



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

Version 2020

Introduction Type: New Product Post Launch Change

Final Version

Date: 7/21/2022

PRODUCT INFORMATION	
Company Name:	Viona Pharmaceuticals Inc.
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	208767
DUNS:	081468959
Proprietary Name (if Applicable) and Established Name:	Clindamycin Phosphate Topical Solution, USP 1%
Selling Unit NDC:	72578-084-02
UDI:	N/A
Unit of Use NDC:	
UPC:	372578084028
CVX Code:	
MXV Code:	N/A
Description:	Clear solution with characteristics odor free from particulate matter. Filled in white HDPE bottle fitted with white PP cap.
Active Ingredient(s):	Clindamycin Phosphate, 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:	Antibacterials

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	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:	customerservice@vionausa.com
c. Special regulations for product in any states?	No
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	Yes
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 mL	Strength:	1.00%
Dosage Form:	Topical Solution	Product Shape:	N/A
Product Color:	Clear solution	Product Imprint:	N/A

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 Bottle of 30 mL
<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 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/Cartron/Pack
<input type="checkbox"/> Other: Write In	1 Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AT
II. Generic Equivalent to What Brand?:	Cleocin T
<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 Bottle	<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: 037257800004
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
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item/Each:	Weight Lbs.	Depth	Width	Height	Volume (Cube)	# Pieces:
Box/Cartron/Bundle/Inner Pack:	36.82 gm	1.16	1.16	2.77		1
Case:	8.8	11.61	9.84	4.72		48
Pallet:	739.2	47.24	39.37	47.24		4032

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		00372578084028	
<input type="checkbox"/> Box/Cartron/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	48		40372578084026	
<input checked="" type="checkbox"/> Pallet	4032		50372578084023	

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)	\$18.50	Whsl. Code #:	
As of date:		FineLine Code:	

Version 2020

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.) Yes</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) Yes</p> <p>a. UN/Identification Number <input type="text" value="UN1993"/></p> <p>b. Proper Shipping Name <input type="text" value="Flammable liquid, n.o.s. (contains isopropanol)"/></p> <p>c. DOT Hazard Class <input type="text" value="Class 3"/></p> <p>d. Packing Group <input type="text" value="III"/></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) Yes</p> <p>a. UN/Identification Number <input type="text" value="UN1993"/></p> <p>b. Proper Shipping Name <input type="text" value="Flammable liquid, n.o.s. (contains isopropanol)"/></p> <p>c. DOT Hazard Class <input type="text" value="Class 3"/></p> <p>d. Packing Group <input type="text" value="III"/></p> <p>e. Inhalation Hazard? No</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 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 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%; border: 1px solid black;"><input type="checkbox"/> Organic</td> <td style="width: 50%; border: 1px solid black;"><input type="checkbox"/> Corrosive</td> </tr> <tr> <td style="border: 1px solid black;"><input type="checkbox"/> Inorganic</td> <td style="border: 1px solid black;"><input type="checkbox"/> Oxidizer</td> </tr> <tr> <td style="border: 1px solid black;"><input type="checkbox"/> Steroid/Androgen</td> <td style="border: 1px solid black;"><input type="checkbox"/> Contact Hazard</td> </tr> <tr> <td colspan="2" style="border: 1px solid black;"> <input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input type="text"/> </td> </tr> <tr> <td colspan="2" style="border: 1px solid black;"> Is the product a NIOSH hazardous drug? No If yes, indicate which: <input type="text"/> </td> </tr> </table> <div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold; margin-top: 10px;">Hazardous Waste Identification</div> <table style="width: 100%; border: 1px solid black;"> <tr> <td style="width: 60%; border: 1px solid black;">EPA Hazardous Waste Code: <input type="text"/></td> <td style="width: 40%; border: 1px solid black;">Waste Characteristics <input type="text"/></td> </tr> </table> <div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold; margin-top: 10px;">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? No Website URL: <input type="text"/></p> <p>Med Guide Required No</p> <p>Limited Distribution Requirement No</p> <p>Comments / Details: (For example, iPledge program?) <input type="text"/></p> <p>REMS:</p> <p>REMS Program Manager Name: <input type="text"/> Phone: <input type="text"/></p> <p>Supplier Manages REMS registry exclusively: <input type="text"/></p> <p>Wholesale distributor support: <input type="text"/></p> <p>Provider Name: <input type="text"/> DEA #: <input type="text"/></p> <p>Site Enrollment Number assigned by Supplier: <input type="text"/> PCPDP#: <input type="text"/></p> <p>NPI #: <input type="text"/></p> <p>Comments <input type="text"/></p> <p>Registry:</p> <p>Registry Program Contact Name: <input type="text"/> Phone: <input type="text"/></p> <p>Comments <input type="text"/></p> <div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold; margin-top: 10px;">RETURN INSTRUCTIONS</div> <p>Contact tel. # if product received damaged: <input type="text" value="888-304-5022"/></p> <p>Is product returnable for credit: Yes</p> <p>URL/Link to returns policy: <input type="text" value="www.vionausa.com"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="text"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p> <div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold; margin-top: 10px;">ADD'L STORAGE INFORMATION</div> <p>Is the Product...</p> <p>Controlled Substance? No Controlled Substance Code <input type="text"/></p> <p>Controlled by State(s)? No Listed Chemical (List I or II) <input type="text"/></p> <p>ARCOS Reportable? No If yes, indicate which: <input type="text"/></p> <p>Schedule No. <input type="text"/> Is it a scheduled listed chemical product?: <input type="text"/></p> <div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold; margin-top: 10px;">CLASS OF TRADE RESTRICTION:</div> <p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="text"/></p> <p>Restricted to retail pharmacy only: <input type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="text"/></p> <p>Restricted from US territories? (explain in comments) <input type="text"/></p> <p>Comments: <input type="text"/></p> <div style="background-color: #003366; color: white; padding: 2px; text-align: center; font-weight: bold; margin-top: 10px;">MISCELLANEOUS NOTES and/or Image of Product Barcode:</div> <div style="border: 1px solid black; height: 30px; width: 100%;"></div>	<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive	<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer	<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard	<input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input type="text"/>		Is the product a NIOSH hazardous drug? No If yes, indicate which: <input type="text"/>		EPA Hazardous Waste Code: <input type="text"/>	Waste Characteristics <input type="text"/>
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