

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014					Introduction	Type:	Post Launch Change		Final Version			Date:			
			PRODUCT INFORM	MATION					SPECIAL HANDLI	NG AND ST	ORAGE REQI	JIREMENTS	*		
Company Name:	Camber Pharmaceuticals Application: ANDA A/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° f							
	A A A A A A A A A A A A A A A A A A A							-			Controlled IX	oom – betwe	en zo and zo	0 (00 - 11 1	
DUNS:	82-667-4775 Duloxetine Delayed Release Capsules 20MG 60CT						Other Temperature Range Requirement (write in)								
Selling Unit NDC:	ble) and Established Name: Duloxetine Delayed Release Capsules 20MG 60CT 31722-581-60 Individual Unit NDC: 31722-581-60 UPC: 331722581608							(wine iii)							
UDI	NA		CVX Code:		MVX Code:	NA		Is this p	oduct to be shipped to	customers	on ice?		No		
Description: Opaque green capsules imprinted with 'H/'190'							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							
URL for Additional Product I	mfa	ususy combornhorms	nom					Number:			Soma Raju 732-529-0423				
Address:	nformation: www.camberpharma.com 1031 Centennial Avenue Address 2:						Group E	somaraju@heterousa.com							
City:	Piscataway	1140			NJ	Zip:	08854		-mun.		oomaraja@i	01010404.00			
Key Contact:	Customer Service			Email:	customerservice(@camberpharm	a.com	c. Special regulations	for product in any st	ates?			No		
Phone Number:	732-529-0430			Fax:	732-562-8788			Special returns requirements for this product? No							
Product Therapeutic Classifi	<u> </u>														
ADDITIONA	AL PRODUCT INFORM	IATION		Pi	RODUCT DESCRI	PTION INFORM	MATION	d. Store product (unit of sale) upright? Protect product (unit of sale) from light? No							
Is the Product				PRODUCT BESCRIPTION IN ORMATION					e. Shelf life:				24 Months		
a legend device?		No							nelf life at launch (if o	different).			24	Months	
reverse numbered?		No	-	Size:	60			linuar Si	ion inc at launon (ii c	annoronty.				Months	
co-licensed?			=	Other with a second sec					0	RDER INFO	RMATION				
Is the Product		Direct-Ship Only		Strength:	20 mg										
Is the Product		Unit of Use	_	Dosage Form:	capsule			Unit of S			What is the		unit?		
								x	Bottle		1 bottle of 60				
If Unit Dose, is item bar code	ed to unit dose for hosp	oital scanning?							Box/Carton Ampule		(Write-in, e.	g. 1 Box of 1	u viais)		
If Unit Dose NDC, indicate NI	DC here:		51	Product Shape	capsule								Yes		
			-	Product Color:					Tube						
Country of Origin		India		Product Color:	green			Vial Liquid Sgl							
Is this product covered under	r the Trade Agreement	s Act (TAA)?	_	Product Imprin	nt: H'/'190'			Vial Liquid Multi If Yes, how many of which package type?							
