



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, Med Device:	90-411
Rx Product/Proprietary Name:	Ropinirole Hydrochloride Tablets, 3 mg 100's
NDC:	68382-342-01
UPC:	368382342010
CVX Code:	
MVX Code:	
Description:	purple-colored, round-shaped, film-coated tablets debossed with "ZF42" on one side and plain on other side
Active ingredients:	Ropinirole
URL for Additional Product Information:	www.zydususa.com
Address:	73 Route 31 North
Address 2:	
City:	Pennington
State:	NJ
Zip:	08534
Key Contact:	
Email:	
Phone Number:	(609) 730 1900
Fax:	(609) 730 1991

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
<input type="checkbox"/>	I. Freezer – between -25 and -10 C (-13° – 14° F)
<input type="checkbox"/>	II. Cold – between 2 and 8 C (36° – 46° F)
<input type="checkbox"/>	III. Cool – between 8 and 15 C (46° – 59° F)
<input checked="" type="checkbox"/>	IV. Controlled Room – between 20 and 25 C (68° – 77° F) allows for excursions between 15 and 30 C (59° – 86° F)
<input type="checkbox"/>	V. Avoid Excessive Heat – above 40 C (>104° F)
<input type="checkbox"/>	VI. Other Temperature Range Requirement (write in) <input type="text"/>
<input type="checkbox"/>	VII. No Requirement
b. Contact for temperature excursion questions:	
Name:	<input type="text"/>
Number:	<input type="text"/>
Is this product to be shipped to customers on ice?	<input type="text" value="No"/>
Is this product to be shipped to customers on dry ice?	<input type="text" value="No"/>
c. Special regulations for product in certain states?	
Special returns requirements for this product?	<input type="text" value="No"/>
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	<input type="text" value="No"/>
e. Shelf life:	
<input type="text" value="24"/> Months	
Initial shelf life at launch (if different):	<input type="text"/> Months

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Brand Name:	Requip
III. Generic Equivalent for Brand:	Ropinirole Hydrochloride Tablets, 3 mg 100's

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
DUNS:	156861945
Is product exempt from DSCSA?	<input type="checkbox"/> No
If yes, select exemption:	<input type="text"/>
Other exemption - Write in:	<input type="text"/>
Is product repackaged?	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes
If Yes, was original product purchased direct from mfr?	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Is product sold by manufacturer's exclusive distributor?	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Are any waivers granted for product ID/barcode?	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes
If yes, attach documentation from FDA	<input type="text"/>

ADDITIONAL PRODUCT INFORMATION		ORDER INFORMATION	
Is the Product... Direct Ship Item	<input type="checkbox"/>	Unit of Sale	<input checked="" type="checkbox"/> Bottle
Legend Device?	<input type="checkbox"/> No	What is the NDC selling unit?	Each
State Control?	<input type="checkbox"/> No	(Write-in, e.g. 1 Box of 10 Vials)	<input type="text"/>
ARCOS reportable?	<input type="checkbox"/> No	Minimum order quantity?	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Co-Licensed?	<input type="checkbox"/> No	If Yes, how many of which package type?	<input type="text"/>
Controlled Substance?	<input type="checkbox"/> No	<input type="checkbox"/> Each	
Schedule No.?	<input type="text"/>	<input type="checkbox"/> Inner/ Carton/Pack	
(incl. N for non-narcotic)		<input type="checkbox"/> Case	
Controlled Substance Code:	<input type="text"/>	<input type="checkbox"/> 1	
Hazardous Material/Cytotoxic Agent?	<input type="checkbox"/> No		
Is Item...	<input type="text"/>		
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="text"/>		
Is it reverse numbered?	<input type="text"/>		

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width:		
Item:	40.05 G		3.025	1.615	4.88538	
Box/ Carton:					0	
Case:	2.71LBS	6.5	3.94	9.72	248.9292	24
Pallet:		47.24	50.39	47	111879.909	198
UPC:	Case:					
	Carton:					

WHOLESALE USE ONLY:		PHARMACY ORDER / BILL UNIT		Other Product Information		COST INFORMATION		
Vendor #:	<input type="text"/>	Rec. sell unit to customer?	<input type="text"/>	Size/Strength/Form:	<input type="text" value="100ct/3mg/Tablets"/>	Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
Whsl. Code #:	<input type="text"/>	(Write-in, e.g. 1 Vial)		Product Shape:	Round		\$50.00	
Fineline Code:	<input type="text"/>	Rx billing unit to pharmacy:	<input checked="" type="checkbox"/> Each	Product Color:	Purple			
		<input type="checkbox"/> Gram		Product Imprint:	ZF42			
		<input type="checkbox"/> Milliliter						

COST INFORMATION		
Regular Cost Per Unit of Sale (\$)	Invoice Cost (WAC) (\$)	Federal Excise Tax Per Unit of Sale
	\$50.00	
As of date: <input type="text" value="9/10/2014"/>		

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: