



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type:

Final Version

Date:

| PRODUCT INFORMATION | | | |
|---|--|----------------------|-----------------------------|
| Company Name: | TWi Pharmaceuticals USA, Inc. | | Application: ANDA |
| Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): | 20209603 | | |
| DUNS: | 080216652 | | |
| Proprietary Name (if Applicable) and Established Name: | | | |
| Selling Unit NDC: | 24979-170-01 | Individual Unit NDC: | UPC: 3 24979 17001 5 |
| UDI | | CVX Code: | MXV Code: |
| Description: | Lebetalol Hydrochloride Tablets, USP, 300 mg | | |
| Active Ingredient(s): | Lebetalol Hydrochloride, USP | | |
| URL for Additional Product Information: | http://www.twipharma.com | | |
| Address: | 115 West Century Road | Address 2: | Suite 180 |
| City: | Paramus | State: | NJ Zip: 07652 |
| Key Contact: | Kari Olson | Email: | kari.olson@twipharmausa.com |
| Phone Number: | 201-762-1409 | Fax: | 201-225-0051 |
| 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° F) |
| Other Temperature Range Requirement (write in) | <input type="text"/> |
| 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: | Kari Olson |
| Number: | 201-762-1409 |
| Group E-mail: | kari.olson@twipharmausa.com |
| c. Special regulations for product in any states? | |
| Special returns requirements for this product? | No |
| d. Store product (unit of sale) upright? | |
| Protect product (unit of sale) from light? | No |
| e. Shelf life: | |
| Initial shelf life at launch (if different): | 24 Months |

| ADDITIONAL PRODUCT INFORMATION | PRODUCT DESCRIPTION INFORMATION |
|--|-----------------------------------|
| Is the Product... a legend device? <input type="checkbox"/> No | Size: 100 tablets |
| reverse numbered? <input type="checkbox"/> No | Strength: 300 mg |
| co-licensed? <input type="checkbox"/> No | Dosage Form: Tablet |
| Is the Product... Direct-Ship Only <input type="checkbox"/> | Product Shape: Round biconvex |
| Is the Product... Unit of Use <input type="checkbox"/> | Product Color: White to off white |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? <input type="checkbox"/> | Product Imprint: AC 372 |
| If Unit Dose NDC, indicate NDC here: <input type="text"/> | |
| Country of Origin: Taiwan | |
| Is this product covered under the Trade Agreements Act (TAA)? <input type="checkbox"/> Yes | |

| ORDER INFORMATION | |
|---|---|
| Unit of Sale | What is the NDC selling unit? |
| <input checked="" type="checkbox"/> Bottle | 1 bottle of 100 tablets |
| <input type="checkbox"/> Box/Carton | (Write-in, e.g. 1 Box of 10 Vials) |
| <input type="checkbox"/> Ampule | |
| <input type="checkbox"/> Glass | Minimum order quantity? <input type="checkbox"/> Yes |
| <input type="checkbox"/> Tube | |
| <input type="checkbox"/> Vial Liquid Sgl | If Yes, how many of which package type? |
| <input type="checkbox"/> Vial Liquid Multi | <input type="checkbox"/> Each |
| <input type="checkbox"/> Vial Powder Sgl | <input type="checkbox"/> Inner/Carton/Pack |
| <input type="checkbox"/> Vial Powder Multi | <input type="checkbox"/> Case |
| <input type="checkbox"/> Other: Write In <input type="text"/> | 1 |

| FOR GENERIC DRUG PRODUCTS | |
|--|---|
| I. Orange Book Rating: AB | <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable |
| II. Generic Equivalent to What Brand?: | Trandate |

| PHARMACY ORDER / BILL UNIT | |
|------------------------------------|-------------------------------------|
| Rec. sell unit to customer? | Rx billing unit to pharmacy: |
| 1 Bottle | 1 Each |
| (Write-in, e.g. 1 Vial) | Gram |
| | Milliliter |