	· ·	No No	_					Vial Powder Sql 24 Each							
<u> </u>								·	Vial Power Multi Other: Write In			Inner/Cartor Case	I/Pack		
			FOR GENERIC DRUG F	PRODUCTS					Other, write in	1		Case			
									BUAR		ED / BULL LINU	-			
				Author	rized Generic	fields are not	d Generic, other section								
I. Orange Book Rating:	AB	Io				neids die nei	аррисавіс	Rec. sell unit to customer?							
II. Generic Equivalent to What Brand?: Cymbalta							(Write-in, e.g. 1 Vial)				Each Gram				
		DRUG SUP	PLY CHAIN SECURITY AC	T (DSCSA) INFORMATION				(vviite-iii, e.g. i viai)				Milliliter			
				, , , ,							ļ				
Does supplier meet DSCSA of		turer?	Yes	GLN:	3.31722E+11			ITEM AND PACKING INFORMATION							
Is product exempt from DSC: If yes, select exemption:	SA!		No	_						Dime	nsions (US m	smts \	Volume		
Other exemption - Write in:									Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:	
Is product repackaged?			No	If Yes, was original	I product purchas	sed direct		Item:	0.05		2.5	1.5	, ,	1	
Is product sold by manufactu			No	from mfr?					0.05		2.0	1.5			
Has FDA granted waiver/exc															
Tias I DA granteu warver/exc	eption/exemption for	product?	No	If yes, attach docur	mentation from F	DA.		Box/Carton/Bundle/							
Tias I DA granteu waiver/exc	eption/exemption for	product?		If yes, attach docu	mentation from F	DA.		Inner Pack:						12	
Tias I DA granted waiver/exce	eption/exemption for	product?	No GTIN PRODUCT INFO	If yes, attach docur	mentation from F	DA.			2.05	9.5	4	6.75			
nas i ba granted waivenexe.	eption/exemption for	product?		If yes, attach docu	mentation from F	DA. Quantity	GTIN-14	Inner Pack:	2.05	9.5	4	6.75		005	
Serialized?	eption/exemption for	product?	GTIN PRODUCT INFO	If yes, attach docur DRMATION Saleable	mentation from F		GTIN-14 00331722581608	Inner Pack: Case:	2.05	9.5	4	6.75		225	
-			GTIN PRODUCT INFO	If yes, attach documents of the composition of the		Quantity		Inner Pack: Case:	Case:	9.5	4	6.75		225	
Serialized?			GTIN PRODUCT INFO Level Item Bow/Carton/Bundle/Inner Pack Case	If yes, attach documents of the second secon	Linear Linear Linear	Quantity		Inner Pack: Case: Pallet:		9.5	4	6.75		225	
Serialized? If not, when?	Yes	x	GTIN PRODUCT INFO Level Item Box/Carton/Bundle/Inner Pack	If yes, attach docum	Linear Linear Linear Linear	Quantity		Inner Pack: Case: Pallet: UPC:	Case: Carton:	9.5			ED LISE ON		
Serialized? If not, when?	Yes	x	GTIN PRODUCT INFO Level Item Bow/Carton/Bundle/Inner Pack Case	If yes, attach document	Linear Linear Linear Linear Linear Linear	Quantity		Inner Pack: Case: Pallet: UPC:	Case:	9.5			ER USE ONL		
Serialized? If not, when?	Yes	x	GTIN PRODUCT INFO Level Item Bow/Carton/Bundle/Inner Pack Case	If yes, attach docum	Linear Linear Linear Linear	Quantity		Inner Pack: Case: Pallet: UPC:	Case: Carton:	9.5			ER USE ONL		
Serialized? If not, when?	Yes	x	GTIN PRODUCT INFO Level Item Bow/Carton/Bundle/Inner Pack Case	If yes, attach documents	Linear Linear Linear Linear Linear Linear Linear	Quantity		Inner Pack: Case: Pallet: UPC: COST	Case: Carton:	9.5	Vendor #:	WHOLESAL	ER USE ONL		
Serialized? If not, when?	Yes	x	GTIN PRODUCT INFO Level Item Bow/Carton/Bundle/Inner Pack Case	If yes, attach documents	Linear Linear Linear Linear Linear Linear Linear Linear Linear	Quantity		Inner Pack: Case: Pallet: UPC: COST Regular Cost [Invoice Cost (WAC) (\$ Federal Excise Tax Pe	Case: Carton: INFORMATION		Vendor #:	WHOLESAL	ER USE ONL		
Serialized? If not, when?	Yes	x	GTIN PRODUCT INFO Level Item Bow/Carton/Bundle/Inner Pack Case	If yes, attach documents	Linear Linear Linear Linear Linear Linear Linear Linear Linear	Quantity		Inner Pack: Case: Pallet: UPC: COST Regular Cost Invoice Cost (WAC) (\$	Case: Carton: INFORMATION		Vendor #: Whsl. Code	WHOLESAL	ER USE ONL		
Serialized? If not, when?	Yes	x	GTIN PRODUCT INFO Level Item Bow/Carton/Bundle/Inner Pack Case Pallet	If yes, attach documents	Linear	Quantity 1 24	00331722581608	Inner Pack: Case: Pallet: UPC: COST Regular Cost Invoice Cost (WAC) (\$ Federal Excise Tax Pe As of date:	Case: Carton: INFORMATION		Vendor #: Whsl. Code	WHOLESAL	ER USE ONL		
Serialized? If not, when?	Yes Yes	x x	GTIN PRODUCT INFO Level Item Bow/Carton/Bundle/Inner Pack Case Pallet	If yes, attach documents	Linear	Quantity 1 24 LIDER TO SERT, LAB	00331722581608	Inner Pack: Case: Pallet: UPC: COST Regular Cost Invoice Cost (WAC) (\$ Federal Excise Tax Pe As of date:	Case: Carton: INFORMATION r Unit of Sale ARCODE.		Vendor #: Whsl. Code	WHOLESAL	ER USE ONL		



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 Comments / Details: (For example, iPledge program?) RQ Threshold: 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?