



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

Version 2021 Introduction Type:  New Item  Final Version Date: 12/13/2023

## PRODUCT INFORMATION

Company Name: Eugia US LLC (f/k/a AuroMedics Pharma LLC) Application: ANDA  
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 214842  
 Medical Device Class, if applicable:   
 DUNS: 968961354  
 Proprietary Name (If Applicable) and Established Name:   
 Selling Unit NDC: 55150-388-01 Unit of Use NDC: 55150-388-01 UPC: 355150388011  
 UDI: CVX Code: MVX Code:   
 Description: Posaconazole Injection 300 mg per 16.7 mL (18 mg/mL)  
 Active Ingredient(s): posaconazole  
 URL for Additional Product Information: eugiaus.com  
 Address: 279 Princeton-Hightstown Road Address 2: State: NJ Zip: 08520  
 City: East Windsor Email: Fax: 732-355-9449  
 Key Contact: Phone Number: 888-238-7880  
 Product Therapeutic Classification: azole antifungals

## SPECIAL HANDLING AND STORAGE REQUIREMENTS\*

a. Temperature – Indicate the USP temperature range for this product.  
 Temperature Range: Cold – between 2 and 8 C (36° – 46° F)  
 Other Temperature Range Requirement (write in):  
 Notes:  
 Is this product to be shipped to customers on ice?  Yes  
 Is this product to be shipped to customers on dry ice?  No  
 b. Contact for temperature excursion questions:  
 Name: Kevin Cagnetti  
 Number: 732.839.9400 ex 8009  
 Group E-mail: kcagnetti@EugiaUS.com  
 c. Special regulations for product in any states?  
 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:  
 Initial shelf life at launch (if different): 24 Months

## ADDITIONAL PRODUCT INFORMATION

The product is a legend device?  No  
 if yes, enter class # a product kit?  No  
 if yes, list NDCs of component parts reverse numbered?  No  
 co-licensed?  No  
 latex-free?  Yes  
 preservative-free?  Yes  
 correctional institution block?  No  
 opioid?  No  
 Cannabinoid?  No  
 If Unit Dose, is item bar coded to unit dose for hospital scanning?  Yes  
 If Unit Dose, indicate NDC here: 55150-388-01  
 Is the Product... Direct-Ship Only   
 Is the Product... Unit Dose   
 Orphan Drug Status   
 FDA Approval Status   
 Allergens Present   
 Country of Origin: India

## PRODUCT DESCRIPTION INFORMATION

Size: Mono Vial  
 Strength: 300 mg per 16.7 mL (18 mg/mL)  
 Dosage Form: Liquid  
 Product Shape:  
 Product Color:  
 Product Imprint:

## ORDER INFORMATION

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

## FOR GENERIC DRUG PRODUCTS

I. Orange Book Rating: AP  Authorized Generic \*If Authorized Generic, other section fields are not applicable  
 II. Generic Equivalent to What Brand?: Noxafil

## PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer? 1 Vial  
 (Write-in, e.g. 1 Vial)  
 Rx billing unit to pharmacy:  
 Each,  Gram,  Milliliter

## DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?  Yes  No  
 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  
 If yes, attach documentation from FDA.  
 GLN:   
 GCP:   
 If yes, was original product purchased direct from mfr?   
 Provide source manufacturer for repackaged product

## ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.127	1.57	2.09	2.76	9.056	1
Box/Carton/Bundle/Inner Pack:	3.558	10.08	8.9	3.78	339.11	24
Case:	23.347	19.291	11.023	12.992	2762.68	144
Pallet:	593.372	48	40	43.98	84441.6	3456

## GTIN AND HIBCC PRODUCT INFORMATION

Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
<input checked="" type="checkbox"/> Item/Each	1		00355150388011	
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack	24		30355150388012	
<input type="checkbox"/> Case	144		50355150388016	
<input type="checkbox"/> Pallet	3456		70355150388010	

## COST INFORMATION

Regular Cost:   
 Invoice Cost (WAC) (\$): \$330.00  
 As of date: 12/26/2023  
 WHOLESALE USE ONLY:  
 Vendor #:   
 Whsl. Code #:   
 Finline 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?  
 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)  No

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)  No

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:  No

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?  
 (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#

### SDS Hazard Classification

Organic  Corrosive  
 Inorganic  Oxidizer  
 Steroid/Androgen  Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:  No  
 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:**  No

REMS Program Manager Name:  Phone:   
 Supplier Manages REMS registry exclusively:   
 Wholesale distributor support:   
 Provider Name:  DEA #:   
 Site Enrollment Number assigned by Supplier:  NCPDP#:   
 NPI #:

Comments

**Registry:**  No

Registry Program Contact Name:  Phone:   
 Comments

### ADD'L STORAGE INFORMATION

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

### CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices  Yes

Restricted to retail pharmacy only:  No

Restricted to hospital, clinics, and physician offices only:  
 Restricted from US territories? (explain in comments)  No

Comments:

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit:  Yes  No  
 URL/Link to returns policy:   
<https://eugiaus.com/policies/return-policy/>

Special regulations or return 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	Standard Order Receipt and Processing
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="checkbox"/></p> <p>b. Autofax <input type="checkbox"/></p> <p>c. Fax <input type="checkbox"/></p> <p>d. Phone only <input type="checkbox"/></p> <p>e. Supplier Web Site only <input type="checkbox"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/></p> <p>Ships for second day receipt: <input type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/></p>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p><b>Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/></p> <p>Restricted to retail pharmacy only: <input type="checkbox"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/></p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/></p> <p>Comments: <input type="text"/></p>	
Other Data Information Required to Process PO:	Return Instructions
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<p><input type="text"/></p>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>