

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

Version 2020					Introduction Type:	Post Launch Change		x Final Version			Date:	7/13/	2023	
		PRODUCT INFORMATION	ON					SPECIAL HANI	DLING AND STO	RAGE REQUI	REMENTS*			
Company Name: Viona Pharmaceuticals Inc. Application: ANDA								a. Temperature – Indicate the USP temperature range for this product.						
	r for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 206560							Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)						
DUNS: 081468959								Other Temperature Range R	equirement					
Proprietary Name (If Applicable)		Metronidazole Tablets, USP 500 mg						(write in)						
Selling Unit NDC:	72578-008-01	Unit of Use NDC:			UPC: 372578	008017		Notes						
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. Is this product to be shipped to customers on ice? No														
								Is this product to be shipped	to customers on o	dry ice?		No		
Active Ingredient(s): Metronidazole, USP														
	b. Contact fo	r temperature excursion que	estions:	Customer Se										
URL for Additional Product Inform Address:	20 Commerce Drive	w.vionausa.com			Address 2: Suite 3	40		Name: Number:		888-304-502				
City:	Cranford			ate:		NJ <b>Zip:</b> 07016		Group E-mail:			customerservice@vionausa.com			
Key Contact:	Chris Urbanski				Email: Curbanski@vionausa.com			1			customerser vice w violidusa.com			
Phone Number:	908-956-0600		F	ax:	908-514-4005		c. Special reg	gulations for product in any	states?			No		
Product Therapeutic Classification	on:						`  ·	Special returns requirements	for this product?					
	ADDITIONAL F	PRODUCT INFORMATION			PRODUCT DESCR	RIPTION INFORMATION	d. Store prod	luct (unit of sale) upright?				Yes		
The product is?		Is the Product	Direct-Ship Only					Protect product (unit of sa	le) from light?			Yes		
a legend device?	No		Neither		Size:	100 count	e. Shelf life:		, , ,			36	Months	
if yes, enter class #		Orphan Drug Status			Size.	100 count		Initial shelf life at launch (i	f different):			24	Months	
a product kit?	No				Strength:	500 mg								
if yes, list NDCs of		FDA Approval Status			<b>.</b> .				ORDER INFORI	MATION				
component parts reverse numbered?	No				Dosage Form:	Tablets		Unit of Sale		What is the	NDC selling	unit?		
co-licensed?	No	Allergens Present					П	1 Bottle		1 Bottle of 10		uiik.		
latex-free?	Yes	7		1		0 101 15:	4	Box/Carton			g. 1 Box of 10	) Vials)		
preservative-free?	Yes				Product Shape:	Oval Shapped, Biconvex		Ampule		,	•	,		
correctional institution block?	No				Product Color:	White to Off-White		Glass		Minimum o	der quantity	/?	Yes	
opioid?	No				Troduct Color:	Willie to Oil Wille		Tube						
Cannabinoid?	No_	Country of Origin	India	ļ	Product Imprint:	"851"		Vial Liquid Sgl						
If Unit Dose, is item bar coded to uscanning?	unit dose for hospital	In this was don't account a second and	la a tha		·		H	Vial Liquid Multi			many of whi Each	ch package t	type?	
If Unit Dose, indicate NDC here:		Is this product covered und Trade Agreements Act (TA						Vial Powder Sql Vial Power Multi		15	Inner/Carton	/Pack		
ii onit bose, indicate NBC fiere.		Trade Agreements Net (17)	110					Other: Write In		1	Case	1 dok		
		FOR GENERIC DRUG PRO	DUCTS											
							1							
				Autho		orized Generic, other section	PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating:	I. Orange Book Rating: AB fields are not applicable						Rec. sell unit to customer? Rx billing unit to pharmacy:							
II. Generic Equivalent to What Bra	II. Generic Equivalent to What Brand?: Flagyl						1 Bottle x Each							
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION (W							(Write-in, e.g	. 1 Vial)			Gram			
	Ļ	DRUG SUPPLY CHAIN SECURITY ACT (DS	SCSA) INFORMATIO	N							Milliliter			
Does supplier meet DSCSA defin	ition of manufacturer?	Yes	GLN:		0372578000004			ITEM	AND PACKING I	NEORMATIO	J			
Is product exempt from DSCSA?	o	No	OLIV.		22,20,000004									
If yes, select exemption:							•		Dimens	ions (US msn	ite l	Volume		
Other exemption - Write in:								Weight Lbs.	Depth	Width	Height	(Cube)	# Pieces:	
Is product repackaged?		No	If Yes, was	s origin	al product purchased		Item/Each:	0.25	2.12	2.12	3.97	·,	1	
Is product sold by manufacturer's	s exclusive distributor?	No	direct from	n mfr?				0.25	2.12	2.12	3.97		'	
Has FDA granted waiver/exception	n/exemption for product	? No	If yes, atta	ich doc	umentation from FDA.		Box/Carton/E	Bundle/						
		CTIN AND HIROS PRODUCT IN	CODMATION				Inner Pack:							
		GTIN AND HIBCC PRODUCT INF	ORMATION				Case:	5.02	10.79	6.54	5.04	· · · · · · · · ·	15	
Saleable Unit of Measure	Quan	ntity HIBCC		GTIN-1	и	Unit of Use GTIN-14	Pallet:			-		<b>—</b>		
Item/Each		1			578008017	Offic of Ose Offit-14	l'allet.	720.58	47.24	39.37	49.21	· · · · · · · · ·	2,100	
Box/Carton/Bundle/Inner Pack							<del> </del>							
Case	1	40372578008015					COST INFORMATION			WHOLESALER USE ONLY:				
Pallet	2,	100		503725	578008012			ı						
							Regular Cost			Vendor #:				
							Invoice Cost	(WAC) (\$)		Whsl. Code Fineline Co		<del></del>		
	-						As of date:			i memie Co	uc.			
							715 of date.							
•		Attach copy of SAFETY DAT	A SHEET (SDS) or no	on haza	rd letter, PACKAGE INSE	RT, LABEL AND PHOTO OF I	PRODUCT PACK	(AGING and BARCODE.		•				
*Please provide any additional in	formation on page 2		,===, 5, 1,		See new n 3 for Desig			Signature:						



