



Standard Pharmaceutical Product Information (Rx Product Only)

© August 2014

Introduction Type: Post Launch Change

Final Version

Date:

| PRODUCT INFORMATION | |
|---|---|
| Company Name: | <input type="text" value="Camber Pharmaceuticals"/> |
| Application: | <input type="text" value="ANDA"/> |
| Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): | <input type="text" value="202801"/> |
| DUNS: | <input type="text" value="82-667-4775"/> |
| Proprietary Name (if Applicable) and Established Name: | <input type="text" value="Levofloxacin Tablets 750MG 20CT"/> |
| Selling Unit NDC: | <input type="text" value="31722-723-20"/> |
| Individual Unit NDC: | <input type="text" value="31722-723-20"/> |
| UPC: | <input type="text" value="331722723206"/> |
| UDI | <input type="text" value="NA"/> |
| CVX Code: | <input type="text" value=""/> |
| MVX Code: | <input type="text" value="NA"/> |
| Description: | <input type="text" value="White, capsule shaped tablets embossed with '18' on upper punch and 'T' on lower"/> |
| Active Ingredient(s): | <input type="text" value="Levofloxacin"/> |
| URL for Additional Product Information: | <input type="text" value="www.camberpharma.com"/> |
| Address: | <input type="text" value="1031 Centennial Avenue"/> |
| City: | <input type="text" value="Piscataway"/> |
| State: | <input type="text" value="NJ"/> |
| Zip: | <input type="text" value="08854"/> |
| Key Contact: | <input type="text" value="Customer Service"/> |
| Phone Number: | <input type="text" value="732-529-0430"/> |
| Email: | <input type="text" value="customerservice@camberpharma.com"/> |
| Fax: | <input type="text" value="732-562-8788"/> |
| Product Therapeutic Classification: | <input type="text" value=""/> |

| SPECIAL HANDLING AND STORAGE REQUIREMENTS* | |
|---|--|
| a. Temperature - Indicate the USP temperature range for this product. | |
| Temperature Range | <input type="text" value="Controlled Room - between 20 and 25 C (68° - 77° F)"/> |
| Other Temperature Range Requirement (write in) | <input type="text" value=""/> |
| 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. Contact for temperature excursion questions: | |
| Name: | <input type="text" value="Soma Raju"/> |
| Number: | <input type="text" value="732-529-0423"/> |
| Group E-mail: | <input type="text" value="somaraju@heterousa.com"/> |
| c. Special regulations for product in any states? | <input type="text" value="No"/> |
| Special returns requirements for this product? | <input type="text" value="No"/> |
| d. Store product (unit of sale) upright? | <input type="text" value="No"/> |
| Protect product (unit of sale) from light? | <input type="text" value="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="text" value="No"/> |
| reverse numbered? | <input type="text" value="No"/> |
| co-licensed? | <input type="text" value="No"/> |
| Is the Product... Direct-Ship Only | <input type="text" value=""/> |
| Is the Product... Unit of Use | <input type="text" value=""/> |
| If Unit Dose, is item bar coded to unit dose for hospital scanning? | <input type="text" value=""/> |
| If Unit Dose NDC, indicate NDC here: | <input type="text" value=""/> |
| Country of Origin | <input type="text" value="India"/> |
| Is this product covered under the Trade Agreements Act (TAA)? | <input type="text" value="No"/> |

| PRODUCT DESCRIPTION INFORMATION | |
|---------------------------------|--|
| Size: | <input type="text" value="20"/> |
| Strength: | <input type="text" value="750 mg"/> |
| Dosage Form: | <input type="text" value="Oral solid tablet"/> |
| Product Shape: | <input type="text" value="capsule shape"/> |
| Product Color: | <input type="text" value="white"/> |
| Product Imprint: | <input type="text" value="18'/T"/> |

