

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 temperature range for this product.						
Application Number for NDA/AN	NDA/BLA (drug); PMA/510(k)(med devi]	Temperature Range	Controlled Room	- between 20	and 25 C (68	° – 77° F)					
DUNS:	081468959						Other Temperature Range F	Requirement					
Proprietary Name (If Applicable)		idazole Tablets, USP 250 mg	1				(write in)						
Selling Unit NDC:	72578-007-01 N/A	Unit of Use NDC: CVX Code:		UPC: 372578 MVX Code: N/A	8007010	'	Notes						
02.				_									
Description: White to off-white, round, biconvex, film coated tablets debossed with '850' on one side and plain on other side. Is this product to be shipped to customers on ice? Is this product to be shipped to customers on dry ice? No													
Active Ingredient(s): Is this product to be shipped to customers on dry ice? No													
3 (,)	b. Contact for t	emperature excursion que	estions:										
URL for Additional Product Infor		<u>com</u>]	Customer Service						
Address:	20 Commerce Drive			Address 2: Suite 340 State: NJ Zip: 07016			Number:		888-304-502				
City: Key Contact:	Cranford Chris Urbanski		Email:	Curbanski@vionaus		Group E-mail: <u>customerservice@vionausa.com</u>							
Phone Number:	908-956-0600		Fax:	908-514-4005	<u>a.com</u>	c. Special regu	lations for product in any	states?			No		
Product Therapeutic Classification	on:						Special returns requirement						
	ADDITIONAL PRODUCT INF	FORMATION		PRODUCT DESCR	RIPTION INFORMATION	d. Store produc	ct (unit of sale) upright?				Yes		
The product is?		Is the Product Direct-Ship 0	Only				Protect product (unit of sa	ale) from light?			Yes	•	
a legend device?	No	Is the Product Neither		Size:	100 count	e. Shelf life:					36	Months	
if yes, enter class # a product kit?	No	Orphan Drug Status				- '	nitial shelf life at launch (i	it different):			24	Months	
if yes, list NDCs of	140	FDA Approval Status		Strength:	250 mg			ORDER INFOR	MATION				
component parts				Dosage Form:	Tablets								
reverse numbered?	No			Dosage i oiiii.	Tableto	_	Jnit of Sale			NDC selling	unit?		
co-licensed? latex-free?	No	Allergens Present				Ц	1 Bottle Box/Carton		1 Bottle of 1	00 Tablets g. 1 Box of 1	0 Viole)		
preservative-free?	Yes Yes			Product Shape:	Round, Biconvex		Ampule		(vviite-iii, e	g. I box of fi	o viais)		
correctional institution block?				Product Color:	White to Off-White	1	Glass		Minimum o	rder quantity	/?	Yes	
opioid?	No			Product Color:	white to On-white		Tube						
Cannabinoid?	<u>No</u>	Country of Origin India		Product Imprint:	"850"		Vial Liquid Sgl						
If Unit Dose, is item bar coded to a scanning?	unit dose for hospital	Is this product covered under the				╂	Vial Liquid Multi Vial Powder Sql		If Yes, how	many of whi Each	ch package t	type?	
If Unit Dose, indicate NDC here:		Trade Agreements Act (TAA)?	No			ll F	Vial Powder Sqr Vial Power Multi		24	Inner/Carton	/Pack		
							Other: Write In		1	Case			
		FOR GENERIC DRUG PRODUCTS								='			
			Auth		norized Generic, other section								
I. Orange Book Rating:						Rec. sell unit to customer? Rx billing unit to pharmacy: 1 Bottle x Each							
II. Generic Equivalent to What Br	and?: Flagyl					(Write-in, e.g. 1		ļ	X	Gram			
	(vviite iii, e.g. i	viai)			Milliliter								
						,				•			
Does supplier meet DSCSA defin Is product exempt from DSCSA?		Yes GI	LN:	0372578000004			ITEM	AND PACKING	INFORMATIO	N_			
If yes, select exemption:						1		Dimono	sions (US msn	ato \	Volume		
Other exemption - Write in:							Weight Lbs.	Depth	Width	Height	(Cube)	# Pieces:	
Is product repackaged?		No If	Yes, was origi	nal product purchased		Item/Each:	0.16	1.68	1.68	3.19		1	
Is product sold by manufacturer's			rect from mfr?					1.00	1.00	3.19		'	
Has FDA granted waiver/exception	on/exemption for product?	No If	yes, attach do	cumentation from FDA.		Box/Carton/Bu Inner Pack:	ndle/						
	GTIN	N AND HIBCC PRODUCT INFORMATION				Case:							
	3					Case.	4.88	10.04	6.69	3.94		24	
Saleable Unit of Measure	Quantity	HIBCC	GTIN-		Unit of Use GTIN-14	Pallet:	799.87	47.24	47.24	49.21		3.840	
Item/Each	1		00372	578007010			100.01			10.21		0,010	
Box/Carton/Bundle/Inner Pack Case	x/Carton/Bundle/Inner Pack se 24 40372578007018						COST INFORMATION WHOLESALER USE ONLY:						
Pallet	3,840			578007015			Joor III ORIIIATION			OLEOAL	LIN OOL ONE		
						Regular Cost			Vendor #:				
						Invoice Cost (V	VAC) (\$)		Whsl. Code				
	┥		-			As of data:		ļ	Fineline Co	de:			
						As of date:							
		Attach copy of SAFETY DATA SHEET (SI	OS) or non haza	ard letter, PACKAGE INSE	RT, LABEL AND PHOTO OF	PRODUCT PACKA	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?					