

## **Standard Pharmaceutical Product Information (Rx Product Only)**

© August 2014							Intro	oduction Type	e:	New Item		Final Version			Date:	4/8/	2020	
				PRODUCT INFORM	ATION							SPECIAL HANDL	ING AND ST	ORAGE REQ	UIREMENTS	*		
Company Name:								a. Temperature – Indicate the USP temperature range for this product.										
Application Number for ND	A/ANDA/BLA (drug);	PMA/510(k)(me	d device):		21	12277					Tempera	ature Range		Controlled F	Room – betwe	en 20 and 25	C (68° – 77° F	
DUNS:	82-667-4775										Other Te	emperature Range Re	equirement					
Proprietary Name (If Applical		Name:	Venlafaxin	ne Hydrochloride Extende		apsules 150MG 9	90CT				(wr	ite in)					]	
Selling Unit NDC:	31722-004-90			Individual Unit NDC:					172200490	9								
UDI				CVX Code:			MVX	Code:			Is this pr	oduct to be shipped t	o customers	on ice?		No	-	
Description: White to off white colored, round to oval shaped pellets filled in size '0' hard gelatin capsules with orange opaque cap imprinted with 'V' in black color, white opaque							Is this product to be shipped to customers on dry ice? No											
Active Ingredient(s): Venlafaxine																		
Active ingredient(s):		veniaraxine									b. Contact for tempera Name:	ture excursion ques	suons:	Soma Raju				
URL for Additional Product In	nformation:	www.camberph	arma.com								Number	:		732-529-042	23			
Address:	1031 Centennial Avenue				Address 2:				Group E	-mail:		somaraju@l	heterousa.co	m				
City:	Piscataway				State: NJ Zip: 08854													
Key Contact:	Customer Service				Email: customerservice@camberpharma.com Fax: 732-562-8788			c. Special regulations			- 10		No	-				
Phone Number:	732-529-0430				Fax: 732-562-8788				Special returns requirements for this product? No					-				
Product Therapeutic Classifi	Product Therapeutic Classification:								al Chana anadush (unit of colo) unviete?									
ADDITIONA	L PRODUCT INFORM						PRODUCT	DESCRIPTIO		ATION	d. Store product (unit of sale) upright? No Protect product (unit of sale) from light? No							
											e. Shelf life:	product (unit of suic	., nom ngne.			24	Months	
Is the Product a legend device?			No				h	~~				nelf life at launch (if	different):			24	Months	
reverse numbered?			No			Size:	9	90					,,				J	
co-licensed?		-	No			Strength:		150MG				C	DRDER INFO	RMATION				
Is the Product		Direct-Ship On	ly			ou engin.	_	1001010							NDC selling			
Is the Product		Unit Dose				Dosage Form	: 0	Capsules			Unit of S	Bottle		1 box of 24		unit?		
							L				x	Box/Carton			.g. 1 Box of 1	0 Vials)		
If Unit Dose, is item bar code	ed to unit dose for hos	pital scanning?				Product Shap		Round to oval				Ampule		( ,	5	. ,		
