

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

Version 2021						Introduction 1	Туре:	Open Stock	1	Final Version			Date:	7/13/	/2023
			PRODUCT INFORMA	TION						SPECIAL	HANDLING AND STO	RAGE REQUI	REMENTS*		
Company Name: Xiromed LLC Application						tion:	ANDA	a. Temperature – Indicate the USP temperature range for this product.							
	ANDA/BLA (drug); PMA/510(k)(med device): 091232							Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)							
Medical Device Class, if applical	ble:										1				
DUNS:	080228637									Other Temperature Ra	nge Requirement				
Proprietary Name (If Applicable) a		ame: Tri-L	o-Estarylla		1	1100	0707004	100050		(write in)					
Selling Unit NDC: UDI	70700-120-85		Unit of Use NDC: CVX Code:			UPC: MVX Code:	3707001	120859		Notes					
-	Nerrestimete : E	C 0 10/0 215/0 25							1	la this was duet to be al		1002		No	1
Description: Norgestimate + EE, 0.18/0.215/0.25-0.025mg - 3 x 28 Pack Is this product to be shipped to customers on ice? No Is this product to be shipped to customers on dry ice? No															
Active Ingredient(s): Norgestimate And Ethinyl Estradiol															
									b. Contact for temperature excursion questions: Name: VIPUL GANDHI						
URL for Additional Product Inform Address:						Address 2:	Suite 10	14					73-953-7867		
City:					NJ	Zip:						PUL.GANDHI@XIROMED.COM;			
Key Contact:					david.hernandez								4		
Phone Number:	973-324-0200	73-324-0200 Fax: 862				862-286-0932	862-286-0932			c. Special regulations for product in any states? No]	
Product Therapeutic Classificatio	n:	Combination Oral	Contraceptive							Special returns require	ments for this product	?		No	
						PRODUCT	PEOODID								1
	ADDITI	ONAL PRODUCT				PRODUCT	DESCRIP	TION INFORMATION	d. Store produ	ict (unit of sale) uprig				Yes	1
The product is?			Is the Product	Direct-Ship C	Only		0	00 De els	o ob alt liter	Protect product (unit	of sale) from light?			Yes	
a legend device? if yes, enter class #		No	Is the Product Orphan Drug Status	Neither		Size:	3	x 28 Pack	e. Shelf life:	Initial shelf life at lau	nch (if different):			24	Months Months
a product kit?			Orphan Drug Status				0).18mg/0.215mg/0.25mg-0		initial shen hie at lau	ien (in unterent).				WOITINS
if yes, list NDCs of			FDA Approval Status			Strength:					ORDER INFOR	MATION			
component parts						Dosage Form	m: T	ablets							
reverse numbered?		No	<u>.</u> .							Unit of Sale			NDC selling		
co-licensed? latex-free?		No	Allergens Present				P	Round		Bottle X Box/Carton			, 3 blisters of : .g. 1 Box of 1		
preservative-free?						Product Sha	ape:	tound		Ampule		(*******************	.g. 1 Dox of 1	0 1013)	
correctional institution block?						Product Col	7	white active; 7 light blue		Glass		Minimum o	rder quantity	?	Yes
opioid?				-		Flourer Con				Tube					
Cannabinoid?			Country of Origin	Spain		Product Imp	orint: 7	active SZ and T5; 7 activ		Vial Liquid S					
If Unit Dose, is item bar coded to u hospital scanning?	unit dose for		Is this product covered u	under the						Vial Liquid N Vial Powder			many of whi Each	ich package i	type?
If Unit Dose, indicate NDC here:			Trade Agreements Act (Yes					Vial Power N		00	Inner/Carton	/Pack	
										Other: Write	In		Case		
			FOR GENERIC DRUG PR	ODUCTS											
							*16 A				PHARMACY ORDE				
	10				AL	uthorized Generic		orized Generic, other fields are not applicable			PHARMACTORDE				
I. Orange Book Rating: AB II. Generic Equivalent to What Brand?: Ortho Tri-Cyclen Lo								Rec. sell unit to customer?			Rx billing unit to pharmacy:				
ii. Generic Equivalent to What Brand?.								(Write-in, e.g. 1 Vial) Gram							
		DRUG SUP	PLY CHAIN SECURITY ACT ((DSCSA) INFOR	RMATION								Milliliter		
			Yes	_	01.11	0370700000007					ITEM AND PACKING		N		
Does supplier meet DSCSA defini Is product exempt from DSCSA?	tion of manufactu		No	-	GLN:	0370700000007					ITEM AND FACKING		N		
If yes, select exemption:					GCP:						Dimen	sions (US msr	nts.)	Volume	Saleable #
Other exemption - Write in:										Weight L	os. Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			riginal product pur	chased		Item/Each:	0.08	4.0	2.0	1.0	8.0	1
Is product sold by manufacturer's Has FDA granted waiver/exception			No No		direct from n	ntr? rce manufacturer fo	or ronooka	aged product	Box/Carton/Bi	undlo/					
If yes, attach documentation from					FIOVICE SOUL	ce manufacturer ic	ог тераска	aged product	Inner Pack:					0	
									Case:	6.9	10.7	8.4	8.5	763.98	80
		G	TIN AND HIBCC PRODUCT I	NFORMATION						0.5	10.7	0.4	0.0	100.00	00
Saleable Unit of Measure	c	Saleable Quantity	HIBCC		GTI	IN-14		Unit of Use GTIN-14	Pallet:					0	
x Item/Each		1	TIBOO			370700120859		01111 01 036 01114-14							
Box/Carton/Bundle/Inner Pack							- ·			COST INFORMAT	ION		WHOLESAL	ER USE ONL	.Y:
X Case		80			203	370700120853									
Pallet					_		-		Regular Cost			Vendor #:			
	-						-		Invoice Cost (WAC) (\$)		Whsl. Code Fineline Co			
	-						-		As of date:			in menne Co			
			Attach copy of SAFETY DA	ATA SHEET (SD	S) or non haza			, LABEL AND PHOTO OF F							
*Please provide any additional inf	*Please provide any additional information on page 2. See new p. 3 for Designated Drop Ship Only. Signature:														

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

Version 2021 For Design	ated Drop Ship Only Products, Please Use Page 3						
MATERIAL HA	AZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply): a. Cytotoxic? No b. CA Prop. 65 Carcinogen or Reproductive Toxicant? Is the product a CA Prop 65 carcinogen? Is the product a CA Prop 65 reproductive toxicant? Does the product label bear a CA Prop 65 warning? No	SDS Hazard Classification Organic Corrosive Inorganic Oxidizer Steroid/Androgen Contact Hazard						
c. Contact Hazard? No d. Does this product require special clean-up instructions? No (If yes, attach SDS with special instructions.) e. Does the product contain DEHP? No Is this product regulated for shipment by DOT? No	Does the product have an Aerosol class? If yes, identify NFPA Storage Level: NFPA Storage Level: Is the product a NIOSH hazardous drug? Yes						
(if yes, answer a-e below and provide SDS) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group	If yes, indicate which: Group 2 items (non-antineoplastic that meets a hazard criterion) Hazardous Waste Identification						
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) a. UN/Identification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group	REMS or REGISTRY RESTRICTIONS Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? Website URL:						
e. Inhalation Hazard? No Is the product restricted for air shipment? If so, indicate restriction: No Passenger Cargo Passenger & Cargo	Med Guide Required Limited Distribution Requirement Comments / Details: (For example, iPledge program?)						
Is this a reportable quantity? No RQ Threshold: Is this a marine pollutant? No Is this product shipped utilizing an authorized DOT exception or Special Permit? No (if yes, identify method below) Limited Quantity Consumer Commodity, ORM-D Small Quantity (49 CFR 173.4) Special Permit; DOT-SP Special Perovision (listed in Column 7 of 49 CFR 172.101);	REMS: Phone: REMS Program Manager Name: Phone: Supplier Manages REMS registry exclusively: Phone: Wholesale distributor support: Provider Name: Site Enrollment Number assigned DEA #: by Supplier: NPI #:						
Special Provision (listed in Column 7 of 49 CFR 172, 101); SP#	Registry:						
ADD'L STORAGE INFORMATION Is the Product	Registry Program Contact Name: Phone: Phone: Comments						
Controlled Substance? No Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II) ARCOS Reportable? No If yes, indicate which: Schedule No. Is it a scheduled listed chemical product?: No	RETURN INSTRUCTIONS Contact tel. # if product received damaged: 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 product in certain states? If so, which states? Other requirements? Comments?						
MISCELLAN	EOUS NOTES and/or Image of Product Barcode:						



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Version 2021 FOR DESIGNATED DROP SHIP PRODUCT ONLY - i	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: c. Fax Fax Number: d. Phone only Phone No.: e. Supplier Web Site only Site Address: Minimum Order Quantity: Supplier's Customer Service Number: Contracted 3PL company / contact #: Name: Phone:	Purchase order daily receipt cut off time by supplier Cut off time: Shipping lead time of PO: Hours Days Ships same day for next day receipt: Ships for second day receipt: Ships regular ground for 3-10 days receipt:
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing
Expedited freight fees billed with each order: Drop Ship service fee billed with each order: Drop Ship miscellaneous fees billed: Comments:	Overnight receipt available: Image: Comparison of the second
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: Order receipt method: Phone: Fax: Fax #: EDI: Other fees apply:
Other Data Information Required to Process PO:	Return Instructions
Patient Procedure Date:	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?
Miscellaneous Notes:	
	ADDITIONAL INFORMATION Is product order for scheduled patient procedure? Is product order for restocking purposes?