

## **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 Pharmaceutica	als Inc.				Application:	ANDA	a. Temperatu	re – Indicate the USP tempe	erature range for	this product.			
Application Number for NDA/AN	IDA/BLA (drug); PMA	/510(k)(med devic	ce):	215	666	·		]	Temperature Range	Controlled Room	- between 20	and 25 C (68	° – 77° F)	
DUNS:	081468959								Other Temperature Range	Requirement				
Proprietary Name (If Applicable) a		e: Bisopro	olol Fumarate and Hydrochlo		ts, USP 2.5 m			]	(write in)					
Selling Unit NDC:	72578-113-05		Unit of Use NDC:				3113056		Notes					
UDI	N/A		CVX Code:			MVX Code: N/A								
Description:		colored with occa	asional greyish to black spe	ckles, round shap	ed, film-coate	d tablets, debossed with '	113' on one side and plain on		Is this product to be shipped				No	
Active Ingredient(s): Bisoprolol Fumarate, USP and Hydrochlorothiazide, USP									Is this product to be shipped		dry ice?		No	
URL for Additional Product Inform	nation:	ww.vionausa.c						b. Contact for	r temperature excursion qu Name:	estions:	Customer Se	anvice		
Address:	20 Commerce Drive		.0111			Address 2: Suite 3	340	11	Number:		888-304-502			
City:				State:		07016	Group E-mail:			customerservice@vionausa.com				
Key Contact:	Chris Urbanski Email:			Curbanski@vionausa	a.com	1								
Phone Number:	908-956-0600				Fax:	908-514-4005		c. Special reg	julations for product in any	states?			No	
Product Therapeutic Classificatio	n: A	ntihypertensive							Special returns requirement	s for this product?			No	
	ADDITIONA	AL PRODUCT INF	ORMATION			PRODUCT DESCR	RIPTION INFORMATION	d. Store prod	uct (unit of sale) upright?				Yes	
The product is?			Is the Product	Direct-Ship Or	nly				Protect product (unit of sa	ale) from light?			No	
a legend device?	N	0	Is the Product	Neither		Size:	500 ct	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status						Initial shelf life at launch (	if different):				Months
a product kit? if yes, list NDCs of	N	0	FDA Approval Status			Strength:	2.5 mg/6.25 mg			ORDER INFOR	MATION			
component parts			I DA Appioval Status											
reverse numbered?	N	.0				Dosage Form:	Tablet		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?	N		Allergens Present						x Bottle		1 Bottle of 50	00 Tablets		
latex-free?		es				Product Shape:	Round		Box/Carton		(Write-in, e.	g. 1 Box of 10	Vials)	
preservative-free?		es							Ampule				_	
correctional institution block?	N					Product Color:	Light Yellow to Yellow		Glass		Minimum o	rder quantity	?	Yes
opioid? Cannabinoid?	<u>N</u>		Country of Origin	India					Tube Vial Liquid Sgl					
If Unit Dose, is item bar coded to u		5	Country of Origin	India		Product Imprint:	113		Vial Liquid Ogl		If Yes, how	many of whi	ch nackage i	vne?
scanning?			Is this product covered u	inder the					Vial Powder Sql			Each	on puonago i	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
If Unit Dose, indicate NDC here:			Trade Agreements Act (	TAA)?	No				Vial Power Multi			Inner/Carton	Pack	
			-	-					Other: Write In		1	Case		
			FOR GENERIC DRUG PR	ODUCTS										
				,										
					Autho		norized Generic, other section re not applicable			ARMACY ORDER				
I. Orange Book Rating:	AB					Tielus a	re not applicable	Rec. sell unit	to customer?	-	Rx billing u	nit to pharma	acy:	
II. Generic Equivalent to What Bra	and?: Zi	ac												
									1 Bottle	1	x	Each		
			Y CHAIN SECURITY ACT (	(DSCSA) INFOR	MATION			(Write-in, e.g.		1	x	Gram		
			Y CHAIN SECURITY ACT (	(DSCSA) INFORI	MATION			(Write-in, e.g.		1	X			
Does supplier meet DSCSA defini	ition of manufacturer	DRUG SUPPLY	Y CHAIN SECURITY ACT ( Yes	(DSCSA) INFOR		0372578000004		(Write-in, e.g.	. 1 Vial)	AND PACKING		Gram Milliliter		
Does supplier meet DSCSA defini Is product exempt from DSCSA?	ition of manufacturer	DRUG SUPPLY				0372578000004		(Write-in, e.g.	. 1 Vial)	I AND PACKING		Gram Milliliter		
	ition of manufacturer	DRUG SUPPLY	Yes			0372578000004		(Write-in, e.g.	. 1 Vial) ITEN			Gram Milliliter	Volume	# Diacocc
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	ition of manufacturer	DRUG SUPPLY	Yes No	GLM	1:				. 1 Vial)		NFORMATIO	Gram Milliliter	Volume (Cube)	# Pieces:
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?		DRUG SUPPLY	Yes No No	GLM 	l: es, was origir	nal product purchased		(Write-in, e.g.	.1 Vial) ITEN Weight Lbs.	Dimens Depth	NFORMATION ions (US msn Width	Gram Milliliter N nts.) Height		# Pieces:
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturers	s exclusive distributor	DRUG SUPPLY ?	Yes No No No	GLM 	N: es, was origir ct from mfr?	nal product purchased	-	Item/Each:	1 Vial) ITEN Weight Lbs. 0.28	Dimens	INFORMATION	Gram Milliliter N		
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	s exclusive distributor	DRUG SUPPLY ?	Yes No No	GLM 	N: es, was origir ct from mfr?	nal product purchased		Item/Each: Box/Carton/B	1 Vial) ITEN Weight Lbs. 0.28	Dimens Depth	NFORMATION ions (US msn Width	Gram Milliliter N nts.) Height		[
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturers	s exclusive distributor	DRUG SUPPLY ?	Yes No No No No	GLM 	N: es, was origir ct from mfr?	nal product purchased		Item/Each: Box/Carton/B Inner Pack:	I Vial) ITEN Weight Lbs. 0.28 Bundle/	Dimens Depth 1.9	INFORMATION ions (US msn Width 1.9	Gram Milliliter N N Height 3.8		1