If Unit Dose NDC, indicate N	DC here:					Froduct onap	,e.					Glass		Minimum o	rder quantity	?	Yes	
Country of Origin		India				Product Colo	r: (	Orange opaqu	ue cap & W	hite opaque body		Tube						
Country of Origin							-				Vial Liquid Sgl Vial Liquid Multi If Yes, how many of which package type?							
Is this product covered under	r the Trade Agreemen	ts Act (TAA)?				Product Impr	int:	V' on cap & '1	1' on body		Vial Powder Sql Each							
		•										Vial Power Multi			Inner/Cartor	/Pack		
												Other: Write In	-	24	Case			
				FOR GENERIC DRUG P	RUDUCIS													
						Auth	orized Gen	eric *lf	Authorized	Generic, other section	PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating: AB			1	fields are not applicable				Rec. sell unit to customer? Rx billing unit to pharmacy:										
II. Generic Equivalent to What	at Brand?:	Effexor XR								Each								
											(Write-in, e.g. 1 Vial)				Gram			
		DRUG	SUPPLY	CHAIN SECURITY ACT	(DSCSA) IN	FORMATION									Milliliter			
Does supplier meet DSCSA of	definition of manufac	turer?		Yes	G	LN:					ITEM AND PACKING INFORMATION							
Is product exempt from DSC			N	lo	-													
If yes, select exemption:					_							Weight Lbs.		nsions (US n		Volume	# Pieces:	
Other exemption - Write in: Is product repackaged?			N	lo	14				line of		lite ma		Depth	Height	Width	(Cube)		
Is product repackaged?	urer's exclusive distr	ibutor?	N	No		Yes, was origin om mfr?	ai produčt	purchased d	mect		Item:	0.17		3.688	2.187			
Has FDA granted waiver/exc				No	lf	yes, attach doc	umentatior	n from FDA.			Box/Carton/Bundle/		1					
		-			_						Inner Pack:							
				GTIN PRODUCT INFOR							Case:	7.49	13.5	9.3	4.8	0.348	24	
				Level	Saleable Unit			0	uantity	GTIN-14	Pallet:							
Serialized?	Yes		X I	Item	0	<b>X</b> 2D		Linear	1	00331722004909								
If not, when?				Box/Carton/Bundle/Inner Pack		2D		Linear			UPC:	Case:						
Items aggregated?	No	_		Case	x	<b>X</b> 2D			24	30331722004900	[	Carton:						
			F	Pallet	$\vdash$	2D 2D		Linear Linear			COST	INFORMATION			WHOLESAL	ER USE ONI	V	
						2D 2D		Linear			0001	IN ORMATION			MIOLEGAL			
						2D		Linear			Regular Cost			Vendor #:				
						2D		Linear			Invoice Cost (WAC) (\$)		\$52.44	Whsl. Code				
											Federal Excise Tax Pe	r Unit of Sale		Fineline Co	de:			
											As of date:			-				
				ttach conv of SAFETY DA		SDS) or non-bor	ard letter		SERT I AP		DUCT PACKAGING and B	ARCODE		I				
*Please provide any addition	al information on pa	ae 2.	A	acon copy of OAFETT DF	UN ONEET (					op Ship Only.	Signatu							
. iouse provide any addition		o- <b>-</b> -					200 HOW			y.	Signatu			-				



