

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

Version 2021						Introduction Typ	De: New Item		x Final Version			Date:	6/29/	/2023
			PRODUCT INFORMA	TION					SPECIAL HAN	NDLING AND STOR	RAGE REQUI	REMENTS*		
Company Name:	Name: XIROMED LLC				Application: ANDA		a. Temperat	a. Temperature – Indicate the USP temperature range for this product. Temperature Range Controlled Room – between 20 and 25 C (68° – 77° F)						
Application Number for NDA/ANDA/BLA (drug); PMA/510(k)(med device): 210639														
Medical Device Class, if applicable:														
DUNS:	080228637								Other Temperature Range	Requirement	It must be pr	eserved in ti	ght container.	Store
Proprietary Name (If Applicable) a		ame: Betar	methasone Valerate Foam, 0.	12%					(write in)		between 15-	25°C in dry p	lace	
Selling Unit NDC:	70700-141-20		Unit of Use NDC:				70700141205		Notes					
UDI			CVX Code:			MVX Code:								
Description:	Betamethasone \	/alerate 0.12% Foan	n - 100g Can						Is this product to be shippe	d to customers on i	ce?		No	1
									Is this product to be shippe	d to customers on	dry ice?		No	
Active Ingredient(s): Betamethasone Valerate						h 0								
						b. Contact fo	b. Contact for temperature excursion questions: Name: VIPUL GANDHI							
URL for Additional Product Inform Address:	180 Park Avenue	www.xiromed.	<u>com</u>		I	Address 2: #	101		Name: Number:		9739537867			
City:	Florham Park	,			State:		Zip: 07932		Group E-mail:		us.quality(ım:	
Key Contact:	DAVID HERNAN	DEZ			Email:		DEZ@XIROMED.COM		Group E-mail.		us.quanty(WCXCILI3.CO	<u>,, , , , , , , , , , , , , , , , , , ,</u>	
Phone Number:	844-947-6633	, L			Fax: 862-286-0932			c. Special re	c. Special regulations for product in any states?				No	1
Product Therapeutic Classification	n:	topical corticostero	oid						Special returns requiremen				No	
					I					•				1
	ADDIT	IONAL PRODUCT II	NFORMATION			PRODUCT DE	SCRIPTION INFORMATION	d. Store pro	d. Store product (unit of sale) upright?					1
The product is?			Is the Product	Direct-Ship O	nly				Protect product (unit of s	ale) from light?			No	ī
a legend device?		No	Is the Product	Neither	-	Ci	100g Can	e. Shelf life:		,			24	Months
if yes, enter class #			Orphan Drug Status			Size:			Initial shelf life at launch	(if different):			24	Months
a product kit?		No				Strength:	0.12%							
if yes, list NDCs of			FDA Approval Status			g				ORDER INFORM	MATION			
component parts		NI.				Dosage Form:	Foam		11-9-40-1-		18/h-4 i- 4h-	NDCIII		
reverse numbered? co-licensed?		No No	Allergens Present						Unit of Sale Bottle		What is the 1 Box contai			
latex-free?		Yes	Allergens Fresent				N/A		X Box/Carton			g. 1 Box of 1		
preservative-free?		Yes				Product Shape	: '*''`		Ampule		(**************************************	g. 1 Dox 01 1	o vidio)	
correctional institution block?		No				Book doors Only on	White		Glass		Minimum or	der quantity	/?	Yes
opioid?		No				Product Color:			Tube					
Cannabinoid?		No	Country of Origin	Spain		Product Imprin	h. N/A		Vial Liquid Sgl					
If Unit Dose, is item bar coded to u	nit dose for					. roudet imprii			Vial Liquid Multi				ich package t	type?
hospital scanning?			Is this product covered u						Vial Powder Sql		32	Each		
If Unit Dose, indicate NDC here:			Trade Agreements Act (1	AA)?	Yes				Vial Power Multi Other: Write In			Inner/Cartor	n/Pack	
			FOR GENERIC DRUG PR	0011070					Other: write in			Case		
			FOR GENERIC DRUG PR	ODUCIS										
					Au	thorized Generic *	If Authorized Generic, other		Pl	HARMACY ORDER	/ BILL UNIT			
I. Orange Book Rating:	AB						ection fields are not applicable	Rec sell un	t to customer?	-	Rx billing u	nit to nharm	acv.	
II. Generic Equivalent to What Brand?: LUXIQ							1 Box containing 1 Canister			x Each				
								(Write-in, e.				Gram		
		DRUG SUPF	LY CHAIN SECURITY ACT (DSCSA) INFOR	MATION							Milliliter		
				_										
Does supplier meet DSCSA defini	tion of manufactu	rer?	Yes No	_	GLN:	0370700000007			IIEI	M AND PACKING I	NFORMATIO	N		
Is product exempt from DSCSA?			INU											
If yes, select exemption:					GCP:				Weight Lbs.		ions (US msn	,	Volume (Cube)	Saleable # Pieces
Other exemption - Write in: Is product repackaged?			No		If you was on	riginal product purch	nond .	Item/Each:		Depth	Width	Height		
Is product repackaged? Is product sold by manufacturer's	exclusive distrib	utor?	No		direct from m		ascu	illeni/Each:	0.992	1.575	1.575	5.512	13.673205	1
Has FDA granted waiver/exception			No	_		 ce manufacturer for r	epackaged product	Box/Carton/	Bundle/				_	
If yes, attach documentation from							.,	Inner Pack:					0	
				'				Case:	34.586	6.693	1.89	1.862	23.553872	32
		GT	IN AND HIBCC PRODUCT II	NFORMATION					34.300	0.095	1.03	1.002	20.000012	32
Outside It is at the			LUDGO		_			Pallet:					0	
Saleable Unit of Measure	\$	Saleable Quantity	HIBCC			N-14 70700141205	Unit of Use GTIN-14	_						
X Item/Each Box/Carton/Bundle/Inner Pack		1			003	70700141205			COST INFORMATION			WHOLESAL	ER USE ONL	γ
x Case		32			103	70700141202			- COOT IN ORMATION			IOI-LOAL	LA GOL ONL	
Pallet		<u> </u>			100			Regular Cos	t		Vendor #:			
	1							Invoice Cos		\$124.12	Whsl. Code	#:		
											Fineline Co			
								As of date:						
			Attack conv. COAFET 13.	TA CHEET (CC	C)		ICEDT LADEL AND DUCTO	II	ACING and DARGORE		<u> </u>			
		•	Auach copy of SAFETY DA	TA SHEET (SD	or non haza ره		ISERT, LABEL AND PHOTO (esignated Drop Ship Only.	JE PRODUCT PACE	AGING and BARCODE. Signature:					
*Please provide any additional infe									aignainte.					



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For Designated Drop Ship Only Products, Please Use Page 3

MA	TERIAL HAZ	ARD CLASSIFICATION and TRANSPORTATION					
Is this product (check all that apply):							
a. Cytotoxic?	No	SDS Hazard Classification					
b. CA Prop. 65 Carcinogen or Reproductive Toxicant?							
Is the product a CA Prop 65 carcinogen?	Organic	Corrosive					
Is the product a CA Prop 65 reproductive toxicant?	Inorganic	Oxidizer					
Does the product label bear a CA Prop 65 warning?	Steroid/Androgen	Contact Hazard					
2000 the product tabor 20th top of that thing.	No		_ oomaat Hazara				
c. Contact Hazard?	No	Does the product have an Aerosol class? If yes,	Yes				
d. Does this product require special clean-up instructions?	identify NFPA Storage Level:						
(If yes, attach SDS with special instructions.)	NFPA Storage Level:	Level 1					
e. Does the product contain DEHP?		THE TYPE STORE LETTER.	2010.1				
·							
Is this product regulated for shipment by DOT?	Yes	Is the product a NIOSH hazardous drug?	No				
(if yes, answer a-e below and provide SDS)		If yes, indicate which:					
a. UN/Identification Number							
1 11 3	b. Proper Shipping Name Aerosols, flammable		Hazardaya Wasta Idontification				
c. DOT Hazard Class 2.1 d. Packing Group N/A		Hazardous Waste Identification					
	V	EDA Hazardana Wasta Cadan		Masta Charastaristics			
e. Inhalation Hazard?	Yes	EPA Hazardous Waste Code:		Waste Characteristics			
Is this product regulated for shipment by IATA?	Yes						
(if yes, answer a-e below and provide SDS)		REMS o	REGISTRY RESTRICTIONS				
a. UN/Identification Number 1950							
b. Proper Shipping Name Aerosols, flammable		Is there a REMS on this product?	No				
c. DOT Hazard Class 2.1		If Yes, is it managed with a pharmacy registry?					
d. Packing Group		Website URL:					
e. Inhalation Hazard?	Yes						
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							
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:		Filotie.			
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)	Бу баррног.		INI I TT.				
Special Permit; DOT-SP	Comments						
Special Provision (listed in Column 7 of 49 CFR 172.101);	Comments						
SP#	Registry:						
SF#				Di			
ADD'L STORAGE INFORMATION		Registry Program Contact Name: Comments		Phone:			
		Comments					
Is the Product							
Controlled Substance? No Controlled Substance Code		RI	ETURN INSTRUCTIONS				
Controlled by State(s)? Listed Chemical (List I or II)							
ARCOS Reportable? If yes, indicate which:		Contact tel. # if product received damaged:					
Schedule No. Is it a scheduled listed chemical product?:		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		1					
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.							
MI	SCELLANEC	OUS 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 Desig	gnated Drop Ship Product	Standard Order Receipt and Processing					
Purchase orders may be accepted by:		Purchase order daily receipt cut off time by supplier					
a. EDI		Cut off time:					
b. Autofax	Fax Number:						
c. Fax	Fax Number:	Shipping lead time of PO: Hours Days					
d. Phone only	Phone No.:	China cama day far nayt day receipts					
e. Supplier Web Site only Minimum Order Quantity:	Site Address:	Ships same day for next day receipt: Ships for second day receipt:					
Supplier's Customer Service Number:		Ships regular ground for 3-10 days receipt:					
Contracted 3PL company / contact #: Name:		Ships regular ground for 3-10 days receipt.					
Phone:							
	Other Designated Drop Ship Fees:	Overnight and Priority Overnight PO Processing					
Expedited freight fees billed with each order:		Overnight receipt available:	_				
Drop Ship service fee billed with each order:		PO Receipt cut off time:					
Drop Ship miscellaneous fees billed:		Days of week overnight is available: Monday					
Comments:		Days of week overnight is available: Tuesday					
Comments.		Wednesday					
		Thursday					
		Friday					
		Priority Overnight receipt available:					
Class of Tro	de Restriction:						
		PO Receipt Cut off time:					
No restriction: Select YES if sold to retail pharmacy,	hospitals, clinics and physician offices	Saturday Overnight receipt available:	_				
Restricted to retail pharmacy only:		PO Receipt Cut off time:	_				
Restricted to hospital, clinics, and physician offices o Restricted from US territories? (explain in comments		Order receipt method: Phone: Phone #: Fax: Fax #:	-				
Comments:	5)	EDI:					
Comments.		Overnight Fees apply:					
		Other fees apply:					
Other Data Information	n Required to Process PO:	Return Instructions					
Patient Procedure Date:		Contact # if product is received damaged:					
Physician Name:		Is product returnable for credit:					
Physician/Clinic Phone #		URL/Link to returns policy:					
Physician State License #							
Physician/Clinic DEA #:		Special regulations or returns requirements for this product in certain states?					
Physician/Clinic Specialty:		If so, which states? Other requirements? Comments?					
Miscelland	neous Notes:						
		ADDITIONAL INFORMATION					
		Is product order for scheduled patient procedure?					
		Is product order for restocking purposes?					