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

| ITEM AND PACKING INFORMATION | | | | | | |
|-------------------------------|-------------|------------------------|--------|-------|---------------|-----------|
| Item: | Weight Lbs. | Dimensions (US msmts.) | | | Volume (Cube) | # Pieces: |
| | | Depth | Height | Width | | |
| Box/Carton/Bundle/Inner Pack: | 0.17 | 2.2 | 3.9 | 2.2 | 18.876 | 1 |
| Case: | 4.47 | 13.1 | 4.5 | 9.5 | 560.025 | 24 |
| Pallet: | 1000 | 40 | 48 | 40 | 76800 | 216 |
| UPC: | Case: | | | | | |
| | Carton: | | | | | |

| GTIN PRODUCT INFORMATION | | | | | | |
|--------------------------|------------------------------|-------------------------------------|----------|----------------|--|--|
| Serialized? | Level | Saleable Unit | Quantity | GTIN-14 | | |
| No | Item | <input checked="" type="checkbox"/> | | 00324979170015 | | |
| If not, when? 11/1/2018 | Box/Carton/Bundle/Inner Pack | <input type="checkbox"/> | | | | |
| Items aggregated? | Case | <input checked="" type="checkbox"/> | | 60324979170017 | | |
| | Pallet | <input type="checkbox"/> | | | | |
| | | <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) (\$) | \$77.46 | Whsl. Code #: | |
| Federal Excise Tax Per Unit of Sale | | Fineline Code: | |
| As of date: | | | |

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

a. Cytotoxic? No

b. CA Prop. 65 Carcinogen or Reproductive Toxicant?

Is the product a CA Prop 65 carcinogen? No

Is the product a CA Prop 65 reproductive toxicant? No

Does the product label bear a CA Prop 65 warning? No

c. Contact Hazard? No

d. Does this product require special clean-up instructions? No
(If yes, attach SDS with special instructions.)

e. Does the product contain DEHP? No

Is this product regulated for shipment by DOT or IATA? No
(if yes, answer a-e below and provide SDS)

a. UN/Identification Number

b. Proper Shipping Name

c. DOT Hazard Class

d. Packing Group

e. Inhalation Hazard? No

Is the product restricted for air shipment? If so, indicate restriction:

Passenger

Cargo

Passenger & Cargo

Is this a reportable quantity? No
RQ Threshold:

Is this a marine pollutant? No

Is this product shipped utilizing an authorized DOT exception or Special Permit?
 (if yes, identify method below)

Limited Quantity

Consumer Commodity, ORM-D

Small Quantity (49 CFR 173.4)

Special Permit; DOT-SP

Special Provision (listed in Column 7 of 49 CFR 172.101);
SP#

ADD'L STORAGE INFORMATION

Is the Product...

Controlled Substance? No

Controlled by State(s)? No

ARCOS Reportable? No

Schedule No. (inc. N for non-narcotic)

Controlled Substance Code

Listed Chemical (List I or II) No

If yes, indicate which:

Is it a scheduled listed chemical product? No

CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

SDS Hazard Classification

Organic Corrosive

Inorganic Oxidizer

Steroid/Androgen Contact Hazard

Aerosol Class; Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug? No
If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code:

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry?

Website URL:

Comments / Details: (For example, iPledge program?)

REMS:

REMS Program Manager Name: Phone:

Supplier Manages REMS registry exclusively:

Wholesale distributor support:
Provider Name:

Site Enrollment Number assigned by Supplier: DEA #:

PCPDP #:

NPI #:

Comments:

Registry:

Registry Program Contact Name: Phone:

Comments:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 201-762-1410

Is product returnable for credit:

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?

