



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

Version 2024

Introduction Type: Post Launch Change

Final Version

Date: 3/18/2026

PRODUCT INFORMATION	
Company Name:	Viona Pharmaceuticals Inc.
Application Number for NDA/ANDA/BLA; PMA/510(k):	207773
Application:	ANDA
Medical Device Class, if applicable:	
DUNS:	081468959
Proprietary Name (If Applicable) and Established Name:	Doxycycline Hyclate Tablets, USP 100 mg
Selling Unit NDC:	72578-001-05
Unit of Use NDC:	
UDI:	N/A
UPC:	372578001056
CVX Code:	
MVX 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:	www.vionausa.com
Address:	20 Commerce Drive
City:	Cranford
Key Contact:	Chris Urbanski
Phone Number:	908-956-0600
Product Therapeutic Classification:	Antibacterial
Address 2:	Suite 340
State:	New Jersey
Zip:	07016
Email:	Curbanski@vionausa.com
Fax:	908-514-4005

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	Temperature Range: <input type="text"/> Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in):	<input type="text"/>
Notes:	<input type="text"/>
Is this product to be shipped to customers on ice?	<input type="checkbox"/> No
Is this product to be shipped to customers on dry ice?	<input type="checkbox"/> No
b. Contact for temperature excursion questions:	Name: <input type="text"/> Customer Service
Number:	<input type="text"/> 888-304-5022
Group E-mail:	<input type="text"/> customerservice@vionausa.com
c. Special regulations for product in any states?	<input type="checkbox"/> No
Special returns requirements for this product?	<input type="checkbox"/> No
d. Store product (unit of sale) upright?	<input type="checkbox"/> Yes
Protect product (unit of sale) from light?	<input type="checkbox"/> Yes
e. Shelf life:	<input type="text"/> 24 Months
Initial shelf life at launch (if different):	<input type="text"/> Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?		Is the Product... Direct-Ship Only	<input type="checkbox"/>
a legend device?	<input type="checkbox"/> No	Is the Product... Neither	<input type="checkbox"/>
if yes, enter class #	<input type="text"/>	Orphan Drug Status	<input type="checkbox"/>
a product kit?	<input type="checkbox"/> No	FDA Approval Status	<input type="text"/>
if yes, list NDCs of component parts	<input type="text"/>	Allergens Present	<input type="text"/>
reverse numbered?	<input type="checkbox"/> No	Country of Origin	<input type="text"/> Macau
co-licensed?	<input type="checkbox"/> No	Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/> No
latex-free?	<input type="checkbox"/> Yes		
preservative-free?	<input type="checkbox"/> Yes		
corrective institution block?	<input type="checkbox"/> No		
opioid?	<input type="checkbox"/> No		
Cannabinoid?	<input type="checkbox"/> No		
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>		
If Unit Dose, indicate NDC here:	<input type="text"/>		
Size:	<input type="text"/> 500 ct	Strength:	<input type="text"/> 100 mg
Dosage Form:	<input type="text"/> Tablet	Product Shape:	<input type="text"/> Round, Biconvex
Product Color:	<input type="text"/> Light Yellow to Beige	Product Imprint:	<input type="text"/> "D77"

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	<input type="text"/> 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? <input type="checkbox"/> 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	<input type="text"/> 12 Each
<input type="checkbox"/> Vial Powder Multi	<input type="text"/> Inner/ Carton/ Pack
<input type="checkbox"/> Other: Write In	<input type="text"/> 1 Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text"/> AB
II. Generic Equivalent to What Brand?:	<input type="text"/> 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?	<input type="text"/> 1 Bottle
Rx billing unit to pharmacy:	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
HCPCS J-Code:	<input type="text"/>
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="checkbox"/> Yes
Is product exempt from DSCSA?	<input type="checkbox"/> No
If yes, select exemption:	<input type="text"/>
Other exemption - Write in:	<input type="text"/>
Is product repackaged?	<input type="checkbox"/> No
Is product sold by manufacturer's exclusive distributor?	<input type="checkbox"/> No
Has FDA granted waiver/exception/exemption for product?	<input type="checkbox"/> No
If yes, attach documentation from FDA.	<input type="text"/>
GLN:	<input type="text"/> 0372578000004
GCP:	<input type="text"/> 0372578
If yes, was original product purchased direct from mfr?	<input type="checkbox"/>
Provide source manufacturer for repackaged product	<input type="text"/>

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/ Carton/ Bundle/ Inner Pack:	0.37	2.45	2.45	4.3		1
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	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14
<input checked="" type="checkbox"/> Item/Each	Y	1		00372578001056
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	Y	12		40372578001054
<input checked="" type="checkbox"/> Pallet	Y	1,512		50372578001051
Unit of Use GTIN-14				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost	<input type="text"/>	Vendor #:	<input type="text"/>
Invoice Cost (WAC) (\$)	<input type="text"/>	Whsl. Code #:	<input type="text"/>
As of date:	<input type="text"/>	Fineline Code:	<input type="text"/>

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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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)

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

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:

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

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

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

Hazardous Waste Identification

EPA Hazardous Waste Code: Waste Characteristics:

REMS or REGISTRY RESTRICTIONS

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

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

REMS: REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: No Yes Wholesale distributor support: No Yes Provider Name: DEA #: Site Enrollment Number assigned by Supplier: NCPDP#: 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: No Yes

URL/Link to returns policy: www.vionausa.com

Special regulations or returns requirements for this product in certain states? No Yes

If so, which states? Other requirements? Comments?



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