

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

Version 2021						Introduction Typ	De: New Item		x Final Version			Date:	9/12/	2023	
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*			
Company Name: Camber Pharmaceuticals, Inc.						Applicatio	n: ANDA	a. Temperatu	re - Indicate the USP tempe	erature range for t	his product.				
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 214419								a. Temperature – 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								Other Temperature Range	Requirement					
Proprietary Name (If Applicable) a		me: Venl	afaxine Extended-Release Ta	blets 225 mg					(write in)	rtoquiromont					
Selling Unit NDC:	31722-126-90		Unit of Use NDC:	Dioto LLo mg	31722-126-90	UPC: 3	31722126908		Notes						
UDI			CVX Code:			MVX Code:									
	Mandatania - Foto	ded Balance Table													
Description:	veniaraxine Exter	nded-Release Table	ts 225 mg						Is this product to be shippe				No		
Active Ingredient(s):		Vanlafavina Hudr	oblorido LICD					_	Is this product to be shippe	a to customers on	ary ice?		No		
Active Ingredient(s): Venlafaxine Hydrochloride, USP									r temperature excursion qu	octions					
URL for Additional Product Information: www.camberpharma.com									Name:	estions.	Soma Raju				
Address:						Address 2:		Number: 732-529-0423							
City:	Piscataway														
Key Contact:	Customer Service					customerservice@car		Group E-Ilian.				<u>ctcrousu.com</u>			
Phone Number:	1-866-827-3647					732-562-8788	- Index priorities.com	c Special rec	gulations for product in any	states?			No		
Product Therapeutic Classification		Selective Seratonin and Norepinephrine Reuptake Inhibitor						o. opoolai iog	Special returns requirements for this product?				No		
Froduct Therapeutic Classification	Ocicolive Ociatori	iir ana reorepinepinine recupi		Special returns requirements for this product?				140							
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION									luct (unit of cale) unright?				No		
	ADDIII	ONALT RODUCT I		D: . 01.	0.1	T KODOOT DE	SSKII TISK IIKI SKIIIATISK	u. Store prou	d. Store product (unit of sale) upright?						
The product is?			Is the Product	Direct-Ship	Only			Ц	Protect product (unit of sa	ale) 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 #			Orphan Drug Status					_	Initial shelf life at launch (if different):				Months	
a product kit?		No				Strength:	225 mg			ODDED INCODE	AATION				
if yes, list NDCs of		FDA Approval Status								ORDER INFORM	MATION				
component parts		IN.				Dosage Form:	Film-coated tablet		Unit of Colo		What is the	NDC selling	unit?		
reverse numbered? co-licensed?		No	All					+	Unit of Sale x Bottle		1 Bottle of 9		unitr		
latex-free?		No	Allergens Present					-14	Box/Carton			.g. 1 Box of 1	0 Viale)		
preservative-free?		Yes Corn, Alcohol, Wheat				Product Shape	Round, biconvex		Ampule		(vviite-iii, e	.g. 1 D0x 01 1	o viais)		
correctional institution block?		No						-	Glass		Minimum	rder quantity		Yes	
opioid?						Product Color:	White to off white		Tube		William	iuei quantity		163	
Cannabinoid?	No Country of Origin USA						'395' on one side and blank								
If Unit Dose, is item bar coded to unit dose for						Product Imprin	on the other side	Vial Liquid Multi If Yes, how many of which package type?						tyne?	
hospital scanning? Is this product covered under the								Vial Powder Sql 24 Each					урс.		
If Unit Dose, indicate NDC here: Trade Agreements Act (TAA)? Yes								Vial Power Multi Inner/Cartor				/Pack			
ii oriii booo, irialoato 1450 fioro.					100				Other: Write In			Case	, aon		
			FOR GENERIC DRUG PR	ODUCTS				-				1			
			TOR GENERIO BROOTR	000010				-							
Authorized Generic "If Authorized Generic, other								PHARMACY ORDER / BILL UNIT							
section fields are not applicable							Rec. sell unit to customer? Rx billing unit to pharmacy:								
I. Orange Book Rating: II. Generic Equivalent to What Brand?: Venlafaxine Hydrochloride Tablets						•••	Rec. sell unit	to customer?	1	KX billing u	nit to pnarm Each	acy:			
vendananie rydiodillonde radiets						(Write-in, e.g. 1 Vial)				Gram					
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION								(vviite-iii, e.g.	. i viai)			Milliliter			
		51100 001 1	2. 0	50007., 0								I MINIMO			
Does supplier meet DSCSA defini	ition of manufactu	rer?	Yes		GLN:	0331722000000			ITEN	I AND PACKING I	NFORMATIO	N			
Is product exempt from DSCSA?			No												
•					CCD.					Dimone	ions (US msr	nte \	Valuma	Calaabla #	
If yes, select exemption: Other exemption - Write in:					GCP:				Weight Lbs.	Dimens	Width	Height	Volume (Cube)	Saleable # Pieces	
Is product repackaged?			No		If yes, was or	iginal product		Item/Each:		Deptil	widii	neight	(Cube)	rieces	
Is product repackaged:	e avelusiva distribi	ıtor?	Yes	-		ect from mfr?		item/Lacii.	0.2	2	2	4	16.00	1	
Has FDA granted waiver/exceptio			No	-	-	e manufacturer for i	renackaged product	Box/Carton/B	Rundle/						
If yes, attach documentation from		ouuci:	110		r rovide sourc	e manulacturer for i	epackageu product	Inner Pack:	Juliule/						
you, attach accamonation no								Case:							
		G1	IN AND HIBCC PRODUCT I	NFORMATION				I Guosi	5.45	12.5	8.5	4.25	451.56	24	
								Pallet:							
Calcable Unit of Massure		aleable Quantity	HIBCC		GTIN	N-14	Unit of Use GTIN-14								
Saleable Unit of Measure	5	aleable Qualitity				31722126908	00331722126908								
	S	1							COST INFORMATION			WHOLESALER USE ONLY:			
x Item/Each Box/Carton/Bundle/Inner Pack	S								COST IN CINIATION			WHOLESAL			
x Item/Each	S				1033	31722126905			COST INFORMATION			WHOLESAL			
X Item/Each Box/Carton/Bundle/Inner Pack	5	1			1033	31722126905		Regular Cost			Vendor #:	WHOLESAL			
X Item/Each Box/Carton/Bundle/Inner Pack X Case	\$	1			1033	31722126905		Regular Cost	ı	\$309.87	Vendor #: Whsl. Code	#:			
X Item/Each Box/Carton/Bundle/Inner Pack X Case	s	1			1033	81722126905			(WAC) (\$)	\$309.87	Vendor #:	#:			
X Item/Each Box/Carton/Bundle/Inner Pack X Case	s	1			1033	31722126905			ı	\$309.87	Vendor #: Whsl. Code	#:			
X Item/Each Box/Carton/Bundle/Inner Pack X Case	S	1			1033	31722126905		Invoice Cost	(WAC) (\$)	\$309.87	Vendor #: Whsl. Code	#:			
X Item/Each Box/Carton/Bundle/Inner Pack X Case	S	1						Invoice Cost As of date:	(WAC) (\$)	\$309.87	Vendor #: Whsl. Code	#:			
X Item/Each Box/Carton/Bundle/Inner Pack X Case		24		TA SHEET (SI		d letter, PACKAGE IN	ISERT, LABEL AND PHOTO OF esignated Drop Ship Only.	Invoice Cost As of date:	(WAC) (\$)	\$309.87	Vendor #: Whsl. Code	#:			