



Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type: Final VersionDate:

PRODUCT INFORMATION	
Company Name:	CREEKWOOD PHARMACEUTICALS LLC
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	DESI
DUNS:	118572848
Proprietary Name (If Applicable) and Established Name:	ESTERIFIED ESTROGENS AND METHYLTESTOSTERONE TABLETS
Selling Unit NDC:	82619-104-01
Individual Unit NDC:	82619-104-01
UPC:	3.82619E+11
UDI	NA
CVX Code:	
MVX Code:	NA
Description:	ESTERIFIED ESTROGENS AND METHYLTESTOSTERONE TABLETS FULL STRENGTH
Active Ingredient(s):	ESTROGENS ESTERIFIED 1.25MG ; METHYLTESTOSTERONE 2.5 MG
URL for Additional Product Information:	https://dailymed.nlm.nih.gov/dailymed/druginfo.cfm?setid=710ec569-b90a-4f30-b66a-7bb6154c584f
Address:	1130, US 46 W, SUITE 21
City:	PARSIPPANY
Key Contact:	PAUL THOMAS
Phone Number:	601-259-4116
Product Therapeutic Classification:	HORMONE

SPECIAL HANDLING AND STORAGE REQUIREMENTS*	
a. Temperature – Indicate the USP temperature range for this product.	
Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No
b. Contact for temperature excursion questions:	
Name:	Sujit Sakpal
Number:	551-303-9330
Group E-mail:	sujit@creekwoodpharma.com
c. Special regulations for product in any states?	No
Special returns requirements for this product?	No
d. Store product (unit of sale) upright?	No
Protect product (unit of sale) from light?	Yes
e. Shelf life:	
Initial shelf life at launch (if different):	<input type="text" value="24"/> Months

ADDITIONAL PRODUCT INFORMATION	
Is the Product... a legend device?	No
reverse numbered?	No
co-licensed?	
Is the Product... Direct-Ship Only	
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:	15 MM
Strength:	1.25 MG + 2.5 MG
Dosage Form:	TABLETS
Product Shape:	OVAL SHAPED BICONVEX TABLETS
Product Color:	LIGHT GREEN
Product Imprint:	830

ORDER INFORMATION	
Unit of Sale	What is the NDC selling unit?
<input checked="" type="checkbox"/> Bottle	1 bottle of 100 tablets
<input type="checkbox"/> Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)
<input type="checkbox"/> Ampule	
<input type="checkbox"/> Glass	
<input type="checkbox"/> Tube	
<input type="checkbox"/> Vial Liquid Sgl	
<input type="checkbox"/> Vial Liquid Multi	
<input type="checkbox"/> Vial Powder Sgl	
<input type="checkbox"/> Vial Powder Multi	
<input type="checkbox"/> Other: Write In	
	Minimum order quantity? Yes
	If Yes, how many of which package type?
	<input type="text" value="12"/> Each
	<input type="text" value="1"/> Inner/Carton/Pack
	<input type="text" value="1"/> Case

FOR GENERIC DRUG PRODUCTS	
I. Orange Book Rating:	<input type="text" value=""/> Authorized Generic
II. Generic Equivalent to What Brand?:	COVARYX, EEMT

*If Authorized Generic, other section fields are not applicable

PHARMACY ORDER / BILL UNIT	
Rec. sell unit to customer?	Rx billing unit to pharmacy:
<input type="text" value="1 bottle of 100 tablets"/>	<input checked="" type="checkbox"/> Each
(Write-in, e.g. 1 Vial)	<input type="text" value=""/> Gram
	<input type="text" value=""/> Milliliter

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION	
Does supplier meet DSCSA definition of manufacturer?	Yes
Is product exempt from DSCSA?	No
If yes, select exemption:	
Other exemption - Write in:	
Is product repackaged?	No
Is product sold by manufacturer's exclusive distributor?	No
Has FDA granted waiver/exception/exemption for product?	No
GLN:	8.50046E+11
If Yes, was original product purchased direct from mfr?	
If yes, attach documentation from FDA.	

ITEM AND PACKING INFORMATION						
Item:	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	# Pieces:
		Depth	Height	Width		
Item:	0.167	1.75	1.75	3.25	9.953125	1
Box/Carton/Bundle/Inner Pack:					0	
Case:	2	7.25	7.33	3.375	179.355938	12
Pallet:	354	48	40	35	67200	177
UPC:	Case:					
	Carton:					

GTIN PRODUCT INFORMATION						
Serialized?	If not, when?	Items aggregated?	Level		Quantity	GTIN-14
			Item	Saleable Unit		
<input checked="" type="checkbox"/>	<input type="text" value=""/>	<input type="text" value=""/>	<input checked="" type="checkbox"/>	2D	Linear	1
			<input checked="" type="checkbox"/>	2D	Linear	12
			<input checked="" type="checkbox"/>	2D	Linear	177
			<input type="checkbox"/>	2D	Linear	
			<input type="checkbox"/>	2D	Linear	
			<input type="checkbox"/>	2D	Linear	
			<input type="checkbox"/>	2D	Linear	
			<input type="checkbox"/>	2D	Linear	

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