

Standard Pharmaceutical Product Information (Rx Product Only)

					Introduction Ty	/pe:	New Item		Final Version			Date:	9/5/2	.022
			PRODUCT INFORMATION						SPECIAL HANDL	ING AND STO	DRAGE REQ	UIREMENTS	*	
Company Name:	Encube Ethicals Inc.				Applie	cation:	ANDA	a. Temperature – Indic	ate the USP temper	ature range f	or this produ	ict.		
Application Number for ND	A/ANDA/BLA (drug); I	MA/510(k)(med device)		211047	•			Tempera	ture Range	_				
DUNS:	11-698-2244							Other Te	mperature Range Re	equirement				
Proprietary Name (If Applica	ble) and Established I	Name: Hydrocor	tisone Valerate Cream USP, 0.2%						ite in)		Store at con	trolled room	temeperature	
Selling Unit NDC:	21922-007-06		Individual Unit NDC:			32192200706	0							
UDI			CVX Code:		MVX Code:			Is this pro	oduct to be shipped t	to customers	on ice?		No	
Description:			nedium potency corticosteroids indic		he inflammatory and	pruritic manife	stations of	Is this pro	oduct to be shipped t	to customers	on dry ice?		No	
	corticosteroid respons		patients. Packed in alumnium collap	sible tube.				ll						
Active Ingredient(s):		Hydrocortisone valerate	cream USP					b. Contact for temperar	ture excursion ques	stions:	Dipti Kaman	i		
URL for Additional Product I	nformation.							Number:			919-767-329			
Address:	200 Meredith Avenue	Suite 101A			Address 2:			Group E			usreg@encu		om	
City:	Durham						27713							•
Key Contact:	Kamesh Venugopal			Email:	Kamesh.V@encube	ethicals.com		c. Special regulations t						
Phone Number:	1-919-767-3292	Cuman himb matamass acuti	in a stancial forms ulations in diseased for		984-439-2761			Special r	eturns requirements	for this produ	ct?			
Product Therapeutic Classifi	cation:	Super-night potency control	icosteroid formulations indicated for	the				1						
ADDITIONA	L PRODUCT INFORM	ATION	1	Di	RODUCT DESCRIPT	ION INFORM	ATION	d. Store product (unit of	of sale) upright? product (unit of sale	\ from light?			No No	
	LEFRODUCT IN ORM	ATION	1		RODUCT DESCRIPT	TON IN ORM	ATION	· [product (unit or sale	e) iroin iigiit:				
Is the Product a legend device?		No						e. Shelf life:	elf life at launch (if	difforont):			24	Months Months
reverse numbered?		140		Size:	45 g tube			illidai Sii	ien me at launch (n	umerem).				WOILUIS
co-licensed?				Strength:	0.2%				C	RDER INFO	RMATION			
Is the Product		Direct-Ship Only		Strength.	0.276									
Is the Product		Unit of Use		Dosage Form:	Topical Cre	am		Unit of S			What is the 21922-007-0		unit?	
		ļ						x	Bottle Box/Carton		(Write-in, e.		0 Vials)	
If Unit Dose, is item bar code	d to unit dose for hosp	tal scanning?		Product Shape					Ampule		(**************************************	g Dox o	0 110.0)	
If Unit Dose NDC, indicate N	DC here:	21922-007-06		Product Snape	J:				Glass		Minimum o	der quantity	/?	
Occupation of October		India		Product Color:	a white smo	ooth, homogen	neous cream		Tube					
Country of Origin									Vial Liquid Sgl Vial Liquid Multi		If Yes, how	many of wh	ich package t	vne?
Is this product covered under	r the Trade Agreements	Act (TAA)?		Product Imprin	nt:				Vial Powder Sql			Each		,,,
			<u> </u>		-				Vial Power Multi			Inner/Cartor	/Pack	
			FOR GENERIC DRUG PRODUCT	TC .					Other: Write In	7	Х	Case		
			FOR GENERIC DRUG PRODUCT	3										
				Autho	rized Generic '	*If Authorized	Generic, other section		PHAR	MACY ORDE	R / BILL UNI	T		
I. Orange Book Rating:	AB				f	fields are not a	applicable	Rec. sell unit to custon	ner?		Rx billing u	nit to pharm	acy:	
II. Generic Equivalent to Wha	t Brand?:	WESTCORT (Hydrocorti	isone Valerate Cream USP, 0.2%)									Each	•	
												C		
		DRUG GURRIA	COLLAIN OF OUR TY A OT (DOOD A	LINEODMATION				(Write-in, e.g. 1 Vial)				Gram		
		DRUG SUPPLY	Y CHAIN SECURITY ACT (DSCSA) INFORMATION				(Write-in, e.g. 1 Vial)				Milliliter		
Does supplier meet DSCSA	definition of manufact		Y CHAIN SECURITY ACT (DSCSA		8906005273444			(Write-in, e.g. 1 Vial)	ITEM A	ND PACKING	INFORMATI	Milliliter		
Is product exempt from DSC		urer?	· · · · · · · · · · · · · · · · · · ·		8906005273444			(Write-in, e.g. 1 Vial)	ITEM A			Milliliter ON		
Is product exempt from DSC If yes, select exemption:		urer?	Yes		8906005273444			(Write-in, e.g. 1 Vial)	ITEM Al	Dimer	nsions (US m	Milliliter ON esmts.)	Volume	# Pieces:
Is product exempt from DSC If yes, select exemption: Other exemption - Write in:		urer?	Yes No	GLN:		d direct			Weight Lbs.	Dimer Depth	nsions (US m Height	Milliliter ON ssmts.) Width	(Cube)	# Pieces:
Is product exempt from DSC If yes, select exemption: Other exemption - Write in: Is product repackaged?	SA?	urer?	Yes	GLN:	8906005273444	d direct		(Write-in, e.g. 1 Vial)		Dimer	nsions (US m	Milliliter ON esmts.)		#Pieces:
Is product exempt from DSC If yes, select exemption: Other exemption - Write in:	SA? urer's exclusive distril	urer?	Yes No	GLN: If Yes, was original from mfr?		_		Item: Box/Carton/Bundle/	Weight Lbs.	Dimer Depth 5.5906	Height 1.378	ON smts.) Width 1.5748	(Cube) 12.1320179	1
Is product exempt from DSC If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufactu	SA? urer's exclusive distril	urer?	Yes No No No No No	GLN: If Yes, was original from mfr? If yes, attach documents of the second se	al product purchased	_		Item: Box/Carton/Bundle/	Weight Lbs.	Dimer Depth	nsions (US m Height	Milliliter ON ssmts.) Width	(Cube)	# Pieces:
Is product exempt from DSC If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufactu	SA? urer's exclusive distril	urer?	Yes No No No No No O O O O O O O O O O O O	GLN: If Yes, was original from mfr? If yes, attach docum	al product purchased	_		Item: Box/Carton/Bundle/	Weight Lbs.	Dimer Depth 5.5906	Height 1.378	ON smts.) Width 1.5748	(Cube) 12.1320179	1
Is product exempt from DSC If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufactu	SA? urer's exclusive distril	urer?	Yes No No No No No	GLN: If Yes, was original from mfr? If yes, attach docum	al product purchased	 A.	GTIN-14	Item: Box/Carton/Bundle/ Inner Pack: Case:	Weight Lbs. 0.1332 0.85956 11.41672	Dimer Depth 5.5906 4.291 12.008	1.378 5.787 9.173	Milliliter ON ssmts.) Width 1.5748 3.307 10.433	(Cube) 12.1320179 82.1194802 1149.18852	1 6 72
Is product exempt from DSC If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufactu	SA? urer's exclusive distril	butor?	Yes No No No No No Saleabl	GLN: If Yes, was original from mfr? If yes, attach docum	al product purchased	A. Quantity (GTIN-14 10321922007060	Item: Box/Carton/Bundle/	Weight Lbs. 0.1332 0.85956	Dimer Depth 5.5906 4.291	Height 1.378 5.787	Milliliter ON ssmts.) Width 1.5748 3.307	(Cube) 12.1320179 82.1194802	6
Is product exempt from DSC If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufact Has FDA granted waiver/exc	SA? urer's exclusive distri eption/exemption for	butor? product?	Yes	GLN: If Yes, was original from mfr? If yes, attach docur N Ie	al product purchased	Quantity C	00321922007060 10321922007067	Item: Box/Carton/Bundle/ Inner Pack: Case:	Weight Lbs. 0.1332 0.85956 11.41672 515.604 Case:	Dimer Depth 5.5906 4.291 12.008 43.465 3219220070	1.378 5.787 9.173 45.276	Milliliter ON ssmts.) Width 1.5748 3.307 10.433	(Cube) 12.1320179 82.1194802 1149.18852	1 6 72
Is product exempt from DSC If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufact Has FDA granted waiver/exc Serialized?	SA? urer's exclusive distri eption/exemption for	butor? product?	Yes	GLN: If Yes, was original from mfr? If yes, attach docur N le X 2D 2D	al product purchased	Quantity (1) (1) (1) (1) (1) (1) (1) (1) (1) (1)	00321922007060 10321922007067 80321922007061	Item: Box/Carton/Bundle/ Inner Pack: Case: Pallet:	Weight Lbs. 0.1332 0.85956 11.41672 515.604	Dimer Depth 5.5906 4.291 12.008 43.465	1.378 5.787 9.173 45.276	Milliliter ON ssmts.) Width 1.5748 3.307 10.433	(Cube) 12.1320179 82.1194802 1149.18852	1 6 72
Is product exempt from DSC If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufact Has FDA granted waiver/exc Serialized? If not, when?	SA? urer's exclusive distril eption/exemption for Yes	butor? product?	Yes	GLN: If Yes, was original from mfr? If yes, attach docus If yes, attach docus If yes, attach docus If yes, attach docus If yes, was original from mfr? If yes, attach docus If y	al product purchased Imentation from FDA Linear Linear X Linear X Linear	Quantity (1) (1) (1) (1) (1) (1) (1) (1) (1) (1)	00321922007060 10321922007067	Item: Box/Carton/Bundle/ Inner Pack: Case: Pallet: UPC:	Weight Lbs. 0.1332 0.85956 11.41672 515.604 Case: Carton:	Dimer Depth 5.5906 4.291 12.008 43.465 3219220070	1.378 5.787 9.173 45.276	Milliliter ON smts.) Width 1.5748 3.307 10.433 37.48	(Cube) 12.1320179 82.1194802 1149.18852 73757.6918	1 6 72 3456
Is product exempt from DSC If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufact Has FDA granted waiver/exc Serialized? If not, when?	SA? urer's exclusive distril eption/exemption for Yes	butor? product?	Yes	If Yes, was original from mfr? If yes, attach docur	al product purchased	Quantity (1) (1) (1) (1) (1) (1) (1) (1) (1) (1)	00321922007060 10321922007067 80321922007061	Item: Box/Carton/Bundle/ Inner Pack: Case: Pallet: UPC:	Weight Lbs. 0.1332 0.85956 11.41672 515.604 Case:	Dimer Depth 5.5906 4.291 12.008 43.465 3219220070	1.378 5.787 9.173 45.276	Milliliter ON smts.) Width 1.5748 3.307 10.433 37.48	(Cube) 12.1320179 82.1194802 1149.18852	1 6 72 3456
Is product exempt from DSC If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufact Has FDA granted waiver/exc Serialized? If not, when?	SA? urer's exclusive distril eption/exemption for Yes	butor? product?	Yes	If Yes, was original from mfr? If yes, attach docur	Linear Li	Quantity (1) (1) (1) (1) (1) (1) (1) (1) (1) (1)	00321922007060 10321922007067 80321922007061	Item: Box/Carton/Bundle/ Inner Pack: Case: Pallet: UPC: COST	Weight Lbs. 0.1332 0.85956 11.41672 515.604 Case: Carton:	Dimer Depth 5.5906 4.291 12.008 43.465 3219220070	1.378 5.787 9.173 45.276 9.61 9.60	Milliliter ON smts.) Width 1.5748 3.307 10.433 37.48	(Cube) 12.1320179 82.1194802 1149.18852 73757.6918	1 6 72 3456
Is product exempt from DSC If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufact Has FDA granted waiver/exc Serialized? If not, when?	SA? urer's exclusive distril eption/exemption for Yes	butor? product?	Yes	If Yes, was original from mfr? If yes, attach docur	Linear	Quantity (1) (1) (1) (1) (1) (1) (1) (1) (1) (1)	00321922007060 10321922007067 80321922007061	Item: Box/Carton/Bundle/ Inner Pack: Case: Pallet: UPC: COST Regular Cost Invoice Cost (WAC) (\$)	Weight Lbs. 0.1332 0.85956 11.41672 515.604 Case: Carton:	Dimer Depth 5.5906 4.291 12.008 43.465 3219220070	1.378 1.378 5.787 9.173 45.276 9.61 9.60 Vendor #: Whsl. Code	Milliliter ON smts.) Width 1.5748 3.307 10.433 37.48	(Cube) 12.1320179 82.1194802 1149.18852 73757.6918	1 6 72 3456
Is product exempt from DSC If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufact Has FDA granted waiver/exc Serialized? If not, when?	SA? urer's exclusive distril eption/exemption for Yes	butor? product?	Yes	If Yes, was original from mfr? If yes, attach docur	al product purchased Imentation from FDA Linear	Quantity (1) (1) (1) (1) (1) (1) (1) (1) (1) (1)	00321922007060 10321922007067 80321922007061	litem: Box/Carton/Bundle/ Inner Pack: Case: Pallet: UPC: COST Regular Cost Invoice Cost (WAC) (\$) Federal Excise Tax Per	Weight Lbs. 0.1332 0.85956 11.41672 515.604 Case: Carton:	Dimer Depth 5.5906 4.291 12.008 43.465 3219220070	1.378 5.787 9.173 45.276 9.61 9.60	Milliliter ON smts.) Width 1.5748 3.307 10.433 37.48	(Cube) 12.1320179 82.1194802 1149.18852 73757.6918	1 6 72 3456
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Is product exempt from DSC If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufact Has FDA granted waiver/exc Serialized? If not, when?	SA? urer's exclusive distril eption/exemption for Yes	butor? product?	Yes	If Yes, was original from mfr? If yes, attach docur	Linear	Quantity 0 1 0 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	00321922007060 10321922007067 30321922007061 50321922007065	Item: Box/Carton/Bundle/ Inner Pack: Case: Pallet: UPC: COST Regular Cost Invoice Cost (WAC) (\$) Federal Excise Tax Pet As of date:	Weight Lbs. 0.1332 0.85956 11.41672 515.604 Case: Carton: INFORMATION	Dimer Depth 5.5906 4.291 12.008 43.465 3219220070	1.378 1.378 5.787 9.173 45.276 9.61 9.60 Vendor #: Whsl. Code	Milliliter ON smts.) Width 1.5748 3.307 10.433 37.48	(Cube) 12.1320179 82.1194802 1149.18852 73757.6918	1 6 72 3456



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. Cytotoxic? b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Organic Is the product a CA Prop 65 carcinogen? No Corrosive Is the product a CA Prop 65 reproductive toxicant? No Inorganic Oxidizer 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? No (if yes, answer a-e below and provide SDS) a. UN/Identification Number Hazardous Waste Identification b. Proper Shipping Name c. DOT Hazard Class EPA Hazardous Waste Code: d. Packing Group e. Inhalation Hazard? REMS or REGISTRY RESTRICTIONS Is the product restricted for air shipment? If so, indicate restriction: Passenger Is there a REMS on this product? Cargo If Yes, is it managed with a pharmacy registry? Passenger & Cargo Website URL: Is this a reportable quantity? No 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: Site Enrollment Number assigned Special Provision (listed in Column 7 of 49 CFR 172.101); DEA #: by Supplier: SP# PCPDP #: NPI#: ADD'L STORAGE INFORMATION Is the Product... Comments Controlled Substance? Nο No Controlled by State(s)? Registry: No Phone: ARCOS Reportable? Registry Program Contact Name: Schedule No. (inc. N for non-narcotic) Comments Controlled Substance Code RETURN INSTRUCTIONS Listed Chemical (List I or II) If yes, indicate which: 1-919-767-3292 Is it a scheduled listed chemical product?: Contact tel. # if product received damaged: 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 URL/Link to returns policy: 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: No 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 orders may be accepted by: a. EDI b. Autofax C. Fax d. Phone only e. Supplier Web Site only Supplier's Customer Service Number: Contracted 3PL company / contact #: Expedited Freight Charges or Other Designated Drop Ship Fees: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments: Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Shipping lead time of
a. EDI b. Autofax c. Fax d. Phone only e. Supplier Web Site only Site Address: Minimum Order Quantity: Contracted 3PL company / contact #: Phone: Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited freight gees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Days Other Designated Drop Ship Fees: Cut off time: Shipping lead time of PO: Ships same day for next day receipt: Ships regular ground for 3-10 days receipt: Ships r
c. Fax
d. Phone only e. Supplier Web Site only Site Address: Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone: Expedited Freight Charges or Other Designated Drop Ship Fees: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments: Days of week overnight is available: Monday Tuesday
e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Phone: Expedited Freight Charges or Other Designated Drop Ship Fees: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments: Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt: Ships regular gro
Minimum Order Quantity: 72 Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone: Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments: Ships for second day receipt: Ships regular ground for 3-10 days receipt: Ships regular ground for 3-
Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone: Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments: Ships regular ground for 3-10 days receipt: Overnight and Priority Overnight PO Processing Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Tuesday
Contracted 3PL company / contact #: Name: Phone: Phone:
Phone: Expedited Freight Charges or Other Designated Drop Ship Fees: Overnight and Priority Overnight PO Processing Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments: Days of week overnight is available: Tuesday
Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments: Overnight and Priority Overnight PO Processing Overnight receipt available: PO Receipt cut off time: Days of week overnight is available: Tuesday
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments: Drop Ship miscellaneous fees billed: Days of week overnight is available: Tuesday
Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments: Drop Ship miscellaneous fees billed: Days of week overnight is available: Tuesday
Drop Ship miscellaneous fees billed: Comments: Days of week overnight is available: Monday Tuesday
Comments: Tuesday
Wednesday
Thursday
Friday
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 Saturday Overnight receipt available:
Restricted to retail pharmacy only: PO Receipt Cut off time:
Restricted to hospital, clinics, and physician offices only: Order receipt method: Phone #:
Restricted from US territories? (explain in comments) Fax: Fax #:
Comments: EDI:
Overnight Fees apply:
Other fees apply:
Other Data Information Required to Process PO: Return Instructions
Patient Procedure Date: Contact # if product is received damaged:
Physician Name: Is product returnable for credit:
Physician/Clinic Phone # URL/Link to returns policy:
Physician State License # Special regulations or returns requirements for this product in certain states?
Physician/Clinic DEA #: If so, which states? Other requirements? Comments?
Physician/Clinic DEA #: Physician/Clinic Specialty: If so, which states? Other requirements? Comments?
Physician/Clinic Specialty:
Physician/Clinic Specialty:
Physician/Clinic Specialty: Miscellaneous Notes: