



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Camber Pharmaceuticals
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	214419
DUNS:	826774775
Proprietary Name (if Applicable) and Established Name:	Venlafaxine Extended-Release Tablets 225 mg, 30 ct.
Selling Unit NDC:	31722-126-30
Individual Unit NDC:	
UPC:	331722126304
UDI	
CVX Code:	
MXV Code:	
Description:	Venlafaxine extended-release tablets 225 mg are white to off white, film coated, round biconvex tablets printed with "395" in black ink.
Active Ingredient(s):	Venlafaxine Hydrochloride, USP
URL for Additional Product Information:	www.camberpharma.com
Address:	1031 Centennial Avenue
City:	Piscataway
Key Contact:	Customer Service
Phone Number:	732-529-0430
Product Therapeutic Classification:	

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)	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	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?	No
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	No
Protect product (unit of sale) from light?	No
e. Shelf life:	
Initial shelf life at launch (if different):	<input type="text" value="24"/> Months

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	No
reverse numbered?	No
co-licensed?	No
Is the Product... Direct-Ship Only	
Is the Product... Neither	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	No
If Unit Dose NDC, indicate NDC here:	
Country of Origin	USA
Is this product covered under the Trade Agreements Act (TAA)?	No

PRODUCT DESCRIPTION INFORMATION	
Size:	30
Strength:	225 mg
Dosage Form:	Tablets
Product Shape:	Round
Product Color:	White to off white
Product Imprint:	Imprinted with 395 in blank ink

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"/> 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="checkbox"/> Inner/Outer/Case
<input type="checkbox"/> Vial Powder Multi	
<input type="checkbox"/> Other: Write In	

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:
<input type="text" value="1 Vial"/>	<input type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	No
Has FDA granted waiver/exception/exemption for product?	No
GLN:	033172200000
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.142	2.015	3.4			1
Box/Carton/Bundle/Inner Pack:						
Case:	3.9	13.1	4.1	8.8		24
Pallet:						
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	Level	Saleable Unit		Quantity	GTIN-14	Item
		Item	Unit			
<input checked="" type="checkbox"/>	Box/Carton/Bundle/Inner Pack	<input checked="" type="checkbox"/>	2D	1	00331722126304	
<input type="checkbox"/>	Case	<input checked="" type="checkbox"/>	2D	24	10331722126301	
<input type="checkbox"/>	Pallet		2D			
<input type="checkbox"/>			2D			
<input type="checkbox"/>			2D			
<input type="checkbox"/>			2D			
<input type="checkbox"/>			2D			
<input type="checkbox"/>			2D			
<input type="checkbox"/>			2D			

