

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

						Introduction Type:	Open Stock		Final Version			Date:	//13/	2023
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	RAGE REQUIF	EMENTS*		
Company Name:	Xiromed LLC					Application:	ANDA	a. Temperature	e - Indicate the USP tempe	rature range for t	his product.			
Application Number for NDA/ANI		IA/510(k)(med devic	e):	090	793				Temperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applicab		. , ,	<i>'</i>											
DUNS:	080228637							'	Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) as	nd Established Na	me: Tri-Esta	arylla						(write in)	•				
Selling Unit NDC:	70700-121-85		Unit of Use NDC:				700121856		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Norgestimate + El	E, 0.18/0.215/0.25-0.0	035mg - 3 x 28 Pack						Is this product to be shipped	to customers on i	ce?		No	
•			•						Is this product to be shipped				No	
Active Ingredient(s):		Norgestimate And E	thinyl Estradiol											
								b. Contact for t	temperature excursion que	estions:				
URL for Additional Product Inform									Name:		VIPUL GAND			
Address:	180 Park Ave						e 101		Number:		973-953-786			
City:	Florham Park				State:		: 07932		Group E-mail:		VIPUL.GAN	DHI@XIRO	MED.COM;	
Key Contact:	David Hernandez				Email: Fax:	david.hernandez@	<u>uromed.com</u>			-4-40			NI.	ı
Phone Number:	973-324-0200				Fax:	862-286-0932			ulations for product in any				No	
Product Therapeutic Classification	1:	Combination Oral Co	ontraceptive						Special returns requirement	s for this product?			No	
	ADDITI	ONAL PRODUCT INC	FORMATION			DRODUCT DESC	DIDTION INCODMATION							ı
	ADDITIO	ONAL PRODUCT INF				PRODUCT DESC	RIPTION INFORMATION		ct (unit of sale) upright?				Yes	
The product is?			Is the Product	Direct-Ship Or	nly				Protect product (unit of sa	le) from light?			Yes	
a legend device?		No	Is the Product	Neither		Size:	3 x 28 Pack	e. Shelf life:					24	Months
if yes, enter class #			Orphan Drug Status						Initial shelf life at launch (i	f different):				Months
a product kit?			FD 4 4			Strength:	0.18mg/0.215mg/0.25mg-0			ORDER INFORM	ATION			
if yes, list NDCs of component parts			FDA Approval Status				Tablets			ORDER INFORM	IATION			
reverse numbered?						Dosage Form:	Tablets		Unit of Sale		What is the	NDC salling	unit?	
co-licensed?		No	Allergens Present						Bottle		1 Box of 84,			
latex-free?		140	7 mor gone i roccine				Round		X Box/Carton		(Write-in, e.d			
preservative-free?						Product Shape:			Ampule		, , ,		,	
correctional institution block?						Product Color:	7 white active; 7 light blue		Glass		Minimum or	der quantity	?	Yes
opioid?						Product Color:	_	ll i	Tube					
Cannabinoid?			Country of Origin	Spain		Product Imprint:	7 active SZ and T2; 7 activ		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for					1 roduct imprint.			Vial Liquid Multi		If Yes, how I		ch package f	type?
hospital scanning?			Is this product covered u						Vial Powder Sql			Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (TAA)?	Yes				Vial Power Multi			Inner/Carton	Pack	
								L	Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS										
									DU	ADMACY ODDED				
				_	Au		uthorized Generic, other			ARMACY ORDER				
	AB				Au		uthorized Generic, other on fields are not applicable	Rec. sell unit to	o customer?	ARMACY ORDER	Rx billing ur		cy:	
I. Orange Book Rating: II. Generic Equivalent to What Brai		Ortho Tri-Cyclen			Au				o customer? 1 Pack 3X28	ARMACY ORDER	Rx billing ur	Each	cy:	
			V CHAIN SECUDITY ACT	(DSCSA) INFOR					o customer? 1 Pack 3X28	ARMACY ORDER	Rx billing ur	Each Gram	ıcy:	
			Y CHAIN SECURITY ACT	(DSCSA) INFOR					o customer? 1 Pack 3X28	ARMACY ORDER	Rx billing ur	Each	ncy:	
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	nd?:	DRUG SUPPL		·					o customer? 1 Pack 3X28 1 Vial)	ARMACY ORDER	Rx billing ur	Each Gram Milliliter	ісу:	
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II. Generic Equivalent to What Brain Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	nd?:	DRUG SUPPL	Yes		GLN:	0370700000007	on fields are not applicable	(Write-in, e.g. 1	o customer? 1 Pack 3X28 1 Vial) ITEM Weight Lbs.	AND PACKING I Dimensi Depth	Rx billing ur x NFORMATION ons (US msm Width	Each Gram Milliliter ts.) Height	Volume (Cube)	Pieces
II. Generic Equivalent to What Bran	d?: ion of manufactur	DRUG SUPPL	Yes No		GLN:	0370700000007	on fields are not applicable		o customer? 1 Pack 3X28 1 Vial) ITEM	I AND PACKING I	Rx billing ur x NFORMATION ons (US msm	Each Gram Milliliter	Volume	
II. Generic Equivalent to What Branch Does supplier meet DSCSA definit Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	ion of manufactur	DRUG SUPPL	Yes No		MATION GLN: GCP: If yes, was or direct from m	0370700000007	on fields are not applicable	(Write-in, e.g. 1	o customer? 1 Pack 3X28 1 Vial) ITEM Weight Lbs. 0.08	AND PACKING I Dimensi Depth	Rx billing ur x NFORMATION ons (US msm Width	Each Gram Milliliter ts.) Height	Volume (Cube)	Pieces
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II. Generic Equivalent to What Brain II. Generic Equivalent to What Brain II. Generic Equivalent to What Brain II. Sproduct exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception If yes, attach documentation from Saleable Unit of Measure X	ion of manufactur exclusive distribu l/exemption for pr n FDA.	DRUG SUPPL er? tor? oduct? GTIN aleable Quantity	Yes No No No No No No		GLN: GCP: If yes, was or direct from m Provide source GTII 003	0370700000007 Oscillation of the control of the co	on fields are not applicable d ackaged product	(Write-in, e.g. 1 Item/Each: Box/Carton/Bu Inner Pack: Case:	o customer? 1 Pack 3X28 1 Viai) ITEM Weight Lbs. 0.08	Dimensi Depth	NFORMATION ons (US msm Width 2.0	Each Gram Millilliter ts.) Height 1.0	Volume (Cube) 8.0 0 763.98	1 80
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II. Generic Equivalent to What Bran	ion of manufactur exclusive distribu l/exemption for pr n FDA.	DRUG SUPPL er? tor? oduct? GTIN aleable Quantity	Yes No No No No No No		GLN: GCP: If yes, was or direct from m Provide source GTII 003	0370700000007 original product purchase of fr? ce manufacturer for rep N-14 70700121856	on fields are not applicable d ackaged product	(Write-in, e.g. 1 Item/Each: Box/Carton/Bu Inner Pack: Case: Pallet:	o customer? 1 Pack 3X28 1 Vial) ITEM Weight Lbs. 0.08 Indle/ 6.9 COST INFORMATION	Dimensi Depth	NFORMATION ons (US msm Width 2.0 8.4 Vendor #: Whsl. Code	Each Gram Milliliter ts.) Height 1.0 8.5	Volume (Cube) 8.0 0 763.98	1 80
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Version 2021 For Designated Drop Ship Only Products, Please Use Page 3 MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

MA MA	ATERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION		
Is this product (check all that apply):				
a. Cytotoxic?	No	SE	S Hazard Classification	
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?				
Is the product a CA Prop 65 carcinogen?	Yes	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,		
d. Does this product require special clean-up instructions?	No	identify NFPA Storage Level:		
(If yes, attach SDS with special instructions.)		NFPA Storage Level:		
e. Does the product contain DEHP?	No			
Is this product regulated for shipment by DOT?	No	Is the product a NIOSH hazardous drug?	Yes	
(if yes, answer a-e below and provide SDS)	INU	If yes, indicate which:		stic that meets a hazard criterion)
a. UN/Identification Number		ii yes, iliulcate wilicii.	Group 2 Items (Horr-aritineopia	sic that meets a nazard enterion)
b. Proper Shipping Name				
c. DOT Hazard Class		Ната	rdous Waste Identification	
d. Packing Group		TIGEG	radas maste lacitamentation	
e. Inhalation Hazard?	No	EPA Hazardous Waste Code:		Waste Characteristics
		Li A hazardous waste code.		Waste Offaracteristics
Is this product regulated for shipment by IATA?	No	27110		
(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:		
RQ Threshold:		REMS Program Manager Name:		Phone:
Is this a marine pollutant? No		Supplier Manages REMS registry exclusively:		
Is this product shipped utilizing an authorized DOT exception or Special Permit?		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		T Hone.
		22		
Is the Product Controlled Substance? No. Controlled Substance Code			ETURN INSTRUCTIONS	
Controlled Substance? Controlled by State(s)? No Controlled Substance Code Listed Chemical (List I or II)		R	ETURNINSTRUCTIONS	
, , , , , , , , , , , , , , , , , , , ,		Contracted #if and doctors in a demand		
	Na	Contact tel. # if product received damaged:		
Schedule No. Is it a scheduled listed chemical product?:	No	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:		Chaniel regulations on nature		
		Special regulations or returns requirements for this product in certain states?		
Restricted to hospital, clinics, and physician offices only:		1 .		
Restricted from US territories? (explain in comments)		If so, which states? Other requirements? Comments?		
Comments:				
	ISCELLANEC	DUS NOTES and/or Image of Product Barcode:		



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

Version 2021

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
Purchase orders may be accepted by: a. EDI b. Autofax Fax Number:	Purchase order daily receipt cut off time by supplier Cut off time:
c. Fax d. Phone only e. Supplier Web Site only Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Fax Number: Site Address: Site Address: Name:	Shipping lead time of PO: Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Phone:	
Expedited Freight Charges or Other Designated Drop Ship Fees: Expedited freight fees billed with each order:	Overnight and Priority Overnight PO Processing Overnight receipt available:
Drop Ship service fee billed with each order:	PO Receipt cut off time:
Drop Ship miscellaneous fees billed: Comments:	Days of week overnight is available: Monday 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 Restricted to retail pharmacy only: Restricted to hospital, clinics, and physician offices only: Restricted from US territories? (explain in comments) Comments:	Saturday Overnight receipt available: PO Receipt Cut off time: Phone: Fax: EDI: Overnight Fees apply: Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date: Physician Name: Physician/Clinic Phone # Physician State License # Physician/Clinic DEA #: Physician/Clinic Specialty: Miscellaneous Notes:	Contact # if product is received damaged: Is product returnable for credit: URL/Link to returns policy: Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?
	ADDITIONAL INFORMATION
	Is product order for scheduled patient procedure? Is product order for restocking purposes?