



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

Version 2024

Introduction Type:  Pre Launch Change  Post Launch Change

Final Version

Date: 10/1/2024

PRODUCT INFORMATION	
Company Name:	Viona Pharmaceuticals Inc.
Application Number for NDA/ANDA/BLA; PMA/510(k):	208989
Application:	ANDA
Medical Device Class, if applicable:	
DUNS:	081468959
Proprietary Name (If Applicable) and Established Name:	Fluocinonide Cream, USP 0.1%
Selling Unit NDC:	72578-087-06
Unit of Use NDC:	
UDI:	N/A
UPC:	372578087067
CVX Code:	
MX Code:	N/A
Description:	White to off white cream.
Active Ingredient(s):	Fluocinonide, USP
URL for Additional Product Information:	<a href="http://www.vionausa.com">www.vionausa.com</a>
Address:	20 Commerce Drive
City:	Cranford
Key Contact:	Chris Urbanski
Phone Number:	908-956-0600
Product Therapeutic Classification:	Anti-Inflammatory & Anti-Pruritic

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
<b>a. Temperature – Indicate the USP temperature range for this product.</b>	
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	
Notes	
Is this product to be shipped to customers on ice?	<input type="checkbox"/> No
Is this product to be shipped to customers on dry ice?	<input type="checkbox"/> No
<b>b. Contact for temperature excursion questions:</b>	
Name:	Customer Service
Number:	888-304-5022
Group E-mail:	<a href="mailto:customerservice@vionausa.com">customerservice@vionausa.com</a>
<b>c. Special regulations for product in any states?</b>	
Special returns requirements for this product?	<input type="checkbox"/> No
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	<input type="checkbox"/> No
<b>e. Shelf life:</b>	
Initial shelf life at launch (if different):	<input type="checkbox"/> 24 Months <input type="checkbox"/> 18 Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is?		Is the Product... Direct-Ship Only	
a legend device?	<input type="checkbox"/> No	Is the Product... Neither	
if yes, enter class #		Orphan Drug Status	
a product kit?	<input type="checkbox"/> No	FDA Approval Status	
if yes, list NDCs of component parts		Allergens Present	
reverse numbered?	<input type="checkbox"/> No	Country of Origin	Italy
co-licensed?	<input type="checkbox"/> No	Is this product covered under the Trade Agreements Act (TAA)?	<input type="checkbox"/> Yes
latex-free?	<input type="checkbox"/> Yes		
preservative-free?	<input type="checkbox"/> Yes		
correctional institution block?	<input type="checkbox"/> No		
opioid?	<input type="checkbox"/> No		
Cannabinoid?	<input type="checkbox"/> No		
If Unit Dose, is item bar coded to unit dose for hospital scanning?	<input type="checkbox"/>		
If Unit Dose, indicate NDC here:			
Size:	30g	Strength:	0.1%
Dosage Form:	Cream	Product Shape:	N/A
Product Color:	White to Off-White	Product Imprint:	N/A

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	1 Tube of 30 g
<input type="checkbox"/> Box/ Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	Minimum order quantity? <input type="checkbox"/> Yes
<input checked="" type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	If Yes, how many of which package type?
<input type="checkbox"/> Vial Powder Sgl	<input type="checkbox"/> 36 Each
<input type="checkbox"/> Vial Power Multi	<input type="checkbox"/> Inner/ Carton/ Pack
<input type="checkbox"/> Other: Write In	<input type="checkbox"/> 1 Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Vanos
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
1 Tube	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="checkbox"/> Gram
HCPCS J-Code:	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Is product exempt from DSCSA?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Is product sold by manufacturer's exclusive distributor?	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Has FDA granted waiver/exception/exemption for product?	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes
If yes, attach documentation from FDA.	
GLN:	0372578000004
GCP:	0372578
If yes, was original product purchased direct from mfr?	<input type="checkbox"/> No <input checked="" type="checkbox"/> Yes
Provide source manufacturer for repackaged product	

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Box/ Carton/ Bundle/ Inner Pack:	0.08	0.98	0.98	4.72		1
Case:	6.8	9.13	6.8	5.9		36
Pallet:	850	47.24	39.37	47.25		4,500

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	RFID tag(Y/N)	Saleable Quantity	HIBCC	GTIN-14
<input checked="" type="checkbox"/> Item/Each	Y	1		00372578087067
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	Y	36		40372578087065
<input checked="" type="checkbox"/> Pallet	Y	4,500		50372578087062

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)		Whsl. Code #:	
As of date:		Fineline Code:	

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

\*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:



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For Designated Drop Ship Only Products, Please Use Page 3

## MATERIAL HAZARD 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?  No
  - Is the product a CA Prop 65 reproductive toxicant?  No
  - Does the product label bear a CA Prop 65 warning?  No
- c. Contact Hazard?  No
- d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)  No
- e. Does the product contain DEHP?  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
- 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
- d. Packing Group
- e. Inhalation Hazard?  No

Is the product restricted for air shipment? If so, indicate restriction:

- Passenger
- Cargo
- 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)
- Special Permit; DOT-SP
- Special Provision (listed in Column 7 of 49 CFR 172.101); SP#

### ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance?  No  Yes  Controlled Substance Code
- Controlled by State(s)?  No  Yes  Listed Chemical (List I or II)
- ARCOS Reportable?  No  Yes  If yes, indicate which:
- Schedule No.  Is it a scheduled listed chemical product?:  Yes  No

### CLASS OF TRADE RESTRICTION:

- 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:

### MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE

### SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:   
NFPA Storage Level:

Is the product a NIOSH hazardous drug? If yes, indicate which:

### Hazardous Waste Identification

EPA Hazardous Waste Code:  Waste Characteristics

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  No  Yes  
If Yes, is it managed with a pharmacy registry?  Yes  No  
Website URL:

Med Guide Required  No  Yes  
Limited Distribution Requirement  No  Yes  
Comments / Details: (For example, iPledge program?)

**REMS:**  
REMS Program Manager Name:  Phone:   
Supplier Manages REMS registry exclusively:  Yes  No  
Wholesale distributor support:  Yes  No  
Provider Name:  DEA #:   
Site Enrollment Number assigned by Supplier:  NCPDP#:   
NPI #:

Comments

**Registry:**  
Registry Program Contact Name:  Phone:   
Comments

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:  888-304-5022

Is product returnable for credit:  Yes  No

URL/Link to returns policy:  [www.vionausa.com](http://www.vionausa.com)

Special regulations or returns requirements for this product in certain states?

If so, which states? Other requirements? Comments?

