

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

Version 2021							Introduction Type: New Item			x Final Version					Date:	9/12/	2023	
PRODUCT INFORMATION								SPECIAL HANDLING AND STOR				AGE REQUIR	EMENTS*					
Company Name:	Camber Pharmaceuticals, Inc.						Applica	tion:	ANDA	a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/ANI			ed device):		21	4419					Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)							
Medical Device Class, if applicab	ole:																	
DUNS:	11-856-3719										Other Te	mperature Range F	Requirement					
Proprietary Name (If Applicable) and		ame:	Venlafaxin		blets 225 mg							ite in)						
Selling Unit NDC: UDI	31722-126-30			Unit of Use NDC: CVX Code:		31722-126-30	UPC: MVX Code:	331722	2126304		Notes							
	Venlafaxine Exter						WVX Code.											
Description:					oduct to be shipped oduct to be shipped				No No									
Active Ingredient(s): Venlafaxine Hydrochloride, USP												buuct to be shipped	to customers on a	ily ice?		INU		
											b. Contact for temperature excursion questions:							
URL for Additional Product Information: www.camberpharma.com											Name:			Soma Raju				
Address:	1031 Centennial Ave (and) 800 Centennial Ave			Ave, Suite 1		Chata.	Address 2:				Number			732-529-0423 somaraju@heterousa.com				
City: Key Contact:	Piscataway State: Customer Service Email:							NJ Zip: 08854 customerservice@camberpharma.com			Group E	-mail:		somaraju@ne	terousa.com			
Phone Number:	1-866-827-3647 Fa									c. Special re	nulations f	or product in any	states?			No		
Product Therapeutic Classification					ake Inhibitor	-				c. Special regulations for product in any states? Special returns requirements for this product?				No			-	
· · · · · · · · · · · · · · · · · · ·																		
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION										d. Store proc	luct (unit c	of sale) upright?				No		
The product is?	Is the Product Direct-Ship			Only					Protect I	product (unit of sa			No					
a legend device?		No		s the Product	Unit of Use		Size:	l I	30 ct	e. Shelf life:		,	.,			24	Months	
if yes, enter class #			(Orphan Drug Status			3ize.	1	30 61		Initial sh	elf life at launch (i	if different):				Months	
a product kit?		No					Strength:		225 mg									
if yes, list NDCs of FDA Approval Status							-	-	-				ORDER INFORM	ATION				
reverse numbered?		No	1				Dosage Forr	m:	Film-coated tablet		Unit of S	ale		What is the	NDC selling	unit?		
co-licensed?		No	#	Allergens Present				L		1	-	Bottle		1 Bottle of 3	-			
latex-free?		Yes			abol Wheat		Product Sha		Round, biconvex	1		Box/Carton		(Write-in, e.	g. 1 Box of 10	0 Vials)		
preservative-free? Yes				Corn, Alcohol, Wheat				Round, biconvex		Ampule				·				
correctional institution block?		No					Product Col	or:	White to off white			Glass		Minimum or	der quantity	?	Yes	
opioid? Cannabinoid?		No No		Country of Origin	USA				'395' on one side and blank	4		Tube Vial Liquid Sgl						
If Unit Dose, is item bar coded to unit dose for						Product Imp		on the other side			Vial Liquid Multi		If Yes. how	manv of whi	ch package	type?		
hospital scanning?		Is this product covered under the								Vial Powder Sql			If Yes, how many of which package type? 24 Each					
If Unit Dose, indicate NDC here:			1	Trade Agreements Act (TAA)? Yes						Vial Power Multi			Inner/Carton/Pack					
												Other: Write In			Case			
FOR GENERIC DRUG PRODUCTS																		
Authorized Generic *If Authorized Generic, other												РН	ARMACY ORDER					
L Orenne Back Betinn	AB						ulonzed Generic		fields are not applicable									
I. Orange Book Rating: AB II. Generic Equivalent to What Brand?: Venlafaxine Hydrochloride Tablets									Rec. seit unit to customer ?				Rx billing unit to pharmacy:					
									(Write-in, e.g. 1 Vial)				Gram					
		DRUG	SUPPLY CH	HAIN SECURITY ACT (DSCSA) INFOR	RMATION									Milliliter			
					_													
Does supplier meet DSCSA definit Is product exempt from DSCSA?	tion of manufactu	irer?	,	Yes	_	GLN:	0331722000000					IIEM	AND PACKING IN	IFORMATION				
				NO									D					
If yes, select exemption: Other exemption - Write in:						GCP:						Weight Lbs.	Dimension	ons (US msm Width	Height	Volume (Cube)	Saleable # Pieces	
Is product repackaged?			1	No		If yes, was or	iginal product			Item/Each:							i icoco	
Is product sold by manufacturer's	exclusive distrib	utor?		Yes	-		rect from mfr?					0.12	1.75	1.75	3.5	10.72	1	
Has FDA granted waiver/exception	n/exemption for p	roduct?		No		Provide sour	ce manufacturer fo	or repact	kaged product	Box/Carton/E	Bundle/							
If yes, attach documentation from	n FDA.									Inner Pack:								
				D HIBCC PRODUCT IN						Case:		3.15	11	7.5	4	330.00	24	
			GTIN AN		VFORMATION					Pallet:								
Saleable Unit of Measure	S	Saleable Quan	ntity H	HIBCC		GTI	N-14		Unit of Use GTIN-14	i unct.								
X Item/Each							31722126304		00331722126304									
Box/Carton/Bundle/Inner Pack										COST INFORMATION				WHOLESALER USE ONLY:				
X Case		24				103	31722126301											
Pallet										Regular Cost			£402.00	Vendor #:				
							-		Invoice Cost (WAC) (\$)			\$103.29	9 Whsl. Code #: Fineline Code:					
	1		1 1					-		As of date:		3/1/2023						
]													1				
								_										
Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PROL																		
*Please provide any additional info	*Please provide any additional information on page 2. See new p. 3 for Designated Drop Ship Only.											Signature:						