



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

Version 2021

Introduction Type: Post Launch Change

Final Version

Date: 11/20/2024

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*			
Company Name: <input type="text" value="Camber Pharmaceuticals, Inc."/>		Application: <input type="text" value="ANDA"/>		a. Temperature – Indicate the USP temperature range for this product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): <input type="text" value="212277"/>				Temperature Range: <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>			
Medical Device Class, if applicable: <input type="text"/>				Other Temperature Range Requirement (write in): <input type="text"/>			
DUNS: <input type="text" value="11-856-3719"/>				Notes: <input type="text"/>			
Proprietary Name (If Applicable) and Established Name: <input type="text" value="Venlafaxine Hydrochloride Extended-Release Capsules, USP 75 mg (base)"/>				Is this product to be shipped to customers on ice? <input type="checkbox"/> No			
Selling Unit NDC: <input type="text" value="31722-003-90"/>		Unit of Use NDC: <input type="text" value="31722-003-90"/>		Is this product to be shipped to customers on dry ice? <input type="checkbox"/> No			
UDI: <input type="text"/>		CVX Code: <input type="text"/>					
Description: <input type="text" value="Venlafaxine Hydrochloride Extended-Release Capsules, USP 75 mg (base)"/>		UPC: <input type="text" value="331722003902"/>					
Active Ingredient(s): <input type="text" value="Venlafaxine hydrochloride, USP"/>		MVX Code: <input type="text"/>					
URL for Additional Product Information: <input type="text" value="www.camberpharma.com"/>				b. Contact for temperature excursion questions:			
Address: <input type="text" value="800 Centennial Ave, Suite 1"/>		Address 2: <input type="text"/>		Name: <input type="text" value="Soma Raju"/>			
City: <input type="text" value="Piscataway"/>		State: <input type="text" value="NJ"/>		Number: <input type="text" value="732-529-0423"/>			
Key Contact: <input type="text" value="Customer Service"/>		Zip: <input type="text" value="08854"/>		Group E-mail: <input type="text" value="somaraju@heterousa.com"/>			
Phone Number: <input type="text" value="1-866-827-3647"/>		Email: <input type="text" value="customerservice@camberpharma.com"/>					
Product Therapeutic Classification: <input type="text" value="Serotonin and norepinephrine reuptake inhibitor (SNRI)"/>		Fax: <input type="text" value="732-562-8788"/>		c. Special regulations for product in any states?			
				Special returns requirements for this product? <input type="checkbox"/> No			
				Protect product (unit of sale) from light? <input type="checkbox"/> No			
				d. Store product (unit of sale) upright? <input type="checkbox"/> No			
				e. Shelf life: <input type="checkbox"/> No			
				Initial shelf life at launch (if different): <input type="text" value="24"/> Months			
				Months: <input type="text"/>			
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"/>		Size: <input type="text" value="90 ct"/>			
if yes, enter class # <input type="text"/>		Is the Product... Unit of Use <input type="checkbox"/>		Strength: <input type="text" value="75 mg"/>			
a product kit? <input type="checkbox"/> No		Orphan Drug Status <input type="text"/>		Dosage Form: <input type="text" value="Hard gelatin capsule"/>			
if yes, list NDCs of component parts reverse numbered? <input type="text"/>		FDA Approval Status <input type="text"/>		Product Shape: <input type="text" value="Capsule"/>			
co-licensed? <input type="checkbox"/> No		Allergens Present <input type="text" value="Gluten, Dye, Alcohol, Sugar"/>		Product Color: <input type="text" value="Peach opaque cap & white opaque body"/>			
latex-free? <input type="checkbox"/> Yes		Country of Origin: <input type="text" value="India"/>		Product Imprint: <input type="text" value="Imprinted with 'V' on cap & '10' on body printed in black color"/>			
preservative-free? <input type="checkbox"/> Yes		Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> No					
correctional institution block? <input type="checkbox"/> No							
opioid? <input type="checkbox"/> No							
Cannabinoid? <input type="checkbox"/> No							
If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/>							
If Unit Dose, indicate NDC here: <input type="text"/>							
FOR GENERIC DRUG PRODUCTS							
I. Orange Book Rating: <input type="text" value="AB"/>		Authorized Generic <input type="checkbox"/>		*If Authorized Generic, other section fields are not applicable			
II. Generic Equivalent to What Brand?: <input type="text" value="Effexor XR"/>							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							
Does supplier meet DSCSA definition of manufacturer? <input type="checkbox"/> Yes		GLN: <input type="text" value="00331722498975"/>					
Is product exempt from DSCSA? <input type="checkbox"/> No		GCP: <input type="text"/>					
If yes, select exemption: <input type="text"/>		If yes, was original product purchased direct from mfr? <input type="checkbox"/>					
Other exemption - Write in: <input type="text"/>		Provide source manufacturer for repackaged product <input type="text"/>					
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. <input type="text"/>							
GTIN AND HIBCC PRODUCT INFORMATION							
Saleable Unit of Measure		Saleable Quantity		HIBCC		GTIN-14	
<input checked="" type="checkbox"/> Item/Each		<input type="text" value="1"/>				<input type="text" value="00331722003902"/>	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack							
<input checked="" type="checkbox"/> Case		<input type="text" value="24"/>				<input type="text" value="30331722003903"/>	
<input type="checkbox"/> Pallet							
Unit of Use GTIN-14						<input type="text" value="00331722003902"/>	
ORDER INFORMATION				PHARMACY ORDER / BILL UNIT			
Unit of Sale		What is the NDC selling unit?		Rx billing unit to pharmacy:			
<input checked="" type="checkbox"/> Bottle		<input type="text" value="1 Bottle of 90 Capsules"/>		<input type="text"/>			
<input type="checkbox"/> Box/ Carton		(Write-in, e.g. 1 Box of 10 Vials)		<input type="text"/>			
<input type="checkbox"/> Ampule				<input type="text"/>			
<input type="checkbox"/> Glass				Minimum order quantity? <input type="checkbox"/> Yes			
<input type="checkbox"/> Tube							
<input type="checkbox"/> Vial Liquid Sgl				If Yes, how many of which package type?			
<input type="checkbox"/> Vial Liquid Multi				<input type="text" value="24"/> Each			
<input type="checkbox"/> Vial Powder Sgl				<input type="text"/>			
<input type="checkbox"/> Vial Powder Multi				<input type="text"/>			
<input type="checkbox"/> Other: Write In				<input type="text"/>			
ITEM AND PACKING INFORMATION							
		Weight Lbs.		Dimensions (US msmts.)		Volume (Cube)	Saleable # Pieces
		Depth		Width		Height	
Item/Each:		<input type="text" value="0.15"/>		<input type="text" value="1.75"/>		<input type="text" value="1.75"/>	<input type="text" value="4"/>
Box/ Carton/ Bundle/ Inner Pack:						<input type="text" value="12.25"/>	<input type="text" value="1"/>
Case:		<input type="text" value="4.45"/>		<input type="text" value="12"/>		<input type="text" value="8.5"/>	<input type="text" value="5.25"/>
Pallet:						<input type="text" value="535.50"/>	<input type="text" value="24"/>
COST INFORMATION				WHOLESALE USE ONLY:			
Regular Cost				Vendor #:		<input type="text"/>	
Invoice Cost (WAC) (\$)		<input type="text" value="\$21.00"/>		Whsl. Code #:		<input type="text"/>	
As of date:		<input type="text" value="12/1/2024"/>		Fineline Code:		<input type="text"/>	
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: <input type="text"/>	



