

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

Version 2021					Introduction 1	Туре:	New Item		x	Final Version			Date:	12/22	/2022	
PRODUCT INFORMATION							SPECIAL HANDLING AND STORAGE REQUIREMENTS*									
Company Name: Xiromed LLC					Applica	tion:	ANDA	a. Temperature – Indicate the USP temperature range fo			erature range for the	r this product.				
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 216656					6656				Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)							
Medical Device Class, if applicable:																
DUNS:	468284866										mperature Range l	Requirement				
Proprietary Name (If Applicable) a		ame: Est	tradiol Valerate Injection								te in)					
Selling Unit NDC: UDI	70700-0273-22		Unit of Use NDC: CVX Code:			UPC: MVX Code:	37070	00273227		Notes						
						INIVA Code.							_			
Description: Estradiol Valerate Injection, USP 50 mg/5 mL (10 mg/mL) Multiple Dose Vial												d to customers on id			No No	
Active Ingredient(s): ESTRADIOL VALERATE								Is this product to be shipped to customers on dry ice?								
							b. Contact for temperature excursion questions:									
URL for Additional Product Information:							Name: Vipul Gandhi									
Address:	180 Park Ave					Address 2:				Number:			862-895-623			
City:	Florham Park David Hernandez				State: Email:	NJ Zip: 07932 <u>david.hernandez@xiromed.com</u> 862-286-0932			Group E-mail:			vipul.gandhi@xiromed.com				
Key Contact: Phone Number:	844-947-6633				Fax:			<u>romea.com</u>	c. Special regulations for product in any states?			etatoe?		-	No	
Product Therapeutic Classificatio					I un.	002-200-0332	002-200-0932			c. Special regulations for product in any states? Special returns requirements for this product?			No			
Froduct Therapeutic Glassificatio	····				-					Opeciai it	starris requiremen	ts for this product:			140	
	ADDITI	ONAL PRODUCT	INFORMATION			PRODUCT	DESCR	IPTION INFORMATION	d. Store prod	luct (unit o	f sale) upright?			1		
The product is?			Is the Product	Direct-Ship C	Only						product (unit of sa	ale) from light?				
a legend device?		No	Is the Product	Neither	,			1 x 5mL multiple dose vial	e. Shelf life:	i rototi p	roduct (dilit or st	aic, iroin iigiit.			24	Months
if yes, enter class #		1	Orphan Drug Status			Size:		'		Initial sh	elf life at launch (if different):				Months
a product kit?		No				Strength:		10mg/mL								
if yes, list NDCs of			FDA Approval Status			ouengui.				ORDER INFORMATION						
component parts		N.				Dosage Forn	m:	INJECTABLE		11-14-40	-1-		M/hat ia tha	NDC selling		
reverse numbered? co-licensed?		No No	Allergens Present							Unit of S	aie Bottle		1 Carton of 1		unit?	
latex-free?		Yes	Vial stoppers are no	t manufacture	d with						Box/Carton			g. 1 Box of 10) Vials)	
preservative-free?		Yes		bber latex		Product Sha	ipe:				Ampule		(**************************************	j. 1 Dox 01 10	, viaio,	
correctional institution block?		Yes				Product Cole	or:				Glass		Minimum or	der quantity	?	Yes
opioid?		No				Product Con	OI.				Tube					
Cannabinoid?		No	Country of Origin	Spain		Product Imp	rint:				Vial Liquid Sgl					
If Unit Dose, is item bar coded to unit dose for				•					Vial Liquid Multi				ch package t	type?		
hospital scanning?			Is this product covered u Trade Agreements Act (T		Yes						Vial Powder Sql 40 Each Vial Power Multi Inner/Carton/Pack			/Pook		
If Unit Dose, indicate NDC here: Trade Agreements Act (TAA)?			162						Other: Write In			Case	rack			
			FOR GENERIC DRUG PRO	ODUCTS												
					Au	thorized Generic		thorized Generic, other	PHARMACY ORDER / BILL UNIT							
I. Orange Book Rating:	AO				section fields are not applicable			n fields are not applicable	Rec. sell unit to customer?			Rx billing unit to pharmacy:				
II. Generic Equivalent to What Bra	ind?:	Delestrogen						1 Vial			x Each					
DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFOR				MATION	ION			(Write-in, e.g	. 1 Vial)			Gram Milliliter				
		DRUG SUI	PPLT CHAIN SECURITY ACT (DSCSA) INFOR	RMATION									Milliter		
Does supplier meet DSCSA defini	ition of manufactu	rer?	Yes	7	GLN:	03707000000074	1		ITEM AND PACKING INFORMATION							
Is product exempt from DSCSA?			No													
If yes, select exemption:					GCP:						Martine A. I. Inc.	Dimensi	ons (US msm	its.)	Volume	Saleable #
Other exemption - Write in:									' <u> </u>		Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			riginal product pur	chased		Item/Each:		0.06615	1.850393701	2.9133858	2.0472441	11.03651	1
Is product sold by manufacturer's			No	_	direct from n											
Has FDA granted waiver/exception If yes, attach documentation from		roduct?	No		Provide sour	ce manufacturer fo	or repac	ckaged product	Box/Carton/E	Bundle/					0	
ir yes, attach documentation from	m FDA.								Case:							
		(GTIN AND HIBCC PRODUCT IN	FORMATION							2.646	10.43307087	7.5590551	7.6771654	605.45318	40
									Pallet:						0	
Saleable Unit of Measure	8	Saleable Quantity	HIBCC			N-14	_	Unit of Use GTIN-14							U	
x Item/Each		1 00370700273227														
Box/Carton/Bundle/Inner Pack		40 10370700273224				-		COST INFORMATION				WHOLESALER USE ONLY:				
X Case 40 10			10/1002/3224			Regular Cost				Vendor #:						
							Invoice Cost			\$119.46	Whsl. Code	#:				
										. , , , , ,			Fineline Cod			
									As of date:							
1				TA 0115 ::					<u> </u>		B.B.B.B.		Ь			
*Please provide any additional inf	formation on name	2	Attach copy of SAFETY DA	IA SHEET (SE	اد) or non haza			RT, LABEL AND PHOTO OF F	KODUCI PACK	AGING and	BARCODE.					



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For Designated Drop Ship Only Products, Please Use Page 3

MATE	RIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply):							
a. Cytotoxic?	No	SDS Hazard Classification					
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?	No	Inorganic	Oxidizer				
Does the product label bear a CA Prop 65 warning?	No	Steroid/Androgen Contact Hazard					
c. Contact Hazard?	No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level:					
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	No	NFPA Storage Level:					
e. Does the product contain DEHP?	No	NI FA Storage Level.					
			N.				
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS)	No	Is the product a NIOSH hazardous drug? If yes, indicate which:	Yes Group 2 items (non-antineoplastic that meets a hazard criterion)				
a. UN/Identification Number		ii yes, indicate which:					
b. Proper Shipping Name							
c. DOT Hazard Class		Hazardous Waste Identification					
d. Packing Group							
e. Inhalation Hazard?	No	EPA Hazardous Waste Code:	Waste Characteristics				
Is this product regulated for shipment by IATA?	No	·					
(if yes, answer a-e below and provide SDS)		REMS o	r REGISTRY RESTRICTIONS				
a. UN/Identification Number							
b. Proper Shipping Name		Is there a REMS on this product?	No				
c. DOT Hazard Class		If Yes, is it managed with a pharmacy registry?					
d. Packing Group		Website URL:					
e. Inhalation Hazard?	No						
Is the product restricted for air shipment? If so, indicate restriction:	No	Med Guide Required	No				
Passenger		Limited Distribution Requirement	No				
Cargo		Comments / Details: (For example, iPledge program?)					
Passenger & Cargo							
Is this a reportable quantity? No		REMS:	Phone				
RQ Threshold: Is this a marine pollutant? No		REMS Program Manager Name: Supplier Manages REMS registry exclusively:	Phone:				
Is this a manne pollutant? No State of the s		Wholesale distributor support:					
No (if yes, identify method below)		Provider Name:	DEA#:				
Limited Quantity		Site Enrollment Number assigned	NCPDP#:				
Consumer Commodity, ORM-D		by Supplier:	NPI #:				
Small Quantity (49 CFR 173.4)		•					
Special Permit; DOT-SP		Comments					
Special Provision (listed in Column 7 of 49 CFR 172.101);							
SP#		Registry:					
		Registry Program Contact Name:	Phone:				
ADD'L STORAGE INFORMATION		Comments					
Is the Product							
Controlled Substance? No Controlled Substance Code		R	ETURN INSTRUCTIONS				
Controlled by State(s)? ARCOS Reportable? No Listed Chemical (List I or II) No If yes, indicate which:	No	Contact tol. # if product received demands					
ARCOS Reportable? Schedule No. No If yes, indicate which: Is it a scheduled listed chemical product?:	No	Contact tel. # if product received damaged:					
	INO	Is product returnable for credit:					
CLASS OF TRADE RESTRICTION:		URL/Link to returns policy:					
No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	Yes						
Restricted to retail pharmacy only:		Special regulations or returns requirements for this					
Restricted to hospital, clinics, and physician offices only:		product in certain states?					
Restricted from US territories? (explain in comments)		If so, which states? Other requirements? Comments?	·				
Comments:							
MISC	CELLANEO	US NOTES and/or Image of Product Barcode:					
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FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Desig	gnated Drop Ship Product	Standard Order Receipt and Processing						
Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier						
a. EDI		Cut off time:						
b. Autofax	Fax Number:							
c. Fax	Fax Number:	Shipping lead time of PO: Hours Days						
d. Phone only	Phone No.:	China cama day far nayt day receipts						
e. Supplier Web Site only Minimum Order Quantity:	Site Address:	Ships same day for next day receipt: Ships for second day receipt:						
Supplier's Customer Service Number:		Ships regular ground for 3-10 days receipt:						
Contracted 3PL company / contact #: Name:		Ships regular ground for 3-10 days receipt.						
Phone:								
	Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing						
Expedited freight fees billed with each order:		Overnight receipt available:	_					
Drop Ship service fee billed with each order:		PO Receipt cut off time:						
Drop Ship miscellaneous fees billed:		Days of week overnight is available: Monday						
Comments:		Days of week overnight is available: Tuesday						
Comments.		Wednesday						
		Thursday						
		Friday						
		Priority Overnight receipt available:						
Class of Tro	de 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 o Restricted from US territories? (explain in comments		Order receipt method: Phone: Phone #: Fax: Fax #:	-					
Comments:	5)	EDI:						
Comments.		Overnight Fees apply:						
		Other fees apply:						
Other Data Information	n 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 #								
Physician/Clinic DEA #:		Special regulations or returns requirements for this product in certain states?						
Physician/Clinic Specialty:		If so, which states? Other requirements? Comments?						
Miscelland	neous Notes:							
		ADDITIONAL INFORMATION						
		Is product order for scheduled patient procedure?						
		Is product order for restocking purposes?						