



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Camber Pharmaceuticals
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	212277
DUNS:	82-667-4775
Proprietary Name (if Applicable) and Established Name:	Venlafaxine Hydrochloride Extended-Release Capsules 37.5MG 90CT
Selling Unit NDC:	31722-002-90
UDI	Individual Unit NDC: <input type="text"/> CVX Code: <input type="text"/> MVX Code: <input type="text"/>
UPC:	331722002905
Description:	White to off white colored, round to oval shaped pellets filled in size 3 hard gelatin capsules with grey opaque cap imprinted with 'V' in black color, white opaque body imprinted with '9' in black color.
Active Ingredient(s):	Venlafaxine
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:	<input type="text"/>
State:	NJ
Zip:	08854
Email:	customerservice@camberpharma.com
Fax:	732-562-8788

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)	<input type="text"/>
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?	
Special returns requirements for this product?	<input type="checkbox"/> No
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="checkbox"/> 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?	<input type="checkbox"/> No
reverse numbered?	<input type="checkbox"/> No
co-licensed?	<input type="checkbox"/> No
Is the Product... Direct-Ship Only	<input type="checkbox"/>
Is the Product... Unit Dose	<input type="checkbox"/>
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>
If Unit Dose NDC, indicate NDC here:	<input type="text"/>
Country of Origin	India
Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/>

PRODUCT DESCRIPTION INFORMATION	
Size:	90
Strength:	37.5MG
Dosage Form:	Capsules
Product Shape:	Round to oval
Product Color:	Grey opaque cap & White opaque body
Product Imprint:	V' on cap & '9' on body

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

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Effexor XR
<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"/>	<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?	<input type="checkbox"/> Yes
Is product exempt from DSCSA?	<input type="checkbox"/> No
If yes, select exemption:	<input type="text"/>
Other exemption - Write in:	<input type="text"/>
Is product repackaged?	<input type="checkbox"/> No
Is product sold by manufacturer's exclusive distributor?	<input type="checkbox"/> No
Has FDA granted waiver/exception/exemption for product?	<input type="checkbox"/> No
GLN:	<input type="text"/>
If Yes, was original product purchased direct from mfr?	<input type="checkbox"/>
If yes, attach documentation from FDA.	<input type="text"/>

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Box/Carton/Bundle/Inner Pack:	0.087		3.256	1.625		
Case:	5.4	11.4	7.6	4.3	0.215	24
Pallet:						
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	Yes	Level		Quantity	GTIN-14	
		Item	Saleable Unit			
If not, when?	<input type="text"/>	<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input type="checkbox"/>	1	00331722002905	
Items aggregated?	No	<input checked="" type="checkbox"/> Case	<input type="checkbox"/>	24	30331722002906	
		<input type="checkbox"/> Pallet	<input type="checkbox"/>			
		<input type="checkbox"/>	<input type="checkbox"/>			
		<input type="checkbox"/>	<input type="checkbox"/>			
		<input type="checkbox"/>	<input type="checkbox"/>			
		<input type="checkbox"/>	<input type="checkbox"/>			
		<input type="checkbox"/>	<input type="checkbox"/>			
		<input type="checkbox"/>	<input type="checkbox"/>			

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text"/>	Vendor #:	<input type="text"/>
Invoice Cost (WAC) (\$)	\$37.14	Whsl. Code #:	<input type="text"/>
Federal Excise Tax Per Unit of Sale	<input type="text"/>	Fineline Code:	<input type="text"/>
As of date:	<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:

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? _____

Does the product label bear a CA Prop 65 warning? _____

c. Contact Hazard? No

d. Does this product require special clean-up instructions? No
(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

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 _____

c. DOT Hazard Class _____

d. Packing Group _____

e. Inhalation Hazard? _____

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

Passenger

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

Controlled by State(s)? No

ARCOS Reportable? No

Schedule No. (inc. N for non-narcotic) _____

Controlled Substance Code _____

Listed Chemical (List I or II) No

If yes, indicate which: _____

Is it a scheduled listed chemical product? No

CLASS OF TRADE RESTRICTION:

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: _____

SDS Hazard Classification

Organic Corrosive

Inorganic Oxidizer

Steroid/Androgen Contact Hazard

Aerosol Class; Identify NFPA Storage Level: _____

Is the product a NIOSH hazardous drug? _____

If yes, indicate which: _____

Hazardous Waste Identification

EPA Hazardous Waste Code: _____

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry? _____

Website URL: _____

Comments / Details: (For example, iPledge program?) _____

REMS: No

REMS Program Manager Name: _____ Phone: _____

Supplier Manages REMS registry exclusively: No

Wholesale distributor support: No

Provider Name: _____

Site Enrollment Number assigned by Supplier: _____ DEA #: No

PCPDP #: No

NPI #: No

Comments _____

Registry: No

Registry Program Contact Name: _____ Phone: _____

Comments _____

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 732-529-0430

Is product returnable for credit: Yes

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

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

If so, which states? Other requirements? Comments? _____

MISCELLANEOUS NOTES and/or Image of Product Barcode:

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: 20%;">a. EDI</td> <td style="width: 10%; text-align: center;"><u>Yes</u></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> <td style="width: 10%;"></td> </tr> <tr> <td>b. Autofax</td> <td style="text-align: center;"><u>No</u></td> <td>Fax Number:</td> <td colspan="3"></td> </tr> <tr> <td>c. Fax</td> <td style="text-align: center;"><u>Yes</u></td> <td>Fax Number:</td> <td colspan="3">732-562-8788</td> </tr> <tr> <td>d. Phone only</td> <td style="text-align: center;"><u>No</u></td> <td>Phone No.:</td> <td colspan="3"></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td style="text-align: center;"><u>No</u></td> <td>Site Address:</td> <td colspan="3"></td> </tr> </table> <p>Minimum Order Quantity: <u>case pack</u></p> <p>Supplier's Customer Service Number: <u>732-529-0430 x466 x465 x467 x470</u></p> <p>Contracted 3PL company / contact #:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Name:</td> <td colspan="5"></td> </tr> <tr> <td>Phone:</td> <td colspan="5"></td> </tr> </table>	a. EDI	<u>Yes</u>					b. Autofax	<u>No</u>	Fax Number:				c. Fax	<u>Yes</u>	Fax Number:	732-562-8788			d. Phone only	<u>No</u>	Phone No.:				e. Supplier Web Site only	<u>No</u>	Site Address:				Name:						Phone:						<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <u>2:30PM</u> Eastern</p> <p>Shipping lead time of PO: <u>24/48</u> Hours <u> </u> Days</p> <p>Ships same day for next day receipt: <u>No</u></p> <p>Ships for second day receipt: <u>No</u></p> <p>Ships regular ground for 3-10 days receipt: <u>Yes</u></p>
a. EDI	<u>Yes</u>																																										
b. Autofax	<u>No</u>	Fax Number:																																									
c. Fax	<u>Yes</u>	Fax Number:	732-562-8788																																								
d. Phone only	<u>No</u>	Phone No.:																																									
e. Supplier Web Site only	<u>No</u>	Site Address:																																									
Name:																																											
Phone:																																											
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing																																										
<p>Expedited freight fees billed with each order: <u>No</u></p> <p>Drop Ship service fee billed with each order: <u>No</u></p> <p>Drop Ship miscellaneous fees billed: <u>No</u></p> <p>Comments: <div style="border: 1px solid black; height: 40px; width: 100%;"></div></p>	<p>Overnight receipt available: <u>Yes</u></p> <p>PO Receipt cut off time: <u>2:30PM</u> Eastern</p> <p>Days of week overnight is available:</p> <table style="width: 100%; border-collapse: collapse;"> <tr><td><input checked="" type="checkbox"/></td><td>Monday</td></tr> <tr><td><input checked="" type="checkbox"/></td><td>Tuesday</td></tr> <tr><td><input checked="" type="checkbox"/></td><td>Wednesday</td></tr> <tr><td><input checked="" type="checkbox"/></td><td>Thursday</td></tr> <tr><td><input checked="" type="checkbox"/></td><td>Friday</td></tr> </table> <p>Priority Overnight receipt available: <u>Yes</u></p> <p>PO Receipt Cut off time: <u>2:30PM EST</u></p> <p>Saturday Overnight receipt available: <u>No</u></p> <p>PO Receipt Cut off time: <u> </u></p> <p>Order receipt method: Phone: <u>Yes</u> Phone #: <u> </u></p> <p>Fax: <u>Yes</u> Fax #: <u>732-562-8788</u></p> <p>EDI: <u>Yes</u></p> <p>Overnight Fees apply: <u>Yes</u></p> <p>Other fees apply: <u>No</u></p>	<input checked="" type="checkbox"/>	Monday	<input checked="" type="checkbox"/>	Tuesday	<input checked="" type="checkbox"/>	Wednesday	<input checked="" type="checkbox"/>	Thursday	<input checked="" type="checkbox"/>	Friday																																
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<input checked="" type="checkbox"/>	Friday																																										
Class of Trade Restriction:	Return Instructions																																										
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <u>No</u></p> <p>Restricted to retail pharmacy only: <u>Yes</u></p> <p>Restricted to hospital, clinics, and physician offices only: <u>No</u></p> <p>Restricted from US territories? (explain in comments) <u>No</u></p> <p>Comments: <div style="border: 1px solid black; height: 40px; width: 100%;"></div></p>	<p>Contact # if product is received damaged: <u>732-529-0430</u></p> <p>Is product returnable for credit: <u>Yes</u></p> <p>URL/Link to returns policy: <u> </u></p> <p>Special regulations or returns requirements for this product in certain states? <u>Yes</u></p> <p>If so, which states? Other requirements? Comments? <div style="border: 1px solid black; height: 40px; width: 100%;"></div></p>																																										
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION																																										
<p>Patient Procedure Date: <u> </u></p> <p>Physician Name: <u> </u></p> <p>Physician/Clinic Phone #: <u> </u></p> <p>Physician State License #: <u> </u></p> <p>Physician/Clinic DEA #: <u> </u></p> <p>Physician/Clinic Specialty: <u> </u></p>	<p>Is product order for scheduled patient procedure? <u>No</u></p> <p>Is product order for restocking purposes? <u>No</u></p>																																										
Miscellaneous Notes:																																											
<div style="border: 1px solid black; height: 80px; width: 100%;"></div>																																											