

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014							Intro	oduction Ty	ype:			Final Version			Date:			
				PRODUCT INFORMA	TION							SPECIAL HANDL	LING AND ST	ORAGE REQ	UIREMENTS	S*		
Company Name:	Camber Pharmaceuticals DA/ANDA/BLA (drug); PMA/510(k)(med device): 204343						ANDA	a. Temperature – Indicate the USP temperature range for this product. Temperature Range Controlled Room – between 20 and 25 C (68° – 77										
		PMA/510(K)(med (aevice):		204	4343						mperature Range		Controlled F	toom – betwe	een 20 and 25	C (00 - // F	
DUNS:	82-667-4775				Out when COMO CONT						Ot	her Temperature Range Re	equirement				1	
Selling Unit NDC:	Duloxetine Delayed Release Capsules 60MG 30CT 31722-583-30 UPC: 331722583305 UPC: 331722583305 UPC: UPC:							(write in)										
UDI	31722-583-30 Individual Unit NDC: 31722-583-30 UPC: 331722583305 NA CVX Code: MVX Code: NA							05	Is this product to be shipped to customers on ice?									
Description:	Opaque green/opaque blue capsules imprinted with 'H'/192'										Is this product to be shipped to customers on dry ice? No						-	
Active Ingredient(s): Duloxetine										b. Contact for temperature excursion questions: Name: Soma Raiu								
											Soma Raju 732-529-0423							
URL for Additional Product II Address:							Address	ess 2:			_	Number: Group E-mail:			732-529-0423 somaraju@heterousa.com			
City:	Piscataway State: NJ Zip: 08854								Group E-mail: Somaraju@neterousa.com									
Key Contact:	Customer Service					Email: customerservice@camberpharma.com					c. Special regula	tions for product in any s	states?			No		
Phone Number:	732-529-0430					Fax: 732-562-8788						ecial returns requirements		uct?		No	_	
Product Therapeutic Classifi											<u> </u>							
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION										d. Store product (unit of sale) upright? No						-		
	L PRODUCT INFORM	IATION				г	KODUCI	DESCRIPT	ION INFORM	WATION	Protect product (unit of sale) from light?							
Is the Product											e. Shelf life:	24			Months			
a legend device? reverse numbered?		No.			Size:	ize: 30				lni				Months				
co-licensed?	No No											ORDER INFORMATION						
Is the Product	Direct-Ship Only					Strength: 60 MG						ONDER IN ORMATION						
Is the Product		Unit of Use				B					Un	nit of Sale		What is the	NDC selling	unit?		
						Dosage Form:		capsule				x Bottle		1 bottle of 3	0 capsules			
If Unit Dose is item har code	d to unit dose for hose	nital scanning?									.	Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)		
If Unit Dose, is item bar coded to unit dose for hospital scanning? Product Shape:						capsule				Ampule								
If Unit Dose NDC, indicate NDC here:								Glass Minimum order quantity? Yes						Yes				
Country of Origin		India	_			Product Color	:	green/blue				Tube Vial Liquid Sgl						
' '											Vial Liquid Gg/ Vial Liquid Multi If Yes, how many of which package type?							
