

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

Version 2020				Introduction Type:	Post Launch Change)	Final Version			Date:	7/21/	/2022
		PRODUCT INFORMATION					SPECIAL HAN	DLING AND STO	RAGE REQUI	REMENTS*		
Company Name:	Viona Pharmaceuticals Inc.			Application:	ANDA	a. Temperature – Ir	dicate the USP temper					
Application Number for NDA/AN	DA/BLA (drug); PMA/510(k)(med device	ce): 2°	10198	•		Tem	perature Range	Controlled Room	– between 20	and 25 C (68	° – 77° F)	
DUNS:	081468959					Othe	r Temperature Range f	Requirement				
Proprietary Name (If Applicable) a		de Cream 0.05%	1				(write in)					
Selling Unit NDC:	72578-086-02	Unit of Use NDC: CVX Code:		UPC: 372578 MVX Code:	086022	Note	S					
""	White to off white cream	CVA Code.		MVX Gode.]]	do - t t - b bi		0		No	
Description:	write to oil write cream						s product to be shipped s product to be shipped				No	
Active Ingredient(s):	Desonide											
							erature excursion qu	estions:	-			
URL for Additional Product Inform Address:	nation: <u>www.vionausa.c</u> 20 Commerce Drive	<u>om</u>		Address 2: Suite 3	40	Nam Num			Customer Se 888-304-502			
City:	Cranford		State:		07016		ip E-mail:			ervice@vic	nausa com	l .
Key Contact:	Chris Urbanski		Email:	Curbanski@vionausa			· - ···-···		cascomers	CIVICE VIC		
Phone Number:	908-956-0600		Fax:	908-514-4005		c. Special regulation	ns for product in any	states?			No	•
Product Therapeutic Classificatio	n: Anti-inflammatory &	anti-pruritic				Spec	ial returns requirement	s for this product?			No	•
	ADDITIONAL PRODUCT INFO	ORMATION		BRODUCT DESCR	IPTION INFORMATION	1 Stana maadust (v	nit of sale) upright?				No	
	ADDITIONAL PRODUCT INFO		<u> </u>	PRODUCT DESCR	IPTION INFORMATION	1	· · · -					
The product is? a legend device?	No	Is the Product Direct-Ship Neither	Only			e. Shelf life:	ect product (unit of sa	ale) from light?			No 24	Months
if yes, enter class #	140	Orphan Drug Status		Size:	60g		Il shelf life at launch (if different):				Months
a product kit?	No			Strength:	0.05%							1
if yes, list NDCs of		FDA Approval Status		ou ou gui	0.0070			ORDER INFORI	MATION			
component parts reverse numbered?	No			Dosage Form:	Cream	Unit	of Sale		What is the	NDC selling	unit?	
co-licensed?	No	Allergens Present					Bottle		1 Tube of 60			
latex-free?	Yes	_		Product Shape:	N/A		Box/Carton		(Write-in, e.	g. 1 Box of 10) Vials)	
preservative-free?	No			Trouder onape.			Ampule				_	
correctional institution block? opioid?	No			Product Color:	White to Off-White	 ,	Glass		Minimum o	rder quantity	1?	Yes
Cannabinoid?	No	Country of Origin Italy			N/A	 	Vial Liquid Sgl					
If Unit Dose, is item bar coded to u				Product Imprint:			Vial Liquid Multi		If Yes, how	many of whi	ch package	type?
scanning?	No	Is this product covered under the					Vial Powder Sql		48	Each		
If Unit Dose, indicate NDC here:		Trade Agreements Act (TAA)?	Yes				Vial Power Multi Other: Write In		1	Inner/Carton Case	/Pack	
		FOR GENERIC DRUG PRODUCTS				<u> </u>	Caron Willow			10000		
									_			
			Autho		orized Generic, other section		PH	ARMACY ORDER	R / BILL UNIT			
I. Orange Book Rating:	AB			fields a	re not applicable	Rec. sell unit to cu	stomer?	7		nit to pharm	асу:	
II. Generic Equivalent to What Bra	nd?: Desowen					(Meita in a g 4 Via	1	1	х	Each Gram		
	DRUG SUPPLY	CHAIN SECURITY ACT (DSCSA) INFO	RMATION			(Write-in, e.g. 1 Via)			Milliliter		
										_		
Does supplier meet DSCSA defini	tion of manufacturer?	Yes G	LN:	0372578000004			ITEN	I AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?		NO]		D	(110	-1-1		
If yes, select exemption: Other exemption - Write in:							Weight Lbs.	Dimens Depth	ions (US msn Width	nts.) Height	Volume (Cube)	# Pieces:
Is product repackaged?		No If	Yes, was origin	nal product purchased		Item/Each:	0.44				(0000)	4
Is product sold by manufacturer's			irect from mfr?				0.14	1.12	1.12	7.09		1
Has FDA granted waiver/exception	n/exemption for product?	No If	yes, attach do	cumentation from FDA.		Box/Carton/Bundle Inner Pack:	1					
	GTIN	AND HIBCC PRODUCT INFORMATION	1			Case:						
							11.7	13.78	8.27	8.07		48
Saleable Unit of Measure	Quantity	HIBCC	GTIN-		Unit of Use GTIN-14	Pallet:	561.6	47.24	39.37	47.24		2304
X Item/Each	1		00372	578086022				1		.= .		
Box/Carton/Bundle/Inner Pack X Case	48		40372	578086020			OST INFORMATION			WHOLESALI	ER US <u>E ON</u> L	.Y:
X Pallet	2304			578086027			· · · · · · · · · · · · · · · · · · ·					
						Regular Cost			Vendor #:			
						Invoice Cost (WAC) (\$)		Whsl. Code Fineline Co			
						As of date:		l	- memie co	uc.		
							•					
	ormation on page 2.	Attach copy of SAFETY DATA SHEET (S	DS) or non haza	ard letter, PACKAGE INSE			G and BARCODE. ature:					



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For Designated Drop Ship Only Products, Please Use Page 3

	WATERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION				
Is this product (check all that apply): a. Cytotoxic? No 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 Inorganic Steroid/Androgen	Corrosive Oxidizer 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?	Aerosol Class; Identify NFPA Storage Level: Is the product a NIOSH hazardous drug? If yes, indicate which:	No				
Is this product regulated for shipment by DOT? (If yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class			Hazardous Waste Identification EPA Hazardous Waste Code:			
d. Packing Group e. Inhalation Hazard?	No					
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class	No	Is there a REMS on this product? If Yes, is it managed with a pharmacy registry? Website URL:	r REGISTRY RESTRICTIONS No			
d. Packing Group e. Inhalation Hazard? Is the product restricted for air shipment? If so, indicate restriction: Passenger Cargo Cargo		Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)	No			
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:		Phone: DEA #: PCPDP#: NPI #:		
Special Permit; DOT-SP Special Provision (listed in Column 7 of 49 CFR 172.101); SP#		Comments Registry:				
ADD'L STORAGE INFORMATION Is the Product		Registry Program Contact Name: Comments		Phone:		
Controlled Substance? Controlled Substance Code Controlled Substance Code Controlled Substance Code Listed Chemical (List I or II) ARCOS Reportable? No If yes, indicate which: Schedule No. CLASS OF TRADE RESTRICTION:	No No	Contact tel. # if product received damaged: Is product returnable for credit: URL/Link to returns policy:	888-304-5022 Yes			
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:	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?					
	MISCELLANEC	US 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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