



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

Version 2021

Introduction Type: New Item

Final Version

Date: 03/21/2023

PRODUCT INFORMATION

Company Name: Encube Ethicals, Inc. Application: ANDA
 Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): A200298
 Medical Device Class, if applicable:
 DUNS: 11-698-2244
 Proprietary Name (If Applicable) and Established Name: Adapalene Gel 0.3%
 Selling Unit NDC: 21922-051-50 Unit of Use NDC: EA UPC: 321922051506
 UDI: CVX Code: MVX Code:
 Description: Adapalene Gel 0.3%
 Active Ingredient(s): Adapalene
 URL for Additional Product Information:
 Address: 200 Meredith Avenue, Suite 202
 City: Durham State: NC Zip: 27713
 Key Contact: Kamesh Venugopal Email: Kamesh.V@encubeethicals.com
 Phone Number: 1-919-767-3292 Fax: 984-439-2761
 Product Therapeutic Classification: Treatment of acne vulgaris in patients 12 years of age and older.

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?
 co-licensed? No
 latex-free? Yes
 preservative-free? 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:

PRODUCT DESCRIPTION INFORMATION

Is the Product... Direct-Ship Only
 Is the Product... Unit of Use
 Orphan Drug Status
 FDA Approval Status
 Allergens Present
 Country of Origin: India
 Is this product covered under the Trade Agreements Act (TAA)? No
 Size: 45 gram
 Strength: 0.30%
 Dosage Form: Gel
 Product Shape:
 Product Color: Off-white aqueous Gel
 Product Imprint:

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?: DIFFERIN

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
 If yes, attach documentation from FDA.
 GLN: 0860002158402
 GCP:
 If yes, was original product purchased direct from mfr?
 Provide source manufacturer for repackaged product

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		00321922051506	EA
<input type="checkbox"/> Box/Carton/Bundle/Inner Pack				
<input checked="" type="checkbox"/> Case	24		30321922051507	
<input checked="" type="checkbox"/> Pallet	2880		50321922051501	

*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.

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):
 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: Dipti Kamani
 Number: 919-767-3292
 Group E-mail: usreg@encubeethicals.com
 c. Special regulations for product in any states?
 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:
 Initial shelf life at launch (if different): 24 Months

ORDER INFORMATION

Unit of Sale: Bottle
 Box/Carton
 Ampule
 Glass
 Tube
 Vial Liquid Sgl
 Vial Liquid Multi
 Vial Powder Sgl
 Vial Powder Multi
 Other: Write In
 What is the NDC selling unit?
 1 box containing 1 tube
 (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
 1 Case

PHARMACY ORDER / BILL UNIT

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

ITEM AND PACKING INFORMATION

Item/Each:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.2	1.77	1.77	5	15.7	1
Box/Carton/Bundle/Inner Pack:						
Case:	5.4	11.22	7.48	5.59	469.1	24
Pallet:	705.4	46.53	39.37	42.99	78752.8	2880

COST INFORMATION

Regular Cost Invoice Cost (WAC) (\$): \$66.52
 As of date:
 Vendor #:
 Whsl. Code #:
 Finline Code:
 Signature: Kamesh Venugopal

Signature: Kamesh Venugopal



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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:
 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

Organic
 Inorganic
 Steroid/Androgen

Corrosive
 Oxidizer
 Contact Hazard

Does the product have an Aerosol class? If yes, identify No

NFPA Storage Level:

NFPA Storage Level:

Is the product a NIOSH hazardous drug?
 If yes, indicate which: No

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

Limited Distribution Requirement

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:

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)

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 Yes

Restricted to retail pharmacy only: No

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

Restricted from US territories? (explain in comments) No

Comments:

RETURN INSTRUCTIONS

Contact tel. # if product received damaged: 1-919-767-3292

Is product returnable for credit: Yes

URL/Link to returns policy:

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:



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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"/> Yes</p> <p>b. Autofax <input type="checkbox"/></p> <p>c. Fax <input type="checkbox"/> Yes Fax Number: 984-439-2761</p> <p>d. Phone only <input type="checkbox"/> Phone No.:</p> <p>e. Supplier Web Site only <input type="checkbox"/> Site Address:</p> <p>Minimum Order Quantity: 24 Units</p> <p>Supplier's Customer Service Number:</p> <p>Contracted 3PL company / contact #: Name: Phone:</p>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: 12:00 PM Eastern</p> <p>Shipping lead time of PO: Hours 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="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:</p>	<p>Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt cut off time:</p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday <input type="checkbox"/> Thursday <input type="checkbox"/> Friday</p> <p>Priority Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time:</p> <p>Saturday Overnight receipt available: <input type="checkbox"/></p> <p>PO Receipt Cut off time:</p> <p>Order receipt method: Phone: Phone #: Fax: Fax #: EDI:</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:</p>	<p>Return Instructions</p> <p>Contact # if product is received damaged: <input type="checkbox"/></p> <p>Is product returnable for credit: <input type="checkbox"/></p> <p>URL/Link to returns policy: <input type="checkbox"/></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:</p>
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION
<p>Patient Procedure Date: <input type="checkbox"/></p> <p>Physician Name: <input type="checkbox"/></p> <p>Physician/Clinic Phone #: <input type="checkbox"/></p> <p>Physician State License #: <input type="checkbox"/></p> <p>Physician/Clinic DEA #: <input type="checkbox"/></p> <p>Physician/Clinic Specialty: <input type="checkbox"/></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:	