

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

Version 2020						Introduction Type:	Post Launch Change		x Final Version	n		Date:	7/13	3/2023
			PRODUCT INFORMA	TION					SPECIA	. HANDLING AND ST	ORAGE REQU	IREMENTS*		
Company Name: Viona Pharmaceuticals Inc. Application: ANDA							a. Temperature – Indicate the USP temperature range for this product.							
Application Number for NDA/AN	DA/BLA (drug); PMA/510(k)(med device): 206560							Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)						
DUNS:	081468959								Other Temperature R	ange Requirement				
Proprietary Name (If Applicable)	and Established Na	ame: Metror	nidazole Tablets, USP 500 m	g					(write in)					
Selling Unit NDC:	72578-008-18		Unit of Use NDC:				008185		Notes					
UDI	N/A		CVX Code:			MVX Code: N/A								
Description:	White to off-white	, oval shaped, bicon	vex, film coated tablets debo	ssed with '851' o	n one side and	d plain on other side.			Is this product to be s				No	_
		1							Is this product to be s	hipped to customers of	n dry ice?		No	_
Active Ingredient(s):		Metronidazole, US	Р					h Contact for	r tomporaturo ovourci	on questions:				
URL for Additional Product Infor	mation:	www.vionausa.	com					b. Contact for	r temperature excursi Name:	on questions:	Customer S	Service		
Address:	20 Commerce Dri		<u>com</u>			Address 2: Suite 3	40		Number:		888-304-50			
City:	Cranford State: NJ Zip: 07016							Group E-mail: customerservice@vionausa.com					n	
Key Contact:	Chris Urbanski Email: Curbanski@vionausa.com													
Phone Number:	908-956-0600	•			Fax:	908-514-4005		c. Special reg	ulations for product	-			No	_
Product Therapeutic Classification	n:								Special returns requir	ements for this produc	t?			
	ADDITIO	NAL BRODUCT IN	FORMATION			PRODUCT DESCR	RIPTION INFORMATION	4 04		-1.10			V	
-	ADDITIC	NAL PRODUCT IN				PRODUCT DESCR	TIFTION INFORMATION	a. Store prod	uct (unit of sale) upri				Yes	-
The product is?			Is the Product	Direct-Ship Or	nly			e. Shelf life:	Protect product (un	t of sale) from light?			Yes 36	T
a legend device? if yes, enter class #		No	Is the Product Orphan Drug Status	Neither		Size:	50 count	e. Shelf life:	Initial shelf life at la	unch (if different):			24	Months Months
a product kit?		No	Orphan Drug Status						miliai shen me at iai	inon (ii dinerent).			24	WOILLIS
if yes, list NDCs of			FDA Approval Status			Strength:	500 mg			ORDER INFO	RMATION			
component parts						Dosage Form:	Tablets							
reverse numbered?		No							Unit of Sale			NDC selling	g unit?	
co-licensed? latex-free?		No Yes	Allergens Present						1 Bottle Box/Carton		1 Bottle of 5	e.g. 1 Box of 1	IO Viole)	
preservative-free?		Yes				Product Shape:	Oval Shapped, Biconvex		Ampule		(vviite-iii, e	.y. 1 box 01 1	io viais)	
correctional institution block?		No				Beerleet Oeless	Milete to Off Milete		Glass		Minimum o	order quantit	γ?	Yes
opioid?		No				Product Color:	White to Off-White		Tube				•	
Cannabinoid?		No	Country of Origin	India		Product Imprint:	"851"		Vial Liquid S	•				
If Unit Dose, is item bar coded to u	unit dose for hospita	l				i roddot imprint.	001		Vial Liquid I				ich package	type?
scanning?			Is this product covered up Trade Agreements Act (1		NI-				Vial Powder		24	Each	- (D1-	
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	AA)?	No				Other: Write		1	Inner/Carto Case	n/Pack	
			FOR GENERIC DRUG PR	ODUCTS					Canon William					
					Autho		orized Generic, other section			PHARMACY ORD	ER / BILL UNIT			
I. Orange Book Rating:	AB					fields a	re not applicable	Rec. sell unit to customer?				Rx billing unit to pharmacy:		
II. Generic Equivalent to What Bra	and?:	Flagyl							1 Bottle		х	Each		
		DRUG GURRI	Y CHAIN SECURITY ACT (DOGGA) INFOR	MATION			(Write-in, e.g.	1 Vial)			Gram		
		DRUG SUPPL	T CHAIN SECURITY ACT (DSCSA) INFORI	WATION							Milliliter		
Does supplier meet DSCSA defin	ition of manufactu	rer?	Yes	GLN	۱:	0372578000004				ITEM AND PACKIN	G INFORMATIC	N		
Is product exempt from DSCSA?			No	_										
If yes, select exemption:									Weight I	Dime	nsions (US ms	mts.)	Volume	# Pieces:
Other exemption - Write in:									weight	Depth	Width	Height	(Cube)	# Pieces:
Is product repackaged?			No			al product purchased		Item/Each:	0.16	1.68	1.68	3.19		1
Is product sold by manufacturer's Has FDA granted waiver/exception			No No	_	ct from mfr?	umentation from FDA.		Box/Carton/B	undle/					
lias i DA granted waiver/exception	illexemption for p		140	_ ", ", "	s, allacii uoc	unientation nom i DA.		Inner Pack:	ullule/					
		GTII	N AND HIBCC PRODUCT II	NFORMATION				Case:	4.88	10.04	6.69	3.94		24
									4.00	10.04	0.09	3.94		24
Saleable Unit of Measure		Quantity	HIBCC		GTIN-1		Unit of Use GTIN-14	Pallet:	799.8	7 47.24	47.24	49.21		3,840
Item/Each		1			003725	578008185		L						
Box/Carton/Bundle/Inner Pack Case	24 40372578008183							COST INFORMATION WHOLESALER USE ONLY:						
Pallet	3,840 50372578008180					COST INTORNIATION								
							Regular Cost			Vendor #:	Vendor #:			
							Invoice Cost (WAC) (\$)				Whsl. Code #:			
											Fineline Co	ode:		
								As of date:						
1			Attach copy of CAFETY DA	TA QUEET (OD)	2) or non ha	rd lotter BACKACE INCE	RT, LABEL AND PHOTO OF I	DECULICE DACK	ACING and BARCOR	=				
*Please provide any additional in	formation on page	2	Auacri copy of SAFETY DA	IIM SHEET (SDS	o non naza	See new p. 3 for Desig		FRODUCT PACK	Signature:					
						p. 0 101 Desig	2. op omp omy.							



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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:
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:	
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	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure?
	Is product order for restocking purposes?
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