

Standard Pharmaceutical Product Information (Rx Product Only)

							Introducti	on Type:		New Item	х	Final Version			Date:	15-09	9-2020
				PRODUCT INFORMATION								SPECIAL HANDLI	NG AND ST	ORAGE REQ	UIREMENTS	;*	
Company Name:	Encube Ethicals Inc.							Application:		ANDA	a. Temperature - In	dicate the USP tempera	ture range	for this produ	uct.		
Application Number for NDA		PMA/510(k)(med	device):					•				erature Range				en 20 and 25	C (68° - 77° F
DUNS:	11-698-2244										Other	Temperature Range Re	nuirement				
Proprietary Name (If Applicat		Name:	Tavaborole	Topical Solution, 5%								(write in)	quirement				1
Selling Unit NDC:	21922-020-12			Individual Unit NDC:			UP	C: 321922	020120		11	(
UDI				CVX Code:	•		MVX Code):			Is this	product to be shipped to	customers	on ice?		No	_
Description:	Tavaborole Topical S	olution, 5% is cle	ear, colorle	ss alcohol based solution free fro	m foreign part	icles. Pack	ed in amber o	colored USP	Type I g	lass bottle with black	Is this	product to be shipped to	customers	on dry ice?		No	
				embly having USP Type I glass p					,, ,					•			•
Active Ingredient(s):		Tavaborole										erature excursion ques	tions:				
											Name			Dipti Kamar			
URL for Additional Product In Address:	nformation: 200 Meredith Avenue	Cuite 1011				۸.	ddress 2:				Numb			+1-781-789			
City:	Durham	, Suite TOTA			St	ate: N		Zip:	27	713	Grou	p E-mail:		usreg@enc	ubeethicals.c	OIII	
Key Contact:	Kamesh Venugopal		_				amesh.v@en			7.10	c. Special regulation	ns for product in any st	ates?				
Phone Number:	+1-269-806-2796 Fax: 984-439-2761						Special returns requirements for this product?										
Product Therapeutic Classific	cation:					<u> </u>					•						-
-		Į.									d. Store product (ur	it of sale) upright?				Yes	
ADDITIONAL	L PRODUCT INFORM	ATION				PRO	DUCT DESC	RIPTION IN	FORMA	TION	Prote	ct product (unit of sale	from light?	?		No	-
Is the Product											e. Shelf life:					24	Months
a legend device?			No		Size:		10 ml				Initial	shelf life at launch (if o	different):				Months
reverse numbered?			No		0.20.												
co-licensed?			No		Streng	th:	5%					0	RDER INFO	RMATION			
Is the Product											Unit (of Sale		What is the	NDC selling	unit?	
is the Froduct					Dosage	e Form:	Solution	on			x			21922-020-		u	
If Unit Dose, is item bar coded	d to unit does for boom	ital accoming?										Box/Carton			.g. 1 Box of 1	0 Vials)	
· ·	•	ital scalling?			Produc	t Shape:						Ampule					
If Unit Dose NDC, indicate NE	DC here:											Glass		Minimum o	rder quantity	/?	Yes
Country of Origin		India			Produc	t Color:	Clear,	colorless ald	cohol bas	sed solution		Tube					
											-	Vial Liquid Sgl Vial Liquid Multi		If Yes how	many of wh	ich package t	vne?
Is this product covered under	the Trade Agreements	s Act (TAA)?			Produc	t Imprint:						Vial Powder Sql Each					.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
		=										Vial Power Multi		1	Inner/Cartor	/Pack	
•												Other: Write In	_		Case		
			F	FOR GENERIC DRUG PRODUC	TS												
						7 A	ed Generic	*16		eneric, other section		DUAD	MACY ORD	ER / BILL UN	IT		
L Owner Brook Books	AD				<u> </u>	Authorize	eu Genenc		re not ap		Dee cell unit to our						
I. Orange Book Rating: II. Generic Equivalent to What	AB	KEDADINI (LV)	/AROPOLE	E) 5% (N204427)							Rec. sell unit to cus	Rx billing unit to pharmacy:					
ii. Generic Equivalent to what	Generic Equivalent to What Brand?: KERYDIN (TAVABOROLE) 5% (N204427)								(Write-in, e.g. 1 Vial	<u> </u>	J		Gram				
		DRUG	SUPPLY	CHAIN SECURITY ACT (DSCS	A) INFORMAT	ION					(**************************************				Milliliter		
						_									•		
Does supplier meet DSCSA d		urer?		Yes	GLN:	89	90600527					ITEM AN	ID PACKING	G INFORMAT	ION		
Is product exempt from DSCS If yes, select exemption:	5A?		No	<u> </u>									Dime	nsions (US n	nsmts)	Volume	
Other exemption - Write in:			_									Weight Lbs.	Depth	Height	Width	(Cube)	# Pieces:
Is product repackaged?			No	0	If Yes, was	original p	roduct purch	nased direct			Item:	0.08155	1.9685039			9.00710463	1
Is product sold by manufactu				No	from mfr?		-		_			0.08100	1.90000039	3.2203405	1.41/3228	9.007 10463	
Has FDA granted waiver/exce	eption/exemption for	product?		No	If yes, attac	ch docume	entation from	FDA.			Box/Carton/Bundle/	0.4628	4.488189	3.7401575	3.4645669	58.1580691	4
			,	GTIN PRODUCT INFORMATIO	N.						Inner Pack:						
				Saleab							Case:	3.5925	11.653543	4.2125984	9.9212598	487.051494	24
				Level Unit				Quantit	v G	ΓIN-14	Pallet:	0.40.00=0					
Serialized?	Yes	Г	X Ite	em X	x	2D	Linear	1		321922020120		246.6276	41.433071	29.897638	36.397638	45087.6082	1440
If not, when?] [lox/Carton/Bundle/Inner Pack	X 2D	2D	Linear		4 10321922020127 24 30321922020121	UPC:	Case:	NA					
Items aggregated?	Yes	_		Case	х	2D				Carton: NA							
	x Pallet 2D x Linear 1440 50321922020125 2D Linear Linear Linear Linear Linear							321922020125	COST INFORMATION WHOLESALER USE ONLY:								
		F	 ⊦			2D	Linear		1 -		00	31 IN ORMATION			WIIOLLSAL	ER OSE ONE	
		F	— h			2D	Linear		1		Regular Cost			Vendor #:			
		ļ ,			╛╚	2D	Linear		i E		Invoice Cost (WAC)	(\$)		Whsl. Code			
		-						-	-		Federal Excise Tax	Per Unit of Sale		Fineline Co	de:		
											As of date:						
				tach copy of SAFETY DATA SHE	TT (CDC)	on honord	latter DACK	OF INCEST	LADE	AND DUOTO OF DD	ODLICT DACKACING	PARCORE		1			
*Please provide any additiona	al information on non	10.2	Att	laun copy or SAFETY DATA SHE	EI (SUS) or n		ee new p. 3				ODUCT PACKAGING and Signa						
i icase provide any additions	ai iiiioiiiiaiioii oii pag	~ ∠.				3	ce new p. 3	o Designat	cu Diop	ompomy.	oigna	nui C.					



Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION Is this product (check all that apply): **SDS Hazard Classification** a. Cvtotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? No Organic Corrosive Is the product a CA Prop 65 reproductive toxicant? Oxidizer No Inorganic Does the product label bear a CA Prop 65 warning? No Steroid/Androgen Contact Hazard 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.) Is the product a NIOSH hazardous drug? e. Does the product contain DEHP? No If yes, indicate which: Is this product regulated for shipment by DOT or IATA? Yes (if yes, answer a-e below and provide SDS) UN1170 a. UN/Identification Number **Hazardous Waste Identification** b. Proper Shipping Name **Ethanol Solution** c. DOT Hazard Class EPA Hazardous Waste Code: d. Packing Group e. Inhalation Hazard? No REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: Passenger Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? Cargo Passenger & Cargo Website URL: Is this a reportable quantity? RQ Threshold: Comments / Details: (For example, iPledge program?) Is this a marine pollutant? Is this product shipped utilizing an authorized DOT exception or Special Permit? (if yes, identify method below) REMS: REMS Program Manager Name: Limited Quantity Phone: Consumer Commodity, ORM-D Supplier Manages REMS registry exclusively: Small Quantity (49 CFR 173.4) Wholesale distributor support: Special Permit; DOT-SP Provider Name: Special Provision (listed in Column 7 of 49 CFR 172.101); Site Enrollment Number assigned DEA #: No by Supplier: No SP# PCPDP #: NPI#: No ADD'L STORAGE INFORMATION Is the Product... Comments Controlled Substance? No Controlled by State(s)? No Registry: ARCOS Reportable? No Registry Program Contact Name: Phone: Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code RETURN INSTRUCTIONS Listed Chemical (List I or II) No If yes, indicate which: 919-767-3292 Is it a scheduled listed chemical product?: No Contact tel. # if product received damaged: CLASS OF TRADE RESTRICTION: Is product returnable for credit: Yes URL/Link to returns policy: Contact Manufacturer No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices No Restricted to retail pharmacy only: Special regulations or returns requirements for this product in certain states? No If so, which states? Other requirements? Comments? Restricted to hospital, clinics, and physician offices only: Nο Restricted from US territories? (explain in comments) No Comments: MISCELLANEOUS 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

Purchase order analy be accepted by: a. ED Yes Autoflox Yes Fax Number: yes Fax Number: Autoflox Au	Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing							
a. EDIO b. Autofax C. Fax Yes Fax Number: d. Phone only e. Supplier Web Site only e. Supplier Country: EL4 Supplier Country: EL4 Supplier Country: EL4 Supplier Country: EL4 Supplier Country: EL7 Sup	Purchase orders may be accepted by:								
b. Autofax c. Fax Yoshore only d. Phone only s. Suppler Yeb Site only s. Site Address Units Site Address	, , ,								
d. Phone only e. Supplier Wide Site only Site Address: Wilnimum Order Quantity Site Address: Wilnimum Order Quantity Site Address: Supplier's Customer Service Number: Contracted SPL company / contract #: Name: Phone: Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited Freight Ges billed with each order: Yes Drop Ship service fee billed with each order: Yes Overnight and Priority Overnight PO Processing Overnight and Priority Overnight PO Processing Overnight receipt available: PO Receipt out off time: Days of week overnight is available: Po Receipt Out off time: Days of week overnight is available: Po Receipt Out off time:									
d. Phone only e. Supplier Veb Site only e. Supplier Veb Site only e. Supplier Veb Site only Site Address: Units Units Ships for second day receipt: Ships regular ground for 3-10 days receipt: Ships regular ground for 3-10	c. Fax Yes Fax Number: 984-439-2761	Shipping lead time of PO: Hours Days							
Minimum Order Quantity: [44	d. Phone only								
Suppliers Customer Service Number: Contracted 3PL company / contact #: Name: Phone: Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited Freight Charges or Other Designated Drop Ship Fees: Overnight and Priority Overnight PO Processing Overnight and Priority Overnight PO Processing Overnight and Priority Overnight PO Processing Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Priority Overnight receipt available: Po Receipt Cut off time: Days of week overnight is available: Priority Overnight receipt available: Priority Overnight		Ships same day for next day receipt:							
Contracted 3PL company / contact #:		Ships for second day receipt:							
Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited Freight Charges or Other Data Information Required to Process PO: Patient Procedure Data Information Required to Process PO: Patient Procedure Data Information Required to Process PO: Physician Role: Physican Role: P		Ships regular ground for 3-10 days receipt: Yes							
Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited freight (fees billed with each order: Drop Ship service fee billed with each order: Yes Drop Ship service fee billed with each order: Yes Comments: Class of Trade Restriction: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices restricted to hospital, clinics, and physician offices only: Restricted for uS territories? (explain in comments) Other Data Information Required to Process PO: Patient Procedure Date: Physician/Clinic DEA #: Physician/Clinic DEA #: Physician/Clinic Specialty: Miscellaneous Notes: Overnight receipt available: Days of week overnight is available: Days of week overnight is available: PO Receipt Cut off time: Days of week overnight is available: Po Receipt Cut off time: Physician/Clinic Specialty: Other receipt available: PO Receipt Cut off time: Phone #: Phone #: Fax: Setural Procedure Date: Phone #: Fax: Fax:									
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Drop Ship service fee billed with each order: Ves Drop Ship miscellaneous fees billed: Yes Comments: Class of Trade Restriction: No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices Restricted to retail pharmacy only: Restricted to nospital, clinics, and physician offices only: No Comments: Other Data Information Required to Process PO: Patient Procedure Date: Physician Name: Physician Name: Physician Name: Physician Select Wes if sold to retail pharmacy notes: Miscollaneous Notes: Miscollaneous Notes: PO Receipt Cut off time: Days of week overnight is available: PO Receipt Cut off time: PO Receipt Cut off tim	Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing							
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Comments: Class of Trade Restriction: Tuesday Wednesday Thursday Friday Friday	Drop Ship service fee billed with each order: Yes	PO Receipt cut off time:							
Comments: Class of Trade Restriction: Tuesday Wednesday Thursday Friday	Drop Ship miscellaneous fees billed: Yes	Days of week overnight is available:							
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Is product order for scheduled patient procedure?	Miscellaneous Notes:								
Is product order for scheduled patient procedure?									
		ADDITIONAL INFORMATION							
Is product order for restocking purposes?		Is product order for scheduled patient procedure?							
		Is product order for restocking purposes?							