



# Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type:  New Item Final VersionDate: 

### PRODUCT INFORMATION

**Company Name:** Encube Ethicals Inc. **Application:** ANDA  
**Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):** 212982  
**DUNS:** 11-698-2244  
**Proprietary Name (If Applicable) and Established Name:** Clobetasol Propionate Cream USP, 0.05%  
**Selling Unit NDC:** 21922-016-06 **Individual Unit NDC:**  **UPC:** 321922016062  
**UDI**  **CVX Code:**  **MXV Code:**   
**Description:** White smooth, homogeneous cream free from foreign particles and without any phase separation and leakage. Packed in striped aluminium collapsible tube fitted with reverse Fez PP white cap and with legible label.  
**Active Ingredient(s):** Clobetasol propionate USP  
**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:** 1-919-767-3292 **Fax:** 984-439-2761  
**Product Therapeutic Classification:** Super-high potency corticosteroid formulations indicated for the

### SPECIAL HANDLING AND STORAGE REQUIREMENTS\*

**a. Temperature – Indicate the USP temperature range for this product.**  
 Temperature Range   
 Other Temperature Range Requirement (write in)   
 Is this product to be shipped to customers on ice?   
 Is this product to be shipped to customers on dry ice?   
**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?   
**d. Store product (unit of sale) upright?**   
 Protect product (unit of sale) from light?   
**e. Shelf life:**  Months  
 Initial shelf life at launch (if different):  Months

#### ADDITIONAL PRODUCT INFORMATION

Is the Product...  
 a legend device?   
 reverse numbered?   
 co-licensed?   
 Is the Product...  
 Direct-Ship Only   
 Unit of Use   
 Is the Product...  
 Unit of Use   
 If Unit Dose, is item bar coded to unit dose for hospital scanning?   
 If Unit Dose NDC, indicate NDC here:   
 Country of Origin   
 Is this product covered under the Trade Agreements Act (TAA)?

#### PRODUCT DESCRIPTION INFORMATION

**Size:** 45 g tube  
**Strength:** 0.05%  
**Dosage Form:** Topical Cream  
**Product Shape:**   
**Product Color:** White smooth, homogeneous cream  
**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?**   
 (Write-in, e.g. 1 Box of 10 Vials)  
**Minimum order quantity?**   
**If Yes, how many of which package type?**  
 Each  
 Inner/ Carton/Pack  
 Case

### FOR GENERIC DRUG PRODUCTS

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

### PHARMACY ORDER / BILL UNIT

**Rec. sell unit to customer?**   
 (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?**  **GLN:**   
**Is product exempt from DSCSA?**   
**If yes, select exemption:**   
**Other exemption - Write in:**   
**Is product repackaged?**  **If Yes, was original product purchased direct from mfr?**   
**Is product sold by manufacturer's exclusive distributor?**   
**Has FDA granted waiver/exception/exemption for product?**  **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	5.5905512	1.5748031	1.3779528	12.1315203	1
Box/Carton/Bundle/Inner Pack:	3.5708	8.6614173	5.984252	6.6929134	346.90778	24
Case:	23.07588	18.582677	9.2913386	14.015748	2419.93026	144
Pallet:	584.898	43.464567	45.354331	38.267717	75437.3923	3456
UPC:	Case:	<input type="text" value="321922016063"/>				
	Carton:	<input type="text" value="321922016069"/>				

### GTIN PRODUCT INFORMATION

Serialized? If not, when? Items aggregated?	Yes <input type="text" value="Yes"/> Yes	Level		Soleable Unit		Quantity	GTIN-14
		Item	Unit	2D	Linear		
		<input checked="" type="checkbox"/>	Box/Carton/Bundle/Inner Pack	<input checked="" type="checkbox"/>	Linear	1	00321922016062
		<input checked="" type="checkbox"/>	Case	<input checked="" type="checkbox"/>	Linear	24	10321922016069
		<input checked="" type="checkbox"/>	Pallet	<input checked="" type="checkbox"/>	Linear	144	30321922016063
				<input checked="" type="checkbox"/>	Linear	3456	50321922016067
					Linear		
					Linear		
					Linear		
					Linear		

### COST INFORMATION

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

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? No  
 (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?

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)

If yes, indicate which:

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:

SDS Hazard Classification	
<input type="checkbox"/> Organic <input type="checkbox"/> Inorganic <input type="checkbox"/> Steroid/Androgen  <input type="checkbox"/> Aerosol Class; Identify NFPA Storage Level: <input style="width: 50%;" type="text"/>	<input type="checkbox"/> Corrosive <input type="checkbox"/> Oxidizer <input type="checkbox"/> Contact Hazard  Is the product a NIOSH hazardous drug? <span style="float: right;">No</span> 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? <span style="float: right;">No</span> If Yes, is it managed with a pharmacy registry? <input style="width: 100%;" type="text"/> Website URL: <input style="width: 100%;" type="text"/>
Comments / Details: (For example, iPledge program?) <input style="width: 100%; height: 20px;" type="text"/>
<b>REMS:</b> <input style="width: 100%;" type="text"/> REMS Program Manager Name: <input style="width: 50%;" type="text"/> Phone: <input style="width: 20%;" type="text"/> Supplier Manages REMS registry exclusively: <input style="width: 50%;" type="text"/> Wholesale distributor support: Provider Name: <input style="width: 50%;" type="text"/> Site Enrollment Number assigned by Supplier: <input style="width: 50%;" type="text"/>
DEA #: <input style="width: 100%;" type="text"/> PCPDP #: <input style="width: 100%;" type="text"/> NPI #: <input style="width: 100%;" type="text"/>

Comments <input style="width: 100%;" type="text"/>
<b>Registry:</b> <input style="width: 100%;" type="text"/>
Registry Program Contact Name: <input style="width: 50%;" type="text"/> Phone: <input style="width: 20%;" type="text"/>
Comments <input style="width: 100%;" type="text"/>

RETURN INSTRUCTIONS
Contact tel. # if product received damaged: <input style="width: 100%; text-align: center; border: 1px solid black;" type="text" value="1-919-767-3292"/>
Is product returnable for credit: <span style="float: right;">Yes</span>
URL/Link to returns policy: <input style="width: 100%;" type="text"/>
Special regulations or returns requirements for this product in certain states? <span style="float: right;">No</span>
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 <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: 150px;" type="text"/></p> <p>Supplier's Customer Service Number: <input style="width: 150px;" type="text"/></p> <p>Contracted 3PL company / contact #:</p> <p style="margin-left: 20px;">Name: <input style="width: 150px;" type="text"/></p> <p style="margin-left: 20px;">Phone: <input style="width: 150px;" 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="text"/></p> <p>Ships for second day receipt: <input style="width: 50px;" type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input style="width: 50px;" type="text"/></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: 100%; height: 80px;" type="text"/></p>	<p><b>Overnight receipt available:</b> <input style="width: 50px;" type="text"/></p> <p>PO Receipt cut off time: <input style="width: 150px;" type="text"/></p> <p>Days of week overnight is available:</p> <p style="margin-left: 20px;"><input type="checkbox"/> Monday</p> <p style="margin-left: 20px;"><input type="checkbox"/> Tuesday</p> <p style="margin-left: 20px;"><input type="checkbox"/> Wednesday</p> <p style="margin-left: 20px;"><input type="checkbox"/> Thursday</p> <p style="margin-left: 20px;"><input type="checkbox"/> Friday</p> <p><b>Priority Overnight receipt available:</b> <input style="width: 50px;" type="text"/></p> <p style="margin-left: 20px;">PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p><b>Saturday Overnight receipt available:</b> <input style="width: 50px;" type="text"/></p> <p style="margin-left: 20px;">PO Receipt Cut off time: <input style="width: 150px;" type="text"/></p> <p>Order receipt method: <input type="checkbox"/> Phone: <input style="width: 50px;" type="text"/> Phone #: <input style="width: 100px;" type="text"/></p> <p style="margin-left: 20px;">Fax: <input style="width: 50px;" type="text"/> Fax #: <input style="width: 100px;" type="text"/></p> <p style="margin-left: 20px;">EDI: <input style="width: 50px;" type="text"/></p> <p>Overnight Fees apply: <input style="width: 50px;" type="text"/></p> <p>Other fees apply: <input style="width: 50px;" type="text"/></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: 100%; height: 40px;" type="text"/></p>	<p>Contact # if product is received damaged: <input style="width: 150px;" type="text"/></p> <p>Is product returnable for credit: <input style="width: 50px;" type="text"/></p> <p>URL/Link to returns policy: <input style="width: 150px;" type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input style="width: 50px;" type="text"/></p> <p style="margin-left: 20px;">If so, which states? Other requirements? Comments?</p> <p style="margin-left: 20px;"><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: 150px;" type="text"/></p> <p>Physician/Clinic Phone #: <input style="width: 150px;" type="text"/></p> <p>Physician State License #: <input style="width: 150px;" type="text"/></p> <p>Physician/Clinic DEA #: <input style="width: 150px;" type="text"/></p> <p>Physician/Clinic Specialty: <input style="width: 150px;" type="text"/></p>	<p>Is product order for scheduled patient procedure? <input style="width: 50px;" type="text"/></p> <p>Is product order for restocking purposes? <input style="width: 50px;" type="text"/></p>
Miscellaneous Notes:	
<p><input style="width: 100%; height: 80px;" type="text"/></p>	