

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

Version 2021						Introduction Type:	Open Stock		Final Version			Date:	7/13	/2023
			PRODUCT INFORMA	TION					SPECIAL F	ANDLING AND ST	ORAGE REQU	REMENTS*		
Company Name:	Xiromed LLC					Application:	ANDA	a. Temperati	ure - Indicate the USP te	nperature range fo	r this product.			
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 202789 Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)														
Medical Device Class, if applicable:														
DUNS:	080228637								Other Temperature Ran	ge Requirement				
Proprietary Name (If Applicable) a	and Established Na	ame: Isiblo							(write in)					
Selling Unit NDC:	70700-113-85		Unit of Use NDC:				700113851		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Desogestrel + EE	E, 0.15mg-0.03mg - 3	3 x 28 Pack						Is this product to be ship				No	
									Is this product to be ship	ped to customers o	n dry ice?		No	
Active Ingredient(s): Desogestrel And Ethinyl Estradiol														
URL for Additional Product Inform	mation:							b. Contact to	or temperature excursion Name:	questions:	VIPUL GAN	IDHI		
Address:	180 Park Ave				I	Address 2: Sui	te 101	1	Number:		973-953-78			
City:	Florham Park				State:		o: 07932		Group E-mail:			i@xiromed.co	om;	
Key Contact:	David Hernandez				Email:	david.hernandez@	xiromed.com		·					
Phone Number:	973-324-0200				Fax:	862-286-0932		c. Special re	gulations for product in	iny states?			No	
Product Therapeutic Classification	on:	Combination Oral	Contraceptive						Special returns requiren	ents for this produc	t?		No	
					4			_						
	ADDITI	IONAL PRODUCT I	NFORMATION			PRODUCT DESC	CRIPTION INFORMATION	d. Store prod	duct (unit of sale) upright	?			Yes	
The product is?			Is the Product	Direct-Ship O	nly				Protect product (unit of	f sale) from light?			Yes	1
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			3126.			Initial shelf life at laun	ch (if different):				Months
a product kit?						Strength:	0.15mg/0.03mg							
if yes, list NDCs of			FDA Approval Status				Tables			ORDER INFO	RMATION			
component parts reverse numbered?		Ne				Dosage Form:	Tablets		Unit of Sale		What is the	NDC selling	unit?	
co-licensed?		No No	Allergens Present						Bottle			, 3 blisters of		
latex-free?		Yes	Allergens i resent				Round		X Box/Carton			.g. 1 Box of 1		
preservative-free?		Yes				Product Shape:			Ampule		(,	
correctional institution block?						Product Color:	21 orange active; 7 green i		Glass		Minimum o	rder quantity	/?	Yes
opioid?						Product Color:	-		Tube					
Cannabinoid?			Country of Origin	Spain		Product Imprint:	21 active debossed SZ and		Vial Liquid Sg					
If Unit Dose, is item bar coded to	unit dose for								Vial Liquid Mu				ich package	type?
hospital scanning?			Is this product covered u		V				Vial Powder S		80	Each	· /D I -	
If Unit Dose, indicate NDC here:			Trade Agreements Act (IAA)?	Yes				Vial Power Mu Other: Write In			Inner/Cartor Case	1/Раск	
			FOR GENERIC DRUG PR	ODUCTS				1	Other. Write ii			Case		
			FOR GENERIC DRUG PR	000013										
					Au	thorized Generic *If A	Authorized Generic, other			PHARMACY ORDE	ER / BILL UNIT			
I. Orange Book Rating:	AB						tion fields are not applicable	Rec sell uni	t to customer?			ınit to pharm	acv.	
II. Generic Equivalent to What Bra		Ortho-Cept						1	1 Pack 3X28		x	Each		
·								(Write-in, e.c	j. 1 Vial)			Gram		
		DRUG SUPP	PLY CHAIN SECURITY ACT (DSCSA) INFOR	MATION							Milliliter		
				_										
Does supplier meet DSCSA defin	ition of manufactu	rer?	Yes No	_	GLN:	0370700000007				EM AND PACKING	INFORMATIO	N .		
Is product exempt from DSCSA?			INO											
If yes, select exemption:					GCP:				Weight Lbs		nsions (US msi	,	Volume	Saleable #
Other exemption - Write in:			No			d loc loc		16 (F 1		Depth	Width	Height	(Cube)	Pieces
Is product repackaged? Is product sold by manufacturer's	a avaluaiva diatribi	utor?	No	_	direct from m	riginal product purchas	ed	Item/Each:	0.08	4.0	2.0	1.0	8.0	1
Has FDA granted waiver/exception			No	-		: ce manufacturer for rep	ackaged product	Box/Carton/l	Rundle/					
If yes, attach documentation fro		- Coddet:			T TOTIGE SOUT	oc manaracturer for rep	ackagea product	Inner Pack:	Dunale,				0	
• • • • • • • • • • • • • • • • • • • •								Case:	0.0	10.7	8.4	0.5	700.00	00
		GT	TIN AND HIBCC PRODUCT I	NFORMATION				111	6.9	10.7	8.4	8.5	763.98	80
								Pallet:					0	
Saleable Unit of Measure	\$	Saleable Quantity	HIBCC			N-14	Unit of Use GTIN-14						"	
x Item/Each		1			003	70700113851			2007 WEODWAT		_	MILOL E0.41	==a= a	
Box/Carton/Bundle/Inner Pack					202	707004420EE			COST INFORMATION	DN		WHOLESAL	ER USE ONL	.Y:
X Case Pallet		80			203	70700113855		Regular Cos			Vendor #:			
I dilet								Invoice Cost			Whsl. Code	· #:		
											Fineline Co	de:		
								As of date:						
								11						
П								Ш						
			Attach copy of SAFETY DA	ATA SHEET (SD	S) or non haza		ERT, LABEL AND PHOTO OF F	PRODUCT PACK						
*Please provide any additional in							gnated Drop Ship Only.		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?