

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

Version 2020				Introduction Type:	New Item	х	Final Version			Date:	4/12/	/2023
		PRODUCT INFORMATION					SPECIAL HAN	IDLING AND STO	RAGE REQUI	REMENTS*		
Company Name:	Viona Pharmaceuticals Inc.	ANDA	a. Temperature – Indicate the USP temperature range for this product.									
Application Number for NDA/AN	IDA/BLA (drug); PMA/510(k)(med devi		Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)									
DUNS:	081468959						Temperature Range	Requirement				
Proprietary Name (If Applicable)		azole Orally Disintegrating Tablets,	USP 10 mg			- 1	(write in)					
Selling Unit NDC:	72578-106-78 N/A	Unit of Use NDC: CVX Code:		UPC: 372578 MVX Code: N/A	106782	Notes						
02.	White to off-white, capsule-shaped, unc		1! an ana aida and alais			]   ]   la shie	nundrint to be object	d to a cotomo and and i			No	
Description:	write to on-write, capsule-snaped, uni	coated tablets debossed with ZF 4	on one side and plair	i on the other side.			product to be shipped product to be shipped				No	•
Active Ingredient(s):	Aripiprazole, USP	1	F		,			•				
	b. Contact for temperature excursion questions:  Name:  Customer Service											
URL for Additional Product Inform Address:	mation: www.vionausa.c	<u>com</u>		Address 2: Suite 3	40	Name			888-304-502			
City:	20 Commerce Drive Cranford			State: NJ Zip: 07016			Number: Group E-mail:			customerservice@vionausa.com		
Key Contact:	Chris Urbanski		Email:	Curbanski@vionausa		1						
Phone Number:	908-956-0600		Fax:	908-514-4005		c. Special regulation	ns for product in any	states?			No	_
Product Therapeutic Classification	Antipsychotics					Speci	al returns requiremen	ts for this product?			No	_
	ADDITIONAL PRODUCT INF	CORMATION		PRODUCT DESCR	IPTION INFORMATION	d. Store product (ur	it of ools)inht?				No	
<b>-</b>	ADDITIONAL PRODUCT INF		. 01: 0.1	PRODUCT DESCR	IPTION INFORMATION							•
The product is? a legend device?	No	Is the Product Direct Is the Product Neith	ct-Ship Only			e. Shelf life:	ct product (unit of s	ale) from light?			No 24	Months
if yes, enter class #	NO	Orphan Drug Status		Size:	30		shelf life at launch (	if different):			2-7	Months
a product kit?	No			Strength:	10 mg			•				
if yes, list NDCs of		FDA Approval Status		on ongun				ORDER INFORI	MATION			
component parts reverse numbered?	No			Dosage Form:	Orally Disintegrating Tablet	Unit	of Sale		What is the	NDC selling	unit?	
co-licensed?	No	Allergens Present			Tablet		Bottle		1 Carton of 3		unit.	
latex-free?	Yes			Product Shape:	Capsule	x	Box/Carton			g. 1 Box of 10	) Vials)	
preservative-free?	Yes			r roudet onape.	Capsule		Ampule					
correctional institution block? opioid?	No No			Product Color:	White to off-white		Glass Tube		Minimum o	rder quantity	?	Yes
Cannabinoid?	No	Country of Origin India	1				Vial Liquid Sgl					
If Unit Dose, is item bar coded to u				Product Imprint:	ZF 41		Vial Liquid Multi		If Yes, how	many of whi	ch package t	type?
scanning?		Is this product covered under the			•		Vial Powder Sql		24	Each		
If Unit Dose, indicate NDC here:		Trade Agreements Act (TAA)?	No				Vial Power Multi Other: Write In		1	Inner/Carton Case	/Pack	
		FOR GENERIC DRUG PRODUCT	rs			<u> </u>	Other, write in		<u> </u>	Case		
		TOR CENERIO DROCT RODOC							_			
			Auth		orized Generic, other section	PHARMACY ORDER / 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	Abilify Discmelt					Each						
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION  (Write-in, e.g. 1 Vial)										Gram Milliliter		
	DR03 30112	TOTAL DECOME TACT (DOCO	A) IN ORMATION							willinter		
Does supplier meet DSCSA defin	ition of manufacturer?	Yes	GLN:	0372578000004			ITEN	I AND PACKING I	NFORMATIO	١		
Is product exempt from DSCSA?		No				1						
If yes, select exemption:					_		Weight Lbs.		ions (US msn	-	Volume	# Pieces:
Other exemption - Write in: Is product repackaged?		No	If Voc was origi	nal product purchased		Item/Each:	-	Depth	Width	Height	(Cube)	
Is product repackaged:	s exclusive distributor?	No	direct from mfr?			item/Lacii.	0.088	5.51	2.36	1.26		1
Has FDA granted waiver/exception	n/exemption for product?	No	If yes, attach do	cumentation from FDA.		Box/Carton/Bundle						
	CTIN	N AND HIBCC PRODUCT INFORM	MATION			Inner Pack:						
	GIIN	AND HIBCC PRODUCT INFORM	MATION			Case:	3.23	11.81	7.87	6.1		24
Saleable Unit of Measure	Quantity	HIBCC	GTIN-	14	Unit of Use GTIN-14	Pallet:	297.348	48	40	39		1.800
X Item/Each	1			578106782			297.348	48	40	39		1,600
Box/Carton/Bundle/Inner Pack							COST INFORMATION WHOLESALER USE ONLY:					
x Case x Pallet	1,800			578106780		C	331 INFORMATION			MIOEESAL	LK USE UNL	<del></del>
A Fund	1,000								Vendor #:			
						Regular Cost Invoice Cost (WAC)	(\$)		Whsl. Code			
	-					A 6 - d - 1			Fineline Co	de:		
						As of date:						
1		Attach copy of SAFETY DATA SH	EET (SDS) or non hazz	ard letter, PACKAGE INSE	RT. LABEL AND PHOTO OF	PRODUCT PACKAGING	and BARCODE.		1			



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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?					