



# 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 Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	206561
DUNS:	156861945
Proprietary Name (If Applicable) and Established Name:	INDOMETHACIN FOR INJECTION USP, 1mg/vial
Selling Unit NDC:	6838247001
Individual Unit NDC:	
UPC:	368382470010
UDI	
CVX Code:	
MVX Code:	
Description:	Sterile Indomethacin for injection, USP is a lyophilized white to yellow powder or plug supplied as single dose vial containing indomethacin sodium
Active Ingredient(s):	INDOMETHACIN
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:	
Application:	ANDA

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="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:	
Country of Origin	
Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/>

PRODUCT DESCRIPTION INFORMATION	
Size:	1 VIAL
Strength:	1MG
Dosage Form:	vial
Product Shape:	N/A
Product Color:	Sterile, lyophilized White to yellow powder
Product Imprint:	N/A

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	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 checked="" 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:	AP
II. Generic Equivalent to What Brand?:	Indocin®
<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:
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?	<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:		0.659	1.486	0.659	0.64534157	1
Box/Carton/Bundle/Inner Pack:	0.014	1.26	2.165	1.26	3.437154	1
Case:	1.5	7.18	5.5	5.88	232.2012	40
Pallet:	520	48	44	40	84480	294
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	Level	Saleable Unit	Quantity	GTIN-14		
No	<input checked="" type="checkbox"/> Item	<input checked="" type="checkbox"/>	1	00368382470010		
If not, when? 3/1/2018	<input type="checkbox"/> Box/Carton/Bundle/Inner Pack	<input type="checkbox"/>				
Items aggregated? Yes	<input checked="" type="checkbox"/> Case	<input type="checkbox"/>	40	40368382470018		
	<input checked="" type="checkbox"/> Pallet	<input type="checkbox"/>		80368382470016		

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$460.00	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:	2/12/2018		