

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

Version 2021						Introduction Type:	Post Launch Change		x Final Version			Date:	11/20	0/2024
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	RAGE REQUI	REMENTS*		
Company Name:	Camber Pharmac	euticals, Inc.				Application:	ANDA	a. Temperatu	ire - Indicate the USP temp	erature range for t	his product.			
Application Number for NDA/AN			ice):	212	2277				Temperature Range	Controlled Room		and 25 C (68	s° – 77° F)	
Medical Device Class, if applicable:														
DUNS:	11-856-3719								Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a	and Established Na	me: Venla	afaxine Hydrochloride Extend	ed-Release Cap	sules, USP 75	mg (base)			(write in)					
Selling Unit NDC:	31722-003-90		Unit of Use NDC		31722-003-90		722003902		Notes					
UDI			CVX Code:			MVX Code:								
Description: Venlafaxine Hydrochloride Extended-Release Capsules, USP 75 mg (base) Is this product to be shipped to customers on ice? No								1						
-									Is this product to be shippe				No	1
Active Ingredient(s): Venlafaxine hydrochloride, USP														
							b. Contact fo	r temperature excursion qu	estions:					
URL for Additional Product Inform		www.camberpharn	na.com						Name:		Soma Raju			
Address:	800 Centennial Av	ve, Suite 1			State:	Address 2:	00054		Number:		732-529-042			
City: Key Contact:	Piscataway Customer Service				Email:	customerservice@cam	08854	Group E-mail: somaraju@heterousa.com						
Phone Number:	1-866-827-3647	,			Fax:	732-562-8788	iberpriama.com	c. Special regulations for product in any states?					1	
Product Therapeutic Classification		Serotonin and nore	pinephrine reuptake inhibitor (\$	NRI)	l ux.	702 302 0700		C. Special re	Special returns requirement				No	-
Froduct Therapeutic Classification	"".	ocrotoriiii aria nore	pineprinile reaptake initibilor (JIVII)					opeciai returno requiremen	is for this product:			INO]
	ADDITIO	ONAL PRODUCT II	NEORMATION			PRODUCT DESC	RIPTION INFORMATION	d Store proc	luct (unit of sale) upright?				No	1
The new decay in 0	7,55111	511/12 1 11 0 D 0 0 1 II		Direct-Ship C	nlv	1 1100001 0200		d. otore proc		.1-) (11-1-10				1
The product is? a legend device?		No	Is the Product Is the Product	Unit of Use	riiy		90 ct	e. Shelf life:	Protect product (unit of sa	ile) from light?			No 24	Mantha
if yes, enter class #		INO	Orphan Drug Status	Offit of Ose		Size:	90 Ct	e. Shell life:	Initial shelf life at launch (if different).			24	Months Months
a product kit?		No	Orphan Drug Status				75 mg		illidai sileli ille at iadiicii (ii uiiiereiity.				WOILLIS
if yes, list NDCs of		140	FDA Approval Status			Strength:				ORDER INFOR	MATION			
component parts						B	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 9	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	J. J	/ooo., ougu.		i roudot onapo.			Ampule					
correctional institution block?		No				Product Color:	Peach opaque cap &		Glass		Minimum o	der quantity	?	Yes
opioid?		No					white opaque body Imprinted with 'V' on cap & '10'		Tube					
Cannabinoid?	and deep fee	No	Country of Origin	India		Product Imprint:	on body printed in black color		Vial Liquid Sgl Vial Liquid Multi		K Vaa haw		ch package	
If Unit Dose, is item bar coded to unhospital scanning?	unit dose for		Is this product covered	inder the			, ,		Vial Elquid Multi Vial Powder Sql			Each	сп раскаде	type?
If Unit Dose, indicate NDC here:			Trade Agreements Act (No				Vial Powder Multi		24	Inner/Cartor	/Pack	
ii Olik Bose, ilidicate NBO licie.			Trado Agroomonio Aor (140				Other: Write In			Case	yr dok	
			FOR GENERIC DRUG PF	ODUCTS								1		
					Au	thorized Generic *If A	authorized Generic, other		Ph	IARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB			T		sect	ion fields are not applicable	Rec. sell unit	to customer?		Rx billing u	nit to pharm	acv.	
II. Generic Equivalent to What Bra		Effexor XR								1	TEX Simily u	Each	,.	
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,								(Write-in, e.g	. 1 Vial)			Gram		
		DRUG SUPF	LY CHAIN SECURITY ACT	(DSCSA) INFOR	MATION							Milliliter		
Does supplier meet DSCSA defini	ition of manufactur	rer?	Yes		GLN:	0331722498975			ITEN	I AND PACKING I	NFORMATIO	V		
Is product exempt from DSCSA?			No					!						
If yes, select exemption:					GCP:				Weight Lbs.		ions (US msn	•	Volume	Saleable #
Other exemption - Write in:									Weight Ebs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			iginal product purchase	ed	Item/Each:	0.15	1.75	1.75	4	12.25	1
Is product sold by manufacturer's			Yes No	-	direct from m		and a management	Day/Ord /						
Has FDA granted waiver/exception If yes, attach documentation from		oduct?	INO		Provide source	ce manufacturer for rep	ackaged product	Box/Carton/E	Sunale/					
ii yes, attacii documentation iro	III FDA.							Case:						
		G1	IN AND HIBCC PRODUCT I	NFORMATION				l louse.	4.45	12	8.5	5.25	535.50	24
								Pallet:						
Saleable Unit of Measure	S	aleable Quantity	HIBCC		GTII	N-14	Unit of Use GTIN-14							
X Item/Each		1				31722003902	00331722003902		·					
Box/Carton/Bundle/Inner Pack									COST INFORMATION			WHOLESAL	ER USE ONL	Y:
X Case		24			3033	31722003903								
Pallet								Regular Cos			Vendor #:	_		
	_							Invoice Cost	(WAC) (\$)	\$21.00	Whsl. Code			
	_							An of date:	12/1/2024		Fineline Co	ae:		
	-							As of date:	12/1/2024		-			
 			Attach copy of SAFETY D	ATA SHEET (SD	S) or non haza	rd letter, PACKAGE INSE	ERT, LABEL AND PHOTO OF F	PRODUCT PACK	AGING and BARCODE		-			
*Please provide any additional inf	formation on nage	2	, 5. 5		.,		gnated Drop Ship Only.		Signature:					



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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 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? If so, which states? Other requirements? Comments?					
Comments:						
MISCELL	NEOUS NOTES and/or Image of Product Barcode:					



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

Order Method fo	r Designated Drop Ship 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:	Fax Number: Fax Number: Phone No.: Site Address:	Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt:					
F	Name: Phone:	Ships regular ground for 3-10 days receipt:					
Expedited Freight Charg	ges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing					
Expedited freight fees billed with each order:		Overnight receipt available:					
Drop Ship service fee billed with each order:		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 only: Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician of Restricted from US territories? (explain in conficulty comments:	offices only:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:					
Other Data Infor	rmation Required to Process 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?					
Mis	scellaneous Notes:						
		ADDITIONAL INFORMATION					
		Is product order for scheduled patient procedure? Is product order for restocking purposes?					