



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: New Item

Final Version

Date:

| PRODUCT INFORMATION | |
|---|---|
| Company Name: | Twi Pharmaceuticals USA, Inc |
| Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): | 207206/S-001 |
| DUNS: | 080216652 |
| Proprietary Name (If Applicable) and Established Name: | Metoprolol Succinate Extended-Release Tablets USP |
| Selling Unit NDC: | 24979-038-02 |
| Individual Unit NDC: | |
| UPC: | 3 24979 03802 5 |
| UDI | |
| CVX Code: | |
| MVX Code: | |
| Description: | White, round tablets imprinted with: e71 |
| Active Ingredient(s): | Metoprolol Succinate |
| URL for Additional Product Information: | |
| Address: | 115 West Century Road |
| City: | Paramus |
| Key Contact: | Kari Olson |
| Phone Number: | 201-762-1409 |
| Product Therapeutic Classification: | Beta Blocker |
| 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° F) |
| Other Temperature Range Requirement (write in) | |
| 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? | No |
| Special returns requirements for this product? | No |
| d. Store product (unit of sale) upright? | No |
| Protect product (unit of sale) from light? | 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? | No |
| reverse numbered? | No |
| co-licensed? | No |
| Is the Product... Direct-Ship Only | |
| Is the Product... Unit of Use | |
| 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 | China |
| Is this product covered under the Trade Agreements Act (TAA)? | No |

| PRODUCT DESCRIPTION INFORMATION | |
|---------------------------------|-----------|
| Size: | 500 count |
| Strength: | 50 mg |
| Dosage Form: | Tablet |
| Product Shape: | Round |
| Product Color: | White |
| Product Imprint: | e71 |

| ORDER INFORMATION | |
|--|--|
| Unit of Sale | What is the NDC selling unit? |
| <input checked="" type="checkbox"/> Bottle | 1 bottle of 500 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? Yes |
| | If Yes, how many of which package type? |
| | <input type="text" value="1"/> Each |
| | <input type="text" value="1"/> Inner/Carton/Pack |
| | <input type="text" value="1"/> Case |

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

| PHARMACY ORDER / BILL UNIT | |
|---------------------------------------|--|
| Rec. sell unit to customer? | Rx billing unit to pharmacy: |
| <input type="text" value="1"/> Bottle | <input type="text" value="1"/> Each |
| (Write-in, e.g. 1 Vial) | <input type="text" value=""/> Gram |
| | <input type="text" value=""/> Milliliter |

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

| ITEM AND PACKING INFORMATION | | | | | | |
|-------------------------------|-------------|------------------------|--------|-------|---------------|-----------|
| Item: | Weight Lbs. | Dimensions (US msmts.) | | | Volume (Cube) | # Pieces: |
| | | Depth | Height | Width | | |
| Item: | 0.35 | 2.49 | 5.9 | 2.49 | 36.58059 | 1 |
| Box/Carton/Bundle/Inner Pack: | | | | | 0 | |
| Case: | 4.19 | 15.4 | 6.1 | 5.3 | 497.882 | 12 |
| Pallet: | 615.93 | 46.2 | 43 | 42.7 | 84827.82 | 147 |
| UPC: | Case: | | | | | |
| | Carton: | | | | | |

| GTIN PRODUCT INFORMATION | | | | | | |
|-------------------------------------|------------------------------|-------------------------------------|----------------------|----------------------|----------------|---------------------------------|
| Serialized? | Level | Saleable Unit | | Quantity | GTIN-14 | If not, when? Items aggregated? |
| | | Item | Case | | | |
| <input checked="" type="checkbox"/> | Box/Carton/Bundle/Inner Pack | <input checked="" type="checkbox"/> | <input type="text"/> | <input type="text"/> | 00324979038025 | |
| <input checked="" type="checkbox"/> | Case | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | 60324979038027 | |
| <input type="checkbox"/> | Pallet | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | | |
| <input type="checkbox"/> | | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | | |
| <input type="checkbox"/> | | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | | |
| <input type="checkbox"/> | | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | | |
| <input type="checkbox"/> | | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | | |
| <input type="checkbox"/> | | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | | |
| <input type="checkbox"/> | | <input type="checkbox"/> | <input type="text"/> | <input type="text"/> | | |

| COST INFORMATION | | WHOLESALE USE ONLY: | |
|-------------------------------------|----------|---------------------|--|
| Regular Cost | | Vendor #: | |
| Invoice Cost (WAC) (\$) | \$115.00 | 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?
 No (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 | |
|--|---|
| <input type="checkbox"/> Organic | <input type="checkbox"/> Corrosive |
| <input type="checkbox"/> Inorganic | <input type="checkbox"/> Oxidizer |
| <input type="checkbox"/> Steroid/Androgen | <input type="checkbox"/> Contact Hazard |
| <input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 100%;" type="text"/> | |
| Is the product a NIOSH hazardous drug? No | |
| If yes, indicate which: <input style="width: 100%;" type="text"/> | |

