

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

Version 2021						Introduction Type:	Post Launch Change		1 Final Version			Date:	11/20	0/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*		
Company Name: Camber Pharmaceuticals, Inc. Application: ANDA						a. Temperature – Indicate the USP temperature range for this product.								
Application Number for NDA/AN	IDA/BLA (drug); PM	A/510(k)(med devi	ce):	212	277		·		Temperature Range	Controlled Room		and 25 C (68	3° – 77° F)	
Medical Device Class, if applica									· -					
DUNS:	11-856-3719								Other Temperature Range I	Requirement				
Proprietary Name (If Applicable) a	and Established Nar	me: Venla	faxine Hydrochloride Extend	ed-Release Caps	sules, USP 150	mg (base)			(write in)					
Selling Unit NDC:	31722-004-30		Unit of Use NDC:		31722-004-30		722004305		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Venlafaxine Hydro	chloride Extended-F	Release Capsules, USP 150	mg (base)					Is this product to be shipped	d to customers on i	ce?		No	1
	·								Is this product to be shipped				No	1
Active Ingredient(s): Venlafaxine hydrochloride, USP														
								b. Contact fo	temperature excursion qu	estions:				
URL for Additional Product Inform		www.camberpharm	a.com						Name:		Soma Raju			
Address:	800 Centennial Av	e, Suite 1			Ctata.	Address 2:	00054		Number:		732-529-042			
City:	Piscataway Customer Service				State: Email:	NJ Zip customerservice@cam	08854		Group E-mail:		somaraju@he	eterousa.com		
Key Contact: Phone Number:	1-866-827-3647				Fax:	732-562-8788	iberpriama.com	a Special rea	julations for product in any	ctotoc?			No	1
Product Therapeutic Classification		Seretonin and neron	pinephrine reuptake inhibitor (\$	NIDI\	ı ax.	732-302-0700		c. Special reg	Special returns requirement				No	-
Product Therapeutic Classification	on:	Serotonin and notep	omeprime reuptake minibilor (s	DINKI)					Special returns requirement	is for this product?			INO	_
	ADDITIC	NAL PRODUCT IN	IFORMATION			PRODUCT DESC	CRIPTION INFORMATION	d Store prod	uct (unit of sale) upright?				No	1
	ADDITIO	MAETRODOOTII		Discoul Obis O	-1	T NODOOT DECC	NULL LIGHT IN SKIII A LIGHT	u. Store prou						1
The product is?		NI.	Is the Product	Direct-Ship O Unit of Use	niy		001	. 01-1/17	Protect product (unit of sa	ile) from light?			No	
a legend device? if yes, enter class #		No	Is the Product Orphan Drug Status	Offit of Ose		Size:	30 ct	e. Shelf life:	Initial shelf life at launch (if different).			24	Months Months
a product kit?		No	Orphan Drug Status				150 mg		illitiai Sileii ille at laulicii (ii dillerelli).				WOULIS
if yes, list NDCs of		140	FDA Approval Status			Strength:	150 mg			ORDER INFORM	MATION			
component parts							Hard gelatin capsule							
reverse numbered?		No				Dosage Form:			Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 3	0 Capsules		
latex-free?		Yes	Gluten Dve	Alcohol, Sugar		Product Shape:	Capsule		Box/Carton		(Write-in, e.	g. 1 Box of 1	0 Vials)	
preservative-free?		Yes	Oluten, Dyc,	Alconol, ougui		r roduct onapc.			Ampule					
correctional institution block?		No				Product Color:	Orange opaque cap &		Glass		Minimum o	rder quantity	/?	Yes
opioid?		No					white opaque body		Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	Imprinted with 'V' on cap & '11' on body printed in black color		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for		to the management and a	and an the		•	or body printed in black color		Vial Liquid Multi				ich package	type?
hospital scanning?			Is this product covered to Trade Agreements Act (No				Vial Powder Sgl Vial Powder Multi		24	Each	/Deels	
If Unit Dose, indicate NDC here:			Trade Agreements Act (IAA)!	INO				Other: Write In			Inner/Cartor Case	/Pack	
			FOR GENERIC DRUG PR	ODUCTS					Other: Write III			Ousc		
			TOR GENERIC DROGT	000013										
					Aut	horized Generic *If A	authorized Generic, other		PH	IARMACY ORDER	/ BILL UNIT			
L Orenzo Book Betimer	AB				7101		tion fields are not applicable	Pac sall unit	to customer?					
I. Orange Book Rating: II. Generic Equivalent to What Bra		Effexor XR						Nec. sen unit	to customer:	1	Rx billing u	Each	acy:	
ii. Generic Equivalent to What Bra	anur.	LITEXOF AIX						(Write-in, e.g	1 Vial)			Gram		
		DRUG SUPPI	LY CHAIN SECURITY ACT	(DSCSA) INFOR	MATION			(**************************************	· viai,			Milliliter		
Does supplier meet DSCSA defin	ition of manufacture	er?	Yes		GLN:	0331722498975			ITEN	I AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No						· · · · · · · · · · · · · · · · · · ·					
If yes, select exemption:					GCP:					Dimensi	ons (US msn	nts.)	Volume	Saleable #
Other exemption - Write in:								1	Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		If yes, was or	ginal product purchase	ed	Item/Each:	0.1	1.55	1.55	3.2	7.88	1
Is product sold by manufacturer's			Yes	_	direct from m					1.00	1.55	5.2	7.00	'
Has FDA granted waiver/exception		oduct?	No		Provide source	e manufacturer for rep	ackaged product	Box/Carton/E	undle/					
If yes, attach documentation fro	m FDA.							Inner Pack:						
		CT	IN AND HIBCC PRODUCT I	NEORMATION				Case:	2.85	9.75	6.75	4.2	299.25	24
		GII	IN AND HIBCC PRODUCT I	NFORMATION				Pallet:						
Saleable Unit of Measure	9.	aleable Quantity	HIBCC		GTIN	J-14	Unit of Use GTIN-14	railet.						
X Item/Each	56	1	TIBOO			31722004305	00331722004305							
Box/Carton/Bundle/Inner Pack					0300				COST INFORMATION			WHOLESAL	ER USE ONL	Y:
X Case		24			3033	31722004306								
Pallet								Regular Cost			Vendor #:			
								Invoice Cost	(WAC) (\$)	\$9.17	Whsl. Code	#:		
											Fineline Co	de:		
								As of date:	12/1/2024					
μ								<u> </u>			ļ			
			Attack seems of CAFETY D	ATA SHEET (SD	S) or non hazar	d letter PACKAGE INSE	ERT, LABEL AND PHOTO OF F	PRODUCT PACK	AGING and BARCODE					
*Please provide any additional in	_		Allach copy of SAFETY D	TIT OFFICE T (OD	o, or morrinazar		gnated Drop Ship Only.		Signature:					



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Version 2021

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL	HAZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning?	SDS Hazard Classification x Organic Corrosive Oxidizer Inorganic Oxidizer Steroid/Androgen Contact Hazard					
c. Contact Hazard? d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? Is this product regulated for shipment by DOT?	identify NFPA Storage Level: NFPA Storage Level: Is the product a NIOSH hazardous drug? No					
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class	If yes, indicate which: Hazardous Waste Identification					
d. Packing Group e. Inhalation Hazard?	EPA Hazardous Waste Code: Waste Characteristics					
Is this product regulated for shipment by IATA?						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:					
Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)					
Is this a reportable quantity? No RQ Threshold: Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit? No (if yes, identify method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4)	REMS: REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: No Phone: DEA #: NCPDP#: NCPDP#: NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Comments Registry: No					
	Registry Program Contact Name: Phone:					
ADD'L STORAGE INFORMATION	Comments					
Is the Product Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS					
Controlled by State(s)? ARCOS Reportable? Schedule No. No Listed Chemical (List I or II) If yes, indicate which: Is it a scheduled listed chemical product?: No CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged: 1-866-827-3647 Yes					
	URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Ye	contact - customerservice@camberpharma.com					
Restricted to retail pharmacy only:	Special regulations or returns requirements for this					
Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) No.	product in certain states? No If so, which states? Other requirements? Comments?					
Comments:						
MISCELL	NEOUS NOTES and/or Image of Product Barcode:					



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Version 2021

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop S	nip 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:
b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone:	per:	Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Expedited Freight Charges or Other Designa	ed Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order:		Overnight receipt available: PO Receipt cut off time:
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		PO Receipt Cut off time:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinic Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	s and physician offices	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to F	rocess 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 certain states? If so, which states? Other requirements? Comments?
Miscellaneous Notes:		
		ADDITIONAL INFORMATION
		Is product order for scheduled patient procedure? Is product order for restocking purposes?