

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

Version 2020					Introduction Type:	New Item	] [	x Final Version			Date:	3/29/	/2024
		PRODUCT INFORMAT	ION					SPECIAL HAN	DLING AND STO	RAGE REQUI	REMENTS*		
Company Name:	Viona Pharmaceuticals Inc.				Application:	ANDA	a. Temperature	e - Indicate the USP tempe					
Application Number for NDA/AN	DA/BLA (drug); PMA/510(k)(med device): 215666							Temperature Range	Controlled Room	- between 20	and 25 C (68	° – 77° F)	
DUNS:	081468959						_	Other Temperature Range F	Requirement				
Proprietary Name (If Applicable)		olol Fumarate and Hydrochlor	othiazide Tablets	s, USP 5 mg				(write in)					
Selling Unit NDC:	72578-114-05 N/A	Unit of Use NDC: CVX Code:			UPC: 372578	114053	4	Notes					
02.	Light pink to pink colored, round shape						<u> </u>	la this anadost to be ables as		0		No	
Description:	Light pink to pink colored, round shape	ed, IIIII-coated tablets, debos	sea with 114 on	one side and	a piain on other side.			Is this product to be shipped Is this product to be shipped				No	-
Active Ingredient(s):  Bisoprolol Fumarate, USP and Hydrochlorothiazide, USP											-		
		temperature excursion qu	estions:	-									
URL for Additional Product Inform Address:	mation: www.vionausa.c	<u>com</u>			Address 2: Suite 3	40	-1	Name: Number:		Customer S 888-304-502			
City:	Cranford			State:		07016		Group E-mail:				nausa.com	1
Key Contact:	Chris Urbanski			Email:	Curbanski@vionausa		1			cascomer	CI VICE C VIC		
Phone Number:	908-956-0600			Fax:	908-514-4005		c. Special regu	lations for product in any	states?			No	_
Product Therapeutic Classification	Antihypertensive							Special returns requirement	s for this product?			No	_
	ADDITIONAL PRODUCT INF	FORMATION			BRODUCT DESCR	IPTION INFORMATION	4 640-0	ct (unit of sale) upright?				Yes	
The area dept to 0	ADDITIONAL PRODUCT INF		Discost Ohio Onl		PRODUCT DESCR	IFTION INFORMATION	11		-l-\				-
The product is? a legend device?	No	Is the Product Is the Product	Direct-Ship On Neither	y			e. Shelf life:	Protect product (unit of sa	ale) from light?			No 24	Months
if yes, enter class #	140	Orphan Drug Status	recurer		Size:	500 ct		Initial shelf life at launch (	if different):			2-7	Months
a product kit?	No				Strength:	5 mg/6.25 mg							•
if yes, list NDCs of		FDA Approval Status			ou ou gun	o mgroizo mg			ORDER INFOR	MATION			
component parts reverse numbered?	No				Dosage Form:	Tablet		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?	No	Allergens Present						x Bottle		1 Bottle of 5		<u> </u>	
latex-free?	Yes	_			Product Shape:	Round		Box/Carton		(Write-in, e	g. 1 Box of 10	0 Vials)	
preservative-free?	Yes				Troudet onape.	rtound		Ampule				_	
correctional institution block? opioid?	No No				Product Color:	Light Pink to Pink		Glass Tube		Minimum o	rder quantity	/?	Yes
Cannabinoid?	No	Country of Origin	India					Vial Liquid Sgl					
If Unit Dose, is item bar coded to u		, ,			Product Imprint:	114		Vial Liquid Multi				ch package t	type?
scanning?		Is this product covered un						Vial Powder Sql		12	Each		
If Unit Dose, indicate NDC here:		Trade Agreements Act (TA	4A)? <u>r</u>	10				Vial Power Multi Other: Write In		1	Inner/Carton Case	/Pack	
		FOR GENERIC DRUG PRO	DUCTS					Other: Wille III			10000		
				Auth		orized Generic, other section		PH	ARMACY ORDER	R / BILL UNIT			
I. Orange Book Rating:							Rec. sell unit to customer? Rx billing unit to pharmacy:						
II. Generic Equivalent to What Bra	and?: Ziac						1	1 Bottle	1	х	Each		
	DRUG SUPPL	Y CHAIN SECURITY ACT (D	SCSA) INFORM	IATION			(Write-in, e.g.	i viai)			Gram Milliliter		
		•	,								1		
Does supplier meet DSCSA defin		Yes	GLN	:	0372578000004			ITEN	AND PACKING	INFORMATIO	N		
Is product exempt from DSCSA?		No	_			_	1						
If yes, select exemption: Other exemption - Write in:								Weight Lbs.	Dimens Depth	ions (US msr Width	nts.) Height	Volume (Cube)	# Pieces:
Is product repackaged?		No	If Ye	s. was origi	nal product purchased		Item/Each:	0.00				(Gube)	
Is product sold by manufacturer's	s exclusive distributor?	No		t from mfr?				0.28	1.9	1.9	3.8		1
Has FDA granted waiver/exception	on/exemption for product?	No	If yes	s, attach do	cumentation from FDA.		Box/Carton/Bu	indle/					
	GTIN	N AND HIBCC PRODUCT IN	FORMATION				Inner Pack: Case:						
	3						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	578114053			002.00		20.0.			_,50 .
Box/Carton/Bundle/Inner Pack  X Case	12			40372	578114051			COST INFORMATION			WHOLESAL	ER USE ONL	Y:
x Pallet	2,604				578114058								
							Regular Cost			Vendor #:			
							Invoice Cost (	WAC) (\$)		Whsl. Code Fineline Co			
							As of date:			1			
							As of date:						
*Please provide any additional in		Attach copy of SAFETY DA	TA SHEET (SDS	) or non haza	ard letter, PACKAGE INSEF	RT, LABEL AND PHOTO OF	PRODUCT PACKA	GING and BARCODE.	•				



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

#### Version 2020

### 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: PPUBLICATION Phone:  DEA #: 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:						



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

### Version 2020

### 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?