



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 Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): | 212438 |
| DUNS: | 11-698-2244 |
| Proprietary Name (If Applicable) and Established Name: | Clindamycin Phosphate and Benzoyl Peroxide Gel, 1.2%/5% |
| Selling Unit NDC: | 21922-022-06 |
| UDI | CVX Code: MVX Code: |
| Application: | ANDA |
| Description: Clindamycin Phosphate and Benzoyl Peroxide Gel, 1.2%/5% is a combination of clindamycin phosphate (a lincosamide antibacterial) and benzoyl peroxide indicated for the topical treatment of inflammatory acne vulgaris. | |
| Active Ingredient(s): | Clindamycin Phosphate and Benzoyl Peroxide |
| URL for Additional Product Information: | |
| Address: | 200 Meredith Avenue, Suite 101A |
| City: | Durham |
| Key Contact: | Kamesh Venugopal |
| Phone Number: | +1-269-806-2796 |
| Product Therapeutic Classification: | |
| State: | NC |
| Address 2: | |
| Zip: | 27713 |
| Email: | kamesh.v@encubeethicals.com |
| Fax: | 984-439-2761 |

| 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) | |
| 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: | 45 g |
| Strength: | 1.2%/5% |
| Dosage Form: | Gel |
| Product Shape: | |
| Product Color: | |
| Product Imprint: | |

| ORDER INFORMATION | |
|--|---|
| Unit of Sale | What is the NDC selling unit? |
| <input checked="" type="checkbox"/> Bottle | 21922-022-06 |
| <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 |

| FOR GENERIC DRUG PRODUCTS | |
|---|---|
| I. Orange Book Rating: | AB |
| II. Generic Equivalent to What Brand?: | DUAC |
| <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: |
| (Write-in, e.g. 1 Vial) | Each |
| | 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: | |
| 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. | |

| ITEM AND PACKING INFORMATION | | | | | | |
|-------------------------------|-------------|------------------------|--------|-------|---------------|-----------|
| Item: | Weight Lbs. | Dimensions (US msmts.) | | | Volume (Cube) | # Pieces: |
| | | Depth | Height | Width | | |
| Item: | 0.1322 | 6.3 | 1.26 | 1.1 | 8.7318 | 1 |
| Box/Carton/Bundle/Inner Pack: | 0.859 | 4.65 | 6.46 | 3.98 | 119.55522 | 6 |
| Case: | 11.416 | 13.39 | 5.12 | 12.4 | 850.10432 | 72 |
| Pallet: | 887.33 | 41.57 | 45.91 | 38.62 | 73705.4474 | 4536 |
| UPC: | Case: | NA | | | | |
| | Carton: | 321922022063 | | | | |

| GTIN PRODUCT INFORMATION | | | | | | |
|-------------------------------------|---------------|-------------------------------------|------------------------------|-------------------------------------|----------|----------------|
| Serialized? | If not, when? | Items aggregated? | Level | | Quantity | GTIN-14 |
| | | | Item | Unit | | |
| <input checked="" type="checkbox"/> | | <input checked="" type="checkbox"/> | Box/Carton/Bundle/Inner Pack | <input checked="" type="checkbox"/> | 1 | 00321922022063 |
| <input checked="" type="checkbox"/> | | <input checked="" type="checkbox"/> | Case | <input checked="" type="checkbox"/> | 6 | 10321922022060 |
| <input checked="" type="checkbox"/> | | <input checked="" type="checkbox"/> | Pallet | <input checked="" type="checkbox"/> | 72 | 30321922022064 |
| | | | | | 4536 | 50321922022068 |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

| 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# []

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 |
| 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: [] |

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

| | |
|---|---|
| Comments [] | |
| Registry: No | |
| Registry Program Contact Name: [] | Phone: [] |
| Comments [] | |

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

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: 50px;" 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: 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 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: 50px;" 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: 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 type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p> |
| Miscellaneous Notes: | |
| <input style="width: 100%; height: 100%;" type="text"/> | |