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Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturers Has FDA granted waiver/exceptio	s exclusive distributo n/exemption for prod	DRUG SUPPLY ?  r?  luct? GTIN	Yes No No No No No No No No No No No No	GLM 	I: es, was origin ct from mfr? es, attach doc 	nal product purchased cumentation from FDA.	Unit of Use GTIN-14	Item/Each: Box/Carton/B Inner Pack: Case:	I Vial) ITEN Weight Lbs. 0.28 Bundle/	Dimens Depth 1.9	INFORMATION ions (US msn Width 1.9	Gram Milliliter N N Height 3.8		1
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Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturers Has FDA granted waiver/exception Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack Case	s exclusive distributo n/exemption for prod	DRUG SUPPLY ?  r? luct? GTIN tuantity 1 12	Yes No No No No No No No No No No No No	GLM 	4: es, was origin ct from mfr? es, attach doc GTIN- 003724 403724	nal product purchased cumentation from FDA.	Unit of Use GTIN-14	Item/Each: Box/Carton/B Inner Pack: Case:	1 Vial) ITEN Weight Lbs. 0.28 Bundle/ 4.36	Dimens Depth 1.9 7.87	NFORMATION ions (US msm Width 1.9 5.98 39.37	Gram Milliliter N Height 3.8 4.8	(Cube)	1 12 2,604
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## **HDA** Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2020 For Designat	ed Drop Ship Only Products, Please Use Page 3					
MATERIAL HAZ	ZARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply): a. Cytotoxic? No 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? Does the product label bear a CA Prop 65 warning? C. Contact Hazard? No	SDS Hazard Classification         Organic       Corrosive         Inorganic       Oxidizer         Steroid/Androgen       Contact Hazard         Aerosol Class; Identify NFPA Storage Level:					
d. Does this product require special clean-up instructions?       No         (If yes, attach SDS with special instructions.)       No         e. Does the product contain DEHP?       No         Is this product regulated for shipment by DOT?       No         (if yes, answer a-e below and provide SDS)       No	Is the product a NIOSH hazardous drug?					
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? No	REMS or REGISTRY RESTRICTIONS					
(if yes, answer a-e below and provide SDS) a. UN/dentification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group	Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? Website URL:					
e. Inhalation Hazard?	Med Guide Required No					
Is the product restricted for air shipment? If so, indicate restriction:	Limited Distribution Requirement No					
Passenger Cargo Passenger & Cargo	Comments / Details: (For example, iPledge program?)					
Is this a reportable quantity? No RQ Threshold:	REMS:     Phone:       REMS Program Manager Name:     Phone:       Supplier Manages REMS registry exclusively:     Phone:       Wholesale distributor support:     Provider Name:       Provider Name:     DEA #:       Site Enrollment Number assigned     PCPDP#:       by Supplier:     NPI #:					
SP#	Registry:					
	Registry Program Contact Name: Phone:					
ADD'L STORAGE INFORMATION	Comments					
Is the Product						
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS					
Controlled by State(s)?         No         Listed Chemical (List I or II)           ARCOS Reportable?         No         If yes, indicate which:	Contact tel. # if product received damaged: 888-304-5022					
Schedule No. Is it a scheduled listed chemical product?:						
CLASS OF TRADE RESTRICTION:	Is product returnable for credit: Yes URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	www.vionausa.com					
Restricted to retail pharmacy only:	Special regulations or returns requirements for this product in certain states?					
Restricted to hospital, clinics, and physician offices only:						
Restricted from US territories? (explain in comments)	If so, which states? Other requirements? Comments?					
Comments:						
MISCELLANE	DUS 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	Y - 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:         a. EDI         b. Autofax         c. Fax         d. Phone only         e. Supplier Web Site only         Supplier's Customer Service Number:         Contracted 3PL company / contact #:         Name:         Phone:	Purchase order daily receipt cut off time by supplier         Cut off time:         Shipping lead time of PO:         Hours         Days         Ships same day for next day receipt:         Ships for second day receipt:         Ships regular ground for 3-10 days receipt:
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:
Class of Trade Restriction:	Priority Overnight receipt available: PO Receipt Cut off time:
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:	Saturday Overnight receipt available:       PO Receipt Cut off time:         Order receipt method:       Phone:         Fax:       EDI:         Overnight Fees apply:       Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:         Physician Name:         Physician/Clinic Phone #         Physician State License #         Physician/Clinic DEA #:         Physician/Clinic Specialty:	Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?
Miscellaneous Notes:	
	ADDITIONAL INFORMATION  Is product order for scheduled patient procedure? Is product order for restocking purposes?