



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

Version 2020

Introduction Type: New Item

Final Version

Date: 1/6/2021

PRODUCT INFORMATION	
Company Name:	Viona Pharmaceuticals Inc.
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	207764
DUNS:	081468959
Proprietary Name (if Applicable) and Established Name:	Nystatin and Triamcinolone Acetonide Ointment USP
Selling Unit NDC:	72578-088-04
Unit of Use NDC:	
UDI:	N/A
CVX Code:	
UPC:	372578088040
MXV Code:	N/A
Description:	Yellow colored ointment.
Active Ingredient(s):	Nystatin and Triamcinolone Acetonide, USP
URL for Additional Product Information:	www.vionausa.com
Address:	20 Commerce Drive
City:	Cranford
Key Contact:	Chris Urbanski
Phone Number:	908-956-0600
Product Therapeutic Classification:	Antifungal

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
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. Contact for temperature excursion questions:	
Name:	Customer Service
Number:	888-304-5022
Group E-mail:	Vionacs@eversana.com
c. Special regulations for product in any states?	
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	
Protect product (unit of sale) from light?	No
e. Shelf life:	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	
if yes, enter class #		Is the Product... Neither	
if yes, list NDCs of component parts		Orphan Drug Status	
reverse numbered?	No	FDA Approval Status	
co-licensed?	No	Allergens Present	
latex-free?	Yes	Country of Origin	India
preservative-free?	Yes	Is this product covered under the Trade Agreements Act (TAA)?	No
correctional institution block?	No		
opioid?	No		
Cannabinoid?	No		
If Unit Dose, is item bar coded to unit dose for hospital scanning?			
If Unit Dose, indicate NDC here:			
Size:	30 g	Strength:	100,000 Units / 1 mg
Dosage Form:	Ointment	Product Shape:	N/A
Product Color:	Yellow	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? 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	48 Each
<input type="checkbox"/> Vial Power Multi	Inner/ Carton/ Pack
<input type="checkbox"/> Other: Write In	1 Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AT
II. Generic Equivalent to What Brand?:	Mycolog-II
<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 checked="" 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:	
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
GLN:	037257800004
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Width	Height		
Box/ Carton/ Bundle/ Inner Pack:						
Case:	7.1	11.0236	6.69291	6.29921		48
Pallet:	710	47.24409	39.3701	47.24409		4800

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		00372578088040	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	48		40372578088048	
<input checked="" type="checkbox"/> Pallet	4800		50372578088045	

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

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION																			
<p>Is this product (check all that apply):</p> <p>a. Cytotoxic? No</p> <p>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</p> <p>c. Contact Hazard? No</p> <p>d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.) No</p> <p>e. Does the product contain DEHP? No</p> <p>Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS) No</p> <p>a. UN/Identification Number <input style="width: 100%;" type="text"/></p> <p>b. Proper Shipping Name <input style="width: 100%;" type="text"/></p> <p>c. DOT Hazard Class <input style="width: 100%;" type="text"/></p> <p>d. Packing Group <input style="width: 100%;" type="text"/></p> <p>e. Inhalation Hazard? No</p> <p>Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) No</p> <p>a. UN/Identification Number <input style="width: 100%;" type="text"/></p> <p>b. Proper Shipping Name <input style="width: 100%;" type="text"/></p> <p>c. DOT Hazard Class <input style="width: 100%;" type="text"/></p> <p>d. Packing Group <input style="width: 100%;" type="text"/></p> <p>e. Inhalation Hazard? <input style="width: 100%;" type="text"/></p> <p>Is the product restricted for air shipment? If so, indicate restriction:</p> <p><input type="checkbox"/> Passenger</p> <p><input type="checkbox"/> Cargo</p> <p><input type="checkbox"/> Passenger & Cargo</p> <p>Is this a reportable quantity? No RQ Threshold: <input style="width: 100%;" type="text"/></p> <p>Is this a marine pollutant? No</p> <p>Is this product shipped utilizing an authorized DOT exception or Special Permit? No (if yes, identify method below)</p> <p><input type="checkbox"/> Limited Quantity</p> <p><input type="checkbox"/> Consumer Commodity, ORM-D</p> <p><input type="checkbox"/> Small Quantity (49 CFR 173.4)</p> <p><input type="checkbox"/> Special Permit; DOT-SP</p> <p><input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101); SP# <input style="width: 100%;" type="text"/></p>	<div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">SDS Hazard Classification</div> <table style="width: 100%; border: 1px solid black;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> Organic <input type="checkbox"/> Inorganic <input type="checkbox"/> Steroid/Androgen <input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 50%;" type="text"/> </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> Corrosive <input type="checkbox"/> Oxidizer <input type="checkbox"/> Contact Hazard Is the product a NIOSH hazardous drug? No If yes, indicate which: <input style="width: 100%;" type="text"/> </td> </tr> </table> <div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">Hazardous Waste Identification</div> <table style="width: 100%; border: 1px solid black;"> <tr> <td style="width: 70%;">EPA Hazardous Waste Code: <input style="width: 90%;" type="text"/></td> <td style="width: 30%;">Waste Characteristics: <input style="width: 90%;" type="text"/></td> </tr> </table> <div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">REMS or REGISTRY RESTRICTIONS</div> <p>Is there a REMS on this product? No</p> <p>If Yes, is it managed with a pharmacy registry? Website URL: <input style="width: 100%;" type="text"/></p> <p>Med Guide Required No</p> <p>Limited Distribution Requirement No</p> <p>Comments / Details: (For example, iPledge program?) <input style="width: 100%;" type="text"/></p> <p>REMS:</p> <table style="width: 100%; border: 1px solid black;"> <tr> <td>REMS Program Manager Name: <input style="width: 80%;" type="text"/></td> <td>Phone: <input style="width: 20%;" type="text"/></td> </tr> <tr> <td>Supplier Manages REMS registry exclusively: Wholesale distributor support: <input style="width: 80%;" type="text"/></td> <td></td> </tr> <tr> <td>Provider Name: <input style="width: 80%;" type="text"/></td> <td>DEA #: <input style="width: 20%;" type="text"/></td> </tr> <tr> <td>Site Enrollment Number assigned by Supplier: <input style="width: 80%;" type="text"/></td> <td>PCPDP#: <input style="width: 20%;" type="text"/></td> </tr> <tr> <td>NPI #: <input style="width: 80%;" type="text"/></td> <td></td> </tr> </table> <p>Comments <input style="width: 100%;" type="text"/></p> <p>Registry:</p> <table style="width: 100%; border: 1px solid black;"> <tr> <td>Registry Program Contact Name: <input style="width: 80%;" type="text"/></td> <td>Phone: <input style="width: 20%;" type="text"/></td> </tr> <tr> <td colspan="2">Comments <input style="width: 100%;" type="text"/></td> </tr> </table>	<input type="checkbox"/> Organic <input type="checkbox"/> Inorganic <input type="checkbox"/> Steroid/Androgen <input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 50%;" type="text"/>	<input type="checkbox"/> Corrosive <input type="checkbox"/> Oxidizer <input type="checkbox"/> Contact Hazard Is the product a NIOSH hazardous drug? 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ADD'L STORAGE INFORMATION																			
<p>Is the Product...</p> <p>Controlled Substance? No Controlled Substance Code: <input style="width: 100%;" type="text"/></p> <p>Controlled by State(s)? No Listed Chemical (List I or II) <input style="width: 100%;" type="text"/></p> <p>ARCOS Reportable? No If yes, indicate which: <input style="width: 100%;" type="text"/></p> <p>Schedule No. <input style="width: 100%;" type="text"/> Is it a scheduled listed chemical product?: <input style="width: 100%;" type="text"/></p>	<div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">RETURN INSTRUCTIONS</div> <p>Contact tel. # if product received damaged: <input style="width: 100%;" type="text" value="888-304-5022"/></p> <p>Is product returnable for credit: Yes</p> <p>URL/Link to returns policy: <input style="width: 100%;" type="text" value="www.vionausa.com"/></p> <p>Special regulations or returns requirements for this product in certain states? <input style="width: 100%;" type="text"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%;" type="text"/></p>																		
CLASS OF TRADE RESTRICTION:																			
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input style="width: 100%;" type="text"/></p> <p>Restricted to retail pharmacy only: <input style="width: 100%;" type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input style="width: 100%;" type="text"/></p> <p>Restricted from US territories? (explain in comments) <input style="width: 100%;" type="text"/></p> <p>Comments: <input style="width: 100%;" type="text"/></p>	<div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold;">MISCELLANEOUS NOTES and/or Image of Product Barcode:</div> <div style="border: 1px solid black; height: 40px; width: 100%;"></div>																		

