



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

Version 2020

Introduction Type:  New Product  Post Launch Change

Final Version

Date: 9/19/2023

PRODUCT INFORMATION	
Company Name:	Viona Pharmaceuticals Inc.
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	215210
DUNS:	081468959
Proprietary Name (If Applicable) and Established Name:	Ivermectin Cream 1%
Selling Unit NDC:	72578-120-08
UDI:	N/A
Description:	White to pale yellow homogenous cream.
Active Ingredient(s):	Ivermectin, 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

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?	No
Is this product to be shipped to customers on dry ice?	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?	No
<b>d. Store product (unit of sale) upright?</b>	
Protect product (unit of sale) from light?	No
<b>e. Shelf life:</b>	24 Months
Initial shelf life at launch (if different):	Months

ADDITIONAL PRODUCT INFORMATION		PRODUCT DESCRIPTION INFORMATION	
The product is a legend device?	No	Is the Product... Direct-Ship Only	Size:
if yes, enter class # a product kit?	No	Is the Product... Orphan Drug Status	45 g
if yes, list NDCs of component parts reverse numbered?	No	FDA Approval Status	Strength:
co-licensed?	No	Allergens Present	1%
latex-free?	Yes	Country of Origin	Cream
preservative-free?	No		Product Shape:
correctional institution block?	No		N/A
opioid?	No		Product Color:
Cannabinoid?	No		White to pale yellow
If Unit Dose, is item bar coded to unit dose for hospital scanning?		Is this product covered under the Trade Agreements Act (TAA)?	Product Imprint:
If Unit Dose, indicate NDC here:		No	N/A

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	1 Tube of 45 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? 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	36 Each
<input type="checkbox"/> Vial Power Multi	Inner/Cartron/Pack
<input type="checkbox"/> Other: Write In	1 Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Soolantra
<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
	<input type="checkbox"/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption:	GLN: 0372578000004
Other exemption - Write in:	
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	No
Has FDA granted waiver/exception/exemption for product?	No

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Item/Each:	0.11	0.98	0.98	5.79		1
Box/Cartron/Bundle/Inner Pack:						
Case:	6.12	9.37	7.28	7.48		36
Pallet:	645	47.24	39.37	47.24		3600

GTIN AND HIBCC PRODUCT INFORMATION				
Saleable Unit of Measure	Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00372578120085	
<input type="checkbox"/> Box/Cartron/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	36		40372578120083	
<input checked="" type="checkbox"/> Pallet	3600		50372578120080	

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



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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?  No
    - 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?  No  
(If yes, attach SDS with special instructions.)
  - e. Does the product contain DEHP?  No
- Is this product regulated for shipment by DOT?  No  
(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?  No  
(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?

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      Controlled Substance Code
- Controlled by State(s)?  No      Listed Chemical (List I or II)
- ARCOS Reportable?  No      If yes, indicate which:
- Schedule No.       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
- Restricted to retail pharmacy only:
- Restricted to hospital, clinics, and physician offices only:
- Restricted from US territories? (explain in comments)
- Comments:

### SDS Hazard Classification

- Organic
- Inorganic
- Steroid/Androgen
- Corrosive
- Oxidizer
- Contact Hazard
- Aerosol Class; Identify 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
- If Yes, is it managed with a pharmacy registry?
- Website URL:
- Med Guide Required  No
- Limited Distribution Requirement  No
- Comments / Details: (For example, iPledge program?)
- REMS:**
- REMS Program Manager Name:  Phone:
- Supplier Manages REMS registry exclusively:
- Wholesale distributor support:
- Provider Name:  DEA #:
- Site Enrollment Number assigned by Supplier:  PCPDP#:
- 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
- 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?

### MISCELLANEOUS 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	
Purchase orders may be accepted by:	
a. EDI	<input type="text"/>
b. Autofax	<input type="text"/>
c. Fax	Fax Number: <input type="text"/>
d. Phone only	Phone No.: <input type="text"/>
e. Supplier Web Site only	Site Address: <input type="text"/>
Minimum Order Quantity:	<input type="text"/>
Supplier's Customer Service Number:	<input type="text"/>
Contracted 3PL company / contact #:	Name: <input type="text"/>
	Phone: <input type="text"/>

Standard Order Receipt and Processing	
<b>Purchase order daily receipt cut off time by supplier</b>	
Cut off time:	<input type="text"/>
Shipping lead time of PO:	<input type="text"/> Hours <input type="text"/> Days
Ships same day for next day receipt:	<input type="text"/>
Ships for second day receipt:	<input type="text"/>
Ships regular ground for 3-10 days receipt:	<input type="text"/>

Expedited Freight Charges or Other Designated Drop Ship Fees:	
Expedited freight fees billed with each order:	<input type="text"/>
Drop Ship service fee billed with each order:	<input type="text"/>
Drop Ship miscellaneous fees billed:	<input type="text"/>
Comments:	<input type="text"/>

Overnight and Priority Overnight PO Processing	
<b>Overnight receipt available:</b>	<input type="text"/>
PO Receipt cut off time:	<input type="text"/>
Days of week overnight is available:	<input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday
<b>Priority Overnight receipt available:</b>	<input type="text"/>
PO Receipt Cut off time:	<input type="text"/>
<b>Saturday Overnight receipt available:</b>	<input type="text"/>
PO Receipt Cut off time:	<input type="text"/>
Order receipt method:	Phone: <input type="text"/> Phone #: <input type="text"/>
	Fax: <input type="text"/> Fax #: <input type="text"/>
	EDI: <input type="text"/>
Overnight Fees apply:	<input type="text"/>
Other fees apply:	<input type="text"/>

Class of Trade Restriction:	
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	<input type="text"/>
Restricted to retail pharmacy only:	<input type="text"/>
Restricted to hospital, clinics, and physician offices only:	<input type="text"/>
Restricted from US territories? (explain in comments)	<input type="text"/>
Comments:	<input type="text"/>

Other Data Information Required to Process PO:	
Patient Procedure Date:	<input type="text"/>
Physician Name:	<input type="text"/>
Physician/Clinic Phone #	<input type="text"/>
Physician State License #	<input type="text"/>
Physician/Clinic DEA #:	<input type="text"/>
Physician/Clinic Specialty:	<input type="text"/>

Return Instructions	
Contact # if product is received damaged:	<input type="text"/>
Is product returnable for credit:	<input type="text"/>
URL/Link to returns policy:	<input type="text"/>
Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?	<input type="text"/>

Miscellaneous Notes:
<input type="text"/>

ADDITIONAL INFORMATION	
Is product order for scheduled patient procedure?	<input type="text"/>
Is product order for restocking purposes?	<input type="text"/>