



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	ZYDUS PHARMACEUTICALS (USA) INC.
Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	210086
DUNS:	156861945
Proprietary Name (If Applicable) and Established Name:	AMITRIPTYLINE HYDROCHLORIDE TABLETS, USP 75MG
Selling Unit NDC:	70710-1228-1
Individual Unit NDC:	
UPC:	370710122812
UDI	
CVX Code:	
MVX Code:	
Description:	Light blue colored, round shaped, biconvex, film-coated tablets debossed with "12" over "28" on one side and plain on other side.
Active Ingredient(s):	AMITRIPTYLINE
URL for Additional Product Information:	
Address:	73 ROUTE 31 NORTH
City:	PENNINGTON
State:	NJ
Address 2:	
Zip:	08534
Key Contact:	
Email:	
Phone Number:	(609) 730 1900
Fax:	(609) 730 1998
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°)
Other Temperature Range Requirement (write in)	
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:	
Number:	
Group E-mail:	
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... Neither	<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	<input type="text"/>
Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/>

PRODUCT DESCRIPTION INFORMATION	
Size:	100 COUNT
Strength:	75MG
Dosage Form:	TABLETS
Product Shape:	ROUND
Product Color:	LIGHT BLUE
Product Imprint:	"12" "28"

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit? <input type="checkbox"/>
<input checked="" type="checkbox"/> Bottle	1 BOTTLE OF 100 TABLETS
<input 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 Powder 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/Cartron/Pack
	<input checked="" type="checkbox"/> Case

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

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer? <input type="checkbox"/>	Rx billing unit to pharmacy:
(Write-in, e.g. 1 Vial)	<input checked="" 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"/> No
Has FDA granted waiver/exception/exemption for product?	<input type="checkbox"/> No
GLN:	036382000002
If Yes, was original product purchased direct from mfr?	<input type="checkbox"/>
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Depth	Height	Width	Volume (Cube)	# Pieces:
Item:	0.11	1.61	2.98	1.61	7.724458	1
Box/Cartron/Bundle/Inner Pack:					0	
Case:	3.81	9.84	6.69	4.45	292.94172	24
Pallet:	627	48	40	48	92160	3840
UPC:	Case:					
	Cartron:					

GTIN PRODUCT INFORMATION						
Serialized?	Level	Saleable Unit	Quantity	GTIN-14		
No	<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/>	1	00370710122812		
If not, when? 4/1/2018	<input type="checkbox"/> Box/Cartron/Bundle/Inner Pack	<input type="checkbox"/>				
Items aggregated? Yes	<input checked="" type="checkbox"/> Case	<input type="checkbox"/>	24	40370710122810		
	<input checked="" type="checkbox"/> Pallet	<input type="checkbox"/>		80370710122818		
		<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		Vendor #:	
Invoice Cost (WAC) (\$)	\$85.86	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:	4/2/2018		

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: