

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	NDA/BLA (drug); PMA/510(k)(med device): 215666				5666	*	•	Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)						
DUNS: 081468959									Other Temperature Range F	Requirement				
Proprietary Name (If Applicable)		e: Bisopre	olol Fumarate and Hydrochlo	rothiazide Table	ets, USP 10 m]	(write in)					
Selling Unit NDC:	72578-115-01		Unit of Use NDC:			UPC: 372578	115012	1	Notes					
02.	N/A		CVX Code:			MVX Code: N/A		<u> </u>						
Description:	White to off-white co other side.	olored with occasion	nal greyish to black speckle	s, round shaped	d, film-coated t	tablets, debossed with '115'	on one side and plain on		s this product to be shipped				No No	-
other side. Active Ingredient(s): Bisoprolol Fumarate, USP and Hydrochlorothiazide, USP Is this product to be shipped to customers on dry ice? No										-				
Active ingredients).									b. Contact for temperature excursion questions:					
URL for Additional Product Infor		www.vionausa.	<u>com</u>						Name:		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		{ `	Group E-mail:		customers	service@vic	nausa.com		
Phone Number:	908-956-0600			Fax: 908-514-4005			c. Special regulations for product in any states?			No				
Product Therapeutic Classification		Antihypertensive							Special returns requirement				No	•
	_				<u> </u>				.,					-
	ADDITION	AL PRODUCT IN	FORMATION			PRODUCT DESCR	IPTION INFORMATION	d. Store produc	ct (unit of sale) upright?				Yes	_
The product is?			Is the Product	Direct-Ship C	Only			F	Protect product (unit of sa	ale) from light?			No	
a legend device?	1	No	Is the Product	Neither		Size:	100 ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status					"	nitial shelf life at launch (if different):				Months
a product kit? if yes, list NDCs of		No	FDA Approval Status			Strength:	10 mg/6.25 mg			ORDER INFOR	MATION			
component parts			1 DA Appiovai Giatas			B	T-1-1-4							
reverse numbered?		No				Dosage Form:	Tablet	<u>_ </u>	Jnit of Sale			NDC selling	unit?	
co-licensed?		No	Allergens Present						x Bottle		1 Bottle of 1			
latex-free?		resres				Product Shape:	Round	II	Box/Carton		(Write-in, e.	.g. 1 Box of 1	0 Vials)	
preservative-free? correctional institution block?		No						II F	Ampule Glass		Minimum o	rder quantity	17	Yes
opioid?		No				Product Color:	White to Off-white	II F	Tube			raor quartity		
Cannabinoid?		No	Country of Origin	India		Product Imprint:	115		Vial Liquid Sgl					
If Unit Dose, is item bar coded to	unit dose for hospital					r roudet imprint.	113		Vial Liquid Multi			many of whi	ch package	type?
scanning?	_		Is this product covered un Trade Agreements Act (1		No				Vial Powder Sql Vial Power Multi		24	Each	/Deels	
If Unit Dose, indicate NDC here:	L		Trade Agreements Act (1	AA)!	No			II ⊢	Other: Write In		1	Inner/Carton Case	/Pack	
			FOR GENERIC DRUG PR	ODUCTS				<u> </u>				1		
Authorized Generic *If Authorized Generic, other section								PHARMACY ORDER / BILL UNIT						
I. Orange Book Rating: AB fields are not					e not applicable	Rec. sell unit to customer? Rx billing unit to pharmacy:								
II. Generic Equivalent to What Brand?: Ziac						1 Bottle			ļ	x Each				
		DRUG SUPPI	Y CHAIN SECURITY ACT (DSCSA) INFOR	RMATION			(Write-in, e.g. 1	Vial)			Gram Milliliter		
		51.00 00.12		2000/., O.								I willinger		
Does supplier meet DSCSA defin		r?	Yes	GL	N:	0372578000004			ITEN	I AND PACKING I	INFORMATIO	N		
Is product exempt from DSCSA?	, _		No	_]						
If yes, select exemption:	_								Weight Lbs.		ions (US msn	-	Volume	# Pieces:
Other exemption - Write in:	L		No			to all one deset according and		11 /E b -	1	Depth	Width	Height	(Cube)	
Is product repackaged? Is product sold by manufacturer	's exclusive distribute	or?	No		res, was origi ect from mfr?	inal product purchased		Item/Each:	0.12	1.61	1.61	2.98		1
Has FDA granted waiver/exception			No	_		cumentation from FDA.		Box/Carton/Bu	ndle/					
								Inner Pack:						
		GTII	N AND HIBCC PRODUCT I	NFORMATION				Case:	3.88	9.72	6.51	3.81		24
Saleable Unit of Measure	,	Quantity	HIBCC		GTIN-	1.4	Unit of Use GTIN-14	Pallet:						
X Item/Each	Ĺ	2uaniity	ПВСС			2578115012	Offic of Ose G file-14	Fallet.	785.64	47.24	39.37	47.24		4,752
Box/Carton/Bundle/Inner Pack														
x Case		24				2578115010			COST INFORMATION			WHOLESAL	ER USE ONL	.Y:
x Pallet	_, -	4,752			50372	2578115017		D 0 1						
	┥ ト				-			Regular Cost Invoice Cost (W	VAC) (\$)		Vendor #: Whsl. Code	#:		
	⊣ ⊦								-/ \+/		Fineline Co			
								As of date:		•				
								11						
*Please provide any additional in	formation on page 2		Attach copy of SAFETY DA	I A SHEET (SD	ාර) or non haz	ard letter, PACKAGE INSER See new p. 3 for Design	RT, LABEL AND PHOTO OF lated Drop Ship Only.		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?