Is this product covered under the Trade Agreements Act (TAA)? No Product Imprint: H//192							H'/'192'			Vial Powder Sql 24 Each					.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			
		_					_				'	Vial Power Multi			Inner/Cartor	n/Pack		
												Other: Write In			Case			
			F	OR GENERIC DRUG PR	RODUCTS													
Authorized Generic *If Authorized Generic, other section									PHARMACY ORDER / BILL UNIT									
	A.D.					Autric	Jiizeu Geii	ieric	fields are not		Dec cell unit to							
I. Orange Book Rating:	AB	Cymbalta									Rec. sell unit to customer? Rx billing unit to pharmacy:							
II. Generic Equivalent to What Brand?: Cymbalta											(Write-in, e.g. 1 \	/ial\			Gram			
		DRUG	SUPPLY	CHAIN SECURITY ACT	(DSCSA) INF	ORMATION					(vviito iii, o.g. i v	na.,			Milliliter			
					· · ·										1			
Does supplier meet DSCSA of		turer?	NI.	Yes	GL	.N:	0331722	2000000			ITEM AND PACKING INFORMATION							
Is product exempt from DSC: If yes, select exemption:	SA?		No	<u> </u>									Dime	ensions (US m	nomto \	M-1		
Other exemption - Write in:										1		Weight Lbs.	Depth	Height	Width	Volume (Cube)	# Pieces:	
Is product repackaged?			No)	If Y	res, was origina	al product	purchased	d direct		Item:	0.5				()		
Is product sold by manufactu	ırer's exclusive distri	ibutor?		No		m mfr?	•				·	0.5		2.5	1.5		1	
Has FDA granted waiver/exc	eption/exemption for	product?		No	If y	es, attach docu	umentatio	n from FDA	۸.		Box/Carton/Bund	dle/						
											Inner Pack:							
				GTIN PRODUCT INFOR							Case:	2.05	9.5	4	6.75		24	
				Level	Saleable Unit				Quantity	GTIN-14	Pallet:			-				
Serialized?	Yes	Г	x Ite			X 2D		Linear	1	00331722583305	1						225	
If not, when?	. 55	7 F		ox/Carton/Bundle/Inner Pack		2D		Linear			UPC:	Case:		-1				
Items aggregated?	Yes	-	X C	ase		x 2D		Linear	24			Carton:						
		_	P	allet		2D		Linear										
						2D		Linear				COST INFORMATION			WHOLESAL	ER USE ONL	_Y:	
		<u> </u>	—- -			2D		Linear										
	2D Linear 2D Linear							Regular Cost	Vendor #:									
	L Linear L Linear							Invoice Cost (WA Federal Excise T	Whsl. Code #: Fineline Code:									
 											As of date:	un i ei oiiit oi oale		- menne co	uc.			
											. 10 01 4410.							
			Att	ach copy of SAFETY DA	TA SHEET (S	SDS) or non haza	ard letter. F	PACKAGE	INSERT, LAB	BEL AND PHOTO OF PF	ODUCT PACKAGING	and BARCODE.		•				
*Please provide any addition	al information on pag	ge 2.		1,	. (-	,				rop Ship Only.		gnature:						



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): SDS Hazard Classification a. Cvtotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? Inorganic Oxidizer Does the product label bear a CA Prop 65 warning? Steroid/Androgen Contact Hazard Aerosol Class; Identify NFPA Storage Level: c. Contact Hazard? No 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 Hazardous Waste Identification b. Proper Shipping Name c. DOT Hazard Class EPA Hazardous Waste Code: d. Packing Group e. Inhalation Hazard? REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: 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 Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) REMS: Limited Quantity REMS Program Manager Name: Phone Consumer Commodity, ORM-D Supplier Manages REMS registry exclusively: No Wholesale distributor support: Small Quantity (49 CFR 173.4) No Special Permit; DOT-SP Provider Name: Site Enrollment Number assigned Special Provision (listed in Column 7 of 49 CFR 172.101); DEA #: by Supplier: No SP# PCPDP #: NPI#: No ADD'L STORAGE INFORMATION Is the Product... Comments Controlled Substance? No Controlled by State(s)? No Registry: ARCOS Reportable? No Registry Program Contact Name Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code Listed Chemical (List I or II) No RETURN INSTRUCTIONS If yes, indicate which: 732-529-0430 Is it a scheduled listed chemical product?: Contact tel. # if product received damaged: No CLASS OF TRADE RESTRICTION: Is product returnable for credit: 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 No Special regulations or returns requirements for this product in certain states? 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: MISCELLANEOUS 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:	Purchase order daily receipt cut off time by supplier							
a. EDI	Cut off time:							
b. Autofax Fax Number:								
c. Fax Number:	Shipping lead time of PO: Hours Days							
d. Phone only								
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 Charges 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:	Days of week overnight is available: Monday							
Comments:	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, clinics and physician offices	Saturday Overnight receipt available:							
Restricted to retail pharmacy only:	PO Receipt Cut off time:							
Restricted to hospital, clinics, and physician offices only:	Phone #:							
Restricted from US territories? (explain in comments)	Order receipt method: Fax: Fax #:							
Comments:	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:							
Physician Name:	Is product returnable for credit:							
Physician/Clinic Phone #	URL/Link to returns policy:							
Physician State License #	Special regulations or returns requirements for this product in certain states?							
Physician/Clinic DEA #:	If so, which states? Other requirements? Comments?							
Physician/Clinic Specialty:								
Miscellaneous Notes:								
	ADDITIONAL INFORMATION							
	Is product order for scheduled patient procedure?							
	Is product order for restocking purposes?							