

Standard Pharmaceutical Product Information (Rx Product Only)

							Intro	duction Type	:	New Item		Final Version			Date:	26-08	3-2020
				PRODUCT INFORMA	TION							SPECIAL HANDL	ING AND STO	ORAGE REQ	JIREMENTS	,	
Company Name: Encube Ethicals Inc. Application: ANDA Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 212982 212982							a. Temperature – Indicate the USP temperature range for this product. Temperature Range										
		IA/510(k)(med	device):		212	982					-	-					
DUNS:	11-698-2244				0.50/							emperature Range Re	quirement	a i			T
Proprietary Name (If Applicab Selling Unit NDC:	21922-016-05	me:	Clobetasol P	Propionate Cream USP, C Individual Unit NDC:	1.05%			UPC: 32	1922016055		(W	rrite in)		Store at con	trolled room t	emeperature	l
UDI	21322 010 00			CVX Code:			MVX	Code:	132201003	,	Is this p	roduct to be shipped to	o customers c	on ice?		No	
Description:	White smooth, homoge	eneous cream f	ree from fore	ign particles and without	any phase se	paration and lea	akage. Pack	ed in striped a	aluminium c	ollapsible tube fitted with	Is this p	roduct to be shipped to	o customers c	on dry ice?		No	-
Active Ingredient(s): Clobetasol propionate USP							b. Contact for tempera										
											Name:			Dipti Kaman			
URL for Additional Product In Address:	200 Meredith Avenue, 5	Suite 101A					Address	2.			Number Group B			919-767-329 usreg@encu		m	
City:	Durham					State:	NC	Zip:	2	27713	0.040			deregoenee			
Key Contact:	Kamesh Venugopal					Email:		V@encubeeth	nicals.com		c. Special regulations						_
Phone Number:	1-919-767-3292					Fax:	984-439-	2761			Special	returns requirements f	for this produc	ct?			_
Product Therapeutic Classific	cation:	Super-nign pot	ency corticos	steroid formulations indica	ated for the						d. Store product (unit	of colo) unright?				No	
ADDITIONA	AL PRODUCT INFORMA	ATION					PRODUCT	DESCRIPTIO		TION		product (unit of sale)) from light?			No	-
Is the Product											e. Shelf life:	product (and or ouro	,			24	Months
a legend device?			No			Size:	3	30 g tube				helf life at launch (if c	different):			21	Months
reverse numbered?							_	-					ORDER INFO				
co-licensed? Is the Product		Direct-Ship On	lv			Strength:	C	0.05%						RMATION			
Is the Product		Unit of Use	<u>, </u>			Dosage Form:		Topical Cream	, ,		Unit of	Sale		What is the	NDC selling	unit?	
	-					Dosage i onn.		ropical crean	I			Bottle		21922-016-0			
If Unit Dose, is item bar coded	d to unit dose for hospita	al scanning?					E E				x	Box/Carton Ampule		(Write-in, e.	g. 1 Box of 1	0 Vials)	
If Unit Dose NDC, indicate ND	DC here:	21922-016-05				Product Shap	e:					Glass		Minimum or	der quantity	?	Yes
	L					Product Color		White smooth.	homogene	ous cream		Tube					
Country of Origin		India				i iouuot ooioi			, nomogene			Vial Liquid Sgl					•
Is this product covered under	the Trade Agreements A	Act (TAA)?				Product Impri	nt:					Vial Liquid Multi Vial Powder Sgl		If Yes, how	many of whi Each	ch package ty	ype?
							L					Vial Power Multi		1	Inner/Cartor	/Pack	
•												Other: Write In	-		Case		
			F	OR GENERIC DRUG PR	ODUCTS												
					1	Auth	orized Gene	eric *If	Authorized	Generic, other section	PHARMACY ORDER / BILL UNIT						
I. Orange Book Rating:	AB1							fiel	lds are not a	applicable	Rec. sell unit to customer? Rx billing unit to pharmacy:						
II. Generic Equivalent to What	at Brand?:	Temovate® (C	lobetasol Pro	ppionate Cream, 0.05%, N	NDA - N01932	2)									Each		
		DBI		CHAIN SECURITY ACT		PMATION					(Write-in, e.g. 1 Vial)				Gram Milliliter		
		DKU	IG SUFFLI	CHAIN SECORITY ACT	(DSCSA) INFO	KMATION					_				Milliter		
Does supplier meet DSCSA d		er?		Yes	GLI	N:	89060052	273444			ITEM AND PACKING INFORMATION						
Is product exempt from DSCS If yes, select exemption:	SA?		No										Dimo	nsions (US m	cente)	Mah	
Other exemption - Write in:	1											Weight Lbs.	Depth	Height	Width	Volume (Cube)	# Pieces:
Is product repackaged? Is product sold by manufactu	-	itor?	No	No	lf Y mfr	es, was origina	al product p	purchased dir	rect from		Item:	0.0882	4.1242938		0.984252	4.79450111	1
Has FDA granted waiver/exce				No		es, attach docu	umentation	from FDA.			Box/Carton/Bundle/	2.4684	6.1417323	5.9448819	4.9606299	181.12189	24
				GTIN PRODUCT INFOR	MATION						Inner Pack: Case:	40	4.0.000	0.70	10.055.15	1070	
					Saleable							16.001	15.393701	6.7322835	12.283465	1272.99387	144
Serialized?	Yes		x Iter	Level	Unit X	X 2D				GTIN-14 00321922016055	Pallet:	751.12	47.598425	49.88189	38.267717	90859.0164	7776
If not, when?	Tes	1		x/Carton/Bundle/Inner Pack	<u>x</u>	x 2D x 2D			24 1	0321922016055	UPC:	Case:	3219220160	056			
Items aggregated?	Yes		x Ca	ase		x 2D		Linear 1		30321922016056		Carton:	3219220160			•	
x Pallet 2D x Linear 7776 50321922016050							COST INFORMATION WHOLESALER USE ONLY:										
		ł	┢──┤┣─			2D 2D		Linear			COST	INFORMATION			WHOLESAL	LER USE ONL	
			┢───┤┝─			2D 2D		Linear			Regular Cost			Vendor #:			
	2D Linear								Invoice Cost (WAC) (\$)			Whsl. Code	Whsl. Code #:				
						-					Federal Excise Tax Pe	r Unit of Sale		Fineline Co	de:		
											As of date:			-			
			Δt	tach copy of SAFETY DA	TA SHEFT (S	DS) or non hav	ard letter P	ACKAGE INS	SERT. LARE		DUCT PACKAGING and BA	ARCODE.		1			
*Please provide any additiona	al information on page	2.	74		(6	.,		p. 3 for Desi			Signatu						
											5			-			

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Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3							
MAT	ERIAL HAZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply): a. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? No	Organic Corrosive						
Does the product label bear a CA Prop 65 warning? No c. Contact Hazard? No	Aerosol Class; Identify NFPA Storage Level:						
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	Is the product a NIOSH hazardous drug? No If yes, indicate which:						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name	Hazardous Waste Identification						
c. DOT Hazard Class d. Packing Group e. Inhalation Hazard?	EPA Hazardous Waste Code:						
Is the product restricted for air shipment? If so, indicate restriction:	REMS or REGISTRY RESTRICTIONS						
Passenger Cargo Passenger & Cargo	Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? Website URL:						
Is this a reportable quantity? No RQ Threshold:	Comments / Details: (For example, iPledge program?)						
No (if yes, identify method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4) Special Permit; DOT-SP	REMS: Phone: REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: Provider Name:						
Special Provision (listed in Column 7 of 49 CFR 172.101); SP#	Site Enrollment Number assigned DEA #: by Supplier: PCPDP #: NPI #:						
Is the Product	Comments						
Controlled Substance? No Controlled by State(s)? No ARCOS Reportable? No	Registry:						
Schedule No. (inc. N for non-narcotic) Controlled Substance Code Listed Chemical (List I or II)	Comments RETURN INSTRUCTIONS						
If yes, indicate which:	Contact tel. # if product received damaged: 1-919-767-3292						
Is it a scheduled listed chemical product?: CLASS OF TRADE RESTRICTION:	Is product returnable for credit: Yes						
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Yes Restricted to retail pharmacy only: No							
Restricted to retail pharmacy only: No Restricted to hospital, clinics, and physician offices only: No	Special regulations or returns requirements for this product in certain states? No						
Restricted to hospital, clinics, and physician onces only. No Restricted from US territories? (explain in comments) No Comments: No							
MIS	CELLANEOUS NOTES and/or Image of Product Barcode:						



Standard Pharmaceutical Product Information (Page 3)

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						
Purchase orders may be accepted by: Yes a. EDI Yes b. Autofax Fax Number: c. Fax Yes d. Phone only Phone No.: e. Supplier Web Site only Site Address: Minimum Order Quantity:	Purchase order daily receipt cut off time by supplier Cut off time: 12pm Eastern Shipping lead time of PO: Hours Days Ships same day for next day receipt: Days Ships for second day receipt: Ships regular ground for 3-10 days receipt: Image: Color of the second day receipt: Image: Color of the second day receipt:						
Contracted 3PL company / contact #: Name: Phone:							
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing						
Expedited freight fees billed with each order: Yes	Overnight receipt available:						
Drop Ship service fee billed with each order: Yes	PO Receipt cut off time:						
Drop Ship miscellaneous fees billed: Yes Comments:	Days of week overnight is available:						
	Priority Overnight receipt available:						
Class of Trade Restriction:	PO Receipt Cut off time:						
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:	Saturday Overnight receipt available: PO Receipt Cut off time: Order receipt method: Phone: Fax: Phone #: EDI: Fax #: Other fees apply: Image: Constraint of the state						
Other Data Information Required to Process PO:	Return Instructions						
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty: Miscellaneous Notes:	Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?						
	ADDITIONAL INFORMATION						
	Is product order for scheduled patient procedure?						