



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

Version 2020

Introduction Type: New Product Post Launch Change

Final Version

Date: 7/13/2023

| PRODUCT INFORMATION | |
|---|---|
| Company Name: | Viona Pharmaceuticals Inc. |
| Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): | 206560 |
| DUNS: | 081468959 |
| Proprietary Name (if Applicable) and Established Name: | Metronidazole Tablets, USP 250 mg |
| Selling Unit NDC: | 72578-007-01 |
| UDI: | N/A |
| Unit of Use NDC: | |
| UPC: | 372578007010 |
| CVX Code: | |
| MXV Code: | N/A |
| Description: | White to off-white, round, biconvex, film coated tablets debossed with '850' 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 |
| City: | Cranford |
| Key Contact: | Chris Urbanski |
| Phone Number: | 908-956-0600 |
| Product Therapeutic Classification: | |

| 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? | |
| 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 |

| 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 | |
| a product kit? | No | Orphan Drug Status | |
| if yes, list NDCs of component parts | | FDA Approval Status | |
| reverse numbered? | No | Allergens Present | |
| co-licensed? | No | Country of Origin | India |
| latex-free? | Yes | Is this product covered under the Trade Agreements Act (TAA)? | No |
| preservative-free? | 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: | 100 count | Strength: | 250 mg |
| Dosage Form: | Tablets | Product Shape: | Round, Biconvex |
| Product Color: | White to Off-White | Product Imprint: | "850" |

| ORDER INFORMATION | |
|--|---|
| Unit of Sale | What is the NDC selling unit? |
| <input checked="" type="checkbox"/> 1 Bottle | 1 Bottle of 100 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?: | Flagyl |
| <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: | 0.16 | 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 |

| GTIN AND HIBCC PRODUCT INFORMATION | | | | |
|------------------------------------|----------|-------|----------------|---------------------|
| Saleable Unit of Measure | Quantity | HIBCC | GTIN-14 | Unit of Use GTIN-14 |
| Item/Each | 1 | | 00372578007010 | |
| Box/ Carton/ Bundle/ Inner Pack | | | | |
| Case | 24 | | 40372578007018 | |
| Pallet | 3,840 | | 50372578007015 | |

| 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? 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? No

- 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?
- 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:

