



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Zydus Pharmaceuticals USA Inc.
Application:	ANDA
Application Number for NDA/ANDA/BLA, Med Device:	77-653
Rx Product/Proprietary Name:	Venlafaxine Hydrochloride Tablets, 100 mg, 100 ct
NDC:	68382-101-01
UPC:	368382101013
CVX Code:	
MVX Code:	
Description:	Peach-colored, round, flat-faced, beveled-edged, uncoated tablets with bisect on one side and plain on the other side; 'ZC' debossed on one side of bisect and '68' on the other side of bisect.
Active ingredients:	Venlafaxine Hydrochloride
URL for Additional Product Information:	www.zydususa.com
Address:	73 Route 31 North
Address 2:	
City:	Pennington
State:	NJ
Zip:	08534
Key Contact:	
Email:	
Phone Number:	(609) 730 1900
Fax:	(609) 730 1991

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
<input type="checkbox"/>	I. Freezer – between -25 and -10 C (-13° – 14° F)
<input type="checkbox"/>	II. Cold – between 2 and 8 C (36° – 46° F)
<input type="checkbox"/>	III. Cool – between 8 and 15 C (46° – 59° F)
<input checked="" type="checkbox"/>	IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
<input type="checkbox"/>	V. Avoid Excessive Heat – above 40 C (>104° F)
<input type="checkbox"/>	VI. Other Temperature Range Requirement (write in) <input type="text"/>
<input type="checkbox"/>	VII. No Requirement
b. Contact for temperature excursion questions:	
Name:	<input type="text"/>
Number:	<input type="text"/>
Is this product to be shipped to customers on ice?	<input type="text" value="No"/>
Is this product to be shipped to customers on dry ice?	<input type="text" value="No"/>
c. Special regulations for product in certain states?	
Special returns requirements for this product?	<input type="text" value="No"/>
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="text" value="No"/>
e. Shelf life:	
<input type="text" value="24"/> Months	
Initial shelf life at launch (if different):	<input type="text"/> Months

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Brand Name:	Effexor
III. Generic Equivalent for Brand:	Venlafaxine Hydrochloride Tablets, 100 mg, 100 ct

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="text" value="Yes"/> Yes <input type="text" value="156861945"/> DUNS:
Is product exempt from DSCSA?	<input type="text" value="No"/> No
If yes, select exemption:	<input type="text"/>
Other exemption - Write in:	<input type="text"/>
Is product repackaged?	<input type="text" value="No"/> No <input type="text" value=""/> If Yes, was original product purchased direct from mfr?
Is product sold by manufacturer's exclusive distributor?	<input type="text" value="No"/> No <input type="text" value=""/> If yes, attach documentation from FDA
Are any waivers granted for product ID/barcode?	<input type="text" value="No"/> No <input type="text" value=""/> If yes, attach documentation from FDA

ADDITIONAL PRODUCT INFORMATION		ORDER INFORMATION	
Is the Product... Direct Ship Item	<input type="text"/>	Unit of Sale	What is the NDC selling unit? <input type="text" value="Each"/>
Legend Device?	<input type="text" value="No"/> No	<input checked="" type="checkbox"/> Bottle	Each
State Control?	<input type="text" value="No"/> No	<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
ARCOS reportable?	<input type="text" value="No"/> No	<input type="checkbox"/> Ampule	
Co-Licensed?	<input type="text" value="No"/> No	<input type="checkbox"/> Glass	
Controlled Substance?	<input type="text" value="No"/> No	<input type="checkbox"/> Tube	Minimum order quantity? <input type="text" value="Yes"/> Yes
Schedule No.?	<input type="text"/>	<input type="checkbox"/> Vial Liquid Sgl	If Yes, how many of which package type?
(incl. N for non-narcotic)		<input type="checkbox"/> Vial Liquid Multi	<input type="text"/>
Controlled Substance Code:	<input type="text"/>	<input type="checkbox"/> Vial Powder Sgl	<input type="text"/> Each
Hazardous Material/Cytotoxic Agent?	<input type="text" value="No"/> No	<input type="checkbox"/> Vial Powder Multi	<input type="text"/> Inner/Carton/Pack
Is Item...	<input type="text"/>	<input type="checkbox"/> Other: Write In	<input type="text"/> Case
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>		
Is it reverse numbered?	<input type="text"/>		

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	61.00 G		3.425	1.878	6.43215	
Box/ Carton:					0	
Case:	4.56LBS	8.7	4.45	12.95	501.35925	24
Pallet:		48	48.03	40	92217.6	104
UPC:	Case:					
	Carton:					

WHOLESALE USE ONLY:		PHARMACY ORDER / BILL UNIT		Other Product Information		COST INFORMATION		
Vendor #:	<input type="text"/>	Rec. sell unit to customer? <input type="text"/>	Size/Strength/Form:	Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale		
Whsl. Code #:	<input type="text"/>	(Write-in, e.g. 1 Vial)	100ct/100mg/Tablets		\$38.00			
Fineline Code:	<input type="text"/>	Rx billing unit to pharmacy:	Product Shape:					
		<input checked="" type="checkbox"/> Each	Product Color:	Round				
		<input type="checkbox"/> Gram	Product Imprint:	Peach				
		<input type="checkbox"/> Milliliter		ZC 68				

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$38.00	
As of date: <input type="text" value="9/10/2014"/>		

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: