

# **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					SPECIAL HAN	DLING AND STO	RAGE REQUI	REMENTS*		
Company Name:	Viona Pharmaceuticals Inc.			Application:	ANDA	a. Temperature	- Indicate the USP tempe					
Application Number for NDA/AN	IDA/BLA (drug); PMA/510(k)(med dev	vice): 20656	0	•		]  т	emperature Range	Controlled Room	– between 20	and 25 C (68	° – 77° F)	
DUNS:	081468959						Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) a		nidazole Tablets, USP 250 mg					(write in)					
Selling Unit NDC: UDI	72578-007-21 N/A	Unit of Use NDC: CVX Code:		UPC: 372578 MVX Code: N/A	3007218		Votes					
									_			
Description:	White to off-white, round, biconvex, fil	Im coated tablets debossed with '850' on one sid	ie and plain	on other side.			s this product to be shipped s this product to be shipped				No No	-
Active Ingredient(s):	Metronidazole, US	SP					s this product to be shipped	to customers on	ily ice:		140	-
	Active ingredient(s).											
URL for Additional Product Inform		.com				1 1	lame:		Customer S			
Address:	20 Commerce Drive			Address 2: Suite 3			lumber:		888-304-502			
City: Key Contact:	Cranford Chris Urbanski		State: Email:	NJ Zip: Curbanski@vionaus			Group E-mail:		customers	ervice@vio	nausa.com	
Phone Number:	908-956-0600		Fax:	908-514-4005	a.com	c. Special regul	ations for product in any	states?			No	
Product Therapeutic Classificatio							Special returns requirements					
·												-
	ADDITIONAL PRODUCT IN	FORMATION		PRODUCT DESCR	RIPTION INFORMATION	d. Store produc	t (unit of sale) upright?				Yes	_
The product is?		Is the Product Direct-Ship Only	,			F	Protect product (unit of sa	le) from light?			Yes	
a legend device?	No	Is the Product Neither		Size:	250 count	e. Shelf life:					36	Months
if yes, enter class #		Orphan Drug Status				II	nitial shelf life at launch (i	f different):			24	Months
a product kit? if yes, list NDCs of	No	FDA Ammental Status		Strength:	250 mg			ORDER INFORI	MATION			
component parts		FDA Approval Status						ORDER IN OR	MATION			
reverse numbered?	No			Dosage Form:	Tablets	ι	Jnit of Sale		What is the	NDC selling	unit?	
co-licensed?	No	Allergens Present					1 Bottle		1 Bottle of 2			
latex-free?	Yes			Product Shape:	Round, Biconvex		Box/Carton		(Write-in, e.	g. 1 Box of 10	) Vials)	
preservative-free? correctional institution block?	Yes No						Ampule Glass		Minimum o	rder quantity		Yes
opioid?	No			Product Color:	White to Off-White	<del> </del>	Tube		Williamum	uer quantity	·	162
Cannabinoid?	No	Country of Origin India		Product Imprint:	"850"	1	Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	unit dose for hospital			Product imprint:	850		Vial Liquid Multi			many of whi	ch package	type?
scanning?		Is this product covered under the				<u> </u>	Vial Powder Sql		15	Each		
If Unit Dose, indicate NDC here:		Trade Agreements Act (TAA)?	<u> </u>			<del> </del>	Vial Power Multi Other: Write In		1	Inner/Carton Case	Pack	
		FOR GENERIC DRUG PRODUCTS				<u> </u>	Other. Write in			Case		
		TOR SENERIO DROCT RODOSTO										
			Autho	orized Generic *If Auth	norized Generic, other section		PH.	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	Orange Book Rating: AB fields are not applicable						customer?		Rx billing u	nit to pharma	асу:	
II. Generic Equivalent to What Brand?: Flagyl							1 Bottle		X	Each		
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION							Vial)			Gram		
					Milliliter							
Does supplier meet DSCSA defini	ition of manufacturer?	Yes GLN:		0372578000004			ITEM	AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?		No										
If yes, select exemption:							Weight Lbs.	Dimens	ons (US msn	nts.)	Volume	# Pieces:
Other exemption - Write in:							weight Lbs.	Depth	Width	Height	(Cube)	# Pieces:
Is product repackaged?				nal product purchased		Item/Each:	0.3	2.12	2.12	3.97		1
Is product sold by manufacturer's Has FDA granted waiver/exception			from mfr?	cumentation from FDA.		Box/Carton/Bur	ndle/		-			
Tras i DA grantea warver/exception			dituon doc	differentiation from FDA.		Inner Pack:	idio)					
	GTI	IN AND HIBCC PRODUCT INFORMATION				Case:	5.68	10.79	6.54	5.04		15
							3.00	10.79	0.54	3.04		15
Saleable Unit of Measure	Quantity	HIBCC	GTIN-1		Unit of Use GTIN-14	Pallet:	813.17	47.24	47.24	49.21		2,100
Item/Each Box/Carton/Bundle/Inner Pack	1		003725	578007218								
Case	15		403725	578007216			COST INFORMATION			WHOLESALI	ER USE ONL	_Y:
Pallet	2,100			578007213								
						Regular Cost			Vendor #:	_		
						Invoice Cost (W	/AC) (\$)		Whsl. Code Fineline Co			
	1					As of date:			Fineline Co	ue.		
111												
			L									
		Attach copy of SAFETY DATA SHEET (SDS)	or non haza	ard letter, PACKAGE INSE	RT, LABEL AND PHOTO OF		GING and BARCODE.					



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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: PDEA #: 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?					