

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

Version 2021						Introduction	Туре:	New Item		x Final Version			Date:	8/15/	2023
			PRODUCT INFORMA	TION						SPECIAL HAN	DLING AND STOP	RAGE REQUI	REMENTS*		
Company Name:	Xiromed LLC					Applica	ition:	ANDA	a. Temperature -	Indicate the USP temp	erature range for t	this product.			
Application Number for NDA/AN	IDA/BLA (drug); P	MA/510(k)(med de	vice):	214	1640					nperature Range	Controlled Room		and 25 C (68	° – 77° F)	
Medical Device Class, if applica	ble:														
DUNS:	468835741								Oth	er Temperature Range	Requirement				
Proprietary Name (If Applicable) a		lame: Joye								(write in)					
Selling Unit NDC:	70700-177-85		Unit of Use NDC:			UPC:	3707001778	53	Not	es		excursion pe	ermitted to 15	°C-30°C (59° to	86°F)
UDI			CVX Code:			MVX Code:									
Description:	Levonorgestrel a	nd Ethinyl Estradiol	Tablets and Ferrous Fumarate	e Tablets 0.1 mg	/0.02 mg and 3	75mg				his product to be shippe				No	
A - 41		1	al anthe formal and the state of the t						Is t	his product to be shippe	to customers on o	dry ice?		No	
Active Ingredient(s):		levonorgestrei ar	d ethinyl estradiol						h Contact for ten	perature excursion qu	estions.				
URL for Additional Product Inform	mation:								Na		23110113.	VIPUL GAN	DHI		
Address:	180 Park Ave.				1	Address 2:	Suite 101			mber:		973-953-786	67		
City:	Florham Park				State:	NJ	Zip: 079	32		oup E-mail:		vipul.gandhi	@xiromed.co	m;	
Key Contact:	David Hernande	z			Email:	david.hernanc	lez@xirome	<u>d.com</u>							
Phone Number:	844-947-6633				Fax:	862-286-0932				ions for product in any				No	
Product Therapeutic Classification	on:	oral contraceptive	9						Spe	ecial returns requirement	s for this product?			No	
						DRODUCT	DECODUCTION								
	ADDIT	IONAL PRODUCT				PRODUCT	DESCRIPTIO	N INFORMATION		unit of sale) upright?				No	
The product is?			Is the Product	Direct-Ship C	Only					tect product (unit of sa	le) from light?			Yes	
a legend device?		No	Is the Product	Neither		Size:		ton containing 3 r cards	e. Shelf life:					24	Months
if yes, enter class # a product kit?		Yes	Orphan Drug Status					g/0.02 mg	Init	ial shelf life at launch (	if different):			24	Months
if yes, list NDCs of	70700-835 (activ		FDA Approval Status			Strength:	0.1 m	ig/0.02 mg			ORDER INFORM	MATION			
component parts	70700-836 (plac		T DA Approval Status				tablet	1							
reverse numbered?		No				Dosage For	m:		Un	t of Sale		What is the	NDC selling	unit?	
co-licensed?		No	Allergens Present							Bottle		1 Box of 84,	3 Blisters of 2	28	
latex-free?		Yes				Product Sha	round	i		X Box/Carton		(Write-in, e.	g. 1 Box of 10	) Vials)	
preservative-free?		Yes								Ampule					
correctional institution block?		No				Product Col		(active tablets)		Glass		Minimum or	der quantity	?	Yes
opioid?		No	O	Casia				n (placebo tablets)		Tube					
Cannabinoid? If Unit Dose, is item bar coded to u	unit doco for	No	Country of Origin	Spain		Product Imp		2 (active tablets) (placebo tablets)		Vial Liquid Sgl Vial Liquid Multi		If Yee, how	many of whi	ch package t	vno2
hospital scanning?	unit dose for		Is this product covered u	inder the			70/12	(pidoebo tabieto)		Vial Powder Sql			Each	сп раскауе і	yper
If Unit Dose, indicate NDC here:			Trade Agreements Act (		Yes					Vial Power Multi			Inner/Carton	/Pack	
										Other: Write In			Case		
			FOR GENERIC DRUG PR	ODUCTS											
												_			
					A	uthorized Generic		d Generic, other			ARMACY ORDER	R / BILL UNIT			
I. Orange Book Rating:	AB						section fields	s are not applicable	Rec. sell unit to c		-	Rx billing u	nit to pharma	acy:	
II. Generic Equivalent to What Bra	and?:	Balcoltra								ox of 3x28		x	Each		
			PLY CHAIN SECURITY ACT	DSCSA) INFOR	MATION				(Write-in, e.g. 1 Vi	al)			Gram		
		DRUG SUP	PET CHAIN SECORITY ACT	(DSCSA) INFOR									Milliliter		
Does supplier meet DSCSA defini	ition of manufactu	irer?	Yes		GLN:	0370700000007				ITEN	I AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			No	-											
If yes, select exemption:					GCP:	0370700					Dimens	ions (US msn	nts.)	Volume	Saleable #
Other exemption - Write in:										Weight Lbs.	Depth	Width	Height	(Cube)	Pieces
Is product repackaged?			No		lf yes, was o	riginal product pur	chased		Item/Each:	0.08	4.0	2.0	1.0	8.0	1.0
Is product sold by manufacturer's			No		direct from n						4.0	2.0	1.0	0.0	1.0
Has FDA granted waiver/exceptio		product?	No		Provide sour	rce manufacturer fo	or repackaged	l product	Box/Carton/Bund	e/				0	
If yes, attach documentation fro	m FDA.								Inner Pack:						
		G	TIN AND HIBCC PRODUCT I	NEORMATION					Case:	6.9	10.7	8.4	8.5	763.98	80
		ų							Pallet:			-		-	
Saleable Unit of Measure		Saleable Quantity	HIBCC		GT	IN-14	Unit	of Use GTIN-14						0	
X Item/Each		1			003	370700177853							1		
Box/Carton/Bundle/Inner Pack										COST INFORMATION			WHOLESALE	ER USE ONL'	Y:
					103	370700177850									
X Case		80													
X Case Pallet	_	80					-		Regular Cost			Vendor #:			
	_	80			-		-		Regular Cost Invoice Cost (WA	C) (\$)	\$721.02	Whsl. Code			
		80					_		Invoice Cost (WA	C) (\$)	\$721.02				
		80								2) (\$)	\$721.02	Whsl. Code			
									Invoice Cost (WA	C) (\$)	\$721.02	Whsl. Code			
			Attach copy of SAFETY D.	ATA SHEET (SD	IS) or non hazz	ard letter, PACKAGF	E INSERT. LAF		Invoice Cost (WA		\$721.02	Whsl. Code			
	formation on page		Attach copy of SAFETY D.	ATA SHEET (SD	PS) or non haza	ard letter, PACKAGE See new p. 3 for			Invoice Cost (WA As of date: PRODUCT PACKAGIN		\$721.02	Whsl. Code			

## **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 H	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? No 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? d. Does this product require special clean-up instructions? (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:       No         NFPA Storage Level:       Image: Storage Level:         Is the product a NIOSH hazardous drug?       Yes						
(if yes, answer a-e below and provide SDS) a. UN/dentification Number b. Proper Shipping Name c. DOT Hazard Class d. Packing Group e. Inhalation Hazard? No	If yes, indicate which: Group 2 items (non-antineoplastic that meets a hazard criterion) Hazardous Waste Identification EPA Hazardous Waste Code: Waste Characteristics						
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS) a. UN/Identification Number	REMS or REGISTRY RESTRICTIONS						
b. Proper Shipping Name     c. DOT Hazard Class     d. Packing Group     e. Inhalation Hazard?     No	Is there a REMS on this product? No If Yes, is it managed with a pharmacy registry? Website URL:						
Is the product restricted for air shipment? If so, indicate restriction:           No           Passenger           Cargo           Passenger & Cargo	Med Guide Required     No       Limited Distribution Requirement     No       Comments / Details: (For example, iPledge program?)     No						
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? 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:     REMS Program Manager Name:       Supplier Manages REMS registry exclusively:     Phone:       Wholesale distributor support:     Provider Name:       Site Enrollment Number assigned     DEA #:       by Supplier:     NCPDP#:       Comments     NPI #:						
SP#ADD'L STORAGE INFORMATION	Registry:     Phone:       Registry Program Contact Name:     Phone:						
Is the Product							
Controlled Substance?       No       Controlled Substance Code         Controlled by State(s)?       Listed Chemical (List I or II)         ARCOS Reportable?       If yes, indicate which:         Schedule No.       Is it a scheduled listed chemical product?:         CLASS OF TRADE RESTRICTION:         No restriction:       Select YES if sold to retail pharmacy, hospitals, clinics and physician offices	RETURN INSTRUCTIONS       Contact tel. # if product received damaged:       Is product returnable for credit:       URL/Link to returns policy:						
Restricted to retail pharmacy only:         Restricted to hospital, clinics, and physician offices only:         Restricted from US territories? (explain in comments)	Special regulations or returns requirements for this product in certain states? If so, which states? Other requirements? Comments?						
Comments:							
MISCELLAN	EOUS 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 - 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?