



# Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2021 Introduction Type:   Final Version Date:

PRODUCT INFORMATION				SPECIAL HANDLING AND STORAGE REQUIREMENTS*																																																													
<b>Company Name:</b> Camber Pharmaceuticals, Inc. <b>Application:</b> ANDA <b>Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):</b> 202801 <b>Medical Device Class, if applicable:</b> _____ <b>DUNS:</b> 11-856-3719 <b>Proprietary Name (If Applicable) and Established Name:</b> Levofloxacin Tablets, USP 500 mg <b>Selling Unit NDC:</b> 31722-722-50 <b>Unit of Use NDC:</b> _____ <b>UPC:</b> 331722722506 <b>UDI</b> _____ <b>CVX Code:</b> _____ <b>MVX Code:</b> _____ <b>Description:</b> Levofloxacin Tablets, USP 500 mg <b>Active Ingredient(s):</b> Levofloxacin, USP <b>URL for Additional Product Information:</b> <a href="http://www.camberpharma.com">www.camberpharma.com</a> <b>Address:</b> 800 Centennial Ave, Suite 1 <b>Address 2:</b> _____ <b>City:</b> Piscataway <b>State:</b> NJ <b>Zip:</b> 08854 <b>Key Contact:</b> Customer Service <b>Email:</b> <a href="mailto:customerservice@camberpharma.com">customerservice@camberpharma.com</a> <b>Phone Number:</b> 1-866-827-3647 <b>Fax:</b> 732-562-8788 <b>Product Therapeutic Classification:</b> Fluoroquinolone antibacterial				<b>a. Temperature – Indicate the USP temperature range for this product.</b> Temperature Range <input type="text" value="Controlled Room – between 20 and 25 C (68° – 77° F)"/>  Other Temperature Range Requirement (write in) _____ Notes _____  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>ADDITIONAL PRODUCT INFORMATION</b>				<b>PRODUCT DESCRIPTION INFORMATION</b>																																																													
The product is a legend device? <input type="text" value="No"/> if yes, enter class # _____ a product kit? <input type="text" value="No"/> if yes, list NDCs of component parts reverse numbered? _____ co-licensed? <input type="text" value="No"/> latex-free? <input type="text" value="Yes"/> preservative-free? <input type="text" value="Yes"/> correctional institution block? <input type="text" value="No"/> opioid? <input type="text" value="No"/> Cannabinoid? <input type="text" value="No"/> If Unit Dose, is item bar coded to unit dose for hospital scanning? _____ If Unit Dose, indicate NDC here: _____		Is the Product... Direct-Ship Only <input type="text" value="Neither"/> Is the Product... Orphan Drug Status _____  <b>FDA Approval Status</b> _____  <b>Allergens Present</b> _____  Country of Origin <input type="text" value="India"/>  Is this product covered under the Trade Agreements Act (TAA)? <input type="text" value="No"/>		<b>Size:</b> <input type="text" value="50 ct"/>  <b>Strength:</b> <input type="text" value="500 mg"/>  <b>Dosage Form:</b> <input type="text" value="Film coated tablet"/>  <b>Product Shape:</b> <input type="text" value="Capsule, biconvex"/>  <b>Product Color:</b> <input type="text" value="Orange"/>  <b>Product Imprint:</b> <input type="text" value="Debossed with '26' on one side and 'I' on the other side"/>																																																													
<b>FOR GENERIC DRUG PRODUCTS</b>				<b>ORDER INFORMATION</b>																																																													
<b>I. Orange Book Rating:</b> <input type="text" value="AB"/> <input type="checkbox"/> Authorized Generic *If Authorized Generic, other section fields are not applicable <b>II. Generic Equivalent to What Brand?:</b> <input type="text" value="Levaquin"/>				<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th>Unit of Sale</th> <th>What is the NDC selling unit?</th> </tr> </thead> <tbody> <tr> <td><input checked="" type="checkbox"/> Bottle</td> <td><input type="text" value="1 Bottle of 50 Tablets"/> (Write-in, e.g. 1 Box of 10 Vials)</td> </tr> <tr> <td><input type="checkbox"/> Box/Carton</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Ampule</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Glass</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Tube</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Vial Liquid Sgl</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Vial Liquid Multi</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Vial Powder Sgl</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Vial Powder Multi</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Other: Write In _____</td> <td></td> </tr> </tbody> </table>				Unit of Sale	What is the NDC selling unit?	<input checked="" type="checkbox"/> Bottle	<input type="text" value="1 Bottle of 50 Tablets"/> (Write-in, e.g. 1 Box of 10 Vials)	<input type="checkbox"/> Box/Carton		<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 _____																																					
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<b>DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION</b>				<b>PHARMACY ORDER / BILL UNIT</b>																																																													
<b>Does supplier meet DSCSA definition of manufacturer?</b> <input type="text" value="Yes"/> <b>Is product exempt from DSCSA?</b> <input type="text" value="No"/> <b>GLN:</b> <input type="text" value="0331722498975"/> <b>If yes, select exemption:</b> _____ <b>Other exemption - Write in:</b> _____ <b>GCP:</b> _____ <b>Is product repackaged?</b> <input type="text" value="No"/> <b>Is product sold by manufacturer's exclusive distributor?</b> <input type="text" value="Yes"/> <b>Has FDA granted waiver/exception/exemption for product?</b> <input type="text" value="No"/> <b>If yes, attach documentation from FDA.</b> _____ <b>If yes, was original product purchased direct from mfr?</b> <input type="text" value="No"/> <b>Provide source manufacturer for repackaged product</b> _____				<b>Rec. sell unit to customer?</b> _____ (Write-in, e.g. 1 Vial)  <b>Rx billing unit to pharmacy:</b> _____ <input type="checkbox"/> Each <input type="checkbox"/> Gram <input type="checkbox"/> Milliliter																																																													
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<b>COST INFORMATION</b>				<b>WHOLESALE USE ONLY:</b>																																																													
<b>Regular Cost</b> _____ <b>Invoice Cost (WAC) (\$)</b> <input type="text" value="\$19.28"/> <b>As of date:</b> <input type="text" value="11/3/2016"/>				<b>Vendor #:</b> _____ <b>Whsl. Code #:</b> _____ <b>Fineline Code:</b> _____																																																													

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: \_\_\_\_\_



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Version 2021

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?  
 (If yes, attach SDS with special instructions.)  No

e. Does the product contain DEHP?  No

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

a. UN/Identification Number

b. Proper Shipping Name

c. DOT Hazard Class

d. Packing Group

e. Inhalation Hazard?  No

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

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:  No

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#

### SDS Hazard Classification

Organic  
 Inorganic  
 Steroid/Androgen

Corrosive  
 Oxidizer  
 Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  No  
 NFPA Storage Level:

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

### Hazardous Waste Identification

EPA Hazardous Waste Code:  Waste Characteristics:

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  No  
 If Yes, is it managed with a pharmacy registry?   
 Website URL:

Med Guide Required  No  
 Limited Distribution Requirement   
 Comments / Details: (For example, iPledge program?)

**REMS:**  No

REMS Program Manager Name:  Phone:

Supplier Manages REMS registry exclusively:   
 Wholesale distributor support:   
 Provider Name:   
 Site Enrollment Number assigned by Supplier:

Comments

**Registry:**  No

Registry Program Contact Name:  Phone:   
 Comments

### ADD'L STORAGE INFORMATION

Is the Product...  
 Controlled Substance?  No Controlled Substance Code   
 Controlled by State(s)?  No Listed Chemical (List I or II)  No  
 ARCOS Reportable?  No If yes, indicate which:   
 Schedule No.  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  Yes

Restricted to retail pharmacy only:  No

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

Restricted from US territories? (explain in comments)  No

Comments:

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 1-866-827-3647

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:



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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> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #:</p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></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="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
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 type="text"/></p>	<p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>	<p><b>Return Instructions</b></p> <p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></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="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input 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="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>
Miscellaneous Notes:	