

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

						Introduction Type	: New Item		x Final Version			Date:	9/12/	2023	
			PRODUCT INFORMA	TION					SPECIAL HANI	DLING AND STOR	AGE REQUIF	REMENTS*			
Company Name: Camber Pharmaceuticals, Inc.						Application	: ANDA	a. Temperature	- Indicate the USP tempe	rature range for th	nis product.				
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 214419									e – Indicate the USP temperature range for this product. Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)						
Medical Device Class, if applical															
DUNS:	11-856-3719				1			، ا	Other Temperature Range F	equirement					
Proprietary Name (If Applicable) a		ame: Venla	afaxine Extended-Release Ta	blets 150 ma				1	(write in)	.oquii oi ii oi ii					
Selling Unit NDC:	31722-125-90	amo:	Unit of Use NDC:	bioto roo mg	31722-125-90	UPC: 33	1722125901	11 .	Notes						
UDI			CVX Code:			MVX Code:		1							
	Mandafarda a Frita	. d. d Dalassa Table						1							
Description:	veniaraxine Exter	nded-Release Table	is 150 mg						Is this product to be shipped				No		
Active Ingredient(s):		Vanlafavina Hudra	oblorido LICD					-	Is this product to be shipped	to customers on d	ry ice?		No		
Active Ingredient(s): Venlafaxine Hydrochloride, USP							h Contact for t	omporatura evaluraien aua	otions						
URL for Additional Product Information: www.camberpharma.com								b. Contact for temperature excursion questions: Name: Soma Raju							
Address:		Ave (and) 800 Centennial Ave, Suite 1				Address 2:		Number: 732-529-0423				13			
City:	Piscataway	State:					ip: 08854	Group E-mail:			somaraju@heterousa.com				
Key Contact:	Customer Service					customerservice@cam		1	0.0up 2u						
Phone Number:	1-866-827-3647					732-562-8788		c. Special regulations for product in any states?					No		
Product Therapeutic Classification		Selective Seratonin and Norepinephrine Reuptake Inhibitor						Special returns requirements for this product?					No		
томает тисторомно опазописацон.									opeoidi retarris reguirement	s for this product:			140		
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION									ct (unit of sale) upright?				No		
								11							
The product is?			Is the Product	Direct-Ship	Only				Protect product (unit of sa	le) from light?			No		
a legend device?		No	Is the Product	Unit of Use		Size:	90 ct	e. Shelf life:					24	Months	
if yes, enter class #		1	Orphan Drug Status					⊣ '	Initial shelf life at launch (i	t different):				Months	
a product kit?		No	EDA Ammanual Status			Strength:	150 mg			ORDER INFORM	ATION				
if yes, list NDCs of			FDA Approval Status							ORDER INFORM	ATION				
component parts reverse numbered?		Ne				Dosage Form:	Film-coated tablet	I .	Unit of Sale		What is the	NDC calling	unit?		
co-licensed?		No No	Allermana Dracent					d i	x Bottle		1 Botle of 90		unit:		
latex-free?		Yes	Allergens Present					'	Box/Carton			g. 1 Box of 1	0 Viale)		
preservative-free?		Yes	Corn, Alco	ohol, Wheat		Product Shape:	Round, biconvex		Ampule		(vviite-iii, e.	g. 1 DOX 01 11) viais)		
correctional institution block?		No						- -	Glass		Minimum or	der auantity	0	yes	
opioid?		No				Product Color:	White to off white		Tube		······································	uci quaitity		ycs	
Cannabinoid?		No	Country of Origin	USA			'394' on one side and blank	 -	Vial Liquid Sgl						
If Unit Dose, is item bar coded to unit dose for					Product Imprint	on the other side	Vial Liquid Multi If Yes, how many of which package type?					type?			
hospital scanning? Is this product covered under the							d	Vial Powder Sql			Each	on paonago i	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
If Unit Dose, indicate NDC here: Trade Agreements Act (TAA)? Yes								Vial Power Multi Inner/Carton			/Pack				
									Other: Write In			Case			
			FOR GENERIC DRUG PR	ODUCTS				_							
			TOR SERENIS BROSTR	3533.3				-							
Authorized Generic "If Authorized Generic, other									PHARMACY ORDER / BILL UNIT						
I Orange Book Pating:	section fields are not applicable														
					Aut			Rec sell unit to				nit to pharm	CV.		
	AB	Venlafaxine Hydro	chloride Tablets		Aut			Rec. sell unit to		ı	Rx billing u		acy:		
II. Generic Equivalent to What Bra		Venlafaxine Hydro	chloride Tablets		Aut				customer?			Each	асу:		
			chloride Tablets	DSCSA) INFO				Rec. sell unit to	customer?				acy:		
				DSCSA) INFO					customer?			Each Gram	асу:		
	nd?:	DRUG SUPP	LY CHAIN SECURITY ACT (DSCSA) INFO					o customer? Vial)	AND PACKING IN	Rx billing u	Each Gram Milliliter	acy:		
II. Generic Equivalent to What Bra	nd?:	DRUG SUPP	LY CHAIN SECURITY ACT (DSCSA) INFO	RMATION	se			o customer? Vial)	AND PACKING IN	Rx billing u	Each Gram Milliliter	acy:		
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