

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

Version 2020				Introduction Type:	New Item]	Final Version			Date:	3/29	/2024	
		PRODUCT INFORMATION					SPECIAL HAN	IDLING AND STO	RAGE REQUI	REMENTS*			
Company Name: Viona Pharmaceuticals Inc. Application: ANDA							ndicate the USP temp	erature range for	this product.				
Application Number for NDA/AN	NDA/BLA (drug); PMA/510(k)(med d	device):	Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)										
DUNS:	081468959					Othe	er Temperature Range	Requirement					
Proprietary Name (If Applicable)	and Established Name: Bisc	oprolol Fumarate and Hydrochlorothiazide Ta	olets, USP 10 m	g/6.25 mg]	(write in)	·					
Selling Unit NDC:	72578-115-06	Unit of Use NDC:		UPC: 372578	115067	Note	es						
UDI	N/A	CVX Code:		MVX Code: N/A]							
Description:		asional greyish to black speckles, round shap	on one side and plain on		is product to be shippe				No	_			
	other side.					Is th	is product to be shippe	d to customers on	dry ice?		No	-	
Active Ingredient(s): Bisoprolol Fumarate, USP and Hydrochlorothiazide, USP b. Contact for temperature excursion questions:													
URL for Additional Product Infor	mation: www.vionaus	sa com				D. Contact for tem		iestions:	Customer S	ervice			
Address:	20 Commerce Drive			Address 2: Suite 340			nber:		888-304-502				
City:	Cranford								customers	service@vic	onausa.com	l	
Key Contact:	Chris Urbanski		Email:	Curbanski@vionausa	.com_	1							
Phone Number:	908-956-0600		Fax:	908-514-4005			ons for product in any				No		
Product Therapeutic Classification	Antihypertensive	е				Spe	cial returns requiremen	ts for this product?	•		No		
	ADDITIONAL PRODUCT	INFORMATION		BRODUCT DESCR	IPTION INFORMATION		Chdwiner (also be him				Vee		
	ADDITIONAL PRODUCT		_	PRODUCT DESCR	IPTION INFORMATION		init of sale) upright?				Yes		
The product is?		Is the Product Direct-Ship	Only			e. Shelf life:	ect product (unit of s	ale) from light?			No	1	
a legend device? if yes, enter class #	No	Is the Product Neither Orphan Drug Status		Size:	30 ct		al shelf life at launch (if different):			24	Months Months	
a product kit?	No	Orphan Drug Status					ai sheli ille at laulich i	ii diiieieitij.				Months	
if yes, list NDCs of		FDA Approval Status		Strength:	10 mg/6.25 mg			ORDER INFOR	MATION				
component parts				Dosage Form:	Tablet								
reverse numbered? co-licensed?	No	Allermana Dresent					of Sale Bottle		1 Bottle of 3	NDC selling	g unit?		
latex-free?	No Yes	Allergens Present				 	Box/Carton			g. 1 Box of 1	∩ \/ials\		
preservative-free?	Yes			Product Shape:	Round		Ampule		(vviite iii, e	.g. 1 Dox 01 1	o viais)		
correctional institution block?	No			Draduat Calari	Mile te Ar Off colete		Glass		Minimum o	rder quantit	y?	Yes	
opioid?	No			Product Color:	White to Off-white		Tube			•	•		
Cannabinoid?	No	Country of Origin India		Product Imprint:	115		Vial Liquid Sgl						
If Unit Dose, is item bar coded to	unit dose for hospital						Vial Liquid Multi				ich 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/Cartor	a/Dools		
II Onit Dose, indicate NDC here.		Trade Agreements Act (TAA)?	No				Other: Write In		1	Case	I/Pack		
		FOR GENERIC DRUG PRODUCTS				<u> </u>	Other Willeam		<u> </u>	10000			
			Autho		orized Generic, other section	PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating:	AB			fields ar	e not applicable	Rec. sell unit to cu	Rx billing unit to pharmacy:						
II. Generic Equivalent to What Br						1 Bottle x Each							
	DDUO CUD	NO. V CHAIN CECURITY ACT (DOCCA) INC	PMATION			(Write-in, e.g. 1 Via	il)			Gram			
	DRUG SUP	PPLY CHAIN SECURITY ACT (DSCSA) INFO	RMATION							Milliliter			
Does supplier meet DSCSA defin	ition of manufacturer?	Yes C	LN:	0372578000004			ITEN	AND PACKING	INFORMATIO	N			
Is product exempt from DSCSA?		No											
If yes, select exemption:							Weight Lbs.	Dimens	sions (US msr	nts.)	Volume	# Pieces:	
Other exemption - Write in:							weight Lbs.	Depth	Width	Height	(Cube)	# Pieces:	
Is product repackaged?				nal product purchased		Item/Each:	0.09	1.61	1.61	2.98		1	
Is product sold by manufacturer's Has FDA granted waiver/exception			irect from mfr?	cumentation from FDA.		Box/Carton/Bundle	n/		+				
lias i DA granted waivenexception		NO II	yes, attach do	cumentation from LDA.		Inner Pack:							
	G	TIN AND HIBCC PRODUCT INFORMATION	ı			Case:	3.24	9.72	6.51	3.81		24	
							3.24	9.72	0.51	3.01		24	
Saleable Unit of Measure	Quantity	HIBCC	GTIN-		Unit of Use GTIN-14	Pallet:	658.35	47.24	39.37	47.24		4,752	
X Item/Each	1		00372	578115067									
Box/Carton/Bundle/Inner Pack Case	ton/Bundle/Inner Pack 24 40372578115065					COST INFORMATION WHOLESALER USE ONLY:							
x Pallet	4,752 4,752					WHOLESALER USE UNLI.							
						Regular Cost Invoice Cost (WAC) (\$)			Vendor #:				
									Whsl. Code #:				
						II			Fineline Co	de:			
						As of date:			_				
1		Attach copy of SAFETY DATA SHEET (\$	'DC) or non h	ard letter BACKACE INCE	DT LABEL AND DUOTO OF	DDODLICT DACKACIN	C and PARCORE		ı				
1	f	Attach copy of SAFETY DATA SHEET (S	טו ווט נטטו non naza	ard letter, PACKAGE INSER See new p. 3 for Design			G and BARCODE.						
*Please provide any additional in													



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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?					