



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

Version 2024

Introduction Type: New Item

Final Version

Date: 3/13/2026

PRODUCT INFORMATION

Company Name: Viona Pharmaceuticals Inc. **Application:** ANDA
Application Number for NDA/ANDA/BLA; PMA/510(k): 220095 **NDA 505(b) Type:** NOT APPLICABLE
Medical Device Class, if applicable: _____
DUNS: 081468959
Proprietary Name (if Applicable) and Established Name: Metronidazole Gel, USP 0.75%
Selling Unit NDC: 72578-209-04 **Unit of Use NDC:** _____ **UPC:** 372578209049
UDI: N/A **CVX Code:** _____ **MXV Code:** N/A
Description: Colorless to light yellow, clear transparent gel, free from lump and foreign matter.
Active Ingredient(s): Metronidazole, USP
URL for Additional Product Information: www.vionausa.com
Address: 20 Commerce Drive **Address 2:** Suite 340
City: Cranford **State:** NJ **Zip:** 07016
Key Contact: Chris Urbanski **Email:** Curbanski@vionausa.com
Phone Number: 908-956-0600 **Fax:** 908-514-4005
Product Therapeutic Classification: Antiprotozoal and antibacterial agent.

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.
Temperature Range: 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?
 Special returns requirements for this product? No
d. Store product (unit of sale) upright? No
 Protect product (unit of sale) from light? No
e. Shelf life: Initial shelf life at launch (if different): 24 Months

ADDITIONAL PRODUCT INFORMATION

The product is?
 a legend device? No
 if yes, enter class # _____
 a product kit? No
 if yes, list NDCs of component parts reverse numbered? _____
 co-licensed? No
 latex-free? Yes
 preservative-free? No
 correctional institution block? No
 opioid? No
 Cannabinoid? No
 If Unit Dose, is item bar coded to unit dose for hospital scanning? No
 If Unit Dose, indicate NDC here: _____
Is the Product... Direct-SHIP Only _____
Is the Product... Neither _____
Orphan Drug Status _____
FDA Approval Status _____
Allergens Present _____
Country of Origin India
 Is this product covered under the Trade Agreements Act (TAA)? No

PRODUCT DESCRIPTION INFORMATION

Size: 45g
Strength: 0.75%
Dosage Form: Gel
Product Shape: N/A
Product Color: Colorless to light yellow
Product Imprint: N/A

ORDER INFORMATION

Unit of Sale
 Bottle
 Box/Carton
 Ampule
 Glass
 Tube
 Vial Liquid Sgl
 Vial Liquid Multi
 Vial Powder Sgl
 Vial Power Multi
 Other: Write In _____
What is the NDC selling unit?
 1 Tube of 45g
 (Write-in, e.g. 1 Box of 10 Vials)
Minimum order quantity? Yes
If Yes, how many of which package type?
 36 Each
 Inner/Carton/Pack
 1 Case

FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AB Authorized Generic *If Authorized Generic, other section fields are not applicable
II. Generic Equivalent to What Brand?: MetroGel®

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? 1 Tube
 (Write-in, e.g. 1 Vial)
HCPCS J-Code: _____
Rx billing unit to pharmacy:
 Each
 Gram
 Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes
Is product exempt from DSCSA? No
GLN: 0372578000004
GCP: 0372578
If yes, was original product purchased direct from mfr? _____
Provide source manufacturer for repackaged product _____
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
 If yes, attach documentation from FDA.

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.15	1.1	1.1	5.51		1
Box/Carton/Bundle/Inner Pack:						
Case:	5.80	10.32	8.19	6.30		36
Pallet:	497.00	47.24	39.37	47.24		2880

GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	Y	1		00372578209049	
<input checked="" type="checkbox"/> Box/Carton/Bundle/Inner Pack	Y	36		40372578209047	
<input checked="" type="checkbox"/> Case	Y	2880		50372578209044	
<input checked="" type="checkbox"/> Pallet	Y				

COST INFORMATION

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



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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?

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

SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard

Does the product have an Aerosol class? If yes, identify No

NFPA Storage Level:

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:

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: 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:



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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
<p>Purchase orders may be accepted by:</p> <ul style="list-style-type: none"> 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"/> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input type="text"/> Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p>	<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="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>Overnight receipt available: <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>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: 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>