| ORDER INFORMATION | |
|--|---|
| Unit of Sale | What is the NDC selling unit? |
| <input checked="" type="checkbox"/> Bottle | <input type="text" value="1 box of 12 bottles"/> |
| <input checked="" 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="text" value=""/> |
| <input type="checkbox"/> Tube | Yes |
| <input type="checkbox"/> Vial Liquid Sgl | |
| <input type="checkbox"/> Vial Liquid Multi | If Yes, how many of which package type? |
| <input type="checkbox"/> Vial Powder Sgl | <input type="text" value=""/> |
| <input type="checkbox"/> Vial Powder Multi | <input type="text" value="12"/> Each |
| <input type="checkbox"/> Other: Write In | <input type="text" value=""/> |
| | <input type="text" value=""/> |
| | <input type="text" value=""/> |
| | <input type="text" value=""/> |
| | <input type="text" value=""/> |

| FOR GENERIC DRUG PRODUCTS | |
|---|---|
| I. Orange Book Rating: | <input type="text" value="AB"/> |
| II. Generic Equivalent to What Brand?: | <input type="text" value="Levquin"/> |
| <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=""/> | <input type="text" value=""/> |
| (Write-in, e.g. 1 Vial) | <input type="text" value=""/> |
| | <input type="text" value=""/> |
| | <input type="text" value=""/> |
| | <input type="text" value=""/> |

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

| ITEM AND PACKING INFORMATION | | | | | | |
|-------------------------------|-------------|------------------------|---------------|-----------|-------|------|
| Item: | Weight Lbs. | Dimensions (US msmts.) | Volume (Cube) | # Pieces: | | |
| | | Depth | Height | Width | | |
| Item: | 0.1 | | 3 | 1.5 | | |
| Box/Carton/Bundle/Inner Pack: | 1.3 | 6.625 | 3 | 4.875 | 0.056 | 12 |
| Case: | 12.6 | 14.5 | 8 | 11.5 | 0.772 | 96 |
| Pallet: | | | | | | 4800 |
| UPC: | Case: | | | | | |
| | Carton: | | | | | |

| GTIN PRODUCT INFORMATION | | | | | | |
|----------------------------------|--|-----------------------------|---------------------------------|----------------|--|--|
| Serialized? | Level | Saleable Unit | Quantity | GTIN-14 | | |
| <input type="text" value="Yes"/> | <input checked="" type="checkbox"/> Item | <input type="checkbox"/> 2D | <input type="text" value="1"/> | 00331722723206 | | |
| If not, when? | <input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack | <input type="checkbox"/> 2D | <input type="text" value="12"/> | 10331722723203 | | |
| Items aggregated? | <input checked="" type="checkbox"/> Case | <input type="checkbox"/> 2D | <input type="text" value="96"/> | 30331722723207 | | |
| | <input type="checkbox"/> Pallet | <input type="checkbox"/> 2D | | | | |
| | | <input type="checkbox"/> 2D | | | | |
| | | <input type="checkbox"/> 2D | | | | |
| | | <input type="checkbox"/> 2D | | | | |
| | | <input type="checkbox"/> 2D | | | | |

| COST INFORMATION | | WHOLESALE USE ONLY: | |
|-------------------------------------|--------------------------------------|---------------------|-------------------------------|
| Regular Cost | <input type="text" value=""/> | Vendor #: | <input type="text" value=""/> |
| Invoice Cost (WAC) (\$) | <input type="text" value="\$14.44"/> | Whsl. Code #: | <input type="text" value=""/> |
| Federal Excise Tax Per Unit of Sale | <input type="text" value=""/> | Fineline Code: | <input type="text" value=""/> |
| As of date: | <input type="text" value=""/> | | |

*Please provide any additional information on page 2. Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE. See new p. 3 for Designated Drop Ship Only. Signature:



Standard Pharmaceutical Product Information (Page 2)

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?
 Does the product label bear a CA Prop 65 warning?

c. Contact Hazard? No

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

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?