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$397.28	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION							
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? No</p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant? No</p> <p style="padding-left: 20px;">Is the product a CA Prop 65 carcinogen? No</p> <p style="padding-left: 20px;">Is the product a CA Prop 65 reproductive toxicant? No</p> <p style="padding-left: 20px;">Does the product label bear a CA Prop 65 warning? No</p> <p>c. Contact Hazard? No</p> <p>d. Does this product require special clean-up instructions? No</p> <p style="padding-left: 20px;">(If yes, attach SDS with special instructions.)</p> <p>e. Does the product contain DEHP? No</p> <p>Is this product regulated for shipment by DOT or IATA? No</p> <p>(if yes, answer a-e below and provide SDS)</p> <p>a. UN/Identification Number <input style="width: 100%;" type="text"/></p> <p>b. Proper Shipping Name <input style="width: 100%;" type="text"/></p> <p>c. DOT Hazard Class <input style="width: 100%;" type="text"/></p> <p>d. Packing Group <input style="width: 100%;" type="text"/></p> <p>e. Inhalation Hazard? No</p> <p>Is the product restricted for air shipment? If so, indicate restriction:</p> <p><input type="checkbox"/> Passenger</p> <p><input type="checkbox"/> Cargo</p> <p><input type="checkbox"/> Passenger & Cargo</p> <p>Is this a reportable quantity? No</p> <p>RQ Threshold: <input style="width: 100%;" type="text"/></p> <p>Is this a marine pollutant? No</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit? <input style="width: 100%;" type="text"/></p> <p>(if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity</p> <p><input type="checkbox"/> Consumer Commodity, ORM-D</p> <p><input type="checkbox"/> Small Quantity (49 CFR 173.4)</p> <p><input type="checkbox"/> Special Permit; DOT-SP</p> <p><input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101);</p> <p>SP# <input style="width: 100%;" type="text"/></p>	<div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">SDS Hazard Classification</div> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"><input type="checkbox"/> Organic</td> <td style="width: 50%; border: none;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Inorganic</td> <td style="border: none;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="border: none;"><input type="checkbox"/> Steroid/Androgen</td> <td style="border: none;"><input type="checkbox"/> Contact Hazard</td> </tr> </table> <p><input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 100%;" type="text"/></p> <p>Is the product a NIOSH hazardous drug? No</p> <p>If yes, indicate which: <input style="width: 100%;" type="text"/></p>	<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive	<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer	<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard
<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive						
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer						
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard						
Hazardous Waste Identification							
EPA Hazardous Waste Code: <input style="width: 100%;" type="text"/>							
REMS or REGISTRY RESTRICTIONS							
<p>Is there a REMS on this product? No</p> <p>If Yes, is it managed with a pharmacy registry? <input style="width: 100%;" type="text"/></p> <p>Website URL: <input style="width: 100%;" type="text"/></p> <p>Comments / Details: (For example, iPledge program?) <input style="width: 100%;" type="text"/></p> <p>REMS: No</p> <p>REMS Program Manager Name: <input style="width: 100%;" type="text"/> Phone: <input style="width: 100%;" type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input style="width: 100%;" type="text"/></p> <p>Wholesale distributor support: <input style="width: 100%;" type="text"/></p> <p>Provider Name: <input style="width: 100%;" type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input style="width: 100%;" type="text"/></p> <p>DEA #: <input style="width: 100%;" type="text"/></p> <p>PCPDP #: <input style="width: 100%;" type="text"/></p> <p>NPI #: <input style="width: 100%;" type="text"/></p> <p>Comments: <input style="width: 100%;" type="text"/></p> <p>Registry: No</p> <p>Registry Program Contact Name: <input style="width: 100%;" type="text"/> Phone: <input style="width: 100%;" type="text"/></p> <p>Comments: <input style="width: 100%;" type="text"/></p>							
ADD'L STORAGE INFORMATION							
<p>Is the Product...</p> <p>Controlled Substance? No</p> <p>Controlled by State(s)? No</p> <p>ARCOS Reportable? No</p> <p>Schedule No. (inc. N for non-narcotic) <input style="width: 100%;" type="text"/></p> <p>Controlled Substance Code <input style="width: 100%;" type="text"/></p> <p>Listed Chemical (List I or II) No</p> <p>If yes, indicate which: <input style="width: 100%;" type="text"/></p> <p>Is it a scheduled listed chemical product?: No</p>							
CLASS OF TRADE RESTRICTION:							
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No</p> <p>Restricted to retail pharmacy only: No</p> <p>Restricted to hospital, clinics, and physician offices only: No</p> <p>Restricted from US territories? (explain in comments) No</p> <p>Comments: <input style="width: 100%;" type="text"/></p>							
RETURN INSTRUCTIONS							
<p>Contact tel. # if product received damaged: <input style="width: 100%; text-align: center; value: 732-529-0430;" type="text"/></p> <p>Is product returnable for credit: Yes</p> <p>URL/Link to returns policy: <input style="width: 100%; text-align: center; value: contact - customerservice@camberpharma.com;" type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? No</p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%;" type="text"/></p>							
MISCELLANEOUS NOTES and/or Image of Product Barcode:							
<input style="width: 100%; height: 100%;" type="text"/>							

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

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing																								
<p>Purchase orders may be accepted by:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%;">a. EDI</td> <td style="width: 25%;"><input type="text"/></td> <td style="width: 25%;">Fax Number:</td> <td style="width: 25%;"><input type="text"/></td> </tr> <tr> <td>b. Autofax</td> <td><input type="text"/></td> <td>Fax Number:</td> <td><input type="text"/></td> </tr> <tr> <td>c. Fax</td> <td><input type="text"/></td> <td>Phone No.:</td> <td><input type="text"/></td> </tr> <tr> <td>d. Phone only</td> <td><input type="text"/></td> <td>Site Address:</td> <td><input type="text"/></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td><input type="text"/></td> <td></td> <td></td> </tr> </table> <p>Minimum Order Quantity: <input style="width: 80%;" type="text"/></p> <p>Supplier's Customer Service Number: <input style="width: 95%;" type="text"/></p> <p>Contracted 3PL company / contact #:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Name:</td> <td><input style="width: 80%;" type="text"/></td> </tr> <tr> <td>Phone:</td> <td><input style="width: 80%;" type="text"/></td> </tr> </table>	a. EDI	<input type="text"/>	Fax Number:	<input type="text"/>	b. Autofax	<input type="text"/>	Fax Number:	<input type="text"/>	c. Fax	<input type="text"/>	Phone No.:	<input type="text"/>	d. Phone only	<input type="text"/>	Site Address:	<input type="text"/>	e. Supplier Web Site only	<input type="text"/>			Name:	<input style="width: 80%;" type="text"/>	Phone:	<input style="width: 80%;" type="text"/>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input style="width: 150px;" type="text"/> Eastern</p> <hr/> <p>Shipping lead time of PO: <input style="width: 50px;" type="text"/> Hours <input style="width: 50px;" type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
a. EDI	<input type="text"/>	Fax Number:	<input type="text"/>																						
b. Autofax	<input type="text"/>	Fax Number:	<input type="text"/>																						
c. Fax	<input type="text"/>	Phone No.:	<input type="text"/>																						
d. Phone only	<input type="text"/>	Site Address:	<input type="text"/>																						
e. Supplier Web Site only	<input type="text"/>																								
Name:	<input style="width: 80%;" type="text"/>																								
Phone:	<input style="width: 80%;" type="text"/>																								
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing																								
<p>Expedited freight fees billed with each order: <input style="width: 100px;" type="text"/></p> <p>Drop Ship service fee billed with each order: <input style="width: 100px;" type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input style="width: 100px;" type="text"/></p> <p>Comments: <input style="width: 95%; height: 80px;" type="text"/></p>	<p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time: <input style="width: 150px;" type="text"/> Eastern</p> <p>Days of week overnight is available:</p> <table style="width: 100%; border-collapse: collapse;"> <tr><td><input type="checkbox"/></td><td>Monday</td></tr> <tr><td><input type="checkbox"/></td><td>Tuesday</td></tr> <tr><td><input type="checkbox"/></td><td>Wednesday</td></tr> <tr><td><input type="checkbox"/></td><td>Thursday</td></tr> <tr><td><input type="checkbox"/></td><td>Friday</td></tr> </table> <p>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p>Order receipt method:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Phone:</td> <td style="width: 20%;"><input style="width: 100%;" type="text"/></td> <td style="width: 20%;">Phone #:</td> <td style="width: 40%;"><input style="width: 100%;" type="text"/></td> </tr> <tr> <td>Fax:</td> <td><input style="width: 100%;" type="text"/></td> <td>Fax #:</td> <td><input style="width: 100%;" type="text"/></td> </tr> <tr> <td>EDI:</td> <td><input style="width: 100%;" type="text"/></td> <td></td> <td></td> </tr> </table> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>	<input type="checkbox"/>	Monday	<input type="checkbox"/>	Tuesday	<input type="checkbox"/>	Wednesday	<input type="checkbox"/>	Thursday	<input type="checkbox"/>	Friday	Phone:	<input style="width: 100%;" type="text"/>	Phone #:	<input style="width: 100%;" type="text"/>	Fax:	<input style="width: 100%;" type="text"/>	Fax #:	<input style="width: 100%;" type="text"/>	EDI:	<input style="width: 100%;" type="text"/>				
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Other Data Information Required to Process PO:	ADDITIONAL INFORMATION																								
<p>Patient Procedure Date: <input style="width: 150px;" type="text"/></p> <p>Physician Name: <input style="width: 250px;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 250px;" type="text"/></p> <p>Physician State License #: <input style="width: 250px;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 250px;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 250px;" type="text"/></p>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>																								
Miscellaneous Notes:																									
<p><input style="width: 95%; height: 100px;" type="text"/></p>																									