## **Standard Pharmaceutical Product Information (Page 2)**

	ated Drop Ship Only Products, Please Use Page 3							
MATERIAL H	IAZARD CLASSIFICATION and TRANSPORTATION							
Is this product (check all that apply):								
a. Cytotoxic? No	SDS Hazard Classification							
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	Organic							
Is the product a CA Prop 65 carcinogen? No								
Is the product a CA Prop 65 reproductive toxicant?	Inorganic Oxidizer							
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard							
c. Contact Hazard? No	Aerosol Class; Identify NFPA Storage Level:							
d. Does this product require special clean-up instructions? No								
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug?							
e. Does the product contain DEHP? No	If yes, indicate which:							
Is this product regulated for shipment by DOT or IATA? No								
(if yes, answer a-e below and provide SDS)								
a. UN/Identification Number								
b. Proper Shipping Name	Hazardous Waste Identification							
c. DOT Hazard Class	EPA Hazardous Waste Code:							
d. Packing Group								
e. Inhalation Hazard?								
In the product restricted for six chipment? If an indicate restriction	REMS or REGISTRY RESTRICTIONS							
Is the product restricted for air shipment? If so, indicate restriction:								
Passenger								
Cargo	If Yes, is it managed with a pharmacy registry?							
Passenger & Cargo	Website URL:							
Is this a reportable quantity? No								
RQ Threshold:	Comments / Details: (For example, iPledge program?)							
Is this a marine pollutant? No								
Is this product shipped utilizing an authorized DOT exception or Special Permit?								
No (if yes, identify method below)	REMS: No							
Limited Quantity								
	REMS Program Manager Name: Phone: Phone:							
Consumer Commodity, ORM-D	Supplier Manages REMS registry exclusively: <u>No</u>							
Small Quantity (49 CFR 173.4)	Wholesale distributor support: No							
Special Permit; DOT-SP	Provider Name:							
Special Provision (listed in Column 7 of 49 CFR 172.101);	Site Enrollment Number assigned DEA #: No							
SP#	by Supplier: PCPDP #: No							
	NPI #: No							
ADD'L STORAGE INFORMATION								
Is the Product	Comments							
Controlled Substance? No	Comments							
	Registry: No							
· · · · · · · · · · · · · · · · · · ·								
ARCOS Reportable? No	Registry Program Contact Name: Phone: Phone:							
Schedule No. (inc. N for non-narcotic)	Comments							
Controlled Substance Code								
Listed Chemical (List I or II) No	RETURN INSTRUCTIONS							
If yes, indicate which:								
Is it a scheduled listed chemical product?: No	Contact tel. # if product received damaged: 732-529-0430							
CLASS OF TRADE RESTRICTION:	Is product returnable for credit: Yes							
	•							
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No	URL/Link to returns policy: contact - customerservice@camberpharma.com							
Restricted to retail pharmacy only: Yes	Special regulations or returns requirements for this product in certain states? No							
Restricted to hospital, clinics, and physician offices only: No	If so, which states? Other requirements? Comments?							
Restricted from US territories? (explain in comments) No								
Comments:								
MISCELLAN	IEOUS NOTES and/or Image of Product Barcode:							



## **Standard Pharmaceutical Product Information (Page 3)**

	not a designated drop ship, do not complete.						
Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing						
Purchase orders may be accepted by: a. EDI Yes b. Autofinia	Purchase order daily receipt cut off time by supplier           Cut off time:         2:30PM           Eastern						
b. Autofax     No     Fax Number:       c. Fax     Yes     Fax Number:     732-562-8788       d. Phone only     No     Phone No.:	Shipping lead time of PO: 24/48 Hours Days						
e. Supplier Web Site only     No     Site Address:       Minimum Order Quantity:     case pack       Supplier's Customer Service Number:     732-529-0430 x466 x465 x467 x470       Contracted 3PL company / contact #:     Name:       Phone:	Ships same day for next day receipt:NoShips for second day receipt:NoShips regular ground for 3-10 days receipt:Yes						
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing						
Expedited freight fees billed with each order: No	Overnight receipt available: Yes						
Drop Ship service fee billed with each order: No	PO Receipt cut off time: 2:30PM Eastern						
Drop Ship miscellaneous fees billed: No Comments:	Days of week overnight is available: X Monday X Tuesday X Wednesday X Thursday X Friday						
	Priority Overnight receipt available: Yes						
Class of Trade Restriction:	PO Receipt Cut off time: 2:30PM EST						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices       No         Restricted to retail pharmacy only:       Yes         Restricted to hospital, clinics, and physician offices only:       No         Restricted from US territories? (explain in comments)       No         Comments:	Saturday Overnight receipt available:       No         Order receipt method:       Phone:       Yes         Order receipt method:       Phone:       Yes       Phone #:       732-562-8788         EDI:       Yes       Yes       Overnight Fees apply:       Yes       Yes         Other fees apply:       No       No						
Other Data Information Required to Process PO:	Return Instructions						
Patient Procedure Date:	Contact # if product is received damaged:       732-529-0430         Is product returnable for credit:       Yes         URL/Link to returns policy:						
Miscellaneous Notes:							
	ADDITIONAL INFORMATION						
	Is product order for scheduled patient procedure?     No       Is product order for restocking purposes?     No						