



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):	A063009
DUNS:	156861945
Proprietary Name (If Applicable) and Established Name:	MINOCYCLINE HYDROCHLORIDE CAPSULES USP, 100 MG 50 COUNT
Selling Unit NDC:	68382-318-18
Individual Unit NDC:	
UPC:	0368382318183
UDI	
CVX Code:	
MVX Code:	
Description:	Capsules containing minocycline hydrochloride, USP equivalent to 100 mg minocycline. The 100 mg capsule is supplied with a pink body and maroon cap and is imprinted "=" on the cap and "318" on the body.
Active Ingredient(s):	MINOCYCLINE
URL for Additional Product Information:	
Address:	73 ROUTE 31 NORTH
City:	PENNINGTON
Key Contact:	
Phone Number:	(609) 730 1900
Product Therapeutic Classification:	
Application:	ANDA
State:	NJ
Zip:	08534
Email:	
Fax:	(609) 730 1998

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	Controlled Room – between 20 and 25 C (68° – 77° F)
Temperature Range	
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. Contact for temperature excursion questions:	
Name:	
Number:	
Group E-mail:	
c. Special regulations for product in any states?	No
Special returns requirements for this product?	
d. Store product (unit of sale) upright?	No
Protect product (unit of sale) from light?	Yes
e. Shelf life:	36 Months
Initial shelf life at launch (if different):	

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?	
If Unit Dose NDC, indicate NDC here:	
Country of Origin	
Is this product covered under the Trade Agreements Act (TAA)?	

PRODUCT DESCRIPTION INFORMATION	
Size:	50 COUNT
Strength:	100MG
Dosage Form:	CAPSULES
Product Shape:	CAPSULES
Product Color:	PINK BODY & MAROON CAP
Product Imprint:	"=" ON THE CAP & "318" ON THE BODY

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 BOTTLE OF 50 CAPSULES
<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? Yes
	If Yes, how many of which package type?
	<input type="checkbox"/> Each
	<input type="checkbox"/> Inner/Carton/Pack
	<input checked="" type="checkbox"/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	MINOCIN
<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:
(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?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	Yes
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:	0.07	1.562	3.031	1.562	7.39516716	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	5.285	14.7	6.95	8.6	878.619	72
Pallet:	377	48	40	47	90240	4320
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	Level	Saleable Unit	Quantity	GTIN-14	Item	Linear
No	Box/Carton/Bundle/Inner Pack		2D			
If not, when? 11/1/2017	Case		2D			
Items aggregated? No	Pallet		2D			
			2D			
			2D			
			2D			
			2D			
			2D			

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$22.63	Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			