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

Version 2024 | Introduction Type: Post Launch Change | x Final Version | Date: 6/1/2026

## PRODUCT INFORMATION

| | | | |
|---|---|---|---|
| Company Name: | Viona Pharmaceuticals Inc. | Application: | ANDA |
| Application Number for NDA/ANDA/BLA; PMA/510(k): | 206560 | NDA 505(b) Type: | NOT APPLICABLE |
| Medical Device Class, if applicable: | | | |
| DUNS: | 081468959 | | |
| Proprietary Name (If Applicable) and Established Name: | Metronidazole Tablets, USP 500 mg | | |
| Selling Unit NDC: | 72578-008-18 | Unit of Use NDC: | UPC: 372578008185 |
| UDI | N/A | CVX Code: | MVX Code: N/A |
| Description: | White to off-white, oval shaped, biconvex, film coated tablets debossed with '851' on one side and plain on other side. | | |
| Active Ingredient(s): | Metronidazole, USP | | |
| URL for Additional Product Information: | www.vionausa.com | | |
| Address: | 20 Commerce Drive | Address 2: | Suite 340 |
| City: | Cranford | State: New Jersey | Zip: 07016 |
| Key Contact: | Chris Urbanski | Email: | Curbanski@vionausa.com |
| Phone Number: | 908-956-0600 | Fax: | 908-514-4005 |
| Product Therapeutic Classification: | Antibiotic & Antiprotozoal | | |

## ADDITIONAL PRODUCT INFORMATION

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

## PRODUCT DESCRIPTION INFORMATION

| | |
|---|---|
| Size: | 50 count |
| Strength: | 500 mg |
| Dosage Form: | Tablet |
| Product Shape: | Oval shaped, Biconvex |
| Product Color: | White to Off-White |
| Product Imprint: | "851" |

## FOR GENERIC DRUG PRODUCTS

Authorized Generic | *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating: AB

II. Generic Equivalent to What Brand?: Flagyl

## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

| | | | |
|---|---|---|---|
| Does supplier meet DSCSA definition of manufacturer? | Yes | GLN: | 0372578000004 |
| Is product exempt from DSCSA? | No | | |
| If yes, select exemption: | | GCP: | 0372578 |
| Other exemption - Write in: | | | |
| Is product repackaged? | No | If yes, was original product purchased direct from mfr? | |
| Is product sold by manufacturer's exclusive distributor? | No | | |
| Has FDA granted waiver/exception/exemption for product? | No | Provide source manufacturer for repackaged product | |
| If yes, attach documentation from FDA. | | | |

## GTIN AND HIBCC PRODUCT INFORMATION

| | Saleable Unit of Measure | RFID tag(Y/N) | Saleable Quantity | HIBCC | GTIN-14 | Unit of Use GTIN-14 |
|---|---|---|---|---|---|---|
| x | Item/Each | Y | 1 | | 00372578008185 | |
| | Box/Carton/Bundle/Inner Pack | | | | | |
| x | Case | Y | 24 | | 40372578008183 | |
| x | Pallet | Y | 3,840 | | 50372578008180 | |

## 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? 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: 36 Months

Initial shelf life at launch (if different): 24 Months

## ORDER INFORMATION

| Unit of Sale | | What is the NDC selling unit? | |
|---|---|---|---|
| x | Bottle | 1 Bottle of 50 Tablets | |
| | Box/Carton | (Write-in, e.g. 1 Box of 10 Vials) | |
| | Ampule | | |
| | Glass | Minimum order quantity? | Yes |
| | Tube | | |
| | Vial Liquid Sgl | | |
| | Vial Liquid Multi | If Yes, how many of which package type? | |
| | Vial Powder Sql | 24 | Each |
| | Vial Power Multi | | Inner/Carton/Pack |
| | Other: Write In | 1 | Case |

## PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer: 1 Bottle

(Write-in, e.g. 1 Vial)

HCPCS J-Code:

Rx billing unit to pharmacy:

| | |
|---|---|
| x | Each |
| | Gram |
| | Milliliter |

## ITEM AND PACKING INFORMATION

| | Weight Lbs. | Dimensions (US msmts.) Depth | Width | Height | Volume (Cube) | Saleable # Pieces |
|---|---|---|---|---|---|---|
| Item/Each: | 0.16 | 1.68 | 1.68 | 3.19 | | 1 |
| Box/Carton/Bundle/ Inner Pack: | | | | | | |
| Case: | 4.88 | 10.04 | 6.69 | 3.94 | | 24 |
| Pallet: | 799.87 | 47.24 | 47.24 | 49.21 | | 3,840 |

## COST INFORMATION

Regular Cost

Invoice Cost (WAC) ($)

As of date:

## WHOLESALER USE ONLY:

Vendor #:

Whsl. Code #:

Fineline Code:

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:

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

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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) | No |
| 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) | No |
| 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: | No |

- ☐ 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#

### 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 |
| 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 | | | |

## 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: | |

## 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:

Release DATE

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

**Version 2024**

**FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.**

## Order Method for Designated Drop Ship Product

Purchase orders may be accepted by:

a. EDI
b. Autofax — Fax Number:
c. Fax — Fax Number:
d. Phone only — Phone No.:
e. Supplier Web Site only — Site Address:

Minimum Order Quantity:
Supplier's Customer Service Number:
Contracted 3PL company / contact #: Name:
Phone:

## Standard Order Receipt and Processing

**Purchase order daily receipt cut off time by supplier**
Cut off time:

Shipping lead time of PO: Hours Days

Ships same day for next day receipt:
Ships for second day receipt:
Ships regular ground for 3-10 days receipt:

## Expedited Freight Charges or Other Designated Drop Ship Fees:

Expedited freight fees billed with each order:
Drop Ship service fee billed with each order:
Drop Ship miscellaneous fees billed:
Comments:

## Overnight and Priority Overnight PO Processing

**Overnight receipt available:**
PO Receipt cut off time:
Days of week overnight is available:
Monday
Tuesday
Wednesday
Thursday
Friday

**Priority Overnight receipt available:**
PO Receipt Cut off time:

**Saturday Overnight receipt available:**
PO Receipt Cut off time:

Order receipt method:
Phone: Phone #:
Fax: Fax #:
EDI:

Overnight Fees apply:
Other fees apply:

## 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:

## Other Data Information Required to Process PO:

Patient Procedure Date:
Physician Name:
Physician/Clinic Phone #
Physician State License #
Physician/Clinic DEA #:
Physician/Clinic Specialty:

## Return Instructions

Contact # if product is received damaged:
Is product returnable for credit:
URL/Link to returns policy:
Special regulations or returns requirements for this product in certain states?
If so, which states? Other requirements? Comments?

## Miscellaneous Notes:

## ADDITIONAL INFORMATION

Is product order for scheduled patient procedure?
Is product order for restocking purposes?