If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

| Order Method for Designated Drop Ship Product | Standard Order Receipt and Processing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|--|--------------------------|----------------------|--------------------------|---------|--------------------------|----------------------|--------------------------|----------------------|--------------------------|--------|----------------------|----------------------|----------------------|----------------------|---------------|----------------------|------------|----------------------|------|---------------------------|----------------------|---------------|----------------------|--|-------|----------------------|--------|----------------------|--|
| <p>Purchase orders may be accepted by:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">a. EDI</td> <td style="width: 20%;"><input type="text"/></td> <td style="width: 20%;"></td> <td style="width: 20%;"></td> <td style="width: 20%;"></td> </tr> <tr> <td>b. Autofax</td> <td><input type="text"/></td> <td>Fax Number:</td> <td><input type="text"/></td> <td></td> </tr> <tr> <td>c. Fax</td> <td><input type="text"/></td> <td>Fax Number:</td> <td><input type="text"/></td> <td></td> </tr> <tr> <td>d. Phone only</td> <td><input type="text"/></td> <td>Phone No.:</td> <td><input type="text"/></td> <td></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td><input type="text"/></td> <td>Site Address:</td> <td><input type="text"/></td> <td></td> </tr> </table> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Name:</td> <td><input type="text"/></td> </tr> <tr> <td>Phone:</td> <td><input type="text"/></td> </tr> </table> | a. EDI | <input type="text"/> | | | | b. Autofax | <input type="text"/> | Fax Number: | <input type="text"/> | | c. Fax | <input type="text"/> | Fax Number: | <input type="text"/> | | d. Phone only | <input type="text"/> | Phone No.: | <input type="text"/> | | e. Supplier Web Site only | <input type="text"/> | Site Address: | <input type="text"/> | | Name: | <input type="text"/> | Phone: | <input type="text"/> | <p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="text"/></p> <p>Ships for second day receipt: <input type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="text"/></p> |
| a. EDI | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| b. Autofax | <input type="text"/> | Fax Number: | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| c. Fax | <input type="text"/> | Fax Number: | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| d. Phone only | <input type="text"/> | Phone No.: | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| e. Supplier Web Site only | <input type="text"/> | Site Address: | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name: | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Phone: | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Expedited Freight Charges or Other Designated Drop Ship Fees: | Overnight and Priority Overnight PO Processing | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p> | <p>Overnight receipt available: <input type="text"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <table style="width: 100%; border-collapse: collapse;"> <tr><td><input type="checkbox"/></td><td>Monday</td></tr> <tr><td><input type="checkbox"/></td><td>Tuesday</td></tr> <tr><td><input type="checkbox"/></td><td>Wednesday</td></tr> <tr><td><input type="checkbox"/></td><td>Thursday</td></tr> <tr><td><input type="checkbox"/></td><td>Friday</td></tr> </table> <p>Priority Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Phone:</td> <td style="width: 20%;"><input type="text"/></td> <td style="width: 20%;">Phone #:</td> <td style="width: 20%;"><input type="text"/></td> </tr> <tr> <td>Fax:</td> <td><input type="text"/></td> <td>Fax #:</td> <td><input type="text"/></td> </tr> <tr> <td>EDI:</td> <td><input type="text"/></td> <td></td> <td></td> </tr> </table> <p>Overnight Fees apply: <input type="text"/></p> <p>Other fees apply: <input type="text"/></p> | <input type="checkbox"/> | Monday | <input type="checkbox"/> | Tuesday | <input type="checkbox"/> | Wednesday | <input type="checkbox"/> | Thursday | <input type="checkbox"/> | Friday | Phone: | <input type="text"/> | Phone #: | <input type="text"/> | Fax: | <input type="text"/> | Fax #: | <input type="text"/> | EDI: | <input type="text"/> | | | | | | | | | |
| <input type="checkbox"/> | Monday | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Tuesday | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Wednesday | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Thursday | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Friday | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Phone: | <input type="text"/> | Phone #: | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fax: | <input type="text"/> | Fax #: | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| EDI: | <input type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Class of Trade Restriction: | Return Instructions | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="text"/></p> <p>Restricted to retail pharmacy only: <input type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="text"/></p> <p>Restricted from US territories? (explain in comments) <input type="text"/></p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p> | <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="text"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="text"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%; height: 40px;" type="text"/></p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Other Data Information Required to Process PO: | ADDITIONAL INFORMATION | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p> | <p>Is product order for scheduled patient procedure? <input type="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Miscellaneous Notes: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input style="width: 100%; height: 80px;" type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |