



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

Version 2020

Introduction Type:  Pre-Launch Change  Post-Launch Change

Final Version

Date: 7/21/2022

PRODUCT INFORMATION	
Company Name:	Viona Pharmaceuticals Inc.
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	077652
DUNS:	081468959
Proprietary Name (if Applicable) and Established Name:	Levofloxacin Tablets, USP 500 mg
Selling Unit NDC:	72578-099-18
UDI:	N/A
Unit of Use NDC:	
UPC:	372578099183
CVX Code:	
MXV Code:	N/A
Description:	White to off white, modified capsule-shaped, biconvex, film-coated tablets debossed with logo of 'ZC56' on one side and plain on other side
Active Ingredient(s):	Levofloxacin Hemihydrate
URL for Additional Product Information:	<a href="http://www.vionausa.com">www.vionausa.com</a>
Address:	20 Commerce Drive
City:	Cranford
Key Contact:	Chris Urbanski
Phone Number:	908-956-0600
Product Therapeutic Classification:	Synthetic antibacterial agent

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	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?	No
Is this product to be shipped to customers on dry ice?	No
b. Contact for temperature excursion questions:	
Name:	Customer Service
Number:	888-304-5022
Group E-mail:	<a href="mailto:customerservice@vionausa.com">customerservice@vionausa.com</a>
c. Special regulations for product in any states?	No
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	Yes
Protect product (unit of sale) from light?	No
e. Shelf life:	24 Months
Initial shelf life at launch (if different):	Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device?	No	Is the Product... Direct-Ship Only	
if yes, enter class #		Is the Product... Neither	
if yes, list NDCs of component parts		Orphan Drug Status	
reverse numbered?	No	FDA Approval Status	
co-licensed?	No	Allergens Present	
latex-free?	Yes	Country of Origin	India
preservative-free?	Yes	Is this product covered under the Trade Agreements Act (TAA)?	No
correctional institution block?	Yes		
opioid?	No		
Cannabinoid?	No		
If Unit Dose, is item bar coded to unit dose for hospital scanning?			
If Unit Dose, indicate NDC here:			
Size:	50ct	Strength:	500 mg
Dosage Form:	Film-coated tablet	Product Shape:	Modified capsule
Product Color:	White to off-white	Product Imprint:	"ZC56"

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Bottle of 50 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? Yes
<input type="checkbox"/> Tube	
<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	24 Each
<input type="checkbox"/> Vial Power Multi	Inner/Cartron/Pack
<input type="checkbox"/> Other: Write In	1 Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Levaquin
<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:
1 Bottle	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
	<input type="checkbox"/> 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:	GLN: 0372578000004
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

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Item/Each:	0.12	1.88	1.88	3.43		1
Box/Cartron/Bundle/Inner Pack:						
Case:	5.09	11.3	7.52	4.33		24
Pallet:	261.92	47.24	39.37	49.21		3,072

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Rem/Each	1		00372578099183	
<input type="checkbox"/> Box/Cartron/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	24		40372578099181	
<input checked="" type="checkbox"/> Pallet	3,072		50372578099188	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)		Whsl. Code #:	
As of date:		Fineline Code:	

\*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:

Version 2020

For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION																																													
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? <span style="float: right;">No</span></p> <p>b. CA Prop. 65 Carcinogen or Reproductive Toxicant?            Is the product a CA Prop 65 carcinogen? <span style="float: right;">No</span>            Is the product a CA Prop 65 reproductive toxicant? <span style="float: right;">No</span>            Does the product label bear a CA Prop 65 warning? <span style="float: right;">No</span></p> <p>c. Contact Hazard? <span style="float: right;">No</span></p> <p>d. Does this product require special clean-up instructions?            (If yes, attach SDS with special instructions.) <span style="float: right;">No</span></p> <p>e. Does the product contain DEHP? <span style="float: right;">No</span></p> <p>Is this product regulated for shipment by DOT?            (if yes, answer a-e below and provide SDS) <span style="float: right;">No</span></p> <p>a. UN/Identification Number <input style="width: 100%;" type="text"/></p> <p>b. Proper Shipping Name <input style="width: 100%;" type="text"/></p> <p>c. DOT Hazard Class <input style="width: 100%;" type="text"/></p> <p>d. Packing Group <input style="width: 100%;" type="text"/></p> <p>e. Inhalation Hazard? <span style="float: right;">No</span></p> <p>Is this product regulated for shipment by IATA?            (if yes, answer a-e below and provide SDS) <span style="float: right;">No</span></p> <p>a. UN/Identification Number <input style="width: 100%;" type="text"/></p> <p>b. Proper Shipping Name <input style="width: 100%;" type="text"/></p> <p>c. DOT Hazard Class <input style="width: 100%;" type="text"/></p> <p>d. Packing Group <input style="width: 100%;" type="text"/></p> <p>e. Inhalation Hazard? <input style="width: 100%;" type="text"/></p> <p>Is the product restricted for air shipment? If so, indicate restriction:</p> <p><input type="checkbox"/> Passenger</p> <p><input type="checkbox"/> Cargo</p> <p><input type="checkbox"/> Passenger &amp; Cargo</p> <p>Is this a reportable quantity? <span style="float: right;">No</span>            RQ Threshold: <input style="width: 100%;" type="text"/></p> <p>Is this a marine pollutant? <span style="float: right;">No</span></p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit?            No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity</p> <p><input type="checkbox"/> Consumer Commodity, ORM-D</p> <p><input type="checkbox"/> Small Quantity (49 CFR 173.4)</p> <p><input type="checkbox"/> Special Permit; DOT-SP</p> <p><input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101);            SP# <input style="width: 100%;" type="text"/></p>	<div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">SDS Hazard Classification</div> <table style="width: 100%; border: 1px solid black;"> <tr> <td style="width: 50%; border: 1px solid black;"><input type="checkbox"/> Organic</td> <td style="width: 50%; border: 1px solid black;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="border: 1px solid black;"><input type="checkbox"/> Inorganic</td> <td style="border: 1px solid black;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="border: 1px solid black;"><input type="checkbox"/> Steroid/Androgen</td> <td style="border: 1px solid black;"><input type="checkbox"/> Contact Hazard</td> </tr> <tr> <td colspan="2" style="border: 1px solid black;"> <input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 100%;" type="text"/> </td> </tr> <tr> <td colspan="2" style="border: 1px solid black;">           Is the product a NIOSH hazardous drug? <span style="float: right;">No</span>            If yes, indicate which: <input style="width: 100%;" type="text"/> </td> </tr> </table> <div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold; margin-top: 10px;">Hazardous Waste Identification</div> <table style="width: 100%; border: 1px solid black; margin-top: 5px;"> <tr> <td style="width: 70%; border: 1px solid black;">EPA Hazardous Waste Code: <input style="width: 95%;" type="text"/></td> <td style="width: 30%; border: 1px solid black;">Waste Characteristics <input style="width: 95%;" type="text"/></td> </tr> </table> <div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold; margin-top: 10px;">REMS or REGISTRY RESTRICTIONS</div> <p>Is there a REMS on this product? <span style="float: right;">No</span></p> <p>If Yes, is it managed with a pharmacy registry?            Website URL: <input style="width: 100%;" type="text"/></p> <p>Med Guide Required <span style="float: right;">No</span></p> <p>Limited Distribution Requirement <span style="float: right;">No</span></p> <p>Comments / Details: (For example, iPledge program?) <input style="width: 100%;" type="text"/></p> <p><b>REMS:</b></p> <table style="width: 100%; border: none;"> <tr> <td style="border: none;">REMS Program Manager Name:</td> <td style="border: none;"><input style="width: 100%;" type="text"/></td> <td style="border: none;">Phone:</td> <td style="border: none;"><input style="width: 100%;" type="text"/></td> </tr> <tr> <td style="border: none;">Supplier Manages REMS registry exclusively:</td> <td style="border: none;"><input style="width: 100%;" type="text"/></td> <td colspan="2" style="border: none;"></td> </tr> <tr> <td style="border: none;">Wholesale distributor support:</td> <td style="border: none;"><input style="width: 100%;" type="text"/></td> <td colspan="2" style="border: none;"></td> </tr> <tr> <td style="border: none;">Provider Name:</td> <td style="border: none;"><input style="width: 100%;" type="text"/></td> <td style="border: none;">DEA #:</td> <td style="border: none;"><input style="width: 100%;" type="text"/></td> </tr> <tr> <td style="border: none;">Site Enrollment Number assigned by Supplier:</td> <td style="border: none;"><input style="width: 100%;" type="text"/></td> <td style="border: none;">PCPDP#:</td> <td style="border: none;"><input style="width: 100%;" type="text"/></td> </tr> <tr> <td style="border: none;">NPI #:</td> <td style="border: none;"><input style="width: 100%;" type="text"/></td> <td colspan="2" style="border: none;"></td> </tr> </table> <p>Comments <input style="width: 100%;" type="text"/></p> <p><b>Registry:</b></p> <table style="width: 100%; border: none;"> <tr> <td style="border: none;">Registry Program Contact Name:</td> <td style="border: none;"><input style="width: 100%;" type="text"/></td> <td style="border: none;">Phone:</td> <td style="border: none;"><input style="width: 100%;" type="text"/></td> </tr> <tr> <td colspan="4" style="border: none;">Comments <input style="width: 100%;" type="text"/></td> </tr> </table>	<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? <span style="float: right;">No</span> If yes, indicate which: <input style="width: 100%;" type="text"/>		EPA Hazardous Waste Code: <input style="width: 95%;" type="text"/>	Waste Characteristics <input style="width: 95%;" 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"/>			Registry Program Contact Name:	<input style="width: 100%;" type="text"/>	Phone:	<input style="width: 100%;" type="text"/>	Comments <input style="width: 100%;" type="text"/>			
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<div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">CLASS OF TRADE RESTRICTION:</div> <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input style="width: 100%;" type="text"/></p> <p>Restricted to retail pharmacy only: <input style="width: 100%;" type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input style="width: 100%;" type="text"/></p> <p>Restricted from US territories? (explain in comments) <input style="width: 100%;" type="text"/></p> <p>Comments: <input style="width: 100%;" type="text"/></p>																																													
<div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">MISCELLANEOUS NOTES and/or Image of Product Barcode:</div> <div style="border: 1px solid black; height: 40px; width: 100%;"></div>																																													



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

Version 2020

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> <ul style="list-style-type: none"> <li>a. EDI <input type="checkbox"/></li> <li>b. Autofax <input type="checkbox"/> Fax Number: <input type="text"/></li> <li>c. Fax <input type="checkbox"/> Fax Number: <input type="text"/></li> <li>d. Phone only <input type="checkbox"/> Phone No.: <input type="text"/></li> <li>e. Supplier Web Site only <input type="checkbox"/> Site Address: <input type="text"/></li> </ul> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <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: <input type="text"/></p> <p>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>	
Other Data Information Required to Process PO:	Return Instructions
<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>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>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<p><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>