



# Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type:  New Item Final VersionDate: 

PRODUCT INFORMATION	
Company Name:	Encube Ethicals Inc.
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	212443
DUNS:	11-698-2244
Proprietary Name (If Applicable) and Established Name:	Ketoconazole Cream 2%
Selling Unit NDC:	21922-025-05
Individual Unit NDC:	
UPC:	321922025057
UDI	
CVX Code:	
MXV Code:	
Description:	Ketoconazole cream, 2% is indicated for the topical treatment of tinea corporis, tinea cruris and tinea pedis
Active Ingredient(s):	Ketoconazole
URL for Additional Product Information:	
Address:	200 Meredith Avenue, Suite 101A
City:	Durham
State:	NC
Zip:	27713
Key Contact:	Kamesh Venugopal
Phone Number:	+1-269-806-2796
Fax:	984-439-2761
Email:	kamesh.v@encubeethicals.com
Product Therapeutic Classification:	

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)	
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:	Dipti Kamani
Number:	+1-781-789-0567
Group E-mail:	usreg@encubeethicals.com
c. Special regulations for product in any states?	
Special returns requirements for this product?	
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):	

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	No
reverse numbered?	No
co-licensed?	No
Is the Product... Is the Product...	
If Unit Dose, is item bar coded to unit dose for hospital scanning?	
If Unit Dose NDC, indicate NDC here:	
Country of Origin	India
Is this product covered under the Trade Agreements Act (TAA)?	

PRODUCT DESCRIPTION INFORMATION	
Size:	30g
Strength:	2%
Dosage Form:	Cream
Product Shape:	
Product Color:	
Product Imprint:	

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	AB
II. Generic Equivalent to What Brand?:	KETOCONAZOLE (TEVA,RS)
<input type="checkbox"/> Authorized Generic	*If Authorized Generic, other section fields are not applicable

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	21922-025-05
<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	1 Each
<input type="checkbox"/> Vial Power Multi	1 Inner/Carton/Pack
<input type="checkbox"/> Other: Write In	Case

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:	890600527
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

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

GTIN PRODUCT INFORMATION						
Serialized?	Level	Unit	Quantity	GTIN-14		
				Serialized?	Level	Unit
Yes	Item	1	00321922025057			
If not, when?	Box/Case/Bundle/Inner Pack	24	10321922025054			
Items aggregated?	Case	144	30321922025058			
	Pallet	5184	50321922025052			

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.0882	5.39	1.42	1.22	9.337636	1
Box/Carton/Bundle/Inner Pack:	2.468	7.56	5.59	5.91	249.758964	24
Case:	16.001	17.17	6.3	15.39	1664.75169	144
Pallet:	622.983	47.24	35.43	47.24	79066.2116	5184
UPC:	Case:	NA				
	Carton:	321922025057				

COST INFORMATION		WHOLESALE USE ONLY:	
Regular Cost		Vendor #:	
Invoice Cost (WAC) (\$)		Whsl. Code #:	
Federal Excise Tax Per Unit of Sale		Fineline Code:	
As of date:			

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 or IATA? Yes

(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# [ ]

SDS Hazard Classification	
<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: <span style="float: right;">[ ]</span>	
Is the product a NIOSH hazardous drug? <span style="float: right;">No</span> If yes, indicate which: <span style="float: right;">[ ]</span>	

Hazardous Waste Identification
EPA Hazardous Waste Code: <span style="float: right;">[ ]</span>

REMS or REGISTRY RESTRICTIONS
Is there a REMS on this product? <span style="float: right;">No</span>
If Yes, is it managed with a pharmacy registry? <span style="float: right;">[ ]</span>
Website URL: <span style="float: right;">[ ]</span>
Comments / Details: (For example, iPledge program?) <span style="float: right;">[ ]</span>
REMS: <span style="float: right;">No</span>
REMS Program Manager Name: <span style="float: right;">[ ]</span> Phone: <span style="float: right;">[ ]</span>
Supplier Manages REMS registry exclusively: <span style="float: right;">[ ]</span>
Wholesale distributor support: <span style="float: right;">[ ]</span>
Provider Name: <span style="float: right;">[ ]</span>
Site Enrollment Number assigned by Supplier: <span style="float: right;">[ ]</span>
DEA #: <span style="float: right;">No</span>
PCDP #: <span style="float: right;">No</span>
NPI #: <span style="float: right;">No</span>

Comments [ ]

**Registry:** No

Registry Program Contact Name: [ ] Phone: [ ]

Comments [ ]

ADD'L STORAGE INFORMATION
Is the Product... Controlled Substance? <span style="float: right;">No</span>
Controlled by State(s)? <span style="float: right;">No</span>
ARCOS Reportable? <span style="float: right;">No</span>
Schedule No. (inc. N for non-narcotic) <span style="float: right;">[ ]</span>
Controlled Substance Code <span style="float: right;">[ ]</span>
Listed Chemical (List I or II) <span style="float: right;">No</span>
If yes, indicate which: <span style="float: right;">[ ]</span>
Is it a scheduled listed chemical product?: <span style="float: right;">No</span>

RETURN INSTRUCTIONS
Contact tel. # if product received damaged: <span style="float: right;">919-767-3292</span>
Is product returnable for credit: <span style="float: right;">Yes</span>
URL/Link to returns policy: <span style="float: right;">Contact Manufacturer</span>
Special regulations or returns requirements for this product in certain states? <span style="float: right;">[ ]</span>
If so, which states? Other requirements? Comments? <span style="float: right;">[ ]</span>

CLASS OF TRADE RESTRICTION:
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <span style="float: right;">No</span>
Restricted to retail pharmacy only: <span style="float: right;">No</span>
Restricted to hospital, clinics, and physician offices only: <span style="float: right;">No</span>
Restricted from US territories? (explain in comments) <span style="float: right;">No</span>
Comments: <span style="float: right;">[ ]</span>

MISCELLANEOUS NOTES and/or Image of Product Barcode:
[ ]

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 <span style="float: right;"><input type="checkbox"/> Yes</span></p> <p>b. Autofax <span style="float: right;"><input type="checkbox"/></span> Fax Number: <input style="width: 150px;" type="text"/></p> <p>c. Fax <span style="float: right;"><input type="checkbox"/> Yes</span> Fax Number: <input style="width: 150px; border-bottom: 1px solid black;" type="text" value="984-439-2761"/></p> <p>d. Phone only <span style="float: right;"><input type="checkbox"/></span> Phone No.: <input style="width: 150px;" type="text"/></p> <p>e. Supplier Web Site only <span style="float: right;"><input type="checkbox"/></span> Site Address: <input style="width: 150px;" type="text"/></p> <p>Minimum Order Quantity: <input style="width: 50px; border-bottom: 1px solid black;" type="text" value="144"/> Units</p> <p>Supplier's Customer Service Number: <input style="width: 250px;" type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input style="width: 250px;" type="text"/> Phone: <input style="width: 250px;" type="text"/></p>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input style="width: 100px; border-bottom: 1px solid black;" type="text" value="12pm"/> Eastern</p> <p>Shipping lead time of PO: <input style="width: 50px;" type="text"/> Hours <input style="width: 50px;" type="text"/> Days</p> <p>Ships same day for next day receipt: <input style="width: 50px;" type="checkbox"/></p> <p>Ships for second day receipt: <input style="width: 50px;" type="checkbox"/></p> <p>Ships regular ground for 3-10 days receipt: <input style="width: 50px;" type="checkbox"/> Yes</p>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<p>Expedited freight fees billed with each order: <span style="float: right;"><input type="checkbox"/> Yes</span></p> <p>Drop Ship service fee billed with each order: <span style="float: right;"><input type="checkbox"/> Yes</span></p> <p>Drop Ship miscellaneous fees billed: <span style="float: right;"><input type="checkbox"/> Yes</span></p> <p>Comments: <input style="width: 400px; height: 80px;" type="text"/></p>	<p><b>Overnight receipt available:</b> <input style="width: 50px;" type="checkbox"/></p> <p>PO Receipt cut off time: <input style="width: 150px;" 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 style="width: 50px;" type="checkbox"/></p> <p>PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input style="width: 50px;" type="checkbox"/></p> <p>PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p>Order receipt method: Phone: <input style="width: 50px;" type="text"/> Phone #: <input style="width: 100px;" type="text"/> Fax: <input style="width: 50px;" type="text"/> Fax #: <input style="width: 100px;" type="text"/> EDI: <input style="width: 50px;" type="text"/></p> <p>Overnight Fees apply: <input style="width: 50px;" type="checkbox"/></p> <p>Other fees apply: <input style="width: 50px;" type="checkbox"/></p>
Class of Trade Restriction:	Return Instructions
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <span style="float: right;"><input type="checkbox"/> Yes</span></p> <p>Restricted to retail pharmacy only: <span style="float: right;"><input type="checkbox"/> No</span></p> <p>Restricted to hospital, clinics, and physician offices only: <span style="float: right;"><input type="checkbox"/> No</span></p> <p>Restricted from US territories? (explain in comments) <span style="float: right;"><input type="checkbox"/> No</span></p> <p>Comments: <input style="width: 400px; height: 40px;" type="text"/></p>	<p>Contact # if product is received damaged: <input style="width: 150px; border-bottom: 1px solid black;" type="text" value="919-767-3292"/></p> <p>Is product returnable for credit: <span style="float: right;"><input type="checkbox"/> Yes</span></p> <p>URL/Link to returns policy: <input style="width: 200px; border-bottom: 1px solid black;" type="text" value="Please contact manufacturer"/></p> <p>Special regulations or returns requirements for this product in certain states? <input style="width: 50px;" type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 400px; height: 40px;" type="text"/></p>
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION
<p>Patient Procedure Date: <input style="width: 100px;" type="text"/></p> <p>Physician Name: <input style="width: 250px;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 250px;" type="text"/></p> <p>Physician State License #: <input style="width: 250px;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 250px;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 250px;" type="text"/></p>	<p>Is product order for scheduled patient procedure? <input style="width: 50px;" type="checkbox"/></p> <p>Is product order for restocking purposes? <input style="width: 50px;" type="checkbox"/></p>
Miscellaneous Notes:	
<input style="width: 450px; height: 80px;" type="text"/>	