

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

Version 2020				Introduction Type:	New Item	x	Final Version			Date:	3/29	/2024		
		PRODUCT INFORMATION					SPECIAL HAN	IDLING AND STO	RAGE REQUI	REMENTS*				
Company Name:	Viona Pharmaceuticals Inc.	ANDA	a. Temperature – Indicate the USP temperature range for this product.											
Application Number for NDA/AN	IDA/BLA (drug); PMA/510(k)(r		Temp	erature Range	Controlled Room	- between 20	and 25 C (68	° – 77° F)						
DUNS:	081468959	Bisoprolol Fumarate and Hydrochlorothiazide				Other	Temperature Range	Requirement						
Proprietary Name (If Applicable) a														
Selling Unit NDC:	72578-113-06	Unit of Use NDC:		UPC: 372578	113063	Notes								
02.	N/A	CVX Code:		MVX Code: N/A										
Description: Light yellow to yellow colored with occasional greyish to black speckles, round shaped, film-coated tablets, debossed with '113' on one side and plain on other side. Is this product to be shipped to customers on ice? No No														
Active Ingredient(s): Bisoprolol Fumarate, USP and Hydrochlorothiazide, USP Bisoprolol Fumarate, USP and Hydrochlorothiazide, USP											•			
/ touve mg. eulem(e).	Biooproioi	b. Contact for temperature excursion questions:												
URL for Additional Product Inforr							Name:				Customer Service			
Address:	20 Commerce Drive			Address 2: Suite 3		Number:			888-304-5022					
City: Key Contact:	Cranford Chris Urbanski			State: NJ Zip: 07016 Email: Curbanski@vionausa.com		Group E-mail:			customerservice@vionausa.com					
Phone Number:	908-956-0600			908-514-4005	i.com	c. Special regulations for product in any states?			No					
Product Therapeutic Classification		ensive	Fax:		Special returns requirements for this pr									
·												•		
	ADDITIONAL PROD	OUCT INFORMATION		PRODUCT DESCR	IPTION INFORMATION	d. Store product (un	it of sale) upright?				Yes			
The product is?		Is the Product Direct-S	hip Only			Prote	ct product (unit of s	ale) from light?			No			
a legend device?	No	Is the Product Neither		Size:	30 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	No	FDA Approval Status		Strength:	2.5 mg/6.25 mg			ORDER INFOR	MATION					
component parts		T DA Approvai Guitas		B	T-1-1-4									
reverse numbered?	No			Dosage Form:	Tablet	Unit o	of Sale			NDC selling	unit?			
co-licensed?	No	Allergens Present				х			1 Bottle of 3					
latex-free?	Yes Yes	_		Product Shape:	Round		Box/Carton		(Write-in, e	.g. 1 Box of 1	0 Vials)			
preservative-free? correctional institution block?	No					 	Ampule Glass		Minimum o	rder quantity	17	Yes		
opioid?	No	_		Product Color:	Light Yellow to Yellow		Tube			raor quartity				
Cannabinoid?	No	Country of Origin India		Product Imprint:	113		Vial Liquid Sgl							
If Unit Dose, is item bar coded to u	unit dose for hospital			r roddot imprint.	110		Vial Liquid Multi			many of whi	ch package	type?		
scanning? If Unit Dose, indicate NDC here:		Is this product covered under the Trade Agreements Act (TAA)?	No			<u> </u>	Vial Powder Sql Vial Power Multi		24	Each Inner/Carton	/Deals			
If Onit Dose, indicate NDC here.		Trade Agreements Act (TAA)?	No			 	Other: Write In		1	Case	/Pack			
		FOR GENERIC DRUG PRODUCTS				<u> </u>				1				
			Auti		orized Generic, other section	PHARMACY ORDER / BILL UNIT								
I. Orange Book Rating:	inge Book Rating: AB fields are not applicable					Rec. sell unit to cus		_		nit to pharm	acy:			
II. Generic Equivalent to What Bra	and?: Ziac						ottle		x	Each				
	DRUG	S SUPPLY CHAIN SECURITY ACT (DSCSA) II	FORMATION			(Write-in, e.g. 1 Vial)			Gram Milliliter					
	DNOC	DOCT ET STANGESSKITT AST (BOSSA)	II ORIMATION							Immine				
Does supplier meet DSCSA defin	ition of manufacturer?	Yes	GLN:	0372578000004			ITEN	M AND PACKING I	INFORMATIO	N				
Is product exempt from DSCSA?		No												
If yes, select exemption:							Weight Lbs.	Dimens	ions (US msr	nts.)	Volume	# Pieces:		
Other exemption - Write in:		No				l	110.9.11 2.00.	Depth	Width	Height	(Cube)			
Is product repackaged? Is product sold by manufacturer's	e exclusive distributor?	No No	direct from mfr	inal product purchased		Item/Each:	0.09	1.61	1.61	2.98		1		
Has FDA granted waiver/exception		No		cumentation from FDA.		Box/Carton/Bundle/								
3			- '			Inner Pack:								
		GTIN AND HIBCC PRODUCT INFORMAT	ION			Case:	3.24	9.72	6.51	3.81		24		
Saleable Unit of Measure	O	LUDOO	OTIN	144	Halt of Han OTIN 44	Pallet:								
X Item/Each	Quantity 1	HIBCC	GTIN	2578113063	Unit of Use GTIN-14	Pallet:	658.35	47.24	39.37	47.24		4,752		
Box/Carton/Bundle/Inner Pack			3007					1						
x Case	24			2578113061		C	OST INFORMATION			WHOLESAL	ER USE ONL	.Y:		
x Pallet	4,752		5037	2578113068					-l.,,					
	-					Regular Cost Invoice Cost (WAC)	(\$)		Vendor #: Whsl. Code	. #-				
							(*/		Fineline Co					
						As of date:		*						
*Please provide any additional inf	formation on page 2	Attach copy of SAFETY DATA SHEE	(SDS) or non haz	zard letter, PACKAGE INSE See new p. 3 for Design		PRODUCT PACKAGING Signa								



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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:					
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:						
	기					
	ADDITIONAL INFORMATION					
	Is product order for scheduled patient procedure?					
	Is product order for restocking purposes?					
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