

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

Version 2021						Introduction Typ	e: 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.						Application: ANDA		a Temperatu	re - Indicate the USP tempe	rature 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							1	Other Temperature Range I	Requirement					
Proprietary Name (If Applicable) a		me: Ve	nlafaxine Extended-Release Ta	blets 37.5 mg				1	(write in)	toquiloniont					
Selling Unit NDC:	31722-123-90		Unit of Use NDC:	5.0.0 07.0 mg	31722-123-90	UPC: 33	31722123907	1	Notes						
UDI			CVX Code:			MVX Code:		1							
	Mantafaciles Fotos	ded Balance Tab												1	
Description:	Venlafaxine Exter	ided-Kelease Tac	olets 37.5 mg						Is this product to be shipped				No		
Active Ingredient(s): Venlafaxine Hydrochloride, USP									Is this product to be shipped	to customers on	ary ice?		No	ļ	
venialazine riyuloulistice, ool									temperature excursion qu	octions					
URL for Additional Product Information: www.camberpharma.com									Name:	sations.	Soma Raju				
Address:	1031 Centennial Ave (and) 800 Centennial Ave, Suite 1					Address 2:		Number: 732-529-0423				23			
City:	Piscataway						Zip: 08854	1	Group E-mail:		somaraju@h				
Key Contact:	Customer Service					customerservice@cam		1	o.oup 2 mam		33				
Phone Number:	1-866-827-3647							c. Special reg	ulations for product in any	states?			No	1	
Product Therapeutic Classification: Selective Seratonin and Norepinephrine Reuptake Inhibitor						732-562-8788		Special returns requirements for this product?					No		
томает глегировно отворятеляют.									Openial returns requirement	s for this product:			140	l	
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION									uct (unit of sale) upright?				No	1	
				Discot Chic	Only			a. o.o.o p. oa.]	
The product is?			Is the Product	Direct-Ship	Offity			Ц ".	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 #			Orphan Drug Status					_	Initial shelf life at launch (f different):				Months	
a product kit?		No Strength: 37.5 mg								ORDER INFORM	AATION				
if yes, list NDCs of			FDA Approval Status							ORDER INFORI	MATION				
component parts reverse numbered?		No				Dosage Form:	Film-coated tablet		Unit of Sale		What is the	NDC selling	unit2		
co-licensed?		No No	Allannana Duanant					+	x Bottle		1 Bottle of 9		unit:		
latex-free?			Allergens Present					4	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 Dox 01 1	o viais)		
correctional institution block?		No						-	Glass		Minimum o	der quantity	12	Yes	
opioid?		No				Product Color:	White to off white		Tube			uci quantity	, .	103	
Cannabinoid?		No	Country of Origin	USA			'392' on one side and blank	-	Vial Liquid Sgl						
If Unit Dose, is item bar coded to unit dose for						Product Imprint	Product Imprint: on the other side on the other side Vial Liquid Multi If Yes, how many of which packa					ich package	type?		
hospital scanning? Is this product covered under the								Ħ	Vial Powder Sql		24	Each	.o pao.ago	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
If Unit Dose, indicate NDC here: Trade Agreements Act (TAA)? Yes								Vial Power Multi Inner/Carton				n/Pack			
								Other: Write In Case							
			FOR GENERIC DRUG PR	ODUCTS				<u>-</u>							
			TON CENERAL DINCO I IN	3533.3											
Authorized Generic "If Authorized Generic, other								PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating: AB Section fields are not applicable							Rec. sell unit to customer? Rx billing unit to pharmacy:								
II. Generic Equivalent to What Brand?: Venlafaxine Hydrochloride Tablets						Nec. sen unit to custom			Each						
in Schola Equitation to What Branch						(Write-in, e.g. 1 Vial)			Gram						
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION								(vviico iii, o.g.	· viai,			Milliliter			
								7				l.			
Does supplier meet DSCSA defini	ition of manufactu	rer?	Yes		GLN:	0331722000000			ITEN	AND PACKING I	NFORMATIO	1			
Is product exempt from DSCSA?			No						· · · · · · · · · · · · · · · · · · ·						
If yes, select exemption:					GCP:			1		Dimens	ions (US msn	nts.)	Volume	Saleable #	
Other exemption - Write in:									Weight Lbs.	Depth	Width	Height	(Cube)	Pieces	
Is product repackaged?			No		If yes, was or	iginal product		Item/Each:	0.4				45.00		
Is product sold by manufacturer's	s exclusive distribu	itor?	Yes			ect from mfr?			0.1	2	2	3.75	15.00	1	
Has FDA granted waiver/exceptio			No		Provide source	e manufacturer for re	epackaged product	Box/Carton/B	undle/						
If yes, attach documentation from	m FDA.			_				Inner Pack:							
								Case:	2.85	12.5	8.5	4	425.00	24	
		(GTIN AND HIBCC PRODUCT II	NFORMATION					2.00	12.0	0.0		420.00	2-7	
								Pallet:							
Saleable Unit of Measure	S	aleable Quantity	HIBCC		GTI		Unit of Use GTIN-14								
x Item/Each		1 003317				31722123907	00331722123907				MILOL COAL COAL COAL				
Box/Carton/Bundle/Inner Pack								COST INFORMATION			WHOLESALER USE ONLY:				
x Case		24			1033	31722123904		11							
Pallet								Regular Cost			Vendor #:	_			
	_							Invoice Cost	(WAC) (\$)	\$120.51					
	_								2/4/0000		Fineline Co	ae:			
								As of date:	3/1/2023						
								11			1				
			Allech convert CAFETY 2.1	TA CUEET (C	DC) as as = 5 = :	d letter DACKAGE ""	CEDT I ADEL AND BUOTO SE	DDODLIGT DAGG	ACING and DARROOM						
*Please provide any additional inf		2	Attach copy of SAFETY DA	TA SHEET (SI	DS) or non hazar		SERT, LABEL AND PHOTO OF I	PRODUCT PACK	AGING and BARCODE. Signature:						