| Hazardous Waste Identification | |
|--------------------------------|---|
| EPA Hazardous Waste Code: | <input style="width: 100%;" type="text"/> |

| REMS or REGISTRY RESTRICTIONS | |
|--|--|
| Is there a REMS on this product? No | |
| If Yes, is it managed with a pharmacy registry? <input style="width: 100%;" type="text"/> | |
| Website URL: <input style="width: 100%;" type="text"/> | |
| Comments / Details: (For example, iPledge program?) <input style="width: 100%; height: 20px;" type="text"/> | |
| REMS: <input style="width: 100%;" type="text"/> | |
| REMS Program Manager Name: <input style="width: 100%;" type="text"/> | Phone: <input style="width: 100%;" type="text"/> |
| Supplier Manages REMS registry exclusively: <input style="width: 100%;" type="text"/> | |
| Wholesale distributor support: <input style="width: 100%;" type="text"/> | |
| Provider Name: <input style="width: 100%;" type="text"/> | DEA #: <input style="width: 100%;" type="text"/> |
| Site Enrollment Number assigned by Supplier: <input style="width: 100%;" type="text"/> | PCPDP #: <input style="width: 100%;" type="text"/> |
| | NPI #: <input style="width: 100%;" type="text"/> |

Comments:

Registry:

Registry Program Contact Name: Phone:

Comments:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

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: 15%;"><input type="text"/></td> <td style="width: 15%;"></td> <td style="width: 15%;"></td> <td style="width: 15%;"></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> <td></td> </tr> <tr> <td>c. Fax</td> <td><input type="text"/></td> <td>Fax Number:</td> <td><input type="text"/></td> <td></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> <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> <td></td> </tr> </table> <p>Minimum Order Quantity: <input style="width: 80%;" type="text"/></p> <p>Supplier's Customer Service Number: <input style="width: 95%;" 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 style="width: 80%;" type="text"/></td> </tr> <tr> <td>Phone:</td> <td><input style="width: 80%;" 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 style="width: 80%;" type="text"/> | Phone: | <input style="width: 80%;" type="text"/> | <p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input style="width: 80%;" type="text"/></p> <p>Shipping lead time of PO: <input style="width: 15%;" type="text"/> Hours <input style="width: 15%;" 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 style="width: 80%;" type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Phone: | <input style="width: 80%;" 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 style="width: 80%;" type="text"/></p> <p>Drop Ship service fee billed with each order: <input style="width: 80%;" type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input style="width: 80%;" type="text"/></p> <p>Comments: <input style="width: 95%; height: 60px;" type="text"/></p> | <p>Overnight receipt available: <input type="text"/></p> <p>PO Receipt cut off time: <input style="width: 80%;" 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 style="width: 80%;" type="text"/></p> <p>Saturday Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input style="width: 80%;" type="text"/></p> <p>Order receipt method:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%;">Phone:</td> <td style="width: 15%;"><input style="width: 50%;" type="text"/></td> <td style="width: 15%;">Phone #:</td> <td style="width: 15%;"><input style="width: 50%;" type="text"/></td> </tr> <tr> <td>Fax:</td> <td><input style="width: 50%;" type="text"/></td> <td>Fax #:</td> <td><input style="width: 50%;" type="text"/></td> </tr> <tr> <td>EDI:</td> <td><input style="width: 50%;" 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 style="width: 50%;" type="text"/> | Phone #: | <input style="width: 50%;" type="text"/> | Fax: | <input style="width: 50%;" type="text"/> | Fax #: | <input style="width: 50%;" type="text"/> | EDI: | <input style="width: 50%;" type="text"/> | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Monday | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Tuesday | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Wednesday | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Thursday | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Friday | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Phone: | <input style="width: 50%;" type="text"/> | Phone #: | <input style="width: 50%;" type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Fax: | <input style="width: 50%;" type="text"/> | Fax #: | <input style="width: 50%;" type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| EDI: | <input style="width: 50%;" 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: 95%; height: 60px;" type="text"/></p> | <p>Contact # if product is received damaged: <input style="width: 80%;" type="text"/></p> <p>Is product returnable for credit: <input type="text"/></p> <p>URL/Link to returns policy: <input style="width: 80%;" 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: 95%; height: 40px;" type="text"/></p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Other Data Information Required to Process PO: | ADDITIONAL INFORMATION | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Patient Procedure Date: <input style="width: 80%;" type="text"/></p> <p>Physician Name: <input style="width: 80%;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 80%;" type="text"/></p> <p>Physician State License #: <input style="width: 80%;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 80%;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 80%;" 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: 95%; height: 80px;" type="text"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |