

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

Version 2020						Introduction Type:	New Item		x Final Version			Date:	3/29/	/2024
			PRODUCT INFORMA	TION					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/Al	IDA/BLA (drug); PMA/510(k)(med device): 215666				5666	•	•	Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)						
DUNS: 081468959							0	ther Temperature Range I	Requirement					
Proprietary Name (If Applicable)		ne: Bisopro	lol Fumarate and Hydrochlo	rothiazide Table	ets, USP 10 m]	(write in)					
Selling Unit NDC:	72578-115-05		Unit of Use NDC:			UPC: 372578	115050	N-	otes					
52 .	N/A		CVX Code:			MVX Code: N/A]			_			
Description:	White to off-white co other side.	olored with occasio	nal greyish to black speckle	s, round shaped	d, film-coated t	ablets, debossed with '115'	on one side and plain on		this product to be shipped				No No	
other side. Is this product to be shipped to customers on dry ice? Active Ingredient(s): Bisoprolol Fumarate, USP and Hydrochlorothiazide, USP									•					
									b. Contact for temperature excursion questions:					
URL for Additional Product Infor		www.vionausa.c	<u>om</u>					4 1	ame:		Customer S			
Address:	20 Commerce Drive			Address 2: Suite 340 State: NJ Zip: 07016			Number:			888-304-5022 customerservice@vionausa.com				
City: Key Contact:	Cranford Chris Urbanski			Email:		Curbanski@vionausa.com		Group E-mail:			<u>customerservice@vionausa.com</u>			
Phone Number:	908-956-0600				Fax:	908-514-4005		c. Special regulations for product in any states?					No	
Product Therapeutic Classification	on:	Antihypertensive							pecial returns requirement				No	
					1				•	·				
	ADDITION	AL PRODUCT INF	ORMATION			PRODUCT DESCR	IPTION INFORMATION	d. Store product	(unit of sale) upright?				Yes	
The product is?			Is the Product	Direct-Ship C	Only				otect product (unit of sa	ale) from light?			No	•
a legend device?		No	Is the Product	Neither		Size:	500 ct	e. Shelf life:					24	Months
if yes, enter class # a product kit?		No	Orphan Drug Status					II In	itial shelf life at launch (if different):				Months
if yes, list NDCs of		140	FDA Approval Status			Strength:	10 mg/6.25 mg			ORDER INFOR	MATION			
component parts						Dosage Form:	Tablet							
reverse numbered?		No				Dosage Form.	rabiet	<u>U</u>	nit of Sale			NDC selling	unit?	
co-licensed? latex-free?		No	Allergens Present						x Bottle Box/Carton		1 Bottle of 5	00 Tablets .g. 1 Box of 10	O Miele)	
preservative-free?		Yes Yes				Product Shape:	Round		Ampule		(vviite-iii, e	.g. i box oi it	J Viais)	
correctional institution block?		No				Product Color:	White to Off-white		Glass		Minimum o	rder quantity	/?	Yes
opioid?	1	No				Product Color:	vvnite to Off-white		Tube					
Cannabinoid?		No	Country of Origin	India		Product Imprint:	115		Vial Liquid Sgl					
If Unit Dose, is item bar coded to scanning?	unit dose for hospital		Is this product covered u						Vial Liquid Multi Vial Powder Sql		If Yes, how	many of whi Each	ch package	type?
If Unit Dose, indicate NDC here:			Trade Agreements Act (1		No				Vial Power Multi		12	Inner/Carton	/Pack	
			1 3	,					Other: Write In		1	Case		
			FOR GENERIC DRUG PR	ODUCTS										
									DI.	IARMAOV ORDE	A COULT LINET			
	4.5			_	Auth		orized Generic, other section e not applicable							
I. Orange Book Rating: II. Generic Equivalent to What Brand?: Ziac					noido di	о постаринално	Rec. sell unit to customer? 1 Bottle			Rx billing unit to pharmacy:				
ii. Generic Equivalent to What Bi	<u> </u>	Ziac						(Write-in, e.g. 1		1		Gram		
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION (Milliliter														
		_	V			007057000004			ITC	A AND DAOIGNO	NEODMATIO	N.		
Does supplier meet DSCSA defing Is product exempt from DSCSA?			Yes No	GL	.rv:	0372578000004			TIEN	I AND PACKING I	MFORMATIO	IN .		
If yes, select exemption:	-			_				1		Dimons	ions (US msr	nte \	Volume	
Other exemption - Write in:	Г								Weight Lbs.	Depth	Width	Height	(Cube)	# Pieces:
Is product repackaged?	L		No	If Y	es, was origi	nal product purchased		Item/Each:	0.28	1.9	1.9	3.8		1
Is product sold by manufacturer			No	_	ect from mfr					1.5	1.5	5.0		'
Has FDA granted waiver/exception	on/exemption for pro	duct?	No	If y	es, attach do	cumentation from FDA.		Box/Carton/Bun Inner Pack:	dle/					
		GTIN	AND HIBCC PRODUCT IF	FORMATION				Case:						
									4.36	7.87	5.98	4.8		12
Saleable Unit of Measure		Quantity	HIBCC		GTIN-		Unit of Use GTIN-14	Pallet:	962.96	47.24	39.37	47.24		2.604
X Item/Each	_	1			00372	2578115050								,
Box/Carton/Bundle/Inner Pack X Case	-	12			40372	2578115058			COST INFORMATION			WHOLESALI	ER USE ONL	Y:
x Pallet		2,604				2578115055								
								Regular Cost			Vendor #:			
	4 [Invoice Cost (W	AC) (\$)		Whsl. Code			
	┥ ト							As of date:			Fineline Co	ue:		
								, 10 0. date.						
			Attach copy of SAFETY DA	TA SHEET (SD	S) or non haz	ard letter, PACKAGE INSEI	RT, LABEL AND PHOTO OF	PRODUCT PACKAG	ING and BARCODE.					
i e	formation on page 2.					See new p. 3 for Design	ated Dren Chin Only	e	anature:					



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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?