



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

Version 2021

Introduction Type: New Item

Final Version

Date: 9/12/2023

PRODUCT INFORMATION	
Company Name:	Camber Pharmaceuticals, Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	214419
Medical Device Class, if applicable:	
DUNS:	82-677-4775
Proprietary Name (If Applicable) and Established Name:	Venlafaxine Extended-Release Tablets 150 mg
Selling Unit NDC:	31722-125-30
Unit of Use NDC:	31722-125-30
UPC:	331722125307
UDI	
CVX Code:	
MVX Code:	
Description:	Venlafaxine Extended-Release Tablets 150 mg
Active Ingredient(s):	Venlafaxine Hydrochloride, USP
URL for Additional Product Information:	www.camberpharma.com
Address:	1031 Centennial Ave (and) 800 Centennial Ave, Suite 1
City:	Piscataway
Key Contact:	Customer Service
Phone Number:	1-866-827-3647
Product Therapeutic Classification:	Selective Serotonin and Norepinephrine Reuptake Inhibitor

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	
Notes	
Is this product to be shipped to customers on ice?	<input type="checkbox"/> No
Is this product to be shipped to customers on dry ice?	<input type="checkbox"/> No
b. Contact for temperature excursion questions:	
Name:	Soma Raju
Number:	732-529-0423
Group E-mail:	somaraju@heterousa.com
c. Special regulations for product in any states?	<input type="checkbox"/> No
Special returns requirements for this product?	<input type="checkbox"/> No
d. Store product (unit of sale) upright?	<input type="checkbox"/> No
Protect product (unit of sale) from light?	<input type="checkbox"/> No
e. Shelf life:	24 Months
Initial shelf life at launch (if different):	

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is? a legend device?	<input type="checkbox"/> No	Is the Product... Direct-Ship Only	<input type="checkbox"/>
if yes, enter class # a product kit?	<input type="checkbox"/> No	Is the Product... Unit of Use	<input type="checkbox"/>
if yes, list NDCs of component parts reverse numbered?		Orphan Drug Status	<input type="checkbox"/>
co-licensed?	<input type="checkbox"/> No	FDA Approval Status	
latex-free?	<input type="checkbox"/> Yes	Allergens Present	Corn, Alcohol, Wheat
preservative-free?	<input type="checkbox"/> Yes	Country of Origin	USA
correctional institution block? opioid?	<input type="checkbox"/> No	Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/> Yes
Cannabinoid?	<input type="checkbox"/> No	Size:	30 ct
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>	Strength:	150 mg
If Unit Dose, indicate NDC here:		Dosage Form:	Film-coated tablet
		Product Shape:	Round, biconvex
		Product Color:	White to off white
		Product Imprint:	'394' on one side and blank on the other side

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Bottle of 30 Tablets
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity?
<input type="checkbox"/> Tube	<input type="checkbox"/> yes
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	24 Each
<input type="checkbox"/> Vial Power Multi	Inner/Carton/Pack
<input type="checkbox"/> Other: Write In	Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Venlafaxine Hydrochloride Tablets
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Each
	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="checkbox"/> Yes
Is product exempt from DSCSA?	<input type="checkbox"/> No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	<input type="checkbox"/> No
Is product sold by manufacturer's exclusive distributor?	<input type="checkbox"/> Yes
Has FDA granted waiver/exception/exemption for product?	<input type="checkbox"/> No
If yes, attach documentation from FDA.	
GLN:	0031722000000
GCP:	
If yes, was original product purchased direct from mfr?	<input type="checkbox"/>
Provide source manufacturer for repackaged product	

ITEM AND PACKING INFORMATION						
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.1	1.75	1.75	3.5	10.72	1
Box/Carton/Bundle/Inner Pack:						
Case:	2.85	11	7.5	4	330.00	24
Pallet:						

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00331722125307	00331722125307
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	24		10331722125304	
<input type="checkbox"/> Pallet				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$49.01	Whsl. Code #:	
As of date:	3/1/2023	Fineline Code:	

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature: