



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: New Item Final Version

Date: 17-04-2021

PRODUCT INFORMATION

Company Name: Encube Ethicals Inc. Application: ANDA
 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: 21922-025-04 Individual Unit NDC: _____ UPC: 321922025040
 UDI: _____ CVX Code: _____ MVX 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 Address 2: _____
 City: Durham State: NC Zip: 27713
 Key Contact: Kamesh Venugopal Email: kamesh.v@encubeethicals.com
 Phone Number: +1-269-806-2796 Fax: 984-439-2761
 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?
 Protect product (unit of sale) from light? Yes No
 e. Shelf life:
 Initial shelf life at launch (if different): Months

ADDITIONAL PRODUCT INFORMATION**PRODUCT DESCRIPTION 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)?

Size: 15g
 Strength: 2%
 Dosage Form: Cream
 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? 21922-025-04 (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: AB Authorized Generic *If Authorized Generic, other section fields are not applicable
 II. Generic Equivalent to What Brand?: KETOCONAZOLE (TEVA,RS)

PHARMACY ORDER / BILL UNIT

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

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer? Yes No GLN: 890600527
 Is product exempt from DSCSA? No
 If yes, select exemption: _____
 Other exemption - Write in: _____
 Is product repackaged? No Yes If Yes, was original product purchased direct from mfr? _____
 Is product sold by manufacturer's exclusive distributor? No Yes If yes, attach documentation from FDA.
 Has FDA granted waiver/exception/exemption for product? No Yes

ITEM AND PACKING INFORMATION

Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.006	4.13	1.18	0.98	4.775932	1
Box/Carton/Bundle/Inner Pack:	1.498	6.14	4.33	4.96	131.867552	24
Case:	10.16	13.58	5.31	12.68	914.352264	144
Pallet:	579.498	42.17	41.34	39.45	68773.4927	7776
UPC:	Case: NA Carton: 321922025040					

GTIN PRODUCT INFORMATION

Serialized? If not, when? Items aggregated?	Yes <input type="checkbox"/> Yes <input type="checkbox"/>	Level		Soleable Unit		Quantity	GTIN-14
		Item	Unit	2D	Linear		
		<input checked="" type="checkbox"/>	Box/Carton/Bundle/Inner Pack	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	1	00321922025040
		<input checked="" type="checkbox"/>	Case	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	24	10321922025047
		<input checked="" type="checkbox"/>	Pallet	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	144	30321922025041
				<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	7776	50321922025045
				<input type="checkbox"/>	<input type="checkbox"/>		
				<input type="checkbox"/>	<input type="checkbox"/>		
				<input type="checkbox"/>	<input type="checkbox"/>		
				<input type="checkbox"/>	<input type="checkbox"/>		

COST INFORMATION**WHOLESALE USE ONLY:**

Regular Cost _____ Vendor #: _____
 Invoice Cost (WAC) (\$) _____ Whsl. Code #: _____
 Federal Excise Tax Per Unit of Sale _____ Finline Code: _____
 As of date: _____

*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: _____

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#

ADD'L STORAGE INFORMATION

Is the Product...

Controlled Substance? No

Controlled by State(s)? No

ARCOS Reportable? No

Schedule No. (inc. N for non-narcotic)

Controlled Substance Code

Listed Chemical (List I or II) No

If yes, indicate which:

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 No

Restricted to retail pharmacy only: No

Restricted to hospital, clinics, and physician offices only: No

Restricted from US territories? (explain in comments) No

Comments:

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: <input style="width: 100%;" type="text"/>	
Is the product a NIOSH hazardous drug? No If yes, indicate which: <input style="width: 100%;" type="text"/>	

Hazardous Waste Identification
EPA Hazardous Waste Code: <input style="width: 100%;" type="text"/>

REMS or REGISTRY RESTRICTIONS
Is there a REMS on this product? No
If Yes, is it managed with a pharmacy registry? No
Website URL: <input style="width: 100%;" type="text"/>
Comments / Details: (For example, iPledge program?) <input style="width: 100%;" type="text"/>
REMS: No
REMS Program Manager Name: <input style="width: 100%;" type="text"/> Phone: <input style="width: 100%;" type="text"/>
Supplier Manages REMS registry exclusively: <input style="width: 100%;" type="text"/>
Wholesale distributor support: <input style="width: 100%;" type="text"/>
Provider Name: <input style="width: 100%;" type="text"/>
Site Enrollment Number assigned by Supplier: <input style="width: 100%;" type="text"/>
DEA #: No
PCDP #: No
NPI #: No
Comments <input style="width: 100%; height: 20px;" type="text"/>
Registry: No
Registry Program Contact Name: <input style="width: 100%;" type="text"/> Phone: <input style="width: 100%;" type="text"/>
Comments <input style="width: 100%; height: 20px;" type="text"/>

RETURN INSTRUCTIONS
Contact tel. # if product received damaged: <input style="width: 100%;" type="text" value="919-767-3292"/>
Is product returnable for credit: Yes
URL/Link to returns policy: <input style="width: 100%;" type="text" value="Contact Manufacturer"/>
Special regulations or returns requirements for this product in certain states? <input style="width: 100%;" type="text"/>
If so, which states? Other requirements? Comments? <input style="width: 100%; height: 40px;" type="text"/>

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 <input type="checkbox"/> Yes</p> <p>b. Autofax <input type="checkbox"/> Fax Number: <input style="width: 150px;" type="text"/></p> <p>c. Fax <input type="checkbox"/> Yes Fax Number: <input style="width: 150px; border-bottom: 1px solid black;" type="text" value="984-439-2761"/></p> <p>d. Phone only <input type="checkbox"/> Phone No.: <input style="width: 150px;" type="text"/></p> <p>e. Supplier Web Site only <input type="checkbox"/> 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: 150px;" type="text"/></p> <p>Contracted 3PL company / contact #: Name: <input style="width: 150px;" type="text"/> Phone: <input style="width: 150px;" type="text"/></p>	<p>Purchase order daily receipt cut off time by supplier</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 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"/> 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: <input type="checkbox"/> Yes</p> <p>Drop Ship service fee billed with each order: <input type="checkbox"/> Yes</p> <p>Drop Ship miscellaneous fees billed: <input type="checkbox"/> Yes</p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p>	<p>Overnight receipt available: <input 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>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p>Saturday Overnight receipt available: <input 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: 50px;" type="text"/> Fax: <input style="width: 50px;" type="text"/> Fax #: <input style="width: 50px;" type="text"/> EDI: <input style="width: 50px;" type="text"/></p> <p>Overnight Fees apply: <input type="checkbox"/></p> <p>Other fees apply: <input type="checkbox"/></p>
Class of Trade Restriction:	Return Instructions
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes</p> <p>Restricted to retail pharmacy only: <input type="checkbox"/> No</p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No</p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/> No</p> <p>Comments: <input style="width: 100%; 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: <input type="checkbox"/> Yes</p> <p>URL/Link to returns policy: <input style="width: 150px; 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 type="checkbox"/></p> <p>If so, which states? Other requirements? Comments? <input style="width: 100%; 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: 150px;" 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 type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>
Miscellaneous Notes:	
<input style="width: 100%; height: 80px;" type="text"/>	