



# Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:  Post Launch Change

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	ZYDUS PHARMACEUTICALS (USA) INC.
Application:	NDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	22224
DUNS:	156861945
Proprietary Name (If Applicable) and Established Name:	Fenofibric Acid Delayed-Release Capsules, 45mg 90s
Selling Unit NDC:	68382-232-16
Individual Unit NDC:	
UPC:	368382232168
UDI	
CVX Code:	
MVX Code:	
Description:	A reddish brown to orange brown cap and a yellow body imprinted in black ink the number "45"
Active Ingredient(s):	Choline Fenofibrate
URL for Additional Product Information:	www.zydususa.com
Address:	73 ROUTE 31 NORTH
City:	PENNINGTON
Key Contact:	
Phone Number:	(609) 730 1900
Product Therapeutic Classification:	
State:	NJ
Address 2:	
Zip:	08534
Email:	
Fax:	(609) 730 1998

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
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?	<input type="checkbox"/> No
Is this product to be shipped to customers on dry ice?	<input type="checkbox"/> No
<b>b. Contact for temperature excursion questions:</b>	
Name:	
Number:	
Group E-mail:	
<b>c. Special regulations for product in any states?</b>	
Special returns requirements for this product?	<input type="checkbox"/> No
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	<input type="checkbox"/> No
<b>e. Shelf life:</b>	
Initial shelf life at launch (if different):	<input type="text" value="36"/> 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:	
Country of Origin	
Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/>

PRODUCT DESCRIPTION INFORMATION	
Size:	90 COUNT
Strength:	45MG
Dosage Form:	CAPSULES
Product Shape:	CAPSULES
Product Color:	REDDISH-BROWN/YELLOQ
Product Imprint:	45

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 BOTTLE OF 90 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="text" value="1"/> Each
	<input type="text" value="1"/> Inner/Carton/Pack
	<input type="text" value="1"/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AG
II. Generic Equivalent to What Brand?:	Trilipix
<input checked="" 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 BOTTLE OF 90 TABLETS"/>	<input checked="" 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:	
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:	0.22 G	1.87	2.949	1.87	10.3123581	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	2.1LBS	7.25	6.5	7.94	374.1725	24
Pallet:	771	48	46	40	88320	180
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	Level	Saleable Unit	Quantity	GTIN-14		
No	<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/>	1	00368382232168		
If not, when? 5/1/2018	<input type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input type="checkbox"/>				
Items aggregated? No	<input checked="" type="checkbox"/> Case	<input type="checkbox"/>	24	40368382232166		
	<input checked="" type="checkbox"/> Pallet	<input type="checkbox"/>		80368382232164		

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$143.88	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:	1/19/2017		