale) upright?				No	
ADDITIONA	AL PRODUCT INFORM	IATION			PRODUC	T DESCRIPTION INF	FORMATION	Protect	product (unit of sale	e) from light?	•		No	_
Is the Product								e. Shelf life:					24	Months
a legend device?		No		Size:		30		Initial sh	nelf life at launch (if o	different):				Months
reverse numbered?		No		0										
co-licensed?		No Direct-Ship Only		Strength		60 MG			(order info	RMATION			
Is the Product Is the Product		Unit of Use				-		Unit of S	Salo		What is the	NDC selling	unit?	
is the Froudet				Dosage I	form:	capsule			Bottle		1 box of 12		uniti	
If Unit Dose, is item bar code		ital ananaian0						x	Box/Carton		(Write-in, e.	.g. 1 Box of 1	0 Vials)	
		ital scanning?		Product	Shane:	capsule			Ampule					
If Unit Dose NDC, indicate NE	DC here:			. router	onapo.	capoulo			Glass		Minimum o	rder quantity	?	Yes
Country of Origin		India		Product	Color:	green/blue			Tube Vial Liquid Sgl					
, .									Vial Liquid Sgl		If Yes, how	many of whi	ch package	type?
Is this product covered under	r the Trade Agreements	s Act (TAA)? No		Product	mprint:	H'/'192'			Vial Powder Sql			Each		
									Vial Power Multi		12	Inner/Carton	/Pack	
				PODUCTS					Other: Write In	7		Case		
			FOR GENERIC DRUG PF	RODUCTS					Other: write in]		Case		
			FOR GENERIC DRUG PR		Authorized Ger	neric *If Autho	prized Generic, other section			RMACY ORD	ER / BILL UNI			
I. Orange Book Rating:	AB		FOR GENERIC DRUG PP		Authorized Ger		prized Generic, other section re not applicable	Rec. sell unit to custo	PHAF			T	acv:	
I. Orange Book Rating: II. Generic Equivalent to Wha	AB at Brand?:	Cymbalta	FOR GENERIC DRUG PP		Authorized Ger			Rec. sell unit to custo	PHAF				acy:	
								Rec. sell unit to custo (Write-in, e.g. 1 Vial)	PHAF			T nit to pharm Each Gram	acy:	
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Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

le this preduct (sheal, all that apply).						
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? No	Organic Corrosive					
Is the product a CA Prop 65 reproductive toxicant?	Ovidizer					
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard					
c. Contact Hazard? No	Aerosol Class; Identify NFPA Storage Level:					
d. Does this product require special clean-up instructions? No						
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug?					
e. Does the product contain DEHP? No	If yes, indicate which:					
Is this product regulated for shipment by DOT or IATA? No						
(if yes, answer a-e below and provide SDS)						
a. UN/Identification Number						
b. Proper Shipping Name	Hazardous Waste Identification					
c. DOT Hazard Class	EPA Hazardous Waste Code: NA					
d. Packing Group						
e. Inhalation Hazard?						
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS					
Passenger	Is there a REMS on this product? No					
Cargo	If Yes, is it managed with a pharmacy registry?					
Passenger & Cargo	Website URL:					
Is this a reportable quantity? No RQ Threshold:	Comments / Details: (For example, iPledge program?)					
Is this a marine pollutant? No	Comments / Details. (For example, inledge program?)					
Is this a manne political is a manne political is the pol						
No (if yes, identify method below)	REMS:					
Limited Quantity	REMS Program Manager Name: Phone:					
Consumer Commodity, ORM-D	Supplier Manages REMS registry exclusively: No					
Small Quantity (49 CFR 173.4)	Wholesale distributor support: No					
Special Permit; DOT-SP	Provider Name:					
Special Provision (listed in Column 7 of 49 CFR 172.101);	Site Enrollment Number assigned DEA #: No					
SP#	by Supplier: PCPDP #: No					
	NPI#: No					
ADD'L STORAGE INFORMATION	· · · · · · · · · · · · · · · · · · ·					
Is the Product	Comments					
Controlled Substance? No						
Controlled by State(s)? No	Registry: No					
ARCOS Reportable? No	Registry Program Contact Name: Phone:					
Schedule No. (inc. N for non-narcotic)	Comments					
Controlled Substance Code						
Listed Chemical (List I or II) No	RETURN INSTRUCTIONS					
If yes, indicate which:						
Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: 732-529-0430					
CLASS OF TRADE RESTRICTION:	Is product returnable for credit: Yes					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No	URL/Link to returns policy: contact - customerservice@camberpharma.com					
Restricted to retail pharmacy only: Yes	Special regulations or returns requirements for this product in certain states? No					
Restricted to hospital, clinics, and physician offices only: No	If so, which states? Other requirements? Comments?					
Restricted from US territories? (explain in comments) No						
Comments:						
oommonia.						
MISCELLA	NEOUS NOTES and/or Image of Product Barcode:					



Standard Pharmaceutical Product Information (Page 3)

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: Autofax Yes b. Autofax No Fax Number: c. Fax Yes Fax Number: d. Phone only No Phone No.: e. Supplier Web Site only No Site Address: Minimum Order Quantity: case pack 732-529-0430 x466 x465 x467 x470 Contracted 3PL company / contact #: Name: Phone:	Purchase order daily receipt cut off time by supplier Cut off time: 2:30PM Eastern Shipping lead time of PO: 24/48 Hours Days Ships same day for next day receipt: No No Ships for second day receipt: No No Ships regular ground for 3-10 days receipt: Yes
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: No Drop Ship service fee billed with each order: No Drop Ship miscellaneous fees billed: No Comments: Image: No Comments: Image: No Class of Trade Restriction: No Restricted to retail pharmacy, hospitals, clinics and physician offices No Yes Restricted to nospital, clinics, and physician offices only: No Restricted from US territories? (explain in comments) No	Overnight receipt available: Yes PO Receipt cut off time: 2:30PM Eastern Days of week overnight is available: X Monday X Tuesday Wednesday X Thursday Friday Priority Overnight receipt available: Yes PO Receipt Cut off time: 2:30PM EST Saturday Overnight receipt available: No PO Receipt Cut off time: No Order receipt method: Phone: No Fax: Yes Fax #:
Comments:	rax. res rax #. res EDI: Yes Overnight Fees apply: Yes Other fees apply: No
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	Contact # if product is received damaged: 732-529-0430 Is product returnable for credit: Yes URL/Link to returns policy:
	ADDITIONAL INFORMATION