



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

Version 2020

Introduction Type:  Pre-Launch Change  Post-Launch Change

Final Version

Date: 8/8/2022

PRODUCT INFORMATION	
Company Name:	Viona Pharmaceuticals Inc.
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	207773
DUNS:	081468959
Proprietary Name (if Applicable) and Established Name:	Doxycycline Hyclate Tablets, USP 100 mg
Selling Unit NDC:	72578-001-05
UDI:	N/A
Unit of Use NDC:	
UPC:	372578001056
CVX Code:	
MXV Code:	N/A
Description:	Light yellow to beige colored, round, beveled edge, biconvex tablets debossed with "D77" on one side and plain on other side.
Active Ingredient(s):	Doxycycline Hyclate, USP
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:	Antibacterial

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?	Yes
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:	500ct	Strength:	100 mg
Dosage Form:	Tablet	Product Shape:	Round, Biconvex
Product Color:	Light Yellow to Beige	Product Imprint:	"D77"

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Bottle of 500 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	12 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?:	Vibra-Tab
<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:	0.37	2.45	2.45	4.3		1
Box/Cartron/Bundle/Inner Pack:						
Case:	5.16	9.8	7.36	5.24		12
Pallet:	697.58	47.24	39.37	49.21		1,512

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00372578001056	
<input type="checkbox"/> Box/Cartron/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	12		40372578001054	
<input checked="" type="checkbox"/> Pallet	1,512		50372578001051	

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



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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?  
(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?  No

Is this product regulated for shipment by IATA?  
(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?  No

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?:  No

### 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?  No
- 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:  No
- Wholesale distributor support:  No
- 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](http://www.vionausa.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										
Purchase orders may be accepted by: a. EDI <input style="width: 50px;" type="text"/> b. Autofax <input style="width: 50px;" type="text"/> Fax Number: <input style="width: 80px;" type="text"/> c. Fax <input style="width: 50px;" type="text"/> Fax Number: <input style="width: 80px;" type="text"/> d. Phone only <input style="width: 50px;" type="text"/> Phone No.: <input style="width: 80px;" type="text"/> e. Supplier Web Site only <input style="width: 50px;" type="text"/> Site Address: <input style="width: 80px;" type="text"/> Minimum Order Quantity: <input style="width: 100px;" type="text"/> Supplier's Customer Service Number: <input style="width: 100px;" type="text"/> Contracted 3PL company / contact #: Name: <input style="width: 60px;" type="text"/> Phone: <input style="width: 60px;" type="text"/>	<b>Purchase order daily receipt cut off time by supplier</b> Cut off time: <input style="width: 100px;" type="text"/>  Shipping lead time of PO: <input style="width: 50px;" type="text"/> Hours <input style="width: 50px;" type="text"/> Days  Ships same day for next day receipt: <input style="width: 50px;" type="text"/> Ships for second day receipt: <input style="width: 50px;" type="text"/> Ships regular ground for 3-10 days receipt: <input style="width: 50px;" type="text"/>										
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing										
Expedited freight fees billed with each order: <input style="width: 50px;" type="text"/> Drop Ship service fee billed with each order: <input style="width: 50px;" type="text"/> Drop Ship miscellaneous fees billed: <input style="width: 50px;" type="text"/> Comments: <div style="border: 1px solid black; height: 80px; width: 100%;"></div>	<b>Overnight receipt available:</b> <input style="width: 50px;" type="text"/> PO Receipt cut off time: <input style="width: 100px;" type="text"/> Days of week overnight is available: <table style="margin-left: 20px; border-collapse: collapse;"> <tr><td><input type="checkbox"/></td><td>Monday</td></tr> <tr><td><input type="checkbox"/></td><td>Tuesday</td></tr> <tr><td><input type="checkbox"/></td><td>Wednesday</td></tr> <tr><td><input type="checkbox"/></td><td>Thursday</td></tr> <tr><td><input type="checkbox"/></td><td>Friday</td></tr> </table> <b>Priority Overnight receipt available:</b> <input style="width: 50px;" type="text"/> PO Receipt Cut off time: <input style="width: 100px;" type="text"/>  <b>Saturday Overnight receipt available:</b> <input style="width: 50px;" type="text"/> PO Receipt Cut off time: <input style="width: 100px;" type="text"/> Order receipt method: Phone: <input style="width: 50px;" type="text"/> Phone #: <input style="width: 50px;" type="text"/> Fax: <input style="width: 50px;" type="text"/> Fax #: <input style="width: 50px;" type="text"/> EDI: <input style="width: 50px;" type="text"/> Overnight Fees apply: <input style="width: 50px;" type="text"/> Other fees apply: <input style="width: 50px;" type="text"/>	<input type="checkbox"/>	Monday	<input type="checkbox"/>	Tuesday	<input type="checkbox"/>	Wednesday	<input type="checkbox"/>	Thursday	<input type="checkbox"/>	Friday
<input type="checkbox"/>	Monday										
<input type="checkbox"/>	Tuesday										
<input type="checkbox"/>	Wednesday										
<input type="checkbox"/>	Thursday										
<input type="checkbox"/>	Friday										
Class of Trade Restriction:	<div style="border: 1px solid black; height: 80px; width: 100%;"></div>										
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input style="width: 50px;" type="text"/> Restricted to retail pharmacy only: <input style="width: 50px;" type="text"/> Restricted to hospital, clinics, and physician offices only: <input style="width: 50px;" type="text"/> Restricted from US territories? (explain in comments) <input style="width: 50px;" type="text"/> Comments: <div style="border: 1px solid black; height: 40px; width: 100%;"></div>											
Other Data Information Required to Process PO:	Return Instructions										
Patient Procedure Date: <input style="width: 50px;" type="text"/> Physician Name: <input style="width: 100px;" type="text"/> Physician/Clinic Phone #: <input style="width: 100px;" type="text"/> Physician State License #: <input style="width: 100px;" type="text"/> Physician/Clinic DEA #: <input style="width: 100px;" type="text"/> Physician/Clinic Specialty: <input style="width: 100px;" type="text"/>	Contact # if product is received damaged: <input style="width: 50px;" type="text"/> Is product returnable for credit: <input style="width: 50px;" type="text"/> URL/Link to returns policy: <input style="width: 100px;" type="text"/>  Special regulations or returns requirements for this product in certain states? <input style="width: 50px;" type="text"/> If so, which states? Other requirements? Comments? <div style="border: 1px solid black; height: 40px; width: 100%;"></div>										
Miscellaneous Notes:	ADDITIONAL INFORMATION										
<div style="border: 1px solid black; height: 100px; width: 100%;"></div>	Is product order for scheduled patient procedure? <input style="width: 50px;" type="text"/> Is product order for restocking purposes? <input style="width: 50px;" type="text"/>										