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

Version 2021 | Introduction Type: New Item | x Final Version | Date: 8/15/2023

PRODUCT INFORMATION

Company Name:	Xiromed LLC	Application:	ANDA
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device):	214640		
Medical Device Class, if applicable:			
DUNS:	468835741		
Proprietary Name (If Applicable) and Established Name:	Joyeaux - LEV/EE/FE 0,1-0,02-75 3X21+7XIROMED US		
Selling Unit NDC:	70700-177-85	Unit of Use NDC:	UPC: 370700177853
UDI		CVX Code:	MVX Code:
Description:	Joyeaux is a progestin/estrogen COC indicated for use by females of reproductive potential to prevent pregnancy.		
Active Ingredient(s):	levonorgestrel and ethinyl estradiol		
URL for Additional Product Information:			
Address:	180 Park Ave.	Address 2:	Suite 101
City:	Florham Park	State: NJ	Zip: 07932
Key Contact:	Xiromed Regulatory	Email:	usregulatory@xiromed.com
Phone Number:	844-947-6633	Fax:	862-286-0932
Product Therapeutic Classification:	oral contraceptive		

ADDITIONAL PRODUCT INFORMATION

The product is?		Is the Product…	Direct-Ship Only
a legend device?	No	Is the Product…	Neither
if yes, enter class #		Orphan Drug Status	
a product kit?	Yes		
if yes, list NDCs of component parts	70700-835 (active tablet) 70700-836 (placebo tablet)	FDA Approval Status	
reverse numbered?	No		
co-licensed?	No	Allergens Present	
latex-free?	Yes		
preservative-free?	Yes		
correctional institution block?	No		
opioid?	No		
Cannabinoid?	No	Country of Origin	Spain
If Unit Dose, is item bar coded to unit dose for hospital scanning?		Is this product covered under the Trade Agreements Act (TAA)?	Yes
If Unit Dose, indicate NDC here:			

PRODUCT DESCRIPTION INFORMATION

Size:	1 carton containing 3 blister cards
Strength:	0.1 mg/0.02 mg
Dosage Form:	tablet
Product Shape:	round
Product Color:	white (active tablets) brown (placebo tablets)
Product Imprint:	SZ/L2 (active tablets) XI/12 (placebo tablets)

FOR GENERIC DRUG PRODUCTS

Authorized Generic | *If Authorized Generic, other section fields are not applicable

I. Orange Book Rating:	AB (information pending product approval and OB listing)
II. Generic Equivalent to What Brand?:	Balcoltra

DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION

Does supplier meet DSCSA definition of manufacturer?	Yes	GLN:	0370700000007
Is product exempt from DSCSA?	No		
If yes, select exemption:		GCP:	0370700
Other exemption - Write in:			
Is product repackaged?	No	If yes, was original product purchased direct from mfr?	
Is product sold by manufacturer's exclusive distributor?	No		
Has FDA granted waiver/exception/exemption for product?	No	Provide source manufacturer for repackaged product	
If yes, attach documentation from FDA.			

GTIN AND HIBCC PRODUCT INFORMATION

	Saleable Unit of Measure	Saleable Quantity	HIBCC	GTIN-14	Unit of Use GTIN-14
x	Item/Each	1		00370700177853	
	Box/Carton/Bundle/Inner Pack				
x	Case	64		20370700177857	
	Pallet				

SPECIAL HANDLING AND STORAGE REQUIREMENTS*

a. Temperature – Indicate the USP temperature range for this product.

Temperature Range	Controlled Room – between 20 and 25 C (68° – 77° F)
Other Temperature Range Requirement (write in)	
Notes	excursion permitted to 15°C-30°C (59° to 86°F)
Is this product to be shipped to customers on ice?	No
Is this product to be shipped to customers on dry ice?	No

b. Contact for temperature excursion questions:

Name:	Xiromed Quality
Number:	973-953-7867
Group E-mail:	US-Quality-Xiromed@xiromed.com

c. Special regulations for product in any states?	No	
Special returns requirements for this product?	No	
d. Store product (unit of sale) upright?	No	
Protect product (unit of sale) from light?	Yes	
e. Shelf life:	24	Months
Initial shelf life at launch (if different):	24	Months

ORDER INFORMATION

Unit of Sale		What is the NDC selling unit?	
	Bottle	1 Box of 84, 3 Blisters of 28	
X	Box/Carton	(Write-in, e.g. 1 Box of 10 Vials)	
	Ampule		
	Glass	Minimum order quantity?	Yes
	Tube		
	Vial Liquid Sgl		
	Vial Liquid Multi	If Yes, how many of which package type?	
	Vial Powder Sql	64	Each
	Vial Power Multi		Inner/Carton/Pack
	Other: Write In		Case

PHARMACY ORDER / BILL UNIT

Rec. sell unit to customer?	Rx billing unit to pharmacy:	
1 Box of 3x28	x	Each
(Write-in, e.g. 1 Vial)		Gram
		Milliliter

ITEM AND PACKING INFORMATION

	Weight Lbs.	Dimensions (US msmts.) Depth	Width	Height	Volume (Cube)	Saleable # Pieces
Item/Each:	0.18	4.4	2.4	2.8	28.7	1.0
Box/Carton/Bundle/ Inner Pack:					0	
Case:	11.6	19.448	11.5748	9.114	2051.6226	64
Pallet:					0	

COST INFORMATION

Regular Cost	
Invoice Cost (WAC) ($)	$721.02
As of date:	

WHOLESALER USE ONLY:

Vendor #:	
Whsl. Code #:	
Fineline Code:	

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.

*Please provide any additional information on page 2.

See new p. 3 for Designated Drop Ship Only.

Signature:

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For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL HAZARD 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?	No
Is the product a CA Prop 65 reproductive toxicant?	No
Does the product label bear a CA Prop 65 warning?	No
c. Contact Hazard?	No
d. Does this product require special clean-up instructions? (If yes, attach SDS with special instructions.)	No
e. Does the product contain DEHP?	No
Is this product regulated for shipment by DOT? (if yes, answer a-e below and provide SDS)	No
a. UN/Identification Number	
b. Proper Shipping Name	
c. DOT Hazard Class	
d. Packing Group	
e. Inhalation Hazard?	No
Is this product regulated for shipment by IATA? (if yes, answer a-e below and provide SDS)	No
a. UN/Identification Number	
b. Proper Shipping Name	
c. DOT Hazard Class	
d. Packing Group	
e. Inhalation Hazard?	No
Is the product restricted for air shipment? If so, indicate restriction:	No

- ☐ Passenger
- ☐ Cargo
- ☐ Passenger & Cargo

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?

☐ (if yes, identify method below)

- ☐ Limited Quantity
- ☐ Consumer Commodity, ORM-D
- ☐ Small Quantity (49 CFR 173.4)
- ☐ Special Permit; DOT-SP
- ☐ Special Provision (listed in Column 7 of 49 CFR 172.101);

SP#

SDS Hazard Classification

- ☐ Organic
- ☐ Inorganic
- ☐ Steroid/Androgen
- ☐ Corrosive
- ☐ Oxidizer
- ☐ Contact Hazard

Does the product have an Aerosol class? If yes, identify NFPA Storage Level:	No
NFPA Storage Level:	
Is the product a NIOSH hazardous drug?	Yes
If yes, indicate which:	Group 2 items (non-antineoplastic that meets a hazard criterion)

Hazardous Waste Identification

EPA Hazardous Waste Code:		Waste Characteristics	

REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?	No
If Yes, is it managed with a pharmacy registry?	
Website URL:	
Med Guide Required	No
Limited Distribution Requirement	No
Comments / Details: (For example, iPledge program?)	

REMS:

REMS Program Manager Name:		Phone:	
Supplier Manages REMS registry exclusively:			
Wholesale distributor support:			
Provider Name:		DEA #:	
Site Enrollment Number assigned by Supplier:		NCPDP#:	
		NPI #:	
Comments			

Registry:

Registry Program Contact Name:		Phone:	
Comments			

ADD'L STORAGE INFORMATION

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	
Restricted to retail pharmacy only:	
Restricted to hospital, clinics, and physician offices only:	
Restricted from US territories? (explain in comments)	
Comments:	

RETURN INSTRUCTIONS

Contact tel. # if product 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 and/or Image of Product Barcode:

Release DATE

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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

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:

Standard Order Receipt and Processing

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:

Expedited freight fees billed with each order:

Drop Ship service fee billed with each order:

Drop Ship miscellaneous fees billed:

Comments:

Overnight and Priority Overnight PO Processing

Overnight receipt available:

PO Receipt cut off time:

Days of week overnight is available:
- Monday
- Tuesday
- Wednesday
- Thursday
- Friday

Priority Overnight receipt available:

PO Receipt Cut off time:

Saturday Overnight receipt available:

PO Receipt Cut off time:

Order receipt method: Phone: Phone #:
Fax: Fax #:
EDI:

Overnight Fees apply:

Other fees apply:

Class of Trade Restriction:

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:

Other Data Information Required to Process PO:

Patient Procedure Date:
Physician Name:
Physician/Clinic Phone #
Physician State License #
Physician/Clinic DEA #:
Physician/Clinic Specialty:

Return Instructions

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?