



# 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):	78537
DUNS:	156861945
Proprietary Name (If Applicable) and Established Name:	FOMEPIZOLE INJECTION 1.5G/1.5ML
Selling Unit NDC:	70710-1478-1
Individual Unit NDC:	
UPC:	370710147815
UDI	
CVX Code:	
MVX Code:	
Description:	Fomepizole Injection is available as a sterile, preservative-free solution for intravenous use, in vials containing 1.5mL (1 g/mL) of fomepizole.
Active Ingredient(s):	FOMEPIZOLE
URL for Additional Product Information:	www.zydususa.com
Address:	73 ROUTE 31 NORTH
City:	PENNINGTON
State:	NJ
Address 2:	
Zip:	08534
Key Contact:	
Phone Number:	(609) 730 1900
Fax:	(609) 730 1998
Product Therapeutic Classification:	

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°)
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>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?	No
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	No
<b>e. Shelf life:</b>	
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?	<input checked="" type="checkbox"/>
If Unit Dose NDC, indicate NDC here:	
Country of Origin	
Is this product covered under the Trade Agreements Act (TAA)?	<input checked="" type="checkbox"/>

PRODUCT DESCRIPTION INFORMATION	
Size:	1 VIAL
Strength:	1.5G/1.5ML
Dosage Form:	vial
Product Shape:	N/A
Product Color:	CLEAR TO YELLOW
Product Imprint:	N/A

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit? <input type="checkbox"/>
<input type="checkbox"/> Bottle	<input type="text" value="1 BOX OF 1 VIAL"/>
<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 Powder Multi	
<input type="checkbox"/> Other: Write In	
	Minimum order quantity? Yes
	If Yes, how many of which package type?
	<input type="text" value="1"/> Each
	<input type="text"/> Inner/Cartron/Pack
	<input type="text"/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AP
II. Generic Equivalent to What Brand?:	ANTIZOL
<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:
<input type="text" value="1 CARTON OF 1 VIAL"/>	<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?	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:	036382000002
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Depth	Height	Width	Volume (Cube)	# Pieces:
Item:		0.6	1.32	0.6	0.4752	1
Box/Cartron/Bundle/Inner Pack:	0.014	1.77	2.95	1.38	7.20567	1
Case:	0.34	5.51	5.7	6.49	203.83143	24
Pallet:	103	48	44	40	84480	12096
UPC:	Case:					
	Cartron:					

GTIN PRODUCT INFORMATION						
Serialized?	Level	Saleable Unit	Quantity	GTIN-14		
No	<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/>	1	00370710147815		
If not, when? <input type="text" value="1/1/2019"/>	<input checked="" type="checkbox"/> Box/Cartron/Bundle/Inner Pack	<input type="checkbox"/>				
Items aggregated? Yes	<input checked="" type="checkbox"/> Case	<input type="checkbox"/>	24	40370710147813		
	<input type="checkbox"/> Pallet	<input type="checkbox"/>		50370710147810		
		<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) (\$)	\$860.94	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:	12/7/2018		