

Standard Pharmaceutical Product Information (Rx Product Only)

					Introduction Type:	New Item	x	Final Version			Date:	12-0	JO EE
			PRODUCT INFORMATION					SPECIAL HANDLI	NG AND ST	ORAGE REQ	UIREMENTS	S*	
Company Name: CREEKWOOD PHARMACEUTICALS LLC Application:						a Tomporaturo – Indio	sate the USD temper	aturo rango f	for this produ	ıct			
	for NDA/ANDA/BLA (drug); PMA/510(k)(med device): DESI						a. Temperature – Indicate the USP temperature range for this product. Temperature Range Controlled Room – between					en 20 and 25	C (68° – 77° F
		T IN A O TO (K)(ITICA ACTIOC)	•	520.			•	=		00110110110	oom bom	5011 E0 G11G E0	0 (00 11 1
DUNS:	118572848	Jeogenia						emperature Range Re	quirement				1
Proprietary Name (If Applica		Name: ESTERIF	TIED ESTROGENS AND METHYL				(W	rite in)					1
Selling Unit NDC:	82619-104-01 NA		Individual Unit NDC: CVX Code:	82619-104-01	UPC: 3.8261	9E+11	la dita a	and and the base bloomed to				N1-	
				133.			roduct to be shipped t				No	-	
Description: ESTERIFIED ESTROGENS AND METHYLTESTOSTERONE TABLETS FULL STRENGTH						Is this product to be shipped to customers on dry ice?							
Active Ingredient(s): ESTROGENS ESTERIFIED 1.25MG ; METHYLTESTOSTERONE 2.5 MG						b. Contact for temperature excursion questions:			[a ::: a				
URL for Additional Product Information: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cc						Name:			Sujit Sakpal				
	Information: https://dailymed.nlm.nih.gov/dailymed/drugInfo.i		fm?setid=710ec569-b90a-4f30-b66a-7bb6154c584f Address 2:		Number: Group E-mail:			551-303-9330 sujit@creekwoodpharma.com					
Address:	1130, US 46 W, SUITE 21 PARSIPPANY						Group E	mail:		sujit@creek	woodpnarma	.com	
City: Key Contact:	PAUL THOMAS			State: NJ Zip: 07054			c. Special regulations	for product in any o	intoo?			No	
Phone Number:	601-259-4116			Fax:				returns requirements		n+2		No	-
Product Therapeutic Classifi		HORMONE		- I ux.			Special	returns requirements	ioi iilis piodu	UI!		INU	-
Product Therapeutic Classifi	ication:	HORIVIONE					4 04	-11-1				NI-	
ADDITIONA	AL BRODUCT INFORM	MATION	Ī	DI	PODLICT DESCRIPTION IN	IEORMATION	d. Store product (unit		\			No	-
ADDITIONAL PRODUCT INFORMATION PRODUCT DESCRIPTION INFORMATION						IFORMATION	1	product (unit of sale) from light?			Yes	=
Is the Product							e. Shelf life:					24	Months
a legend device?		No		Size:	15 MM		Initial sl	helf life at launch (if	different):			24	Months
reverse numbered?		No											
co-licensed?		Strength: 1.25 MG + 2.5 MG			6	RDER INFO	RMATION						
Is the Product		Direct-Ship Only Unit of Use					11-2	0-1-		What is the	NDCIII		
Is the Product		Unit of Use		Dosage Form:	TABLETS		Unit of S	Bottle		1 bottle of 1		j unit ?	
								Box/Carton			g. 1 Box of 1	O Viale)	
If Unit Dose, is item bar code	ed to unit dose for hosp	oital scanning?					 	Ampule		(vviite-iii, e.	g. 1 box 01 1	o viais)	
If Unit Dose NDC, indicate NDC here:				Product Shape: OVAL SHAPED BICONVEX TABLETS			 	Glass		Minimum o	rder quantit	u2	Yes
ii onit bose Nbo, indicate N	IDO NOIC.							Tube		i i i i i i i i i i i i i i i i i i i	uci quantit	,.	103
Country of Origin				Product Color:	LIGHT GREEN			Vial Liquid Sql					
						Vial Liquid Sgi Vial Liquid Multi If Yes, how many of which package type?							
Is this product covered under	r the Trade Agreement	s Act (TAA)?		Product Imprin	t: 830			Vial Powder Sql			Each		
					•	-		Vial Power Multi			Inner/Cartor	n/Pack	
			•				"	Other: Write In		1	Case		
			FOR GENERIC DRUG PRODUC	TS							•		
			FOR GENERIC DRUG PRODUC]		-		
			FOR GENERIC DRUG PRODUC			horized Generic, other section		PHAR	MACY ORDE	ER / BILL UN	IT		
I. Orange Book Rating:			FOR GENERIC DRUG PRODUC			horized Generic, other section are not applicable	Rec. sell unit to custo		MACY ORDE	ER / BILL UN		acy:	
I. Orange Book Rating: II. Generic Equivalent to Wha	at Brand?:	COVARYX, EEMT	FOR GENERIC DRUG PRODUC				Rec. sell unit to custo	mer?	MACY ORDE			асу:	
	at Brand?:	·		Autho				mer?	MACY ORDE		nit to pharm	acy:	
	at Brand?:	·	FOR GENERIC DRUG PRODUC Y CHAIN SECURITY ACT (DSCS.	Autho			1 bottle of 1	mer?	MACY ORDE		nit to pharm Each	асу:	
II. Generic Equivalent to Wha		DRUG SUPPL	Y CHAIN SECURITY ACT (DSCS.	Autho A) INFORMATION	fields :		1 bottle of 1	mer? 00 tablets]	Rx billing u	nit to pharm Each Gram Milliliter	acy:	
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II. Generic Equivalent to What Does supplier meet DSCSA is product exempt from DSC if yes, select exemption:	definition of manufac	DRUG SUPPL	Y CHAIN SECURITY ACT (DSCS.	Autho A) INFORMATION	fields :		1 bottle of 1	mer? 00 tablets	ND PACKING	Rx billing u x BINFORMAT	nit to pharm Each Gram Milliliter	Volume	# Pieces:
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