



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

Version 2020

Introduction Type:  New Item

Final Version

Date:

PRODUCT INFORMATION	
Company Name:	Viona Pharmaceuticals Inc.
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	205206
DUNS:	081468959
Proprietary Name (if Applicable) and Established Name:	Desoximetasone Ointment, USP 0.25%
Selling Unit NDC:	72578-095-02
UDI:	N/A
Unit of Use NDC:	
UPC:	372578095024
CVX Code:	
VMX Code:	N/A
Description:	Desoximetasone Ointment, USP 0.25% is supplied as a white to off-white color ointment. Each gram of Desoximetasone Ointment, USP 0.25% contains 2.5 mg desoximetasone in an ointment base.
Active Ingredient(s):	Desoximetasone, USP
URL for Additional Product Information:	<a href="http://www.vionausa.com">www.vionausa.com</a>
Address:	20 Commerce Drive
City:	Cranford
Phone Contact:	Chris Urbanski
Phone Number:	908-956-0600
Product Therapeutic Classification:	Anti-inflammatory and Anti-Pruritic

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:	Vionacs@eversana.com
c. Special regulations for product in any states?	No
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	No
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? if yes, enter class #	No	Is the Product... Direct-Ship Only	
if yes, list NDCs of component parts reverse numbered?	No	Is the Product... Neither	
co-licensed?	No	Orphan Drug Status	
latex-free?	Yes	FDA Approval Status	
preservative-free?	Yes	Allergens Present	
correctional institution block?	Yes	Country of Origin	India
opioid?	No	Is this product covered under the Trade Agreements Act (TAA)?	No
Cannabinoid?	No		
If Unit Dose, is item bar coded to unit dose for hospital scanning?			
If Unit Dose, indicate NDC here:			
Size:	60g	Strength:	0.25%
Dosage Form:	Ointment	Product Shape:	-
Product Color:	White to off-white	Product Imprint:	-

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input type="checkbox"/> Bottle	1 Tube of 60g
<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	If Yes, how many of which package type?
<input type="checkbox"/> Vial Liquid Multi	48 Each
<input type="checkbox"/> Vial Powder Sgl	Inner/ Carton/ Pack
<input type="checkbox"/> Vial Power Multi	1 Case
<input type="checkbox"/> Other: Write In	

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	Topicort
<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	x Each
(Write-in, e.g. 1 Vial)	Gram
	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:	0.15	1.25	1.25	6.1	9.53125	1
Box/ Carton/ Bundle/ Inner Pack:						
Case:	10.9	15.08	9.06	6.89	941.34487	48
Pallet:	557	47.24	39.37	47.24	87858.785	2304

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		00372578095024	
<input type="checkbox"/> Box/ Carton/ Bundle/ Inner Pack				
<input checked="" type="checkbox"/> Case	48		40372578095022	
<input checked="" type="checkbox"/> Pallet	2304		50372578095029	

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

\*Please provide any additional information on page 2.

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

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?  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?

- (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      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?  No
- 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?  No
- If so, which states? Other requirements? Comments?

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



Version 2020

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										
Order Method for Designated Drop Ship Product											
Purchase orders may be accepted by: a. EDI <input type="checkbox"/> _____ b. Autofax <input type="checkbox"/> _____ Fax Number: _____ c. Fax <input type="checkbox"/> _____ Fax Number: _____ d. Phone only <input type="checkbox"/> _____ Phone No.: _____ e. Supplier Web Site only <input type="checkbox"/> _____ Site Address: _____ Minimum Order Quantity: _____ Supplier's Customer Service Number: _____ Contracted 3PL company / contact #: _____ Name: _____ Phone: _____											
Standard Order Receipt and Processing											
<b>Purchase order daily receipt cut off time by supplier</b> Cut off time: _____  Shipping lead time of PO: _____ Hours _____ Days  Ships same day for next day receipt: <input type="checkbox"/> _____ Ships for second day receipt: <input type="checkbox"/> _____ Ships regular ground for 3-10 days receipt: <input type="checkbox"/> _____											
Expedited Freight Charges or Other Designated Drop Ship Fees:											
Expedited freight fees billed with each order: _____ Drop Ship service fee billed with each order: _____ Drop Ship miscellaneous fees billed: _____ Comments: _____											
Overnight and Priority Overnight PO Processing											
<b>Overnight receipt available:</b> <input type="checkbox"/> _____ PO Receipt cut off time: _____ Days of week overnight is available: <table style="margin-left: 100px; border: none;"> <tr><td><input type="checkbox"/></td><td>Monday</td></tr> <tr><td><input type="checkbox"/></td><td>Tuesday</td></tr> <tr><td><input type="checkbox"/></td><td>Wednesday</td></tr> <tr><td><input type="checkbox"/></td><td>Thursday</td></tr> <tr><td><input type="checkbox"/></td><td>Friday</td></tr> </table>		<input type="checkbox"/>	Monday	<input type="checkbox"/>	Tuesday	<input type="checkbox"/>	Wednesday	<input type="checkbox"/>	Thursday	<input type="checkbox"/>	Friday
<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="checkbox"/> _____ PO Receipt Cut off time: _____											
<b>Saturday Overnight receipt available:</b> <input type="checkbox"/> _____ PO Receipt Cut off time: _____											
Order receipt method: <table style="margin-left: 20px; border: none;"> <tr> <td>Phone: _____</td> <td>Phone #: _____</td> </tr> <tr> <td>Fax: _____</td> <td>Fax #: _____</td> </tr> <tr> <td>EDI: _____</td> <td></td> </tr> </table>		Phone: _____	Phone #: _____	Fax: _____	Fax #: _____	EDI: _____					
Phone: _____	Phone #: _____										
Fax: _____	Fax #: _____										
EDI: _____											
Overnight Fees apply: <input type="checkbox"/> _____ Other fees apply: <input type="checkbox"/> _____											
Class of Trade Restriction:											
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> _____ Restricted to retail pharmacy only: <input type="checkbox"/> _____ Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> _____ Restricted from US territories? (explain in comments) <input type="checkbox"/> _____ Comments: _____											
Other Data Information Required to Process PO:											
Patient Procedure Date: _____ Physician Name: _____ Physician/Clinic Phone #: _____ Physician State License #: _____ Physician/Clinic DEA #: _____ Physician/Clinic Specialty: _____											
Return Instructions											
Contact # if product is received damaged: _____ Is product returnable for credit: <input type="checkbox"/> _____ URL/Link to returns policy: _____  Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> _____ If so, which states? Other requirements? Comments? _____ _____											
Miscellaneous Notes:											
_____ _____ _____											
ADDITIONAL INFORMATION											
Is product order for scheduled patient procedure? <input type="checkbox"/> _____ Is product order for restocking purposes? <input type="checkbox"/> _____											