



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

Version 2020

Introduction Type: New Product 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 750 mg
Selling Unit NDC:	72578-100-06
UDI:	N/A
Unit of Use NDC:	
UPC:	372578100063
CVX Code:	
MXV Code:	N/A
Description:	White to off white, modified capsule-shaped, biconvex, film-coated tablets debossed with logo of 'ZC57' on one side and plain on other side
Active Ingredient(s):	Levofloxacin Hemihydrate
URL for Additional Product Information:	www.vionausa.com
Address:	20 Commerce Drive
City:	Cranford
State:	NJ
Zip:	07016
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:	customerservice@vionausa.com
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? if yes, enter class #	No	Is the Product... Direct-Ship Only	30ct
if yes, list NDCs of component parts	No	Is the Product... Orphan Drug Status	750 mg
reverse numbered?	No	FDA Approval Status	Film-coated tablet
co-licensed?	No	Allergens Present	Modified capsule
latex-free?	Yes	Country of Origin	White to off-white
preservative-free?	Yes	India	"ZC57"
correctional institution block?	Yes		
opioid?	No		
Cannabinoid?	No		
If Unit Dose, is item bar coded to unit dose for hospital scanning?		Is this product covered under the Trade Agreements Act (TAA)?	No
If Unit Dose, indicate NDC here:			

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Bottle of 30 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
	If Yes, was original product purchased direct from mfr?
	If yes, attach documentation from FDA.

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Item/Each:	0.11	1.61	1.61	2.98		1
Box/Cartron/Bundle/Inner Pack:						
Case:	4.28	9.72	6.49	3.81		24
Pallet:	223.04	47.24	39.37	49.21		4,752

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		00372578100063	
<input type="checkbox"/> Box/Cartron/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	24		40372578100061	
<input checked="" type="checkbox"/> Pallet	4,752		50372578100068	

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

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? No</p> <p>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</p> <p>c. Contact Hazard? No</p> <p>d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) No</p> <p>e. Does the product contain DEHP? No</p> <p>Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) No</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? No</p> <p>Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) No</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 & Cargo</p> <p>Is this a reportable quantity? No RQ Threshold: <input style="width: 100%;" type="text"/></p> <p>Is this a marine pollutant? No</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%; vertical-align: top;"> <input type="checkbox"/> Organic <input type="checkbox"/> Inorganic <input type="checkbox"/> Steroid/Androgen <input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 50%;" type="text"/> </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> Corrosive <input type="checkbox"/> Oxidizer <input type="checkbox"/> Contact Hazard Is the product a NIOSH hazardous drug? No 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;">Hazardous Waste Identification</div> <table style="width: 100%; border: 1px solid black;"> <tr> <td style="width: 60%;">EPA Hazardous Waste Code: <input style="width: 90%;" type="text"/></td> <td style="width: 40%;">Waste Characteristics <input style="width: 90%;" type="text"/></td> </tr> </table> <div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">REMS or REGISTRY RESTRICTIONS</div> <p>Is there a REMS on this product? No</p> <p>If Yes, is it managed with a pharmacy registry? Website URL: <input style="width: 100%;" type="text"/></p> <p>Med Guide Required No</p> <p>Limited Distribution Requirement No</p> <p>Comments / Details: (For example, iPledge program?) <input style="width: 100%;" type="text"/></p> <p>REMS:</p> <table style="width: 100%; border: 1px solid black;"> <tr> <td>REMS Program Manager Name: <input style="width: 80%;" type="text"/></td> <td>Phone: <input style="width: 20%;" type="text"/></td> </tr> <tr> <td>Supplier Manages REMS registry exclusively: <input style="width: 80%;" type="text"/></td> <td></td> </tr> <tr> <td>Wholesale distributor support: <input style="width: 80%;" type="text"/></td> <td></td> </tr> <tr> <td>Provider Name: <input style="width: 80%;" type="text"/></td> <td>DEA #: <input style="width: 20%;" type="text"/></td> </tr> <tr> <td>Site Enrollment Number assigned by Supplier: <input style="width: 80%;" type="text"/></td> <td>PCPDP#: <input style="width: 20%;" type="text"/></td> </tr> <tr> <td></td> <td>NPI #: <input style="width: 20%;" type="text"/></td> </tr> </table> <p>Comments <input style="width: 100%;" type="text"/></p> <p>Registry:</p> <table style="width: 100%; border: 1px solid black;"> <tr> <td>Registry Program Contact Name: <input style="width: 80%;" type="text"/></td> <td>Phone: <input style="width: 20%;" type="text"/></td> </tr> <tr> <td colspan="2">Comments <input style="width: 100%;" type="text"/></td> </tr> </table>	<input type="checkbox"/> Organic <input type="checkbox"/> Inorganic <input type="checkbox"/> Steroid/Androgen <input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 50%;" type="text"/>	<input type="checkbox"/> Corrosive <input type="checkbox"/> Oxidizer <input type="checkbox"/> Contact Hazard Is the product a NIOSH hazardous drug? 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ADD'L STORAGE INFORMATION																					
<p>Is the Product...</p> <p>Controlled Substance? No Controlled Substance Code <input style="width: 100%;" type="text"/></p> <p>Controlled by State(s)? No Listed Chemical (List I or II) <input style="width: 100%;" type="text"/></p> <p>ARCOS Reportable? No If yes, indicate which: <input style="width: 100%;" type="text"/></p> <p>Schedule No. <input style="width: 100%;" type="text"/> Is it a scheduled listed chemical product?: <input style="width: 100%;" type="text"/></p>	<div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">RETURN INSTRUCTIONS</div> <p>Contact tel. # if product received damaged: <input style="width: 100%; text-align: center; value: 888-304-5022;" type="text"/></p> <p>Is product returnable for credit: Yes</p> <p>URL/Link to returns policy: <input style="width: 100%; text-align: center; value: www.vionausa.com;" type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input style="width: 100%;" type="text"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%;" type="text"/></p>																				
CLASS OF TRADE RESTRICTION:																					
<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>																				

