

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

Version 2021						Introduction T	ype:	Open Stock		Final Version			Date:	7/13	3/2023
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STOR	AGE REQUI	REMENTS*		
Company Name:	Xiromed LLC					Applicat	tion:	ANDA	a. Temperati	re - Indicate the USP tempe	rature range for t	his product			
Company Name: Xiromed LLC Application: ANDA Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 202689 a. Temperature – Indicate the USP temperature range for this product. Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)															
Medical Device Class, if applical			,.										•		
DUNS:	080228637									Other Temperature Range F	Requirement				
Proprietary Name (If Applicable) a		ame: Volnea	1							(write in)	toquiioinont				
Selling Unit NDC:	70700-122-85		Unit of Use NDC:			UPC:	370700	0122853		Notes					
UDI			CVX Code:			MVX Code:									
	D	0.55.0.450.00								La de la considerada a la calciona de		0		NI.	
Description:	Desogestrei + EE	& EE, 0.15mg-0.02m	ng & 0.01mg - 3 x 28 Pack							Is this product to be shipped				No No	-
Active Ingredient(s):		Desogestrel And Et	hinyl Estradial							Is this product to be shipped	i to customers on c	iry ice?		INO	_
Active ingredient(s).		Desogestiel And Et	IIIIIyi Estiauloi						h Contact fo	r temperature excursion que	actions.				
URL for Additional Product Inform	nation:								b. Contact to	Name:	sations.	VIPUL GAN	DHI		
Address:	180 Park Ave					Address 2:	Suite 1	101		Number:		973-953-786			
City:	Florham Park				State:	NJ		07932		Group E-mail:			NDHI@XIRC	MED.COM	:
Key Contact:	David Hernandez				Email:	david.hernande									
Phone Number:	973-324-0200				Fax:	862-286-0932			c. Special re	gulations for product in any	states?			No	1
Product Therapeutic Classificatio	n:	Combination Oral C	Contraceptive							Special returns requirement				No	1
					l										1
	ADDITI	ONAL PRODUCT IN	FORMATION			PRODUCT D	DESCRI	PTION INFORMATION	d. Store prod	luct (unit of sale) upright?				Yes	1
The product is?			Is the Product	Direct-Ship O	nlv					Protect product (unit of sa	le) from light?			Yes	i
a legend device?		No	Is the Product	Neither	····y		1	3 x 28 Pack	e. Shelf life:	Frotect product (unit or se	ie) iroin iigiit:			24	Months
if yes, enter class #		140	Orphan Drug Status			Size:		O X 20 1 doi:	0. 0	Initial shelf life at launch (f different):				Months
a product kit?								0.15mg/0.02mg & 0.01mg							1
if yes, list NDCs of			FDA Approval Status			Strength:					ORDER INFORM	IATION			
component parts						Dosage Form	n.	Tablets							
reverse numbered?		No				Dosage i oili	"			Unit of Sale			NDC selling		
co-licensed?		No	Allergens Present							Bottle			3 blisters of 2		
latex-free?						Product Shar	pe:	Round		X Box/Carton		(Write-in, e.	.g. 1 Box of 10	0 Vials)	
preservative-free?										Ampule				_	
correctional institution block?						Product Cold	or:	21 white active; 5 yellow ac		Glass		Minimum o	rder quantity	?	Yes
opioid?			0	Spain				04 15 07 1 D4 - 5 1		Tube					
Cannabinoid? If Unit Dose, is item bar coded to u	it daaa faa		Country of Origin	Spain		Product Impr	rint:	21 active SZ and D1; 5 act		Vial Liquid Sgl Vial Liquid Multi		If Van ham	many of whi	-bb	h
hospital scanning?	init dose for		Is this product covered u	inder the			Į.			Vial Powder Sql			Each	cii package	typer
If Unit Dose, indicate NDC here:			Trade Agreements Act (Yes					Vial Power Multi		- 00	Inner/Carton	/Pack	
ii oint Bood, maioato NBO noro.				,.	. 00					Other: Write In			Case	, aon	
			FOR GENERIC DRUG PR	ODUCTS											
			1011 021121110 21100 1 11	0500.0											
					Au	thorized Generic	*If Auth	horized Generic, other		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						section	fields are not applicable	Rec sell unit	to customer?		Ry hilling u	nit to pharma	acv.	
II. Generic Equivalent to What Bra		Mircette							11001 0011 0111	1 Pack 3X28	1	X	Each	ucy.	
conone equivalent to timat en									(Write-in, e.g		1		Gram		
		DRUG SUPPL	Y CHAIN SECURITY ACT ((DSCSA) INFOR	MATION				, ,	,			Milliliter		
													_		
Does supplier meet DSCSA defini	tion of manufactu	rer?	Yes		GLN:	0370700000007				ITEN	I AND PACKING II	NFORMATIO	N		
Is product exempt from DSCSA?			No												
If yes, select exemption:					GCP:					Maint I ha	Dimensi	ons (US msn	nts.)	Volume	Saleable #
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No			riginal product purd	chased		Item/Each:	0.08	4.0	2.0	1.0	8.0	1
Is product sold by manufacturer's			No		direct from n							2.0	1.0	0.0	i i
Has FDA granted waiver/exception		roduct?	No		Provide sour	ce manufacturer fo	r repaci	kaged product	Box/Carton/E	Bundle/				0	
If yes, attach documentation from	m FDA.								Inner Pack:						
		CTI	N AND HIBCC PRODUCT I	NEODMATION					Case:	6.9	10.7	8.4	8.5	763.98	80
		GII	N AND HIBCC PRODUCT II	NFORMATION					Pallet:						
Saleable Unit of Measure		Saleable Quantity	HIBCC		GTI	N-14		Unit of Use GTIN-14	Pallet:					0	
x Item/Each		1	ПВСС			70700122853		Offic of Ose G file-14							
Box/Carton/Bundle/Inner Pack		· ·			000	70700122000				COST INFORMATION			WHOLESALI	ER USE ONL	Y:
x Case		80			203	70700122857									
Pallet		- 00							Regular Cos	t		Vendor #:			
									Invoice Cost			Whsl. Code	#:		
	1								1			Fineline Co			
									As of date:						
									1						
<u> </u>									1						
*Please provide any additional inf		•	Attach copy of SAFETY DA	ATA SHEET (SD	S) or non haza			T, LABEL AND PHOTO OF F ated Drop Ship Only.	RODUCT PACK	AGING and BARCODE. Signature:					



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Version 2021 For Designated Drop Ship Only Products, Please Use Page 3

MATERI	IAL HAZARD CLASSIFICATION and TRANSPORTATION						
Is this product (check all that apply):							
a. Cytotoxic?	SDS 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?	identify NFPA Storage Level:						
(If yes, attach SDS with special instructions.)	NFPA Storage Level:						
e. Does the product contain DEHP?	No 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)	If yes, indicate which: Group 2 items (non-antineoplastic that meets a hazard criterion)						
a. UN/Identification Number							
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 l						
(if yes, answer a-e below and provide SDS)	REMS or REGISTRY RESTRICTIONS						
a. UN/Identification Number							
b. Proper Shipping Name	Is there a REMS on this product?						
c. DOT Hazard Class	If Yes, is it managed with a pharmacy registry?						
d. Packing Group	Website URL:						
	No						
Is the product restricted for air shipment? If so, indicate restriction:	No Med Guide Required						
Passenger	Limited Distribution Requirement						
Cargo	Comments / Details: (For example, iPledge program?)						
Passenger & Cargo	Commonday Soldmer, C. S. Salamper, T. Telegopinogrammy						
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 a manne politicant? NO 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)	зу сарына						
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	RETURN INSTRUCTIONS						
Controlled Substance Code Controlled by State(s)? No Listed Chemical (List I or II)	RETORN INSTRUCTIONS						
ARCOS Reportable? No If yes, indicate which:	Contact tel. # if product received damaged:						
	M-						
	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?						
	a set annot season out of season one of season						
Comments:							
MISCE	LLANEOUS 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 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?