

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

Version 2020				Introduction Type:	Post Launch Change	х	Final Version			Date:	4/28	/2023		
		PRODUCT INFORMATION					SPECIAL HAN	IDLING AND STO	RAGE REQUI	REMENTS*				
Company Name:	Viona Pharmaceuticals Inc. Application: ANDA  Application: ANDA  Application: ANDA  Application: 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) a		azole Orally Disintegrating Tablets, USP 1	5 mg			4	(write in)							
Selling Unit NDC:	72578-107-06 N/A	Unit of Use NDC: CVX Code:		UPC: 372578 MVX Code: N/A	107062	Notes	•							
02.			401 11	_		]   }								
Description:	White to off-white, round-shaped, bicor	nvex, uncoated tablets debossed with 'ZF	42' on one side	and plain on other side.			product to be shipped				No No			
Active Ingredient(s):  Aripiprazole, USP  Is this product to be shipped to customers on dry ice?  No														
3 (,,	11	b. Contact for temp	erature excursion qu	estions:										
URL for Additional Product Inform							Name:				Customer Service			
Address:	20 Commerce Drive			Address 2: Suite 340 State: NJ Zip: 07016		Number:			888-304-5022					
City: Key Contact:	Chris Urbanski	Cranford Chris Urbanski			Email: Curbanski@vionausa.com			Group E-mail:			customerservice@vionausa.com			
Phone Number:	908-956-0600		Fax:	908-514-4005		c. Special regulation	ns for product in any	states?			No			
Product Therapeutic Classification	n: Antipsychotics						al returns requiremen				No			
•			_			·	•	•						
	ADDITIONAL PRODUCT INF	ORMATION		PRODUCT DESCR	IPTION INFORMATION	d. Store product (ur	nit of sale) upright?				Yes			
The product is?		Is the Product Direct-Ship	Only				ct product (unit of s	ale) from light?			No	_		
a legend device?	No	Is the Product Neither		Size:	30ct	e. Shelf life:					24	Months		
if yes, enter class # a product kit?	Ne	Orphan Drug Status				Initia	shelf life at launch (	(if different):				Months		
if yes, list NDCs of	No	FDA Approval Status		Strength:	15 mg			ORDER INFOR	MATION					
component parts		. Dr. r.pp. o va. otatao		Deceme Fermi	Ozolly Digintograting									
reverse numbered?	No			Dosage Form:	Orally Disintegrating		of Sale			NDC selling	unit?			
co-licensed?	No	Allergens Present				x			1 Bottle of 3					
latex-free? preservative-free?	Yes Yes			Product Shape:	Round	<del>                                </del>	Box/Carton Ampule		(Write-in, e	.g. 1 Box of 10	) Viais)			
correctional institution block?	Yes					-	Glass		Minimum o	rder quantity	1?	Yes		
opioid?	No			Product Color:	White to off-white		Tube							
Cannabinoid?	No	Country of Origin India		Product Imprint:	"ZF 42"		Vial Liquid Sgl							
If Unit Dose, is item bar coded to u	unit dose for hospital			i roudot iii.priiiti	22		Vial Liquid Multi			many of whi	ch package	type?		
scanning? If Unit Dose, indicate NDC here:		Is this product covered under the Trade Agreements Act (TAA)?	No				Vial Powder Sql Vial Power Multi		24	Each Inner/Carton	/Dook			
Il Offit Dose, indicate NDC fiere.		Trade Agreements Act (TAA):	No				Other: Write In		1	Case	/rack			
		FOR GENERIC DRUG PRODUCTS				<u> </u>								
			Auth		orized Generic, other section	n PHARMACY ORDER / BILL UNIT								
I. Orange Book Rating:	AB			fields ai	e not applicable	Rec. sell unit to cus		=		nit to pharm	асу:			
II. Generic Equivalent to What Bra	Abilify Discmelt						ottle		х	Each				
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION  (Write-in, e.g. 1 Vial)  Gram  Milliliter														
	2.100 00.1 2.1		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,							willinger				
Does supplier meet DSCSA defin	ition of manufacturer?		LN:	0372578000004			ITEN	M AND PACKING I	NFORMATIO	N				
Is product exempt from DSCSA?		No												
If yes, select exemption:							Weight Lbs.		ions (US msn	-	Volume	# Pieces:		
Other exemption - Write in:		Ne				h		Depth	Width	Height	(Cube)			
Is product repackaged? Is product sold by manufacturer's	e evolucive distributor?		res, was orig	inal product purchased		Item/Each:	0.086	1.57	1.57	3.86		1		
Has FDA granted waiver/exception				cumentation from FDA.		Box/Carton/Bundle	,							
3			-			Inner Pack:								
	GTIN	AND HIBCC PRODUCT INFORMATION	ı			Case:	3.02	7.87	5.91	8.66		24		
Saleable Unit of Measure	Quantita	LUDOO	OTIN	44	Helicat Hay OTIN 44	Pallet:		-						
X Item/Each	Quantity	HIBCC	GTIN	-14 2578107062	Unit of Use GTIN-14	Pallet:	417.82	48	40	46.6		2,880		
Box/Carton/Bundle/Inner Pack														
x Case	24 40372578107060					С	OST INFORMATION			WHOLESAL	ER USE ONL	.Y:		
x Pallet	2,880		50372	2578107067										
	┥		+ -			Regular Cost Invoice Cost (WAC)	(\$)		Vendor #: Whsl. Code	#-				
	1					roide dost (WAO)	(+)		Fineline Co					
						As of date:		*						
*Please provide any additional inf		Attach copy of SAFETY DATA SHEET (S	SDS) or non haz	ard letter, PACKAGE INSEI See new p. 3 for Design			and BARCODE.							



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

MATERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic? 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	SDS Hazard Classification  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?  No  Is this product regulated for shipment by DOT?	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 e. Inhalation Hazard?  No	Hazardous Waste Identification  EPA Hazardous Waste Code:  Waste Characteristics					
Is this product regulated for shipment by IATA?  (if yes, answer a-e below and provide SDS)  a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group	REMS or REGISTRY RESTRICTIONS  Is there a REMS on this product?  If Yes, is it managed with a pharmacy registry?  Website URL:					
e. Inhalation Hazard?  Is the product restricted for air shipment? If so, indicate restriction:  Passenger Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)					
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:  POPDP#:  NPI #:					
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#  ADD'L STORAGE INFORMATION	Registry:  Registry Program Contact Name:  Comments  Phone:					
Is the Product  Controlled Substance?  Controlled Substance Code  Controlled by State(s)?  No Listed Chemical (List I or II)	RETURN INSTRUCTIONS					
ARCOS Reportable?  Schedule No.  If yes, indicate which:  Is it a scheduled listed chemical product?:  CLASS OF TRADE RESTRICTION:	Contact tel. # if product received damaged:  Is product returnable for credit:  URL/Link to returns policy:  Yes					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  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?					
MISCELLANE	DUS 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?					