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### For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL I	AZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply): a. Cytotoxic?  No	SDS Hazard Classification						
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  Is the product a CA Prop 65 carcinogen?  Is the product a CA Prop 65 reproductive toxicant?  No  Does the product label bear a CA Prop 65 warning?  No	Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard						
c. Contact Hazard?  d. Does this product require special clean-up instructions?  (If yes, attach SDS with special instructions.)  e. Does the product contain DEHP?  Is this product regulated for shipment by DOT?  No	Aerosol Class; Identify NFPA Storage Level:  Is the product a NIOSH hazardous drug?  If yes, indicate which:						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group	Hazardous Waste Identification  EPA Hazardous Waste Code:  Waste Characteristics						
e. Inhalation Hazard?  Is this product regulated for shipment by IATA?  No	REMS or REGISTRY RESTRICTIONS						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class	Is there a REMS on this product?  If Yes, is it managed with a pharmacy registry?  Website URL:						
d. Packing Group e. Inhalation Hazard?  Is the product restricted for air shipment? If so, indicate restriction:  Passenger Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)						
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)	REMS:  REMS Program Manager Name: Supplier Manages REMS registry exclusively: Wholesale distributor support: Provider Name: Site Enrollment Number assigned by Supplier: PPUBLICATION Phone:  DEA #: PCPDP#: NPI #:						
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Registry:  Registry Program Contact Name:  Phone:						
ADD'L STORAGE INFORMATION Is the Product	Comments						
Controlled Substance?  Controlled Substance Code  Controlled by State(s)?  ARCOS Reportable?  Schedule No.  If yes, indicate which:  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	Contact tel. # if product received damaged:  Is product returnable for credit:  URL/Link to returns policy:  Www.vionausa.com						
Restricted to retail pharmacy only:  Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments)  Comments:	Special regulations or returns requirements for this product in certain states?  If so, which states? Other requirements? Comments?						
MISCELLAI	IEOUS 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:	Purchase order daily receipt cut off time by supplier						
a. EDI	Cut off time:						
b. Autofax Fax Number:							
c. Fax Number:	Shipping lead time of PO: Hours Days						
d. Phone only Phone No.:							
e. Supplier Web Site only Site Address:	Ships same day for next day receipt:						
Minimum Order Quantity:	Ships for second day receipt:						
Supplier's Customer Service Number:	Ships regular ground for 3-10 days receipt:						
Contracted 3PL company / contact #: Name:							
Phone:							
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing						
Expedited freight fees billed with each order:	Overnight receipt available:						
Drop Ship service fee billed with each order:	PO Receipt cut off time:						
Drop Ship miscellaneous fees billed:	Days of week overnight is available: Monday						
Comments:	Tuesday						
	Wednesday						
	Thursday						
	Friday						
	Priority Overnight receipt available:						
Class of Trade Restriction:	PO Receipt Cut off time:						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Saturday Overnight receipt available:						
Restricted to retail pharmacy only:	PO Receipt Cut off time:						
Restricted to hospital, clinics, and physician offices only:	Phone: Phone #:						
Restricted from US territories? (explain in comments)	Order receipt method: Fax: Fax #:						
Comments:	EDI:						
	Overnight Fees apply:						
	Other fees apply:						
Other Data Information Required to Process PO:	Return Instructions						
Patient Procedure Date:	Contact # if product is received damaged:						
Physician Name:	Is product returnable for credit:						
Physician/Clinic Phone #	URL/Link to returns policy:						
Physician State License #							
Physician/Clinic DEA #:	Special regulations or returns requirements for this product in certain states?						
Physician/Clinic Specialty:	If so, which states? Other requirements? Comments?						
Miscellaneous Notes:							
	ADDITIONAL INFORMATION						
	Is product order for scheduled patient procedure?						
	Is product order for restocking purposes?						