



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: Post Launch Change

Final Version

Date:

| PRODUCT INFORMATION | |
|---|--|
| Company Name: | ZYDUS PHARMACEUTICALS (USA) INC. |
| Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): | 91525 |
| DUNS: | 156861945 |
| Proprietary Name (If Applicable) and Established Name: | Benzotropine Mesylate Injection USP, 1mg/mL |
| Selling Unit NDC: | 68382-860-10 |
| Individual Unit NDC: | |
| UPC: | 368382860101 |
| UDI | |
| CVX Code: | |
| MVX Code: | |
| Description: | clear, colorless solution and is supplied in 2 mL vial. Five (5) such vials are packaged in a carton |
| Active Ingredient(s): | Benzotropine Mesylate |
| 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* | |
|---|---|
| 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? | <input type="checkbox"/> No |
| Special returns requirements for this product? | <input type="checkbox"/> No |
| d. Store product (unit of sale) upright? | <input type="checkbox"/> Yes |
| 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: | <input type="text"/> |
| Country of Origin | <input type="text"/> |
| Is this product covered under the Trade Agreements Act (TAA)? | <input type="checkbox"/> |

| PRODUCT DESCRIPTION INFORMATION | |
|---------------------------------|-----------------|
| Size: | 1 ml |
| Strength: | 1 mg |
| Dosage Form: | Injection |
| Product Shape: | N/A |
| Product Color: | Clear Colorless |
| Product Imprint: | N/A |

| ORDER INFORMATION | |
|--|--|
| Unit of Sale | What is the NDC selling unit? <input type="checkbox"/> |
| <input checked="" type="checkbox"/> Bottle | each |
| <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="text"/> Each |
| | <input type="text"/> Inner/Carton/Pack |
| | <input type="text" value="1"/> Case |

| FOR GENERIC DRUG PRODUCTS | |
|---|---|
| I. Orange Book Rating: | AP |
| II. Generic Equivalent to What Brand?: | Cogentin |
| <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: | 6.8 G | 0.57 | 1.26 | 0.57 | 0.409374 | 1 |
| Box/Carton/Bundle/Inner Pack: | 960 G | 5.118 | 2.047 | 2.205 | 23.1007839 | 120 |
| Case: | 9.35 LBS | 7.28 | 7.48 | 9.37 | 510.237728 | 480 |
| Pallet: | | | | | | |
| UPC: | Case: | | | | | |
| | Carton: | | | | | |

| GTIN PRODUCT INFORMATION | | | | | | |
|--------------------------|---|-------------------------------------|----------|----------------|--|--|
| Serialized? | Level | Saleable Unit | Quantity | GTIN-14 | | |
| No | <input checked="" type="checkbox"/> Item | <input checked="" type="checkbox"/> | 1 | 00368382860101 | | |
| If not, when? 1/1/2018 | <input type="checkbox"/> Box/Carton/Bundle/Inner Pack | <input type="checkbox"/> | | | | |
| Items aggregated? Yes | <input checked="" type="checkbox"/> Case | <input type="checkbox"/> | 480 | 40368382860109 | | |
| | <input checked="" type="checkbox"/> Pallet | <input type="checkbox"/> | | 80368382860107 | | |
| | | | | | | |
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| COST INFORMATION | | WHOLESALE USE ONLY: | |
|-------------------------------------|----------|---------------------|--|
| Regular Cost | | Vendor #: | |
| Invoice Cost (WAC) (\$) | \$235.00 | Whsl. Code #: | |
| Federal Excise Tax Per Unit of Sale | | Fineline Code: | |
| As of date: | 7/6/2017 | | |