

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

						Introduction Type:	Post Launch Change		Final Version			Date:	11/23/	/2020
			PRODUCT INFORMA	TION					SPECIAL HAN	DLING AND STOR	AGE REQUIF	EMENTS*		
Company Name:	Xiromed LLC					Application:	ANDA	a. Temperature	- Indicate the USP tempe	rature range for the	nis product.			
Application Number for NDA/AN	DA/BLA (drug); PMA/5	10(k)(med device	a):	212	2976			T-	emperature Range	Controlled Room -	between 20	and 25 C (68	' – 77° F)	
DUNS:	080228637				1			O	other Temperature Range F	equirement				
Proprietary Name (If Applicable) a		FLUOCIN							(write in)					
Selling Unit NDC:	70700-146-16		Unit of Use NDC:				0146163	N	lotes					
UDI			CVX Code:			MVX Code:								
Description:	Fluocinonide Ointment	USP, 0.05% 30g	Tube					Is	this product to be shipped	to customers on ic	e?		No	
Active Ingredient(s):	FLI	JOCINONIDE						Is	this product to be shipped	to customers on d	ry ice?		No	
b. Contact for temperature excursion questions:														
URL for Additional Product Inforn									lame:		Steven Yeun			
Address:	180 Park Ave				State:	Address 2: Suite 1		-	lumber:		844-947-663		-1	
City:	Florham Park David Hernandez				Email:	david.hernandez@x	07932	-	roup E-mail:		steven.yeu	ng@xirom	<u>ad.com</u>	
Key Contact: Phone Number:	844-947-6633				Fax:	862-286-0932	iromeu.com	C Special regula	ations for product in any	states?			No	
Product Therapeutic Classification					l un.	002 200 0302			pecial returns requirements				No	
Froduct Therapeutic Glassification					j			3	peciai returns requirement	s for this product:				
	ADDITIONAL	PRODUCT INFO	RMATION			PRODUCT DESCR	RIPTION INFORMATION	d. Store produc	t (unit of sale) upright?					
The new decestion				Discost Ohio C				-1		I-) (II-I-10				
The product is? a legend device?	No		Is the Product Is the Product	Direct-Ship O Neither	nly		30 grams	e. Shelf life:	rotect product (unit of sa	le) from light?		ĺ	24	Months
if yes, enter class #	No		Orphan Drug Status	Neither		Size:	30 grams		nitial shelf life at launch (i	f different):			24	Months
a product kit?	No		Orphan Drug Status				0.05%	"	illiai Sileii ille at iaulicii (i	i dillerentj.				WOILLIS
if yes, list NDCs of	140		FDA Approval Status			Strength:	0.0070			ORDER INFORM	IATION			
component parts						D	OINTMENT							
reverse numbered?	No					Dosage Form:		ll u	nit of Sale		What is the	NDC selling	unit?	
co-licensed?	No		Allergens Present						Bottle		1 Box contain			
latex-free?	No		Not made with nat	ural rubber late	ay.	Product Shape:			x Box/Carton		(Write-in, e.g	g. 1 Box of 10	Vials)	
preservative-free?	Yes		Not made with hat	urai rubber late	Α.	i roduct snape.			Ampule					
correctional institution block?	Yes					Product Color:			Glass		Minimum or	der quantity	? _	Yes
opioid?	No							II	Tube					
Cannabinoid?	No		Country of Origin	Spain		Product Imprint:			Vial Liquid Sgl					_
If Unit Dose, is item bar coded to u	init dose for hospital		In this case that a consent of	and a subse				11 ⊢	Vial Liquid Multi Vial Powder Sql		If Yes, how		ch package ty	ype?
scanning? If Unit Dose, indicate NDC here:			Is this product covered u Trade Agreements Act (7		Vee			II ⊢	Vial Powder Sqi Vial Power Multi		48	Each Inner/Carton	/Dools	
Il Offit Dose, indicate NDC fiele.			rrade rigicements rici (70191	Yes			11 -	Other: Write In			Case	rack	
			FOR GENERIC DRUG PR	ODUCTS				<u>-</u>	Outer: Write iii			Ousc		
			OR GENERIC DROGTR	000013										
					Auth	orized Generic *If Auth	norized Generic, other section		PH	ARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB			–			are not applicable	Rec. sell unit to			Rx billing ur	it to phorm	2011	
II. Generic Equivalent to What Bra		ex											icy.	
								1			x			
									1 Tube			Each Gram		
		DRUG SUPPLY	CHAIN SECURITY ACT (DSCSA) INFOR	MATION			(Write-in, e.g. 1	1 Tube			Gram Milliliter		
		DRUG SUPPLY							1 Tube Vial)		х	Gram Milliliter		
Does supplier meet DSCSA defini	tion of manufacturer?	DRUG SUPPLY	Yes	(DSCSA) INFOR		0370700000007			1 Tube Vial)	AND PACKING IN	х	Gram Milliliter		
Does supplier meet DSCSA definites product exempt from DSCSA?	tion of manufacturer?	DRUG SUPPLY				0370700000007			1 Tube Vial)		X	Gram Milliliter		
Is product exempt from DSCSA? If yes, select exemption:	ition of manufacturer?	DRUG SUPPLY	Yes			0370700000007			1 Tube Vial) ITEM	Dimensi	IFORMATION	Gram Milliliter ts.)	Volume	# Pieces:
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in:	ition of manufacturer?	DRUG SUPPLY	Yes No	GLI	N:			(Write-in, e.g. 1	1 Tube Vial)		X	Gram Milliliter	Volume (Cube)	# Pieces:
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?			Yes No	GLI	N: 'es, was origin	nal product purchased			1 Tube Vial) ITEM	Dimensi	IFORMATION	Gram Milliliter ts.)		# Pieces:
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	s exclusive distributor?	-	Yes No No No	GLI	N: 'es, was originect from mfr?	nal product purchased		(Write-in, e.g. 1	1 Tube Vial) ITEM Weight Lbs. 0.066	Dimensi Depth	IFORMATION Ons (US msm Width	Gram Milliliter ts.) Height	(Cube) 9.6916522	
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged?	s exclusive distributor?	-	Yes No	GLI	N: 'es, was originect from mfr?	nal product purchased		(Write-in, e.g. 1	1 Tube Vial) ITEM Weight Lbs. 0.066	Dimensi Depth	IFORMATION Ons (US msm Width	Gram Milliliter ts.) Height	(Cube)	
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	s exclusive distributor?		Yes No No No	GLI If Y	N: 'es, was originect from mfr?	nal product purchased		(Write-in, e.g. 1	1 Tube Vial) ITEM Weight Lbs. 0.066	Dimensi Depth 1.457	x IFORMATION Ons (US msm Width 6.142	Gram Milliliter ts.) Height	9.6916522 0	1
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	s exclusive distributor?		Yes No No No No	GLI If Y	N: 'es, was originect from mfr?	nal product purchased		(Write-in, e.g. 1	1 Tube Vial) ITEM Weight Lbs. 0.066	Dimensi Depth	IFORMATION Ons (US msm Width	Gram Milliliter ts.) Height	(Cube) 9.6916522	
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's	s exclusive distributor? n/exemption for produ		Yes No No No No	GLI If Y	N: 'es, was originect from mfr?	nal product purchased cumentation from FDA.	Unit of Use GTIN-14	(Write-in, e.g. 1	1 Tube Vial) ITEM Weight Lbs. 0.066	Dimensi Depth 1.457	x IFORMATION Ons (US msm Width 6.142	Gram Milliliter ts.) Height	9.6916522 0 617.472	1
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception	s exclusive distributor? n/exemption for produ	ct?	Yes No No No No No No AND HIBCC PRODUCT I	GLI If Y	N: 'es, was origined from mfr? es, attach doo	nal product purchased cumentation from FDA.	Unit of Use GTIN-14	(Write-in, e.g. 1 Item/Each: Box/Carton/Bun Inner Pack: Case:	1 Tube Vial) ITEM Weight Lbs. 0.066	Dimensi Depth 1.457	x IFORMATION Ons (US msm Width 6.142	Gram Milliliter ts.) Height	9.6916522 0	1
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception Saleable Unit of Measure Item/Each Box/Carton/Bundle/Inner Pack	s exclusive distributor? n/exemption for produ	GTIN A	Yes No No No No No No AND HIBCC PRODUCT I	GLI If Y	Yes, was origined from mfr? es, attach doo	nal product purchased cumentation from FDA.	Unit of Use GTIN-14	(Write-in, e.g. 1 Item/Each: Box/Carton/Bun Inner Pack: Case:	1 Tube Vial) ITEM Weight Lbs. 0.066 ddle/ 5.35	Dimensi Depth 1.457	x IFORMATION Ons (US msm Width 6.142 7.2	Gram Milliliter ts.) Height 1.083	9.6916522 0 617.472	1 48
Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception Saleable Unit of Measure Item/Each Box/Carton/Bundle/Inner Pack X Case	s exclusive distributor? n/exemption for produ	ct? GTIN A	Yes No No No No No No AND HIBCC PRODUCT I	GLI If Y	Yes, was origined from mfr? es, attach doo	nal product purchased cumentation from FDA.	Unit of Use GTIN-14	(Write-in, e.g. 1 Item/Each: Box/Carton/Bun Inner Pack: Case:	1 Tube Vial) ITEM Weight Lbs. 0.066	Dimensi Depth 1.457	x IFORMATION Ons (US msm Width 6.142 7.2	Gram Milliliter ts.) Height 1.083	9.6916522 0 617.472	1 48
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Is product exempt from DSCSA? If yes, select exemption: Other exemption - Write in: Is product repackaged? Is product sold by manufacturer's Has FDA granted waiver/exception Saleable Unit of Measure Item/Each Box/Carton/Bundle/Inner Pack X Case	s exclusive distributor? n/exemption for produ	GTIN A	Yes No No No No No No AND HIBCC PRODUCT I	GLI If Y	Yes, was origined from mfr? es, attach doo	nal product purchased cumentation from FDA.	Unit of Use GTIN-14	(Write-in, e.g. 1 Item/Each: Box/Carton/Bur Inner Pack: Case: Pallet: Regular Cost	1 Tube Vial) ITEM Weight Lbs. 0.066 ddle/ 5.35 COST INFORMATION	Dimensi Depth 1.457	x IFORMATION ons (US msm Width 6.142 7.2 Vendor #:	Gram Milliliter ts.) Height 1.083	9.6916522 0 617.472	1 48
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Standard Pharmaceutical Product and Medical Device Information (Rx Product Only)

Version 2020 For Designated Drop Ship Only Products, Please Use Page 3

MATERIAL	HAZARD CLASSIFICATION and TRANSPORTATION							
Is this product (check all that apply):								
a. Cytotoxic?	SDS Hazard Classification							
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?								
·	Organic Corrosive							
Is the product a CA Prop 65 carcinogen?								
Is the product a CA Prop 65 reproductive toxicant?	Oxidizer							
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen Contact Hazard							
c. Contact Hazard?	Aerosol Class; Identify NFPA Storage Level:							
d. Does this product require special clean-up instructions?								
(If yes, attach SDS with special instructions.)	Is the product a NIOSH hazardous drug? No							
e. Does the product contain DEHP?	If yes, indicate which:							
Is this product regulated for shipment by DOT?								
(if yes, answer a-e below and provide SDS)	Hazardous Waste Identification							
a. UN/Identification Number	Hazardous waste identification							
b. Proper Shipping Name	FRAU LANGE L							
c. DOT Hazard Class	EPA Hazardous Waste Code: Waste Characteristics							
d. Packing Group								
e. Inhalation Hazard?	<u> </u>							
Is this product regulated for shipment by IATA?	REMS or REGISTRY RESTRICTIONS							
(if yes, answer a-e below and provide SDS)	Is there a REMS on this product? No							
a. UN/Identification Number	If Yes, is it managed with a pharmacy registry?							
b. Proper Shipping Name	Website URL:							
c. DOT Hazard Class	Website Urt.							
d. Packing Group	— Mad Cride Remined							
e. Inhalation Hazard?	Med Guide Required No							
Is the product restricted for air shipment? If so, indicate restriction:	Limited Distribution Requirement No							
Passenger	Comments / Details: (For example, iPledge program?)							
Cargo								
Passenger & Cargo								
	REMS:							
Is this a reportable quantity? No								
RQ Threshold:	REMS Program Manager Name: Phone:							
Is this a marine pollutant? No	Supplier Manages REMS registry exclusively:							
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 PCPDP#:							
Consumer Commodity, ORM-D	by Supplier: NPI #:							
Small Quantity (49 CFR 173.4)								
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	Registry Program Contact Name: Prione: Prione:							
	Comments							
Is the Product								
Controlled Substance? No Controlled Substance Code	RETURN INSTRUCTIONS							
Controlled by State(s)? No Listed Chemical (List I or II) No								
ARCOS Reportable? No If yes, indicate which:	Contact tel. # if product received damaged:							
Schedule No. Is it a scheduled listed chemical product?: No	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?							
Comments:								
Commonio.								
MISCELL ₁	NEOUS NOTES and/or Image of Product Barcode:							



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

Version 2020

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 c. Fax d. Phone only e. Supplier Web Site only 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: PO Receipt cut off time: Days of week overnight is available: Monday Tuesday Wednesday Thursday Friday
	Priority Overnight receipt available:
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:	PO Receipt Cut off time: Saturday Overnight receipt available: PO Receipt Cut off time: Phone: 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?