



# Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:

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, 5 mg 100's   |
| NDC:   | 68382-344-01   |
| UPC:   | 368382344014   |
| CVX Code:  |  |
| MVX Code:  |  |
| Description:                                     | blue-colored, round-shaped, film-coated tablets debossed with "ZF26" 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*                                   |  |
|--|--|
| <b>a. Temperature – Indicate the USP temperature range for this product.</b> |  |
| <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)<br>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<br>(write in) <input type="text"/>   |
| <input type="checkbox"/>   | VII. No Requirement  |
| <b>b. Contact for temperature excursion questions:</b>                       |  |
| 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"/>  |
| <b>c. Special regulations for product in certain states?</b>                 |  |
| Special returns requirements for this product?                               | <input type="text" value="No"/>  |
| <b>d. Store product (unit of sale) upright?</b>                              |  |
| Protect product (unit of sale) from light?                                   | <input type="text" value="No"/>  |
| <b>e. Shelf life:</b>  |  |
| <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, 5 mg 100's |

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

| ADDITIONAL PRODUCT INFORMATION                                      |                                    |
|---|------------------------------------|
| Is the Product... Direct Ship Item                                  | <input type="text"/>               |
| Legend Device?  | <input type="text" value="No"/> No |
| State Control?  | <input type="text" value="No"/> No |
| ARCOS reportable?   | <input type="text" value="No"/> No |
| Co-Licensed?  | <input type="text" value="No"/> No |
| Controlled Substance?   | <input type="text" value="No"/> No |
| Schedule No.?   | <input type="text"/>               |
| (incl. N for non-narcotic)  |                                    |
| Controlled Substance Code:  | <input type="text"/>               |
| Hazardous Material/Cytotoxic Agent?                                 | <input type="text" value="No"/> 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"/>               |

| ORDER INFORMATION                       |   |
|---|---|
| Unit of Sale                            | <input checked="" type="checkbox"/> Bottle                    |
|   | <input type="checkbox"/> Box/Carton                           |
|   | <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 <input type="text"/> |
| What is the NDC selling unit?           | Each  |
| (Write-in, e.g. 1 Box of 10 Vials)      | <input type="text"/>  |
| Minimum order quantity?                 | <input type="text" value="Yes"/> Yes                          |
| If Yes, how many of which package type? |   |
|   | <input type="text"/> Each                                     |
|   | <input type="text"/> Inner/Carton/Pack                        |
|   | <input type="text"/> Case                                     |
|   | <input type="text" value="1"/> 1                              |

| 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: |                      |
|---------------------|----------------------|
| Vendor #:           | <input type="text"/> |
| Whsl. Code #:       | <input type="text"/> |
| Fineline Code:      | <input type="text"/> |

| PHARMACY ORDER / BILL UNIT                     | Other Product Information |
|--|---------------------------|
| Rec. sell unit to customer?                    | Size/Strength/Form:       |
| <input type="text" value="100ct/5mg/Tablets"/> | 100ct/5mg/Tablets         |
| (Write-in, e.g. 1 Vial)                        | Product Shape:            |
| Rx billing unit to pharmacy:                   | Round                     |
| <input checked="" type="checkbox"/> Each       | Product Color:            |
| <input type="checkbox"/> Gram                  | Blue                      |
| <input type="checkbox"/> Milliliter            | Product Imprint:          |
|  | ZF26                      |

| 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: