



Date: 12/22/2022

PRODUCT INFORMATION				
Company Name:		Xiromed LLC	Application: ANDA	
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):		216656		
Medical Device Class, if applicable:				
DUNS:				
Proprietary Name (If Applicable) and Established Name:		Estradiol Valerate Injection		
Selling Unit NDC:	70700-0274-22	Unit of Use NDC:		UPC: 370700274224
UDI		CVX Code:		MVX Code:
Description:	Estradiol Valerate Injection, USP 100 mg/5 mL (20 mg/mL) Multiple Dose Vial			
Active Ingredient(s):	ESTRADIOL VALERATE			
URL for Additional Product Information:				
Address:	180 Park Ave	State:	NJ	Address 2:
City:	Florham Park	Zip:	07932	
Key Contact:	David Hernandez	Email:	david.hernandez@xiromed.com	
Phone Number:	844-947-6633	Fax:	862-286-0932	
Product Therapeutic Classification:				

ADDITIONAL PRODUCT INFORMATION			PRODUCT DESCRIPTION INFORMATION	
The product is?	No	Is the Product...	Direct-Skip Only	Size: 1 x 5mL multiple dose vial Strength: 20mg/mL Dosage Form: INJECTABLE
a legend device?		Is the Product...	Neither	
if yes, enter class #		Orphan Drug Status		
a product kit?	No			
if yes, list NDCs of component parts		FDA Approval Status		
reverse numbered?	No	Allergens Present	Vial stoppers are not manufactured with natural rubber latex	
co-licensed?	No			
latex-free?	Yes	Country of Origin	Spain	
preservative-free?	Yes			
correctional institution block?	Yes			
opioid?	No			
Cannabinoid?	No			
If Unit Dose, is item bar coded to unit dose for hospital scanning?		Is this product covered under the Trade Agreements Act (TAA)?	Yes	
If Unit Dose, indicate NDC here:				

FOR GENERIC DRUG PRODUCTS				
I. Orange Book Rating:	AO	Authorized Generic	*If Authorized Generic, other section fields are not applicable	
II. Generic Equivalent to What Brand?:	Delestrogen			

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION						
Does supplier meet DSCSA definition of manufacturer?	Yes	GLN:	0370700000007			
Is product exempt from DSCSA?	No	GCP:				
If yes, select exemption:		If yes, was original product purchased direct from mfr?				
Other exemption - Write in:		Provide source manufacturer for repackaged product				
Is product repackaged?	No					
Is product sold by manufacturer's exclusive distributor?	No					
Has FDA granted waiver/exemption for product?	No					
If yes, attach documentation from FDA.						

GTIN AND HIBCC PRODUCT INFORMATION						
Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14		
x Item/Each	1		00370700274224			
x Box/Carton/Bundle/Inner Pack						
x Case	40		10370700274221			
Pallet						

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) Notes				
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: Vipul Gandhi Number: 862-895-6230 Group E-mail: vipul.gandhi@xiromed.com				
c. Special regulations for product in any states? Special returns requirements for this product? No				
d. Store product (unit of sale) upright? Protect product (unit of sale) from light?				
e. Shelf life: Initial shelf life at launch (if different): 24 Months				

ORDER INFORMATION				
Unit of Sale	Bottle	What is the NDC selling unit?	1 Carton of 1 Vial	
	Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)		
	Ampule	Minimum order quantity?	Yes	
	Glass			
	Tube			
	Vial Liquid Sgl			
x	Vial Liquid Multi	If Yes, how many of which package type?	40 Each	
	Vial Powder Sgl		Inner/Carton/Pack	
	Vial Power Multi		Case	
	Other: Write In			

PHARMACY ORDER / BILL UNIT				
Rec. sell unit to customer?	1 Vial	Rx billing unit to pharmacy:	x Each	
(Write-in, e.g. 1 Vial)			Gram	
			Milliliter	

ITEM AND PACKING INFORMATION						
	Weight Lbs.	Dimensions (US msmts.)			Volume (Cube)	Saleable # Pieces
		Depth	Width	Height		
Item/Each:	0.0881849	47	74	52	180856	1
Box/Carton/Bundle/ Inner Pack:					0	
Case:	3.5274	265	195	192	9921600	40
Pallet:					0	

COST INFORMATION			WHOLESALE USE ONLY:		
Regular Cost		Vendor #:			
Invoice Cost (WAC) (\$)	\$130.95	Whsl. Code #:			
As of date:		Fineline Code:			

*Please provide any additional information on page 2.

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

See new p. 3 for Designated Drop Ship Only.

Signature:



Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION			
Is this product (check all that apply):			
a. Cytotoxic?	<input type="checkbox"/>	No	
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?	<input type="checkbox"/>	No	
Is the product a CA Prop 65 carcinogen?	<input type="checkbox"/>	No	
Is the product a CA Prop 65 reproductive toxicant?	<input type="checkbox"/>	No	
Does the product label bear a CA Prop 65 warning?	<input type="checkbox"/>	No	
c. Contact Hazard?	<input type="checkbox"/>	No	
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	<input type="checkbox"/>	No	
e. Does the product contain DEHP?	<input type="checkbox"/>	No	
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS)		<input type="checkbox"/> No	
a. UN/Identification Number			
b. Proper Shipping Name			
c. DOT Hazard Class			
d. Packing Group			
e. Inhalation Hazard?	<input type="checkbox"/>	No	
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)		<input type="checkbox"/> No	
a. UN/Identification Number			
b. Proper Shipping Name			
c. DOT Hazard Class			
d. Packing Group			
e. Inhalation Hazard?	<input type="checkbox"/>	No	
Is the product restricted for air shipment? If so, indicate restriction:		<input type="checkbox"/> No	
<input type="checkbox"/> Passenger			
<input type="checkbox"/> Cargo			
<input type="checkbox"/> Passenger & Cargo			
Is this a reportable quantity?	<input type="checkbox"/> No		
RQ Threshold:			
Is this a marine pollutant?	<input type="checkbox"/> No		
Is this product shipped utilizing an authorized DOT exception or Special Permit?			
<input type="checkbox"/> No	(if yes, identify method below)		
<input type="checkbox"/> Limited Quantity			
<input type="checkbox"/> Consumer Commodity, ORM-D			
<input type="checkbox"/> Small Quantity (49 CFR 173.4)			
<input type="checkbox"/> Special Permit; DOT-SP			
<input type="checkbox"/> Special Provision (listed in Column 7 of 49 CFR 172.101);			
SP#			
ADD'L STORAGE INFORMATION			
Is the Product...			
Controlled Substance?	<input type="checkbox"/> No	Controlled Substance Code	
Controlled by State(s)?	<input type="checkbox"/> No	Listed Chemical (List I or II)	<input type="checkbox"/> No
ARCOS Reportable?	<input type="checkbox"/> No	If yes, indicate which:	
Schedule No.		Is it a scheduled listed chemical product?:	<input type="checkbox"/> No
CLASS OF TRADE RESTRICTION:			
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices		<input type="checkbox"/> Yes	
Restricted to retail pharmacy only:		<input type="checkbox"/>	
Restricted to hospital, clinics, and physician offices only:		<input type="checkbox"/>	
Restricted from US territories? (explain in comments)		<input type="checkbox"/>	
Comments:			
SDS Hazard Classification			
<input type="checkbox"/> Organic	<input type="checkbox"/> Corrosive		
<input type="checkbox"/> Inorganic	<input type="checkbox"/> Oxidizer		
<input type="checkbox"/> Steroid/Androgen	<input type="checkbox"/> Contact Hazard		
Does the product have an Aerosol class? If yes, identify			
NFPA Storage Level:			
NFPA Storage Level:			
Is the product a NIOSH hazardous drug?		<input type="checkbox"/> Yes	
If yes, indicate which:		Group 2 items (non-antineoplastic that meets a hazard criterion)	
Hazardous Waste Identification			
EPA Hazardous Waste Code:		Waste Characteristics	
REMS or REGISTRY RESTRICTIONS			
Is there a REMS on this product?		<input type="checkbox"/> No	
If Yes, is it managed with a pharmacy registry?		<input type="checkbox"/>	
Website URL:			
Med Guide Required		<input type="checkbox"/> No	
Limited Distribution Requirement		<input type="checkbox"/> No	
Comments / Details: (For example, iPledge program?)			
REMS:			
REMS Program Manager Name:		Phone:	
Supplier Manages REMS registry exclusively:			
Wholesale distributor support:			
Provider Name:		DEA #:	
Site Enrollment Number assigned by Supplier:		NCPDP#:	
Comments			
Registry:			
Registry Program Contact Name:		Phone:	
Comments			
RETURN INSTRUCTIONS			
Contact tel. # if product received damaged:			
Is product returnable for credit:		<input type="checkbox"/>	
URL/Link to returns policy:			
Special regulations or returns requirements for this product in certain states?		<input type="checkbox"/>	
If so, which states? Other requirements? Comments?			
MISCELLANEOUS NOTES and/or Image of Product Barcode:			

Release DATE



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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
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="text"/></p> <p>b. Autofax <input type="text"/></p> <p>c. Fax <input type="text"/></p> <p>d. Phone only <input type="text"/></p> <p>e. Supplier Web Site only <input type="text"/></p> <p>Minimum Order Quantity: <input type="text"/></p> <p>Supplier's Customer Service Number: <input type="text"/></p> <p>Contracted 3PL company / contact #: <input type="text"/></p> <p>Name: <input type="text"/></p> <p>Phone: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Fax Number: <input type="text"/></p> <p>Phone No.: <input type="text"/></p> <p>Site Address: <input type="text"/></p>	<p>Purchase order daily receipt cut off time by supplier</p> <p>Cut off time: <input type="text"/></p> <p>Shipping lead time of PO: <input type="text"/> Hours <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="text"/></p> <p>Ships for second day receipt: <input type="text"/></p> <p>Ships regular ground for 3-10 days receipt: <input type="text"/></p>
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
<p>Expedited freight fees billed with each order: <input type="text"/></p> <p>Drop Ship service fee billed with each order: <input type="text"/></p> <p>Drop Ship miscellaneous fees billed: <input type="text"/></p> <p>Comments: <input type="text"/></p>	<p>Overnight receipt available: <input type="text"/></p> <p>PO Receipt cut off time: <input type="text"/></p> <p>Days of week overnight is available:</p> <p><input type="checkbox"/> Monday</p> <p><input type="checkbox"/> Tuesday</p> <p><input type="checkbox"/> Wednesday</p> <p><input type="checkbox"/> Thursday</p> <p><input type="checkbox"/> Friday</p> <p>Priority Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Saturday Overnight receipt available: <input type="text"/></p> <p>PO Receipt Cut off time: <input type="text"/></p> <p>Order receipt method: <input type="text"/></p> <p>Phone: <input type="text"/> Phone #: <input type="text"/></p> <p>Fax: <input type="text"/> Fax #: <input type="text"/></p> <p>EDI: <input type="text"/></p> <p>Overnight Fees apply: <input type="text"/></p> <p>Other fees apply: <input type="text"/></p>
Class of Trade Restriction:	
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="text"/></p> <p>Restricted to retail pharmacy only: <input type="text"/></p> <p>Restricted to hospital, clinics, and physician offices only: <input type="text"/></p> <p>Restricted from US territories? (explain in comments) <input type="text"/></p> <p>Comments: <input type="text"/></p>	
Other Data Information Required to Process PO:	Return Instructions
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p>	<p>Contact # if product is received damaged: <input type="text"/></p> <p>Is product returnable for credit: <input type="text"/></p> <p>URL/Link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="text"/></p> <p>If so, which states? Other requirements? Comments? <input type="text"/></p>
Miscellaneous Notes:	ADDITIONAL INFORMATION
<input type="text"/>	<p>Is product order for scheduled patient procedure? <input type="text"/></p> <p>Is product order for restocking purposes? <input type="text"/></p>