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: Yes

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?
 If yes, indicate which:

Hazardous Waste Identification

EPA Hazardous Waste Code: NA

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product? No

If Yes, is it managed with a pharmacy registry? No
 Website URL: N/A

Comments / Details: (For example, iPledge program?)
 None

REMS: No

REMS Program Manager Name: Phone:

Supplier Manages REMS registry exclusively: No

Wholesale distributor support: No

Provider Name:

Site Enrollment Number assigned by Supplier:

DEA #: No
 PCPDP #: No
 NPI #: No

Comments None

Registry: No

Registry Program Contact Name: Phone:

Comments

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 732-529-0430

Is product returnable for credit: Yes
 URL/Link to returns policy: contact - customerservice@camberpharma.com

Special regulations or returns requirements for this product in certain states? No

If so, which states? Other requirements? Comments?

MISCELLANEOUS NOTES and/or Image of Product Barcode:



Standard Pharmaceutical Product Information (Page 3)

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 |
|--|--|
| Purchase orders may be accepted by: a. EDI <input type="checkbox"/> Yes b. Autofax <input type="checkbox"/> No Fax Number: <input type="text"/> c. Fax <input type="checkbox"/> Yes Fax Number: <input type="text"/> d. Phone only <input type="checkbox"/> No Phone No.: <input type="text"/> e. Supplier Web Site only <input type="checkbox"/> No Site Address: <input type="text"/> Minimum Order Quantity: <input type="text" value="case pack"/> Supplier's Customer Service Number: <input type="text" value="732-529-0430 x466 x465 x467 x470"/> Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/> | Purchase order daily receipt cut off time by supplier Cut off time: <input type="text" value="2:30PM"/> Eastern Shipping lead time of PO: <input type="text" value="24/48"/> Hours <input type="text"/> Days Ships same day for next day receipt: <input type="checkbox"/> No Ships for second day receipt: <input type="checkbox"/> No Ships regular ground for 3-10 days receipt: <input type="checkbox"/> Yes |
| Expedited Freight Charges or Other Designated Drop Ship Fees: | Overnight and Priority Overnight PO Processing |
| Expedited freight fees billed with each order: <input type="checkbox"/> No Drop Ship service fee billed with each order: <input type="checkbox"/> No Drop Ship miscellaneous fees billed: <input type="checkbox"/> No Comments: <input type="text"/> | Overnight receipt available: <input type="checkbox"/> Yes PO Receipt cut off time: <input type="text" value="2:30PM"/> Eastern Days of week overnight is available: <input checked="" type="checkbox"/> Monday <input checked="" type="checkbox"/> Tuesday <input checked="" type="checkbox"/> Wednesday <input checked="" type="checkbox"/> Thursday <input checked="" type="checkbox"/> Friday Priority Overnight receipt available: <input type="checkbox"/> Yes PO Receipt Cut off time: <input type="text" value="2:30PM EST"/> Saturday Overnight receipt available: <input type="checkbox"/> No PO Receipt Cut off time: <input type="text"/> Order receipt method: Phone: <input type="checkbox"/> No Phone #: <input type="text"/> Fax: <input type="checkbox"/> Yes Fax #: <input type="text" value="732-562-8788"/> EDI: <input type="checkbox"/> Yes Overnight Fees apply: <input type="checkbox"/> Yes Other fees apply: <input type="checkbox"/> No |
| Class of Trade Restriction: | |
| No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> No Restricted to retail pharmacy only: <input type="checkbox"/> Yes Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No Restricted from US territories? (explain in comments) <input type="checkbox"/> No Comments: <input type="text"/> | |
| Other Data Information Required to Process PO: | Return Instructions |
| Patient Procedure Date: <input type="text"/> Physician Name: <input type="text"/> Physician/Clinic Phone #: <input type="text"/> Physician State License #: <input type="text"/> Physician/Clinic DEA #: <input type="text"/> Physician/Clinic Specialty: <input type="text"/> | Contact # if product is received damaged: <input type="text" value="732-529-0430"/> Is product returnable for credit: <input type="checkbox"/> Yes URL/Link to returns policy: <input type="text"/> Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> Yes If so, which states? Other requirements? Comments? <input type="text"/> |
| Miscellaneous Notes: | ADDITIONAL INFORMATION |
| <input type="text"/> | Is product order for scheduled patient procedure? <input type="checkbox"/> No Is product order for restocking purposes? <input type="checkbox"/> No |