

Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014					Introduction Type:	New Item		Final Version			Date:	10/2	1/2020
			PRODUCT INFORMATION					SPECIAL HANDLI	NG AND ST	ORAGE REQ	UIREMENTS	*	
Company Name:	Camber Pharmaceuti	cale			Applicatio	n: ANDA	Tomporatura India	ata the USB temper	sturo rongo f	ior thin produ	ot		
				214419			a. Temperature – Indicate the USP temperature range for this product. Temperature Range Controlled Room – between 20 and 25 C (6					5 C (68° – 77° F	
		- MASTO(K)(IIIed device)		-			Controlled	JOIN DOWN	cii zo ana zo	77 00) 07			
	826774775							emperature Range Re	quirement				-
Proprietary Name (If Applical		Name: Venlafax	ine Extended-Release Tablets 75 r	mg 90ct			(wr	rite in)					
	31722-124-90		Individual Unit NDC:			22124904							
UDI			CVX Code:		MVX Code:		Is this pr	roduct to be shipped t	o customers	on ice?		No	_
Description: Venlafaxine extended-release tablets 75 mg are white to off white, film coated, round biconvex tablets printed with "393" in black ink						ink	Is this product to be shipped to customers on dry ice? No					=	
Active Ingredient(s): Venlafaxine Hydrochloride, USP							b. Contact for temperature excursion questions:			Soma Raju			
URL for Additional Product Information: www.camberpharma.com							Number:			732-529-0423			
Address:	1031 Centennial Avenue			Address 2:			Group E-mail: somaraju@heterousa.com				m		
City:	Piscataway			State: NJ Zip: 08854			11						
Key Contact:	Customer Service			Email: CI	Email: customerservice@camberpharma.com			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 Classific	ication:						-						
·							d. Store product (unit	of sale) upright?				No	
ADDITIONA	L PRODUCT INFORM	ATION	1	PRO	DUCT DESCRIPTION	INFORMATION		product (unit of sale) from light?	•		No	_
			1				-1	product (dilit or odio	,				
Is the Product							e. Shelf life:					24	Months
a legend device?		No		Size:	90		Initial st	nelf life at launch (if	different):				Months
reverse numbered?		No							DDED INCO	DMATION			
co-licensed?		No No		Strength:	75 mg			U	RDER INFO	RWATION			
Is the Product		Direct-Ship Only Neither						3-1-		What is the	NDCIII		
Is the Product		Neitrier		Dosage Form:	Tablets		Unit of S					unit?	
							x	Bottle		1 bottle of 9		0.16-1-1	
If Unit Dose, is item bar code	ed to unit dose for hosp	ital scanning?					.	Box/Carton		(vvrite-in, e.	g. 1 Box of 1	u viais)	
		INO		Product Shape:	Round		 	Ampule		Minimum			
If Unit Dose NDC, indicate NI	DC nere:						 	Glass		Minimum o	der quantit	<i>y ?</i>	yes
Country of Origin		USA		Product Color:	White to off whit	е		Tube Vial Liquid Sgl					
-							Vial Liquid Multi If Yes, how many of which package type?						
Is this product covered under	r the Trade Agreement	s Act (TAA)? No		Product Imprint:	imprinted with 3	93 in blank ink	Vial Powder Sql 24 Each						
								Vial Power Multi			Inner/Cartor	/Pack	
			•	•			-	Other: Write In			Case		
			FOR GENERIC DRUG PRODUCT	·e					1				
				9									
Authorized Generic *If Authorized Generic, other section													
								PHAR	MACY ORDE	ER / BILL UN	Т		
I. Orange Book Rating:	AB					uthorized Generic, other section are not applicable	Rec. sell unit to custor		MACY ORDE			acy:	
I. Orange Book Rating: II. Generic Equivalent to Wha		Venlafaxine Hydrochlori	de Tablets						MACY ORDE	Rx billing u		асу:	
		Venlafaxine Hydrochlori	de Tablets				Rec. sell unit to custor		MACY ORDE		nit to pharm	асу:	
			de Tablets / CHAIN SECURITY ACT (DSCSA	Authorize					MACY ORDE		nit to pharm Each	асу:	
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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 Is this product (check all that apply): SDS Hazard Classification No a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No Organic Corrosive No Oxidizer Is the product a CA Prop 65 reproductive toxicant? Inorganic Does the product label bear a CA Prop 65 warning? No 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 Hazardous Waste Identification b. Proper Shipping Name c. DOT Hazard Class EPA Hazardous Waste Code: d. Packing Group e. Inhalation Hazard? No 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? RQ Threshold: Comments / Details: (For example, iPledge program?) Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) No Phone: Limited Quantity REMS Program Manager Name: Consumer Commodity, ORM-D Supplier Manages REMS registry exclusively Small Quantity (49 CFR 173.4) Wholesale distributor support: Special Permit: DOT-SP Provider Name: Special Provision (listed in Column 7 of 49 CFR 172.101): Site Enrollment Number assigned DEA #: by Supplier: PCPDP #: NPI#: ADD'L STORAGE INFORMATION Is the Product... Comments Controlled Substance? Nο Controlled by State(s)? No Registry: 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 ves. indicate which: 732-529-0430 Is it a scheduled listed chemical product?: No Contact tel. # if product received damaged: CLASS OF TRADE RESTRICTION Is product returnable for credit: contact - customerservice@camberpharma.com No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices URL/Link to returns policy: Restricted to retail pharmacy only: No 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: 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: a. EDI		Purchase order daily receipt cut off time by supplier Cut off time:	Eastern			
b. Autofax Fax Number: c. Fax Fax Number: d. Phone only Phone No.: e. Supplier Web Site only Site Address:		Shipping lead time of PO: Hours Ships same day for next day receipt:	Days			
Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:		Ships for second day receipt: Ships regular ground for 3-10 days receipt:				
Expedited Freight Charges or Other Designated Drop Ship	Fees:	Overnight and Priority Overnight PO Pr	ocessing			
Expedited freight fees billed with each order:		Overnight receipt available:				
Drop Ship service fee billed with each order:		PO Receipt cut off time:	Eastern			
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: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physicia Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	n offices No No No No	PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:				
Other Data Information Required to Process 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 cell f so, which states? Other requirements? Comments?	ertain states?			
Miscellaneous Notes:						
		ADDITIONAL INFORMATION				
		Is product order for scheduled patient procedure? Is product order for restocking purposes?				