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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? No
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?
 - Is the product a CA Prop 65 carcinogen? No
 - Is the product a CA Prop 65 reproductive toxicant? No
 - Does the product label bear a CA Prop 65 warning? No

- c. Contact Hazard? No
- d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) No
- e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT? (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? No

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? No

Is the product restricted for air shipment? If so, indicate restriction:

- Passenger No
- Cargo
- Passenger & Cargo

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)
- Special Permit; DOT-SP
- Special Provision (listed in Column 7 of 49 CFR 172.101); SP#

ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance? No Yes Controlled Substance Code
- Controlled by State(s)? No Yes Listed Chemical (List I or II) No Yes
- ARCOS Reportable? No Yes If yes, indicate which:
- Schedule No. Is it a scheduled listed chemical product?: No Yes

CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes No
- Restricted to retail pharmacy only: No Yes
- Restricted to hospital, clinics, and physician offices only: No Yes
- Restricted from US territories? (explain in comments) No Yes

Comments:

SDS Hazard Classification

- Organic Corrosive
- Inorganic Oxidizer
- Steroid/Androgen Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level: No

Is the product a NIOSH hazardous drug? If yes, indicate which: No

Hazardous Waste Identification

EPA Hazardous Waste Code: Waste Characteristics

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No Yes If Yes, is it managed with a pharmacy registry? No Yes Website URL:

Med Guide Required No Yes Limited Distribution Requirement No Yes Comments / Details: (For example, iPledge program?)

REMS: No Yes REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: No Yes Wholesale distributor support: No Yes Provider Name: DEA #: Site Enrollment Number assigned by Supplier: NCPDP#: NPI #:

Comments

Registry: No Yes Registry Program Contact Name: Phone: Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 1-866-827-3647

Is product returnable for credit: No Yes

URL/Link to returns policy: contact - customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states? No Yes

If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:

