

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

						Introduction Type:	New Item	X	Final Version			Date:	2/10/	/2025
			PRODUCT INFORMAT	TION					SPECIAL HAND	LING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Viona Pharmace	uticals Inc.				Application:	ANDA	a. Temperature – Indic	ate the USP temp	erature range for	this product			
Application Number for NDA/Al			1			NDA 505(b) Type:	NOT APPLICABLE	- ·		Controlled Room			8° – 77° F)	
Medical Device Class, if applica	able:							1						
DUNS:	081468959							Other Te	mperature Range F	Requirement				
Proprietary Name (If Applicable)	and Established N	Name: Tretino	oin Cream, USP 0.1%						ite in)	•				
Selling Unit NDC:	72578-153-08		Unit of Use NDC:			UPC: 3725	78153083	Notes	,					
UDI	N/A		CVX Code:			MVX Code: N/A		1						
Description:	Light vellow to ve	llow hydrophilic home	ogeneous cream, free from I	lump and foreig	matter withou	ıt nhase senaration		ls this no	oduct to be shipped	to customers on	ice?		No	1
	Light your to yo	now riyaroprimo nomo,	gonoodo orodin, noo nom i	amp and foreign	Tinduoi Williot	at phace coparation.		11	oduct to be shipped				No	1
Active Ingredient(s):		Tretinoin, USP						10 11.10 pm	очин то во отпри	2 10 00010111010 011	a.,	I.		1
		·						b. Contact for tempera	ture excursion qu	estions:				
URL for Additional Product Infor	mation:	www.vionausa.co	<u>:om</u>					Name:			Customer Se	ervice		
Address:	20 Commerce Dr	ive				Address 2: Suite	340	Number	:		888-304-502			
City:	Cranford				State:		07016	Group E	-mail:		customers	service@vic	<u>nausa.con</u>	<u>n</u>
Key Contact:	Chris Urbanski				Email:	Curbanski@vionaus	<u>a.com</u>					,		1
Phone Number:	908-956-0600				Fax:	908-514-4005		c. Special regulations	-				No	-
Product Therapeutic Classification	on:	Acne agent						Special r	eturns requirement	s for this product?			No	1
	ADDITI	ONAL PROPUST IN	FORMATION.			PROPUST PESSE	NOTION INCODMATION	.				,		ī
	ADDITI	ONAL PRODUCT INF	ORMATION			PRODUCT DESCR	RIPTION INFORMATION	d. Store product (unit of	of sale) upright?				No	1
The product is?			Is the Product	Direct-Ship O	nly			11	product (unit of sa	ile) from light?			No	
a legend device?		No	Is the Product	Neither		Size:	45 g	e. Shelf life:					24	Months
if yes, enter class #		IN.	Orphan Drug Status					Initial sh	elf life at launch (if different):				Months
a product kit? if yes, list NDCs of		No	EDA Approval Status			Strength:	0.1%			ORDER INFORM	AATION			
component parts			FDA Approval Status							ORDER INFORM	IATION			
reverse numbered?		No				Dosage Form:	Cream	Unit of S	Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present						Bottle		1 Tube of 45			
latex-free?		Yes	J			Bar Lat Olama	N1/A		Box/Carton			g. 1 Box of 10	0 Vials)	
preservative-free?		No				Product Shape:	N/A		Ampule				,	
correctional institution block?	?	No			-	Product Color:	Light Yellow to Yellow		Glass		Minimum or	rder quantity	/?	Yes
opioid?		No				i roduct color.	Light reliew to reliew	X	Tube					
Cannabinoid?		No	Country of Origin	Germany		Product Imprint:	N/A		Vial Liquid Sgl					_
If Unit Dose, is item bar coded to	unit dose for		to different fortune and for			'			Vial Liquid Multi			many of whi	ch package	type?
hospital scanning? If Unit Dose, indicate NDC here:			Is this product covered under Trade Agreements Act (**)		Vaa				Vial Powder Sql Vial Power Multi			Each	/Dools	
If Only Dose, indicate NDC here:			Trade Agreements Act (174):	Yes				Other: Write In			Inner/Carton, Case	/Pack	
			FOR GENERIC DRUG PRO	ODUCTS					Other. Write in			Case		
			FOR GENERIC DRUG PR	ODUCIS							1			
				i	Au	thorized Generic *If Au	uthorized Generic, other		PHA	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB			_ '			on fields are not applicable	Rec. sell unit to custor				nit to pharma	2011	
II. Generic Equivalent to What Br		Retin-A Cream						1 Tube			X Dilling th	Each	acy.	
Concine Equitations to Timas 2.		rtouri / t oroani						(Write-in, e.g. 1 Vial)				Gram		
		DRUG SUPPLY	Y CHAIN SECURITY ACT (DSCSA) INFO	MATION							4		
		•		DOCOR) IN OI	IMATION			HCPCS J-Code:			1	Milliliter		
Does supplier meet DSCSA defir	nition of manufacti			(DOCOA) INI OI	MATION			HCPCS J-Code:				Milliliter		
	muon on mananaou	urer?	Yes		GLN:	0372578000004		HCPCS J-Code:	ITEM	AND PACKING I	NFORMATION]		
Is product exempt from DSCSA?		urer?				0372578000004		HCPCS J-Code:	ITEM	AND PACKING II	NFORMATIO]		
Is product exempt from DSCSA? If yes, select exemption:		urer?	Yes			0372578000004		HCPCS J-Code:			NFORMATION	N	Volume	Saleable #
		urer?	Yes		GLN:			HCPCS J-Code:	ITEM Weight Lbs.			N	Volume (Cube)	Saleable #
If yes, select exemption: Other exemption - Write in: Is product repackaged?	,		Yes No		GLN: GCP: If yes, was o	0372578 riginal product		Item/Each:	Weight Lbs.	Dimensi Depth	ons (US msm Width	nts.) Height		
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer	's exclusive distrik	butor?	Yes No No		GLN: GCP: If yes, was or purchased di	0372578 riginal product irect from mfr?		Item/Each:		Dimensi	ons (US msm	N nts.)		
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer' Has FDA granted waiver/exception	's exclusive distrik on/exemption for p	butor?	Yes No		GLN: GCP: If yes, was or purchased di	0372578 riginal product	ackaged product	Item/Each: Box/Carton/Bundle/	Weight Lbs.	Dimensi Depth	ons (US msm Width	nts.) Height		
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer	's exclusive distrik on/exemption for p	butor?	Yes No No		GLN: GCP: If yes, was or purchased di	0372578 riginal product irect from mfr?	ackaged product	Item/Each: Box/Carton/Bundle/ Inner Pack:	Weight Lbs.	Dimensi Depth	ons (US msm Width	nts.) Height		
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer' Has FDA granted waiver/exception	's exclusive distrik on/exemption for p	butor? product?	Yes No No No No		GLN: GCP: If yes, was or purchased di	0372578 riginal product irect from mfr?	ackaged product	Item/Each: Box/Carton/Bundle/	Weight Lbs.	Dimensi Depth	ons (US msm Width	nts.) Height		
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer' Has FDA granted waiver/exception	's exclusive distrik on/exemption for p	butor? product?	Yes No No		GLN: GCP: If yes, was or purchased di	0372578 riginal product irect from mfr?	ackaged product	Item/Each: Box/Carton/Bundle/ Inner Pack: Case:	Weight Lbs.	Dimensi Depth 1.11 8.27	ons (US msm Width	nts.) Height 6.51		Pieces 1
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer' Has FDA granted waiver/exception If yes, attach documentation from	's exclusive distrik on/exemption for p om FDA.	butor? product?	Yes No		GLN: GCP: If yes, was or purchased di Provide sour	0372578 riginal product frect from mfr? ce manufacturer for repa		Item/Each: Box/Carton/Bundle/ Inner Pack:	Weight Lbs.	Dimensi Depth 1.11	ons (US msm Width	nts.) Height 6.51		Pieces 1
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer' Has FDA granted waiver/exception	's exclusive distrik on/exemption for p	butor? product? GTIN Saleable	Yes No No No No		GLN: GCP: If yes, was or purchased di Provide sour	0372578 riginal product irect from mfr?	ackaged product Unit of Use GTIN-14	Item/Each: Box/Carton/Bundle/ Inner Pack: Case:	Weight Lbs. 0.15 3.964	Dimensi Depth 1.11 8.27	ons (US msm Width 1.11	N hts.) Height 6.51 7.28		Pieces 1 24
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer' Has FDA granted waiver/exception If yes, attach documentation from	's exclusive distrik on/exemption for p om FDA.	butor? product?	Yes No		GLN: GCP: If yes, was or purchased di Provide sour	0372578 riginal product frect from mfr? ce manufacturer for repa		Item/Each: Box/Carton/Bundle/ Inner Pack: Case:	Weight Lbs. 0.15 3.964	Dimensi Depth 1.11 8.27	ons (US msm Width 1.11	N hts.) Height 6.51 7.28		Pieces 1 24
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer Has FDA granted waiver/exception of the selection	's exclusive distrik on/exemption for p om FDA.	butor? product? GTIN Saleable	Yes No		GLN: GCP: If yes, was or purchased di Provide sour	0372578 riginal product irect from mfr? ce manufacturer for repa		Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet:	Weight Lbs. 0.15 3.964	Dimensi Depth 1.11 8.27	ons (US msm Width 1.11 7.08 39.37	N hts.) Height 6.51 7.28	(Cube)	Pieces 1 24 2,880
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer! Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure	's exclusive distrik on/exemption for p om FDA.	butor? product? GTIN Saleable	Yes No		GLN: GCP: If yes, was or purchased di Provide sour GTI 003 403	0372578 riginal product frect from mfr? ce manufacturer for repair N-14 72578153083		Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet:	Weight Lbs. 0.15 3.964 508.68	Dimensi Depth 1.11 8.27	ons (US msm Width 1.11 7.08 39.37	nts.) Height 6.51 7.28 47.24	(Cube)	Pieces 1 24 2,880
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer' Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure x	's exclusive distrik on/exemption for p om FDA. RFID tag(Y/N)	GTIN Saleable Quantity 1	Yes No		GLN: GCP: If yes, was or purchased di Provide sour GTI 003 403	0372578 riginal product irect from mfr? ce manufacturer for repair irect		Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet: COST	Weight Lbs. 0.15 3.964 508.68	Dimensi Depth 1.11 8.27	ons (US msm Width 1.11 7.08 39.37	nts.) Height 6.51 7.28 47.24	(Cube)	Pieces 1 24 2,880
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer' Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack Case	's exclusive distrite on/exemption for pom FDA. RFID tag(Y/N)	GTIN Saleable Quantity 1 24	Yes No		GLN: GCP: If yes, was or purchased di Provide sour GTI 003 403	0372578 riginal product frect from mfr? ce manufacturer for repair N-14 72578153083		Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet:	Weight Lbs. 0.15 3.964 508.68	Dimensi Depth 1.11 8.27	ons (US msm Width 1.11 7.08 39.37	N hts.) Height 6.51 7.28 47.24 WHOLESALE	(Cube)	Pieces 1 24 2,880
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer' Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack Case	's exclusive distrite on/exemption for pom FDA. RFID tag(Y/N)	GTIN Saleable Quantity 1 24	Yes No		GLN: GCP: If yes, was or purchased di Provide sour GTI 003 403	0372578 riginal product frect from mfr? ce manufacturer for repair N-14 72578153083		Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet: Cost Regular Cost Invoice Cost (WAC) (\$)	Weight Lbs. 0.15 3.964 508.68	Dimensi Depth 1.11 8.27	ons (US msm Width 1.11 7.08 39.37	N hts.) Height 6.51 7.28 47.24 WHOLESALE	(Cube)	Pieces 1 24 2,880
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer' Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X Item/Each Box/Carton/Bundle/Inner Pack Case	's exclusive distrite on/exemption for pom FDA. RFID tag(Y/N)	GTIN Saleable Quantity 1 24	Yes No		GLN: GCP: If yes, was or purchased di Provide sour GTI 003 403	0372578 riginal product frect from mfr? ce manufacturer for repair N-14 72578153083		Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet: COST	Weight Lbs. 0.15 3.964 508.68	Dimensi Depth 1.11 8.27	ons (US msm Width 1.11 7.08 39.37	N hts.) Height 6.51 7.28 47.24 WHOLESALE	(Cube)	Pieces 1 24 2,880
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer' Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X	's exclusive distrite on/exemption for pom FDA. RFID tag(Y/N)	GTIN Saleable Quantity 1 24	Yes No		GLN: GCP: If yes, was or purchased di Provide sour GTI 003 403	0372578 riginal product frect from mfr? ce manufacturer for repair N-14 72578153083		Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet: Cost Regular Cost Invoice Cost (WAC) (\$)	Weight Lbs. 0.15 3.964 508.68	Dimensi Depth 1.11 8.27	ons (US msm Width 1.11 7.08 39.37	N hts.) Height 6.51 7.28 47.24 WHOLESALE	(Cube)	Pieces 1 24 2,880
If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer' Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X	's exclusive distrite on/exemption for pom FDA. RFID tag(Y/N)	GTIN Saleable Quantity 1 24 2,880	Yes No No No No No HIBCC PRODUCT IN	NFORMATION	GLN: GCP: If yes, was or purchased di Provide sour GTI 003 403 503	0372578 riginal product frect from mfr? ce manufacturer for repair N-14 72578153083 72578153081 72578153088		Item/Each: Box/Carton/Bundle/ Inner Pack: Case: Pallet: COST Regular Cost Invoice Cost (WAC) (\$) As of date:	Weight Lbs. 0.15 3.964 508.68	Dimensi Depth 1.11 8.27	ons (US msm Width 1.11 7.08 39.37	N hts.) Height 6.51 7.28 47.24 WHOLESALE	(Cube)	Pieces 1 24 2,880



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

Version 2024 For Designated Drop Ship Only Products, Please Use Page 3

MA	TERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION	
Is this product (check all that apply):			
a. Cytotoxic?	No	SDS	S Hazard Classification
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?			
Is the product a CA Prop 65 carcinogen?	No	Organic	Corrosive
Is the product a CA Prop 65 reproductive toxicant?	No	Inorganic	Oxidizer
Does the product label bear a CA Prop 65 warning?	No	Steroid/Androgen	Contact Hazard
Bood the product tabor bodi a OAT Top of Walthing.	110	Storota// triarogon	Contact Fidzard
c. Contact Hazard?	No	Does the product have an Aerosol class? If yes,	No
d. Does this product require special clean-up instructions?	No	identify NFPA Storage Level:	110
(If yes, attach SDS with special instructions.)	140	NFPA Storage Level:	
e. Does the product contain DEHP?	No	1411 / Otorage Level.	
•			
Is this product regulated for shipment by DOT?	No	Is the product a NIOSH hazardous drug?	Yes
(if yes, answer a-e below and provide SDS)		If yes, indicate which:	Group 3 items (primarily adverse reproductive effects)
a. UN/Identification Number			
b. Proper Shipping Name			
c. DOT Hazard Class		Hazar	dous Waste Identification
d. Packing Group			
e. Inhalation Hazard?	No	EPA Hazardous Waste Code:	Waste Characteristics
Is this product regulated for shipment by IATA?	No		
(if yes, answer a-e below and provide SDS)		REMS or	REGISTRY RESTRICTIONS
a. UN/Identification Number			
b. Proper Shipping Name		Is there a REMS on this product?	No
c. DOT Hazard Class		If Yes, is it managed with a pharmacy registry?	
d. Packing Group		Website URL:	
e. Inhalation Hazard?	No		
Is the product restricted for air shipment? If so, indicate restriction:	No	Med Guide Required	No
Passenger		Limited Distribution Requirement	No
Cargo		Comments / Details: (For example, iPledge program?)	
Passenger & Cargo			
Is this a reportable quantity? No		REMS:	
RQ Threshold:		REMS Program Manager Name:	Phone:
Is this a marine pollutant? No		Supplier Manages REMS registry exclusively:	1 Hone.
Is this product shipped utilizing an authorized DOT exception or Special Permit?		Wholesale distributor support:	
No (if yes, identify method below)		Provider Name:	DEA #:
Limited Quantity		Site Enrollment Number assigned	NCPDP#:
Consumer Commodity, ORM-D		by Supplier:	NPI#:
Small Quantity (49 CFR 173.4)		Бу Сиррнот.	TWITH.
Special Permit; DOT-SP		Comments	
Special Provision (listed in Column 7 of 49 CFR 172.101);		Comments	
SP#		Registry:	
Or#			Dhana
ADD'L STORAGE INFORMATION		Registry Program Contact Name:	Phone:
		Comments	
Is the Product			
Controlled Substance? No Controlled Substance Code		RE	TURN INSTRUCTIONS
Controlled by State(s)? No Listed Chemical (List I or II)			200 004 5000
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?:		Is product returnable for credit:	Yes
CLASS OF TRADE RESTRICTION:		URL/Link to returns policy:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices		www.vionausa.co	<u>m</u>
Restricted to retail pharmacy only:		Special regulations or returns requirements for this	
		Special regulations or returns requirements for this product in certain states?	
Restricted to hospital, clinics, and physician offices only:		i ·	
Restricted from US territories? (explain in comments)		If so, which states? Other requirements? Comments?	
Comments:			
	SCELLANEC	US NOTES and/or Image of Product Barcode:	



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

Version 2024

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: a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: 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:			
Drop Ship service fee billed with each order:	PO Receipt cut off time:			
Drop Ship miscellaneous fees billed: Comments:	Days of week overnight is available: Monday 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 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: 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: Miscellaneous Notes:	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?			
	ADDITIONAL INFORMATION			
	Is product order for scheduled patient procedure? Is product order for restocking purposes?			