



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): | 203499 |
| DUNS: | 156861945 |
| Proprietary Name (If Applicable) and Established Name: | GLIPIZIDE EXTENDED-RELEASE TABLETS, 2.5MG 30 COUNT |
| Selling Unit NDC: | 68382-335-06 |
| Individual Unit NDC: | |
| UPC: | 368382335067 |
| UDI | |
| CVX Code: | |
| MVX Code: | |
| Description: | Yellow colored, round, biconvex film-coated tablets imprinted with "2" on one side with black ink and plain on the other side |
| Active Ingredient(s): | GLIPIZIDE |
| URL for Additional Product Information: | |
| 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* | |
|--|---|
| a. Temperature – Indicate the USP temperature range for this product. | |
| 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? | <input type="checkbox"/> No |
| Is this product to be shipped to customers on dry ice? | <input type="checkbox"/> No |
| b. Contact for temperature excursion questions: | |
| Name: | |
| Number: | |
| Group E-mail: | |
| c. Special regulations for product in any states? | |
| Special returns requirements for this product? | <input type="checkbox"/> No |
| d. Store product (unit of sale) upright? | |
| Protect product (unit of sale) from light? | <input type="checkbox"/> No |
| e. Shelf life: | |
| 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: | 30 COUNT |
| Strength: | 2.5MG |
| Dosage Form: | TABLETS |
| Product Shape: | ROUND |
| Product Color: | YELLOW |
| Product Imprint: | 2 |

| ORDER INFORMATION | |
|--|--|
| Unit of Sale | What is the NDC selling unit? <input type="checkbox"/> |
| <input checked="" type="checkbox"/> Bottle | 1 BOTTLE OF 30 TABLETS |
| <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? <input type="checkbox"/> Yes |
| | |
| | If Yes, how many of which package type? |
| | <input type="checkbox"/> Each |
| | <input type="checkbox"/> Inner/Cartron/Pack |
| | <input checked="" type="checkbox"/> Case |

| FOR GENERIC DRUG PRODUCTS | |
|---|---|
| I. Orange Book Rating: | AB |
| II. Generic Equivalent to What Brand?: | GLUCOTROL XL |
| <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: |
| (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? | <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: | 0.06 | 1.61 | 2.98 | 1.61 | 7.724458 | 1 |
| Box/Cartron/Bundle/Inner Pack: | | | | | 0 | |
| Case: | 2.92 | 10.08 | 6.73 | 4.02 | 272.710368 | 24 |
| Pallet: | 484.23 | 48 | 40 | 48 | 92160 | 3840 |
| UPC: | Case: | | | | | |
| | Carton: | | | | | |

| GTIN PRODUCT INFORMATION | | | | | | |
|--------------------------|--|-------------------------------------|----------|----------------|--|--|
| Serialized? | Level | Saleable Unit | Quantity | GTIN-14 | | |
| No | <input checked="" type="checkbox"/> Item | <input checked="" type="checkbox"/> | 1 | 00368382335067 | | |
| If not, when? 9/1/2018 | <input type="checkbox"/> Box/Cartron/Bundle/Inner Pack | <input type="checkbox"/> | | | | |
| Items aggregated? Yes | <input checked="" type="checkbox"/> Case | <input type="checkbox"/> | 24 | 40368382335065 | | |
| | <input checked="" type="checkbox"/> Pallet | <input type="checkbox"/> | | 80368382335063 | | |
| | | <input type="checkbox"/> | | | | |
| | | <input type="checkbox"/> | | | | |
| | | <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) (\$) | \$5.07 | Whsl. Code #: | |
| Federal Excise Tax Per Unit of Sale | | Fineline Code: | |
| As of date: | 7/18/2018 | | |

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: