



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

Version 2020

Introduction Type: Pre-Launch Change Post-Launch Change

Final Version

Date: 8/4/2022

PRODUCT INFORMATION	
Company Name:	Viona Pharmaceuticals Inc.
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	206747
DUNS:	081468959
Proprietary Name (if Applicable) and Established Name:	Voriconazole Tablets 200 mg
Selling Unit NDC:	72578-063-06
UDI	N/A
Unit of Use NDC:	
CVX Code:	
UPC:	372578063061
MXV Code:	N/A
Description:	White to off-white, oval, biconvex, film-coated tablet debossed with "736" on one side and plain on the other side
Active Ingredient(s):	Voriconazole, USP
URL for Additional Product Information:	www.vionausa.com
Address:	20 Commerce Drive
City:	Cranford
Key Contact:	Chris Urbanski
Phone Number:	908-956-0600
Product Therapeutic Classification:	Antifungal

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?	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	MT, ES
preservative-free?	Yes	Is this product covered under the Trade Agreements Act (TAA)?	Yes
correctional institution block?	No		
opioid?	No		
Cannabinoid?	No		
If Unit Dose, is item bar coded to unit dose for hospital scanning?			
If Unit Dose, indicate NDC here:			
Size:	30ct	Strength:	200 mg
Dosage Form:	Tablets	Product Shape:	Oval, Biconvex
Product Color:	White to off-white	Product Imprint:	"736"

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/ Carton/Pack
<input type="checkbox"/> Other: Write In	1 Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	VFEND
<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:	
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:	0372578000004
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Depth	Width	Height	Volume (Cube)	# Pieces:
Box/ Carton/ Bundle/ Inner Pack:	0.1	1.61	1.61	2.98		1
Case:	3.63	9.72	6.5	3.82		24
Pallet:	735.53	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		00372578063061	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	24		40372578063069	
<input checked="" type="checkbox"/> Pallet	4,752		50372578063066	

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:



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

Version 2020

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? No
 - 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? 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 this product regulated for shipment by 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 Substance Code
- Controlled by State(s)? No Listed Chemical (List I or II)
- ARCOS Reportable? No If yes, indicate which:
- Schedule No. Is it a scheduled listed chemical product?:

CLASS OF TRADE RESTRICTION:

- No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices
- Restricted to retail pharmacy only:
- Restricted to hospital, clinics, and physician offices only:
- Restricted from US territories? (explain in comments)
- Comments:

SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard
- Aerosol Class; Identify 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 No
- Comments / Details: (For example, iPledge program?)
- REMS:**
 - REMS Program Manager Name: Phone:
 - Supplier Manages REMS registry exclusively:
 - Wholesale distributor support:
 - Provider Name: DEA #:
 - Site Enrollment Number assigned by Supplier: PCPDP#:
 - NPI #:
- Comments
- Registry:**
 - Registry Program Contact Name: Phone:
 - Comments

RETURN INSTRUCTIONS

- Contact tel. # if product received damaged: 888-304-5022
- Is product returnable for credit: Yes
- URL/Link to returns policy: www.vionausa.com
- 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:



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> <table style="width:100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">a. EDI</td> <td style="width: 20%;"><input type="text"/></td> <td style="width: 30%;"></td> </tr> <tr> <td>b. Autofax</td> <td><input type="text"/></td> <td>Fax Number: <input type="text"/></td> </tr> <tr> <td>c. Fax</td> <td><input type="text"/></td> <td>Fax Number: <input type="text"/></td> </tr> <tr> <td>d. Phone only</td> <td><input type="text"/></td> <td>Phone No.: <input type="text"/></td> </tr> <tr> <td>e. Supplier Web Site only</td> <td><input type="text"/></td> <td>Site Address: <input type="text"/></td> </tr> </table> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #:</p> <table style="width:100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Name:</td> <td><input type="text"/></td> </tr> <tr> <td>Phone:</td> <td><input 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 type="text"/>	Phone:	<input type="text"/>	<p>Purchase order daily receipt cut off time by supplier</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="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 type="text"/>																			
Phone:	<input 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 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 style="width:100%; height: 80px;" type="text"/></p>	<p>Overnight receipt available: <input type="text"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <table style="width:100%; border-collapse: collapse;"> <tr><td><input type="checkbox"/> Monday</td></tr> <tr><td><input type="checkbox"/> Tuesday</td></tr> <tr><td><input type="checkbox"/> Wednesday</td></tr> <tr><td><input type="checkbox"/> Thursday</td></tr> <tr><td><input type="checkbox"/> Friday</td></tr> </table> <p>Priority Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method:</p> <table style="width:100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">Phone:</td> <td style="width: 20%;"><input type="text"/></td> <td style="width: 50%;">Phone #:</td> </tr> <tr> <td>Fax:</td> <td><input type="text"/></td> <td>Fax #:</td> </tr> <tr> <td>EDI:</td> <td><input type="text"/></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 type="text"/>	Phone #:	Fax:	<input type="text"/>	Fax #:	EDI:	<input type="text"/>						
<input type="checkbox"/> Monday																				
<input type="checkbox"/> Tuesday																				
<input type="checkbox"/> Wednesday																				
<input type="checkbox"/> Thursday																				
<input type="checkbox"/> Friday																				
Phone:	<input type="text"/>	Phone #:																		
Fax:	<input type="text"/>	Fax #:																		
EDI:	<input 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:100%; height: 80px;" type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="text"/></p> <p>URL/Link to returns policy: <input style="width:100%;" 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:100%; height: 80px;" 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="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p>																			
Miscellaneous Notes:																				